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Pesticide residues in food 2008

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2008

World Health Organization

Food and Agriculture Organization of the United Nations

Pesticide residues in food 2008

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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, 9–18 September 2008

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

D, dietary risk assessment; R, residue and analytical aspects; T, toxicological evaluation.

* New compound

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

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ROME, 9–18 SEPTEMBER 2008

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ABBREVIATIONS

ADI	acceptable daily intake
ai	active ingredient
ALP	alkaline phosphatase
ALT	alanine aminotransferase
ARfD	acute reference dose
AST	aspartate aminotransferase
AUC	area under the curve for concentration–time
BBCH	derives from Biologische **B**undesanstalt, **B**undessortenamt and **CH**emical industry
$BMDL_{10}$	benchmark-dose lower 95% confidence level
bw	body weight
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCN	Codex classification number (for compounds or commodities)
CCPR	Codex Committee on Pesticide Residues
C_{max}	maximum concentration
CV	co-efficient of variation
dw	dry weight
EC_{50}	the concentration of agonist that elicits a response that is 50% of the possible maximum
F_0	parental generation
F_1	first filial generation
F_2	second filial generation
FAO	Food and Agricultural Organization of the United Nations
FOB	functional observational battery
GAP	good agricultural practice
GC	gas chromatography
GC-NPD	gas chromatography coupled with Nitrogen-Phosphorous detector
GGT	gamma-glutamyltransferase
GEMS/Food	Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme
GPC	gel permeation 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
IC_{50}	concentration required to inhibit activity by 50%
IEDI	international estimated daily intake
IESTI	international estimate of short-term dietary intake
ISO	International Organization for Standardization

IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint Expert Committee on Food Additives
JMPR	Joint Meeting on Pesticide Residues
JMPS	Joint FAO/WHO Meeting on Pesticide Specifications
LC	liquid chromatography
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOAEC	lowest-observed-adverse-effect concentration
LOD	limit of detection
LOQ	limit of quantification
MCH	mean corpuscular haemoglobin
MCV	mean corpuscular volume
MEQ	methylethoxyquin
mrl	maximum residue level
MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NAFTA	North American Free Trade Agreement
NOAEL	no-observed-adverse-effect level
OECD	Organization for Economic Co-operation and Development
PPARα	peroxisome proliferator-induced receptor alpha
PHI	pre-harvest interval
ppm	parts per million
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
T3	triiodothyronine
T4	thyroxine
TRR	total radiolabelled residue
TSH	thyroid stimulating hormone
TMDI	theoretical maximum daily intake
WHO	World Health Organization

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 2008 JOINT FAO/WHO MEETING OF EXPERTS

INTRODUCTION

A Joint FAO/WHO Meeting on Pesticide Residues (JMPR) was held at the headquarters of the Food and Agriculture Organization of the United Nations (FAO), Rome, Italy, from 9 to 18 September 2008. The Meeting brought together the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group.

The Meeting was opened by Mr Shivaji Pandey, Director, Plant Production and Protection Division of FAO, on behalf of the Director-General of FAO and the Director-General of WHO.

Mr Pandey welcomed the participants, noting that there were 40 participants from 16 countries. Mr Pandey stated that the importance of the work of the JMPR had been highlighted in several important events that had taken place at FAO recently. These included the FAO Independent External Evaluation (IEE), the High Level Conference on World Food Security and the Global Minor Use Summit.

The IEE, an independent evaluation of all aspects of the technical and policy work, governance and structure of FAO, was the first to be carried out since the establishment of FAO in 1945. While the impact of this evaluation was hard to predict, Mr Pandey noted that the IEE report gave a high priority to the work of JMPR, the Joint Meeting on Pesticide Specifications (JMPS) and other scientific advisory bodies that provide scientific advice to Codex Alimentarius to support the Codex standards, and the collaboration between FAO and WHO in the field of food safety standard and pesticide management (Code of Conduct).

The aim of the High Level Conference on World Food Security, held in June 2008 at FAO headquarters by the United Nations and FAO, was to address the impact of soaring food prices, climate change and bio-energy production on world food security. Mr Pandey mentioned how the JMPR recommendations on Codex maximum residue limits (MRLs) for food and feed make an important contribution to the improvement of food availability and enhanced food safety and thus contribute to the resolution adopted by the Conference to continue the fight against food insecurity, hunger and malnutrition.

Mr Pandey mentioned the Global Minor Use Summit – a joint initiative of FAO, the United States Department of Agriculture (USDA), the United States Environmental Protection Agency (US EPA) – which had taken place at FAO headquarters in December 2007. The purpose of the Summit was to seek ways to improve the harmonization of protection measures and residue standards for speciality crops and minor uses. He reminded the JMPR participants that the JMPR had considered the issue of minor uses at its meeting in 2005 and that the Summit was thus an outcome of the JMPR recommendations.

Mr Pandey highlighted the challenges faced by the present Meeting, not only because of the large number of pesticides to be evaluated but also in view of the need to consider some important general issues, in particular, the proposal of achieving globally harmonized MRLs through Codex and also the issue of combination of residue data for the estimation of MRLs and STMRs.

Mr Pandey thanked the participants for their efforts and their dedication to the Meeting.

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 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. The estimation of MRLs and supervised trials median residues (STMR) values for commodities of animal origin was elaborated. The WHO Core Assessment Group was responsible for reviewing toxicological and related data in order to establish ADIs, and ARfDs, where necessary and possible.

The Meeting evaluated 28 pesticides, including six new compounds and five compounds that were re-evaluated within the Code Committee on Pesticide Residues (CCPR) periodic review programme for toxicity or residues, or both. The Meeting allocated ADIs and ARfDs, estimated MRLs and recommended them for use by the CCPR, and estimated STMR and highest residue (HR) levels as a basis for estimating dietary intakes.

The Meeting also estimated the dietary intakes (both short-term and long-term) of the pesticides reviewed and, on this basis, performed a dietary risk assessment in relation to their ADIs or ARfDs. Cases in which ADIs or ARfDs may be exceeded were clearly indicated in order to facilitate the decision-making process by the CCPR. The rationale for methodologies for long-term and short-term dietary risk assessment are described in detail in the reports of the 1997 JMPR (Annex 5, reference 80, section 2.3) and 1999 JMPR (Annex 5, reference 86, section 2.2). Additional considerations are described in the report of the 2000 JMPR (Annex 5, reference 89, sections 2.1–2.3).

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

DECLARATION OF INTEREST

The Secretariat informed the Committee that all experts participating in the 2008 JMPR had completed declaration-of-interest forms, and that no conflicts of interest had been identified.

GENERAL CONSIDERATIONS

2.1 COMMENTS FROM JMPR ON A PILOT POCESS FOR JMPR TO RECOMMEND MAXIMUM RESIDUE LEVELS PRIOR TO NATIONAL GOVERNMENT REGISTRATION

Background

At the 40th Session of the Codex Committee on Pesticide Residues (CCPR), the Delegation of the United States (US) presented a document describing recommendations for the development of a process to accelerate the evaluation of new pesticides, which would allow JMPR to recommend maximum residue levels (MRLs) to CCPR before the new pesticide has been registered by national governments. This might facilitate the alignment of national MRLs with Codex.

CCPR agreed to establish an electronic working group led by the US delegation and co-chaired by Australia and Kenya; the objective of this working group was to prepare a discussion paper describing in more detail a proposal for a pilot process and report back to CCPR at its Forty-first Session (April 2009). CCPR noted that this pilot process would have significant implications. The Joint JMPR Secretariats requested comments from the present Meeting.

Comments from the JMPR on the pilot process

The Meeting indicated that it would embrace any development that would improve the efficiency with which public health is protected from exposures to pesticide residues.

The Meeting considered that there were several potential advantages in the proposal to accelerate the evaluation of new pesticides by giving the JMPR evaluator access to the relevant joint (work-share) assessment documents and deliberations of participating national governments and the full data packages. In particular, many of the technical issues involved would be identified by the governments and authorities during the commenting process. However, the Meeting noted that there are some issues that required further consideration before implementation of any pilot project.

The Meeting emphasized for the pilot process that all relevant procedural issues need to be resolved and the data need to be available at least 6 months prior to the annual meeting of the JMPR in September.

Successful completion of an evaluation by JMPR requires registered label information, including good agricultural practice (GAP), for estimation of maximum residue levels. GAP for a pesticide means more than just the maximum proposed use pattern (rate of application, pre-harvest interval, efficacy). It also includes advice relevant to worker/operator and environmental exposure as well as management of pesticide resistance. JMPR is concerned that national government evaluation of these additional aspects may lead to changes in the GAP that is ultimately registered. Those governments involved in the pilot project should ensure that the proposed GAP is as final as possible before submission of the residue data to the JMPR.

For the JMPR evaluation to be completed before final registration of the new pesticide by national governments, interaction is required between the JMPR evaluator preparing the first draft of documents for the Meeting and reviewers from governments and authorities participating in the pilot project. The Meeting noted that increased correspondence would increase time involved but not necessarily change the meeting process. However, the process timeframes should align with JMPR timeframes including the time needed to prepare papers for the Meeting. Therefore the JMPR Secretariats will need to assign evaluators/reviewers and provide them with the necessary contacts and access to relevant information.

2.2 COMMENTS ON THE "GLOBAL ASSESSMENT" OF CHLORANTRANILIPROLE IN TERMS OF ITS USEFULNESS AS A WORK-SHARING TOOL FOR JMPR

The Meeting had previously used work-sharing reports on trifloxystrobin (JMPR, 2004) and quinoxyfen (JMPR, 2006) to develop monographs for these chemicals. The Meeting had concluded that evaluations conducted by national and regional authorities were useful in the preparation of JMPR evaluations. Appropriate use of material from these evaluations reduced the amount of time required by the JMPR temporary advisor to prepare toxicological and residue monographs.

A pilot assessment entitled "Chlorantraniliprole (DPX-E2Y45) global assessment[1]" was conducted in 2006–2008 by several regulatory authorities under the auspices of the Organization for Economic Cooperation and Development (OECD) with the aims of accelerating the timeline between review and approval and furthering regulatory harmonization. Ten countries were involved in the preparation of a global assessment of chlorantraniliprole. The global assessment was presented in the OECD format.[2]

In continuation of its support of work-sharing, the present Meeting used this global assessment to aid in the preparation of a JMPR toxicology monograph on chlorantraniliprole, which was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR). The JMPR Secretariat provided the JMPR temporary advisors responsible for the preparation of the first draft of the JMPR monograph with the relevant documents used for toxicological evaluations in the global assessment of chlorantraniliprole.

The final version of the residue component of the global assessment was not available at the time the JMPR residue evaluation was prepared.

The Meeting made a number of comments on the usefulness of the toxicological component of the global assessment to assist the work of the JMPR.

Format of the global assessment

The general format of the toxicology component of the global assessment was similar to that of a JMPR monograph.

The study evaluations within each section were summarized at the end of the section. A summary of mammalian toxicology and the selection of end-points was then presented, with a brief conclusion that summarized the toxicological profile of the substance. Again, this had some similarities to the style of the JMPR monograph.

Since the toxicology of the substance under evaluation was summarized at several places in the global assessment, this leads to considerable redundancy.

Study evaluations in the global assessment

The study evaluations in the global assessment were lengthy, describing in great detail the study design, methods and materials, results and conclusions. In addition, the study evaluations often contained a considerable number of tables presenting the values for the parameters investigated, irrespective of whether or not these parameters were affected by treatment with chlorantraniliprole. As the studies with chlorantraniliprole were modern and complied with current OECD guidelines and the degree of toxicity observed was very low, the extensive descriptions of the study methods in the evaluations of the global assessment were of limited value. Owing to such lengthy description of basic information, the key findings of the study were not always immediately clear, although detailed

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[1] Referred to as 'Joint Review of Chlorantraniliprole (DPX-E2Y45)' by OECD

[2] OECD monograph guidance
http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html

descriptions of the study results may avoid the need to consult the original study reports[3]. The description of arguments used in the identification of no-observed-adverse-effect levels (NOAELs) was also helpful for the preparation of the JMPR monograph.

These study evaluations formed a useful basis for the JMPR monograph, although it was necessary to considerably reduce the lengthy descriptions in order to focus on the essential points of the studies.

In general, the Meeting agreed with the conclusions of the global assessment for chlorantraniliprole. However, it should be noted that this was a straightforward assessment of a compound that was without potential for severe toxicity.

Reporting table, including comments of the peer reviewers

An extensive reporting table was provided with the global assessment, which presented the comments and questions that had been raised by the regulatory authorities or the applicant, and the response of the Rapporteur Member State.

The reporting table clarified the points of discussion, presented the different arguments raised by the participants and, in general, made clear what final decision was reached and on what basis. This table was considered to be very useful for the preparation of the JMPR monograph, although it was noted that a considerable part of the table dealt with minor issues (e.g., editorial points), which made it more difficult to identify the critical points of discussion.

Conclusion

The global assessment of chlorantraniliprole (particularly the accompanying reporting table with the reviewer comments) was helpful for the preparation of the JMPR monograph on this pesticide.

In summary, some suggestions are listed below that might make the global assessment more useful for the JMPR:

- Decrease the level of methodological detail provided.
- Reduce the level of reporting of inconsequential findings.
- Continue to give details of comments and responses by participants.
- If possible, separate critical discussion points from minor issues in the reporting table.

2.4 A PROCESS TO ENSURE THE SCIENTIFIC ROBUSTNESS AND TRANSPARENCY OF RETROSPECTIVE ANALYSES OF TOXICITY DATA ON PESTICIDE CHEMICALS

The current paradigm of toxicity testing that is used to assess the potential risk of pesticide chemicals has been in place for many years. Such risk assessments have been conducted for hundreds of chemicals. Together they form a rich database on the toxicity of these chemicals. Compilation and analysis (known as “retrospective analyses”) of this existing extensive toxicity database can play an important role, for example, in refining test methods and guiding changes in data requirements, in identifying and prioritizing key issues associated with current tests for toxicity, in enhancing

[3] The Meeting noted that in 2001 and 2002 the OECD had published two guidance documents in the OECD *Series on Testing and Assessment* that recommended ways of providing an adequate level of detail in toxicology reports without including unnecessary information or duplicating information that was common to different types of studies.

interpretation of data from current tests for toxicity, and in supporting predictions of toxicity (e.g., building and testing of SAR/QSAR models).

A number of different retrospective analyses by national and supranational bodies of various studies of toxicity in experimental animals have either been completed or are ongoing. These retrospective analyses address issues such as the duration of a study of toxicity in dogs that is appropriate for the determination of an acceptable daily intake (ADI), the amount of additional information relevant to hazard and risk assessment provided currently by the bioassay for cancer in mice, and the contribution of the F_2 generation in studies of reproductive toxicity in rats in order to consider a possible replacement of the multigeneration study of reproductive toxicity by the "extended F_1" study.

Given the interest in retrospective analyses, the OECD Working Group on Pesticides has established a task group to develop a document that describes, in general terms, a process for improving the transparency and harmonization of retrospective analyses. In considering which organizations need to be involved in this process and what their roles should be, that task group asked the WHO Core Assessment Group on Pesticide Residues of the JMPR to comment on how retrospective analyses could be used most effectively to improve the risk assessment of pesticides.

Comments from the JMPR

The present Meeting acknowledged the importance of retrospective analyses of toxicity databases for pesticides and recommended that the WHO Core Assessment Group on Pesticide Residues of the JMPR or a working group established by the WHO Joint Secretariat of the JMPR could serve a valuable role in the review of these analyses that are conducted by national/supranational bodies. The JMPR would provide an independent international opinion on the scientific robustness and transparency of these analyses, make suggestions on how they may be improved, and provide comment on the implications of the results. If multiple analyses by different countries have been or will be conducted, the JMPR could also make recommendations on how to harmonize the approach and interpretation of the results. Retrospective analyses may be submitted to the JMPR/WHO Joint Secretariat for consideration by national authorities or other organizations or by the OECD Working Group on Pesticides. Given that the JMPR convenes once each year, in order for the JMPR to provide meaningful input, the analyses would need to be made available to the WHO Core Assessment Group at least 6 months before the JMPR annual meeting normally held in September and such analyses would need to be well documented (i.e., not anonymized, if possible).

The Meeting also recommended that the JMPR take on a pilot process and thus asked the JMPR/WHO Joint Secretariat to liaise with the OECD Working Group on Pesticides to identify a suitable retrospective analysis.

2.4 COMMENTS ON OECD DRAFT GUIDANCE DOCUMENT FOR DERIVATION OF AN ACUTE REFERENCE DOSE

The present Meeting discussed the most recent draft version of the OECD *Guidance Document for Derivation of an Acute Reference Dose* (Version 6, 30 June 2008), the purpose of which is to provide harmonized guidance on how to use all available information to derive acute reference values (ARV)[4] and how to proceed should additional data be necessary. Although it was not possible to discuss the document in detail since it was not provided to the JMPR before the present meeting, the Meeting was able to offer some general comments, summarized below.

[4] In the OECD draft guidance, the term "acute reference value (ARV)" is applied, which is related not only to the amount of a substance that can be ingested from food or drinking-water, but also that can be tolerated by dermal and inhalation exposures.

The OECD guidance document is generally based on the JMPR *Guidance on the Establishment of Acute Reference Doses,*[5] which is intended to be used for the assessment of dietary exposure to pesticide residues. In contrast to the guidance provided by JMPR, the most recent OECD guidance document also applies to dermal and inhalational exposure, which complicates the guidance offered, e.g., the principles for not setting an ARV based on a NOAEL of > 500 mg/kg bw are very specific for oral ingestion of pesticide residues.

The Meeting recommended that the OECD guidance document should address only oral exposure. The issues associated with setting ARVs for inhalation and dermal exposure, including route-to-route extrapolation methods, should be moved to a separate guidance document or to an annex attached to the current document.

The present Meeting noted that the provision of more guidance on issues relating to assessment of acute risk would improve both the WHO and the OECD guidance on setting of acute reference doses (ARfDs). Several of these issues were recently discussed and published by the JMPR (e.g., section 2.6 of the present report; sections 2.1 and 2.4 of the JMPR report 2007; section 2.4 of the JMPR report 2006).

2.5 CUMULATIVE RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOOD: ACTIVITIES OF THE EUROPEAN FOOD SAFETY AUTHORITY

The Meeting was informed that the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) of the European Food Safety Authority had issued an opinion "to evaluate the suitability of existing methodologies and, if appropriate, the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005".[6] It was also informed of an ongoing application of the tiered approach provided in the opinion to risk assessment of cumulative dietary exposure of triazole fungicides. The Meeting was aware of other similar evaluations conducted by other bodies and considered the relevance of cumulative risk assessment for pesticide residues in food. The Meeting would continue to monitor ongoing activities in this field and eventually advise on the need for cumulative risk assessment for certain groups of compounds.

2.6 SAFETY FACTORS FOR ACUTE C_{MAX}-DEPENDENT EFFECTS: SPECIFIC CONSIDERATIONS WITH RESPECT TO CARBAMATES SUCH AS CARBOFURAN

General considerations

In deriving health-based guidance values for exposure-based risk assessment, i.e., ADI and ARfD, the JMPR uses the paradigm developed by the International Programme on Chemical Safety (IPCS) and widely adopted by risk-assessment bodies throughout the world. For toxicological effects that would be anticipated to have a biological threshold and for which there is an experimentally observable threshold, the ADI or ARfD, as appropriate, is derived from the NOAEL, or other suitable point of departure, by application of an appropriate safety factor.[7] The safety factor allows for inter-species

[5] In: Pesticide Residues in Food—2004. Report of the JMPR 2004, FAO Plant Production and Protection Paper, 178, FAO, Rome, pp 3–9.

[6] http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1178712607885.htm

[7] Safety factors are also known as "assessment factors", "adjustment factors" (AFs) or "uncertainty factors" (UFs). In the IPCS document on chemical-specific adjustment factors (CSAFs), the term "uncertainty factor" applies to default factors, while "adjustment factor" applies to data-derived factors. In this IPCS terminology, the overall safety factor is known as the "combined uncertainty factor" (CUF).

and human inter-individual differences in sensitivity attributable to both toxicokinetics and toxicodynamics. When using data obtained from experimental animals, the default safety factor is 100. This comprises a factor of 10 to allow for inter-species differences and a factor of 10 for intra-species (human inter-individual) differences. The overall safety factor is the product of these two factors, i.e., 10×10.

While this approach allows for the use of data either from experimental animals (safety factor of 100) or from humans (safety factor of 10), it does not allow quantitative incorporation of specific information on toxicokinetic or toxicodynamic differences for a chemical, either between or within species, in the risk assessment. To overcome this limitation, IPCS recommended that the two 10-fold factors each be further subdivided into toxicokinetic and toxicodynamic sub-factors. The sub-factors agreed were 4-fold and 2.5-fold for inter-species toxicokinetic and toxicodynamic differences, respectively, and 3.16 ($10^{1/2}$) each for human inter-individual toxicokinetic and toxicodynamic differences. The resulting sub-factors were termed "default sub-factors" (uncertainty factors or UFs).[8] Where available, information on one or more specific sources of variability and uncertainty could be used to enable derivation of one or more chemical-specific adjustment factors, CSAFs, replacing the defaults.

Table 1 Values for IPCS default sub-factors for uncertainty[8]

Source of uncertainty	Default sub-factor		
	Toxicokinetic	Toxicodynamic	Combined
Interspecies variation	4.0	2.5	10
Human inter-individual variation	3.16	3.16	10

IPCS, International Programme on Chemical Safety

The overall or combined uncertainty factor (CUF; equivalent to the safety factor as used by JMPR) is obtained from the product of the CSAFs, using defaults for those sub-factors for which chemical specific information is not available. Hence:

Combined UF (safety factor) = (AK_{AF} or AK_{UF}) × (AD_{AF} or AD_{UF}) × (HK_{AF} or HK_{UF}) × (HD_{AF} or HD_{UF})

where AK represents inter-species toxicokinetic variability

AD represents inter-species toxicodynamic variability

HK represents human interindividual toxicokinetic variability

HD represents human interindividual toxicodynamic variability

AF represents a chemical-specific adjustment factor

UF represents a default uncertainty subfactor

CSAFs enable information on inter-species or human interindividual differences in the toxicokinetics or toxicodynamics of a specific chemical to be incorporated into the risk assessment. Although such information is often not available, information on pathways of elimination or mode of action may be available. As information is available on the extent to which some of these pathways or processes vary between or within species, an approach has been proposed to enable this information to be used to inform the choice of safety factors.[9] This approach is therefore somewhere between the

[8] WHO. Chemical-specific adjustment factors for interspecies differences and human variability: guidance document for use of data in dose/concentration–response assessment. Geneva, World Health Organization, 2005 (http://whqlibdoc.who.int/publications/2005/9241546786_eng.pdf)

[9] Renwick AG, Lazarus NR. Human variability and noncancer risk assessment – an analysis of the default uncertainty factor. *Regul. Toxicol. Pharmacol*., 1998;27:3–20.

normal default situation (100-fold safety factor) and the derivation of CSAFs on the basis of chemical-specific information. Such factors have been termed "categorical factors".[10]

The default uncertainty factors for inter-species and human inter-individual toxicokinetic differences were derived on the basis of protection from long-term exposure to chemicals.[11] As such, these factors reflect differences in clearance processes, i.e., are-under-the-curve of concentration–time (AUC)-dependent effects. As the effects of acute exposure are often dependent on C_{max}, it is pertinent to ask whether this parameter varies to the same extent as AUC or clearance (*CL*) between or within species.

Kinetically, $C_{\max} = \frac{k_a \times D \times F\left(e^{-kt_{\max}} - e^{-k_a t_{\max}}\right)}{V \times \left(k_a - k\right)}$

where

k_a = absorption rate constant

k = elimination rate constant

V = apparent volume of distribution

t_{max} = time of maximum plasma concentration (C_{max})

F = systemic bioavailability

D = administered dose

Hence, C_{max} does not depend directly upon either *CL* or AUC. Although k depends upon both *CL* and V, in general k_a exceeds k. Hence, the main determinants of C_{max} are k_a and V, i.e., the rate of absorption and the volume of distribution.[12] These are determined largely by physicochemical properties and basic body composition. Basic body composition, e.g., the thickness and composition of the plasma membrane, major determinants of passive diffusion, do not vary widely between or within species. Analysis of a database on pharmaceuticals used in humans confirmed that C_{max} varied less between species than did *CL* or AUC.[11] Hence, it was concluded on the basis of these considerations that a reduction in the inter-species toxicokinetic factor (AK_{AF}) from the default of 4 to 2 was justified (Renwick, 2000) for rapidly eliminated compounds, the effects of which were dependent on C_{max}. The JMPR reached a similar conclusion at its meeting in 2000.

C_{max} is influenced by the presence of food in the gastrointestinal tract, for example, because o f effects on gastric emptying.[13] However, as it is assumed that a large portion of a particular relevant f ood commodity would be present when undertaking an acute risk assessment of residues of a pesticid e, this factor would make a less important contribution to inter-individual variability in Cmax.

Hence, some reduction in the adjustment factor for human toxicokinetic differences (HK_{AF}), from its default value of 3.16, would seem to be justified. The JMPR in 2000 had previously suggested that a 50% reduction would be appropriate. Hence, for compounds whose effects are dependent on C_{max}, and which are rapidly eliminated, the combined adjustment factor would be:

$$CUF = AK_{AF} \times AD_{UF} \times HK_{AF} \times HD_{UF}$$

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[10] Walton K, Dorne JL & Renwick AG. Categorical default factors for interspecies differences in the major routes of xenobiotic elimination. Hum. *Ecol. Risk Assess*., 2001;7:181–201.

[11] WHO. Principles for the toxicological assessment of pesticide residues in food. Environmental Health Criteria 104. (http://www.inchem.org/documents/ehc/ehc/ehc104.htm)

[12] Renwick AG. The use of safety or uncertainty factors in the setting of acute reference doses. *Food Addit. Contam*., 2000;17:627–635.

[13] Krishna R, Jensen BK. Pharmacokinetics: effects of food and fasting. In: Swarbrick J, editor. *Encyclopaedia of Pharmaceutical Technology*, Third Edition, Informa Healthcare, London; 2004: pp 2816–2828.

= 2 (categorical) × 2.5 (default) × 1.58 (categorical) × 3.16 (default)

= 25

The example of carbamates

The toxicological effects of carbamates such as carbofuran are C_{max} dependent. As carbamates are rapidly absorbed and eliminated, the above considerations would apply, and the combined uncertainty factor would be 25, rather than the default of 100.

The toxicity of carbamates such as carbofuran is caused by inhibition of neuronal acetylcholinesterase activity. The clinical signs indicate that neurons in the central nervous system are the primary target, and are responsible for the critical effects upon which the risk assessment is based. This is true for acute (single dose) and for long-term exposure. The NOAELs for the toxicological effect of carbofuran are the same, regardless of the duration of exposure. This is a consequence of the toxicokinetics of carbofuran, which is rapidly absorbed and eliminated, and the toxicodynamics of the effect, in which acetylcholinesterase is rapidly reactivated because of spontaneous hydrolysis. There is therefore no opportunity for progressive effects to develop, due to either bioaccumulation or to cumulative inhibition from one exposure to another.

Neuronal acetylcholinesterase, which is identical to the acetylcholinesterase protein expressed in erythrocytes, is well conserved between species. Studies in vitro have shown that erythrocyte acetylcholinesterase from a number of species, including humans, shows similar sensitivity to inhibition by carbamates.[14] This has been confirmed in vivo, for example with carbofuran (see report of the present Meeting). The NOAELs for inhibition of acetylcholinesterase activity by this compound and for effects dependent upon such inhibition in rats, dogs and humans were very similar (see report of the present Meeting). The default uncertainty subfactor for interspecies toxicodynamic differences (AD_{UF}) of 2.5 assumes that humans are more sensitive than the test species. As there is good evidence that this is not the case for carbofuran, some modification of AD_{AF} would be justified.

The default uncertainty subfactor for human inter-individual differences in toxicodynamics (HD_{UF}) is 3.16. In the case of carbamates such as carbofuran, such differences will depend on the level of expression of acetylcholinesterase and the rate of enzyme reactivation, which is a passive process. Rat pups were more sensitive to inhibition of acetylcholinesterase activity by carbofuran than were adults. Hence, in basing the risk assessment on this end-point, one component of potential variability within the population has already been taken into account and the remaining inter-individual differences are likely to be less than the default, as they are due to passive processes.

On the basis of the above considerations, the Meeting concluded that the default uncertainty sub-factors for toxicodynamic differences between and within species for carbofuran were conservative and that some modification of these sub-factors to account for the reduced variability expected for such compounds would be justified, on the basis of both chemical-specific and generic information. This, together with the arguments for categorical toxicokinetic factors for compounds where toxicity is dependent on C_{max}, provides strong support for the use of a combined uncertainty factor (safety factor) of no more than 25 for carbofuran.

[14] Rao PS, Roberts GS, Pope CN & Ferguson PW. Comparative inhibition of rodent and human erythrocyte acetylcholinesterase by carbofuran and carbaryl. *Pestic. Biochem. Physiol.*, 1994;48:79–84.

2.7 TRANSPARENCY IN THE MAXIMUM RESIDUE LEVEL ESTIMATION PROCESS OF THE JMPR

The JMPR adopted the statistically based methodology used in the NAFTA[15] countries at its 2005 Meeting as an aid in the estimation of maximum residue levels (2005 Report). Prior to that, estimations of the maximum residue level (mrl) were based solely on the collective scientific judgment of the JMPR after careful consideration of the results of the relevant supervised trials. Values were rounded according to a step system (1, 2, 3, 5, 7, 10…). With the inclusion of the NAFTA spreadsheet in the estimation process, the step system of rounding was abandoned and values were rounded up to *one* significant figure (with the addition of 15). The Meeting has reported each year on its experiences with the NAFTA calculation routine.

The Meeting has been using the NAFTA spreadsheet as a tool and not as the primary determinant of estimations. This means that the evaluator considers the data set, the crop, the properties of the particular pesticide, and supporting data, and then proposes an estimate. This estimate is checked against the NAFTA spreadsheet. The evaluator's preliminary estimates are debated by the entire FAO expert group and may be changed on reconsideration of the data and knowledge of the particular pesticide and its uses and properties and the situations with each crop data set, as well as review of the NAFTA spreadsheet results. The estimation is not a simple matter of entering the residue trial numbers into a spreadsheet and recording the output.

The NAFTA spreadsheet is <u>not</u> a statistical model for the accurate estimation of maximum residue levels. Rather it is a decision-tree logic that utilizes statistical calculations to arrive at a reasonable maximum residue level that should be acceptable to different parties considering the same data set. It is designed to give a consistent decision, independent of the prejudice of the reviewer(s). The spreadsheet looks only at numbers and not at the basis of those numbers. The JMPR looks both at the numbers and the basis of those numbers (See General Consideration 2.8).

It is imperative that the JMPR consider all relevant aspects in arriving at its maximum residue level estimates. Otherwise, a value intended as an international trade standard may be set too low thereby creating trade difficulties for a commodity that was treated in accordance with a national GAP. On the other hand, the JMPR attempts to not overestimate the maximum residue level and thereby allow commodities in trade from applications in excess of the GAP. Many such aspects that cannot be factored in by a spreadsheet.

The 40th Session of the CCPR requested that the JMPR Secretaries consider providing brief explanations on the derivation of each maximum residue level estimate and publishing a calculation summary table.

The Meeting acknowledged that following the derivation of a maximum residue level from the data set recorded in the JMPR Report may not be a facile process.

A simple example will illustrate the process, but no number of examples can address all the situations encountered by the Meeting in reaching decisions on maximum residue levels. Residue data for the foliar application of spirotetramat to hops was considered by the Meeting. The data set consists of 4 independent data points: 2.8, 4.5, 5.8, 5.8 mg/kg. The data set is very small (n = 4) and is only acceptable because the crop is minor or specialty. There is little confidence that the four values include the maximum residue that might be encountered from treatment according to GAP. Moreover, the FAO realized from experience that residues on dried hops can be extremely variable. Therefore, the Meeting concluded to estimate 15 mg/kg, the choices being 6, 7, 8, 9, 10, 15, 20 mg/kg, and checked this against the statistical analysis which selected 8.85 mg/kg based on log normality at the 99th percentile. The opinion of the FAO experts was that a lesser value (such as 9 mg/kg) might lead to violations for crops treated in accordance with GAP.

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[15] North American Free Trade Agreement

The Meeting proposed to provide to the CCPR, on a trial basis, a concise form summarizing the derivation of maximum residue levels from the 2008 Meeting. The form will provide summary numerical information and will briefly state the basis for estimates as necessary. The "comments" indicate when the NAFTA spreadsheet recommendation is discounted, e.g., when there is an insufficient number of data values. The completed form for each pesticide considered is attached to this general consideration.

The JMPR requests that the members of CCPR review the forms, evaluate the usefulness of the information, and decide if they wish JMPR to include the information routinely in an annex to the JMPR Report.

Listed below are summaries of the derivation of MRL estimates.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
AZOXYSTROBIN (229)										
Citrus fruit	8	2.6	8.8	5.1	4.9	0	Lognormal 95/99 rule, 99th	12.3	15	There are too few data points for the NAFTA calculator
Stone fruit	14	0.28	1.4	0.73	0.74	0	Lognormal 95/99 rule, 99th	1.79	2	Agreed
Berries and other small fruits, except cranberry, grapes, and strawberry	10	0.52	3.6	1.4	1.0	0	Lognormal 95/99 rule, 99th	4.48	5	There are too few data points for the NAFTA calculator
Cranberry	4	0.15	0.31	0.23	0.23	0	Lognormal 95/99 rule, 99th	0.46	0.5	There are too few data points for the NAFTA calculator
Grapes	15	0.11	0.80	0.48	0.53	0	Lognormal 95/99 rule, 99th	1.63	2	Agreed
Strawberry	7	0.26	4.5	1.8	1.3	0	Lognormal UCLMedian 95th	9.43	10	There are too few data points for the NAFTA calculator
Bananas and plantains	6	0.58	1.1	0.84	0.84	0	Lognormal 95/99 rule, 99th	1.40	2	There are too few data points for the NAFTA calculator
Mango	3	0.08	0.44	0.27	0.28	0	Lognormal 95/99 rule, 99th (Mean+3SD)	1.67 (0.81)	0.7	There are too few data points for the NAFTA calculator
Papaya	7	< 0.05	0.15	0.09	0.09	2	Lognormal 95/99 rule, 99th	0.23	0.3	There are too few data points for the NAFTA calculator
Bulb vegetables	7	0.67	6.3	2.6	2.2	0	Lognormal 95/99 rule, 99th (Mean+3SD)	11.1 (8.19)	10	There are too few data points for the NAFTA calculator
Brassica vegetables	8	0.25	2.3	1.3	1.2	0	Lognormal 95/99 rule, 99th (Mean+3SD)	6.86 (3.55)	5	There are too few data points for the NAFTA calculator
Fruiting vegetables, Cucurbits	14	0.03	0.75	0.23	0.17	0	Lognormal UCLMedian 95th	0.96	1	Agreed

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	Comment/ Explanation
Fruiting vegetables, other than Cucurbits, except fungi and sweet corn	11	0.08	1.4	0.48	0.35	0	Lognormal UCLMedian 95th	2.17	3	There are too few data points for the NAFTA calculator
Lettuce	20	< 0.01	1.6	0.46	0.28	5	Not lognormal Mean+3SD	1.97	3	Not lognormal distribution
Legume vegetables	6	0.11	1.5	0.94	1.0	0	Lognormal 95/99 rule, 99th (Mean+3SD)	7.34 (2.64)	3	There are too few data points for the NAFTA calculator
Soya beans, dry	19	< 0.01	0.33	0.09	0.06	1	Lognormal 95/99 rule, 99th (UCLMedian95th)	0.64 (0.33)	0.5	Lognormality plot indicated saturation, resulting in overestimated 95/99th percentile
Root and tuber vegetables	15	0.03	0.45	0.23	0.23	0	Not lognormal Mean+3SD	0.57	1	Not lognormal distribution
Artichoke, globe	3	1.6	2.4	1.9	1.8	0	Lognormal 95/99 rule, 99th	3.09	5	There are too few data points for the NAFTA calculator
Asparagus	6	< 0.01	< 0.02		0.01	6			0.01*	Data < LOQ
Celery	7	0.23	3.2	1.2	0.43	0	Lognormal UCLMedian 95th	3.12	5	There are too few data points for the NAFTA calculator
Witloof chicory (sprouts)	5	0.03	0.11	0.06	0.05	0	Lognormal 95/99 rule, 99th	0.24	0.3	There are too few data points for the NAFTA calculator
Barley and oat	38	0.01	0.28	0.08	0.08	0	Not lognormal Mean+3SD	0.28	0.5	Not lognormal distribution, HR value equal the estimate
Wheat, rye and triticale	31	< 0.01	0.14	0.02	0.01	13	Not lognormal Mean+3SD	0.09	0.2	Not lognormal distribution, HR value higher than the estimate
Maize	20	< 0.01	0.02	0.01	0.01	17			0.02	Most data < LOQ
Rice	16	0.07	3.3	1.1	0.68	0	Lognormal 95/99 rule, 99th (UCL Median 95th)	8.91 (3.85)	5	Lognormality plot indicated saturation, resulting in overestimated 95/99th percentile
Tree nuts, except pistachios	9	< 0.01	0.01	0.01	0.01	8			0.01	Most data < LOQ
Pistachios	3	0.25	0.48	0.39	0.44	0	Lognormal 95/99 rule, 99th	0.86	1	There are too few data points for the NAFTA calculator
Cotton seed	12	< 0.01	0.54	0.06	0.01	5	Not lognormal Mean+3SD	0.51	0.7	There are too few data points for the NAFTA calculator

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	Comment/ Explanation
Peanuts	11	< 0.01	0.13	0.03	0.01	5	Not lognormal Mean+3SD	0.14	0.2	There are too few data points for the NAFTA calculator
Sunflower seed	6	0.01	0.24	0.07	0.04	0	Lognormal UCLMedian 95th	0.31	0.5	There are too few data points for the NAFTA calculator
Herbs, fresh	7	17	48	26	23	0	Lognormal 95/99 rule, 99th	52.3	70	There are too few data points for the NAFTA calculator
Peanut fodder (dw)	11	1.8	15	6.8	5.1	0	Lognormal 95/99 rule, 99th	25.0	30	There are too few data points for the NAFTA calculator
Soya bean fodder (dw)	19	8.0	62	36	36	0	Not lognormal Mean+3SD	77.3	100	Not lognormal distribution
Straw and fodder (dry) of cereal grains, except maize (dw)	87	0.25	11	2.3	1.7	0	Lognormal 95/99 rule, 95th (95/99 rule, 99th)	8.57 (11.75)	15	HR higher that the estimate
Maize fodder (dw)	20	1.1	25	7.0	5.0	0	Lognormal 95/99 rule, 99th	32.3	40	Agreed
Dried herbs, except dry hops	4	135	235	169	152	0	Lognormal 95/99 rule, 99th (Mean+3SD)	297 (307)	300	There are too few data points for the NAFTA calculator
Hops, dry	4	5.7	12	9.9	11	0	Not lognormal Mean+3SD	18.5	30	There are too few data points for the NAFTA calculator
Almond hulls (dw)	5	0.77	3.3	2.0	2.1	0	Lognormal 95/99 rule, 99th	6.47	7	There are too few data points for the NAFTA calculator
BOSCALID (219)										
Banana	22	0.05	0.42	0.1	0.08	6	Log-normal 95/99	0.6	0.6	MLE method was used to replace the non-detects. AA 8.1×0.08=0.645
Kiwi	4	0.8	2.38	1.42	1.24	0	-		5	The Meeting took into account that post harvest treatment normally produce more uniform residue distribution than foliar application, AA 5.1×1.24=6.2
BUPROFEZIN (173)										
Citrus	16	0.11	0.46	0.26	0.23	none	95/99 rule	0.61	1	Good agreement
Mango	5	< 0.01	0.045	0.021	0.01	2	UCLmedian 95th	0.09	0.1	Too many data points below LOQ There are too few data points for calculator
Cucumber	8	< 0.01	0.1	0.043	0.035	1	95/99 rule	0.17	0.2	Too few data points for calculator

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
Tomato	8	0.05	0.52	0.27	0.24	none	95/99 rule	1.40	1	Too few data points for calculator
CHLORANTRANILIPROLE (230)										
Pome fruit	25	0.01	0.23	0.07	0.07	0	95th lognormal	0.32	0.4	Agreed with expert opinion and modelling
Cherry (stone fruit)	8	0.06	0.57	0.25	0.2	0	99th lognormal	1.13	1	Agreed with expert opinion and modelling
Grape	17	0.02	0.52	0.2	0.12	0	99th lognormal	1.39	1	NAFTA calculator did not agree with experience, rounded down
Melons (cucurbits)	7	0.01	0.1	0.06	0.07	0	99th lognormal	0.33	0.3	Agreed with expert opinion
Chilli pepper (fruiting vegetables other than cucurbits)	9	0.02	0.41	0.12	0.07	0	UCLmed 95th	0.43	0.6	Agreed with expert opinion
Spinach (leafy vegetables)	7	3.4	8.9	6.86	7.3	0	99th lognormal	14.16	20	Experience and modelling suggested higher residues, rounded to 20
Celery	7	0.99	3.6	2.34	2.1	0	99th lognormal	6.46	7	Agreed with expert opinion
Cotton seed	13	0.01	0.25	0.07	0.05	1	UCLmed 95th	0.29	0.3	Agreed with expert opinion
Cereal hay	11	0.01	0.15	0.06	0.05	1	UCLmed 95th	0.28	0.3	Agreed with expert opinion
CYPERMETHRIN (118) (including alpha- and zeta-Cypermethrin)										
Alfalfa fodder	6	8.2	18	11.6	10.3	0	99	22.4	30	The MRL was estimated before the NAFTA SC was used. '*n*' is too small for the NAFTA calculator.
Bean straw	7	0.32	1.1	0.60	0.51	0	99	1.61	2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Cabbage	53	0.003	0.65	0.047	0.02	30	X(mean)+3 SD	0.32	1	The MRL was estimated before the NAFTA estimate was calculated. There are too many '< LOQ' values for the NAFTA calculator.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	Comment/ Explanation
Carambola	5	0.02	0.09	0.036	0.02	3	X+3SD	0.13	0.2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator. There are too many '< LOQ' values for the NAFTA calculator.
Cereal grains	26	0.01	0.22	0.052	0.036	4	95UCL	0.26	0.3	The MRL was estimated before the NAFTA estimate was calculated. The data originate from barley trials in 4 countries. There is no evidence for random or stratified random selection to represent areas of commercial production (an implicit assumption required by the NAFTA calculation).
Chilli peppers	6	0.24	0.69	0.47	0.495	0	99	1.2	2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Cucurbits	8	0.01	0.048	0.019	0.01	5	X+3SD	0.06	0.07	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator. There are too many '< LOQ' values for the NAFTA calculator.
Durian	6	0.04	0.47	0.21	0.135	0	99	1.32	1	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	Comment/ Explanation
Grapes	18	0.01	0.09	0.028	0.01	10	X+3SD	0.11	0.2	The MRL was estimated before the NAFTA estimate was calculated. There are too many '< LOQ' values for the NAFTA calculator.
Leafy vegetables	12	0.01	0.52	0.11	0.066	1	UCLmed	0.48	0.7	The MRL was estimated before the NAFTA estimate was calculated. The data originate from lettuce trials in 4 countries. There is no evidence for random or stratified random selection to represent areas of commercial production (an implicit assumption required by the NAFTA calculation).
Leeks	8	0.01	0.03	0.015	0.01	4	X+3SD	0.04	0.05	The MRL was estimated before the NAFTA SC was used. '*n*' is too small for the NAFTA calculator. There are too many '< LOQ' values for the NAFTA calculator.
Legume vegetables	12	0.01	0.45	0.19	0.22	3	X+3SD	0.69	0.7	The MRL was estimated before the NAFTA SC was used. The data originate from bean trials in one country. There is no evidence for random or stratified random selection to represent areas of commercial production (an implicit assumption required by the NAFTA calculation).

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
Litchi	6	0.25	0.79	0.50	0.495	0	99	1.16	2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Longan	6	0.25	0.47	0.33	0.3	0	99	0.54	2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Mango	6	0.09	0.35	0.20	0.19	0	99	0.61	0.7	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Oilseeds	20	0.01	0.06	0.035	0.05	19	X+3SD	0.1	0.1	The MRL was estimated before the NAFTA estimate was calculated. There are too many '< LOQ' values for the NAFTA calculator.
Okra	6	0.01	0.2	0.095	0.08	0	UCLmed	0.92	0.5	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Papaya	6	0.08	0.23	0.14	0.135	0	99	0.31	0.5	The MRL was estimated before the NAFTA SC was used. '*n*' is too small for the NAFTA calculator.
Pea hay	10	0.24	1	0.44	0.37	0	99	1.09	2	The MRL was estimated before the NAFTA SC was used. The data originate from pea trials in 3 countries. There is no evidence for random or stratified random selection to represent areas of commercial production (an implicit assumption required by the NAFTA calculation).

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
Pea pods	6	0.02	0.13	0.052	0.04	0	99	0.22	0.2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Peppers, sweet	6	0.02	0.07	0.043	0.05	5	99	0.13	0.1	The MRL was estimated before the NAFTA estimate was calculated. 'n' is too small for the NAFTA calculator. There are too many '< LOQ' values for the NAFTA calculator.
Pome fruit	34	0.05	0.56	0.21	0.205	0	95UCL	0.68	0.7	The MRL was estimated before the NAFTA estimate was calculated. The data originate from trials on apples and pears in the USA and it is understood that site selection was based on zones and percentage national production, i.e., stratified random selection. Sufficient data are available to minimize errors of extrapolation. The NAFTA estimate agrees with the JMPR estimate.
Rice	22	0.15	1.1	0.57	0.57	0	X+3SD	1.16	2	The MRL was estimated before the NAFTA estimate was calculated. The data originate from trials on rice in USA and it is understood that site selection was based on zones and percentage national production, i.e., stratified random selection. The NAFTA estimate agrees with the JMPR estimate.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
Stone fruit	12	0.52	0.94	0.66	0.59	0	99	1.05	1	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is marginally too small for the NAFTA calculator and the lognormal probability plot is not ideal for extrapolation.
Straw and fodder of cereal grains	16	0.7	6.1	3.04	3.2	0	99	12.44	10	The MRL was estimated before the NAFTA estimate was calculated. The data originate from wheat trials in the USA, where it is understood that site selection was based on zones and percentage national production, i.e., stratified random site selection. The NAFTA estimate is higher than the JMPR estimate.
Strawberries	8	0.01	0.048	0.017	0.01	5	X+3SD	0.06	0.07	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Sugar cane	9	0.01	0.17	0.05	0.05	6	99	0.39	0.2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator.
Sugar cane	9	0.01	0.17	0.050	0.05	6	99	0.39	0.2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator. There are too many '< LOQ' values for the NAFTA calculator.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
Sugar cane	9	0.05	0.17	0.068	0.05	6	X+3SD	0.19	0.2	The MRL was estimated before the NAFTA estimate was calculated. '*n*' is too small for the NAFTA calculator. There are too many '< LOQ' values for the NAFTA calculator.
Tomato	12	0.05	0.08	0.060	0.05	6	X+3SD	0.1	0.2	The MRL was estimated before the NAFTA estimate was calculated. There are too many '< LOQ' values for the NAFTA calculator.
CYHALOTHRIN (146) (includes lambda-Cyhalothrin)										
Citrus fruit	15	0.02	0.16	0.06	0.05	0	99th	0.16	0.2	
Pome fruit	8	0.05	0.1	0.08	0.08	0	99th	0.15	0.2	There are too few datapoints for NAFTA calculation
Cherries	10	0.05	0.18	0.12	0.13	0	99th	0.28	0.3	There are too few datapoints for NAFTA calculation
Peaches and apricots	14	0.02	0.33	0.11	0.1	0	99th	0.34	0.5	There are too few datapoints for NAFTA calculation
Plums	12	0.01	0.1	0.03	0.02	2	Mean+3xSD	0.15	0.2	There are too few datapoints to usethe NAFTA calculation
Berries and other small fruit	18	0.01	0.09	0.03	0.02	1	Mean+3xSD	0.13	0.2	
Olives	12	0.03	0.42	0.17	0.13	0	99th	0.75	1	There are too few datapoints to usethe NAFTA calculation
Mango	5	0.01	0.07	0.03	0.03	0	99th	0.15	0.2	There are too few datapoints to usethe NAFTA calculation
Bulb vegetables	8	0.02	0.11	0.06	0.05	0	99th	0.15	0.2	There are too few datapoints to usethe NAFTA calculation
Flowerhead brassica	10	0.04	0.3	0.19	0.22	0	Mean+3xSD	0.5	0.5	There are too few datapoints to usethe NAFTA calculation

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	Comment/ Explanation
Head cabbages	6	0.01	0.17	0.08	0.08	0	99th	0.74	0.5	There are too few datapoints to usethe NAFTA calculation
Fruiting vegetables, Cucurbits	22	0.01	0.02	0.01	0.01	16	Mean+3xSD	0.02	0.05	There are too many datapoints < LOQ for NAFTA calculation
Fruiting vegetables, other than Cucurbits except mushrooms	37	0.01	0.18	0.05	0.03	8	Mean+3xSD	0.19	0.3	Difference HR-MRL considered not sufficient
Legume vegetables	23	0.01	0.11	0.03	0.02	5	Mean+3xSD	0.11	0.2	
Pulses	33	0.01	0.05	0.01	0.01	32	not calculated	-	0.05	Too many datapoints < LOQ for NAFTA calculation
Root and tuber vegetables	15	0.01	0.01	0.01	0.01	15	not calculated	-	0.01*	There are too many datapoints < LOQ for NAFTA calculation
Asparagus	6	0.01	0.01	0.01	0.01	0	not calculated	-	0.02	Too few datapoints for NAFTA calculation
Barley grain	29	0.01	0.33	0.04	0.02	3	Mean+3xSD	0.22	0.5	MRL recommended above HR
Maize grain	29	0.01	0.01	0.01	0.01	18	not calculated	-	0.02	Too many datapoints < LOQ for NAFTA calculation
Oats, rye, triticale and wheat grain	33	0.01	0.03	0.01	0.01	25	not calculated	-	0.05	There are too many datapoints < LOQ for NAFTA calculation
Rice grain	16	0.06	0.79	0.34	0.295	0	99th	1.33	1	
Sugar cane	9	0.01	0.03	0.02	0.02	2	Mean+3xSD	0.04	0.05	There are too few datapoints for NAFTA calculation
Oilseeds	16	0.01	0.15	0.02	0.01	10	Mean+3xSD	0.13	0.2	There are too many datapoint < LOQ for NAFTA calculation
Cereal straw and fodder, dry	16	0.17	1.6	0.7	0.54	0	99th	2.73	2	
Almond hulls, dry	5	0.32	1.1	0.56	0.42	0	99th	1.55	2	There are too few datapoints for NAFTA calculation
DIMETHOATE (027)										
Peppers, sweet	5	0.03	0.26	0.1	0.06	0	UCL med 95th	0.52	0.5	There are too few data points for the NAFTA calculator
Lettuce. head	25	0.01	0.17	0.04	0.02	7	95th lognormal	0.33	0.3	

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
IMIDACLOPRID (206)										
Almond hull	10	0.23	2.6	1.6	1.45	0	Mean+3SD, 99th Percentile	4.0	5	There are too few data points for the NAFTA calculator
Berries and other small fruits (except cranberries, grapes and strawberries)	7	0.38	2.8	1.20	0.89	0	95/99 Rule, 99th Percentile	6.0	5	There are too few data points for the NAFTA calculator
Coffee	5	0.19	0.48	0.34	0.35	0	95/99 Rule, 99th Percentile	0.80	1	There are too few data points for the NAFTA calculator
Peas (dry)	6	0.14	1.0	0.59	0.62	0	95/99 Rule, 99th Percentile	3.5	2	There are too few data points for the NAFTA calculator
Peas (pods and succulent, immature seeds)	4	0.20	3.8	1.30	0.60	0	UCLMedian 95%, 99th Percentile	7.0	5	There are too few data points for the NAFTA calculator
Peas, shelled (succulent seeds)	6	0.31	1.1	0.65	0.58	0	95/99 Rule, 99th Percentile	1.8	2	There are too few data points for the NAFTA calculator
Peanut	12	0.05	0.40	0.15	0.12	4	95/99 Rule, 99th Percentile	0.70	1	There are too few data points for the NAFTA calculator
Peanut fodder	12	0.95	24	10.8	8.7	0	UCLMedian 95%, 99th Percentile	55	30	There are too few data points for the NAFTA calculator
Pomegranate	3	0.42	0.55	0.47	0.43	0	95/99 Rule, 99th Percentile	0.70	1	There are too few data points for the NAFTA calculator
Radish leaves	5	0.53	2.7	1.28	0.70	0	95/99 Rule, 99th Percentile	6.0	5	There are too few data points for the NAFTA calculator
Strawberry	9	0.12	0.35	0.20	0.17	0	95/99 Rule, 99th Percentile	0.45	0.5	There are too few data points for the NAFTA calculator
Sunflower seed	7	0.05	0.05	0.05	0.05	7	95/99 Rule, 99th Percentile	0.05	0.05*	There are too few data points for the NAFTA calculator
Tree nuts	20	0.01	0.01	0.01	0.01	19	Mean+3SD, 99th Percentile	0.01	0.01*	19 values lower than LOQ
MALATHION (049)										
Wheat	3	13	15	14.3	15	0	Mean + 3SD	18	10	Actual level limited by amount applied in first post-harvest application. There are too few data points for NAFTA Calculation.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
MANDIPROPAMID (231)										
Broccoli	6	0.29	0.70	0.46	0.435	0	95/99 Rule	1.0	2	There are too few datapoints to usethe NAFTA calculation
Cabbage, head	6	0.90	1.80	1.30	1.21	0	95/99 Rule	2.5	3	There are too few datapoints for NAFTA calculation
Celery	6	0.74	7.80	3.66	2.70	0	95/99 Rule and UCLMedian 95th	25	20	There are too few datapoints for NAFTA calculation
Cucumber	7	0.01	0.07	0.02	0.02	0	99/95 Rule	0.15	0.2	There are too few datapoints for NAFTA calculation
Grapes	13	0.20	0.85	0.47	0.43	0	95/99 Rule	1.5	2	Rounded up
Leafy vegetables	22	1.20	11.5	6.28	5.65	0	95/99 Rule	25	25	Agreed
Melons except watermelon	6	0.06	0.26	0.14	0.115	0	95/99 Rule	0.45	0.5	There are too few datapoints for NAFTA calculation
Onion, bulb	8	0.01	0.04	0.02	0.01	5	mean+3σ	0.05	0.1	There are too many values below LOQ
Peppers	9	0.04	0.38	0.17	0.12	0	95/99 Rule	0.80	1	There are too few datapoints for NAFTA calculation
Potatoes	17	0.01	0.01	0.01	0.01	17	Not calculated	-	0.01*	All values below LOQ
Spring onion	3	0.25	1.74	0.82	0.48	0	95/99 Rule	6.0	7	There are too few datapoints for NAFTA calculation
Summer squash	5	0.02	0.08	0.05	0.04	0	95/99 Rule	0.20	0.2	There are too few datapoints for NAFTA calculation
Tomato	11	0.02	0.20	0.07	0.06	0	95/99 Rule	0.30	0.3	Agreed
METHOMYL (094)										
Apples	15	0.03	0.17	0.1	0.09	0	95/99 Rule	0.26	0.3	
Grapes (wine)	11	0.01	0.2	0.09	0.09	0	Mean+3SD	0.24	0.3	There are too few data points for NAFTA calculation
Lettuce	16	0	0.07	0.02	0.01	8	95/99 Rule	0.09	0.2	50% < LOQ and HR almost twice the penultimate value
PROFENOFOS (171)										
Cotton seed	11	< 0.05	1.2	0.49	0.35	3	UCLMedian	2.5	3	There are too few data points for NAFTA calculation.
Mango	6	< 0.01	0.07	0.05	0.06	1	Mean+3SD	0.15	0.2	There are too few data points for NAFTA calculation.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	Comment/ Explanation
Mangosteen	4	1.9	3.7	2.45	2.1	0	95/99 Rule	5.0	10	There are too few data points for NAFTA calculation.
Tomato	9	0.18	4.7	1.74	1.3	0	UCLMedian	9.0	10	There are too few data points for NAFTA calculation.
PROTHIOCONAZOLE (232)										
Barley, wheat straw	30	0.07	1.2	0.38	0.25	0	Log-normal	1.8	2	MRL estimated on dry weight basis, 7.4×Med would give 1.85
Peanut	12	0.02	0.02			12			0.02	Statistical methods are not applicable
Barley and wheat	32	0.01	0.02		0.01	28			0.05	28 values at or below 0.01. Statistical methods are not applicable
Rape seed	11	0.01	0.02	0.01	0.01	7			0.05	10 values at or below 0.01. Statistical methods are not applicable
SPINETORAM (233)										
Oranges	6	< 0.01	0.03		0.02	2	Mean+3SD	0.007	0.007	There are too few data points for NAFTA calculation.
Apple	10	< 0.01	0.03		0.01	4	Mean+3SD	0.05	0.05	There are too few data points for NAFTA calculation. There are too many values below LOQ.
Tomato	6	< 0.01	0.03		0.01	2	99/95 Rule	0.06	0.06	There are too few data points for NAFTA calculation.
Leaf lettuce	6	0.15	7.80	1.58	0.33	0	Mean+3SD	11	10	There are too few data points for NAFTA calculation.
Sugar beet	6	< 0.01	< 0.01		0.01	6			0.01(*)	There are too few data points for NAFTA calculation. There are too many values below LOQ.
Tree nuts	6	< 0.01	0.01		0.01	3^{Φ}			0.01	There are too few datapoints to usethe NAFTA calculation. There are too many values below LOQ. MRL based on pecan trial results, supported by trials on almonds. $^{\Phi}$In five trials, samples were

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
										harvested earlier than required PHI.
SPIROTETRAMAT (234)										
Citrus	23	0.10	0.32	0.17	0.18	3	Mean+3SD	0.37	0.5	
Pome fruit	18	0.04	0.49	0.15	0.13	0	LN99	0.65	0.7	Adequate *n* = 18.
Stone fruit	6	0.68	1.6	1.3	1.3	0	Mean+3SD	2.19	3	There are too few samples for NAFTA calculation. Supporting data from peaches and plums for cherry.
Grapes	15	0.06	1.0	0.37	0.32	0	LN99	1.50	2	Adequate *n* = 15.
Flowering Brassica	8	0.08	0.39	0.19	0.16	0	LN99	0.69	1	There are too few samples for NAFTA calculation. Diversity in flowering Brassica.
Cucurbit	21	0.02	0.13	0.04	0.02	12	Mean+3SD	0.15	0.2	Excessive LOQ for NAFTA calculation.
Fruiting vegetables	8	0.27	0.76	0.43	0.40	0	LN99	0.93	1	Small field trial data set but substantial supporting data from greenhouse trials. There are too few samples for NAFTA calculation.
Leafy vegetables	10	0.61	5.0	2.5	2.8	0	Mean+3SD	6.95	7	Based on mustard green, but substantial supporting data from lettuce, spinach. There are too few samples for NAFTA calculation.
Potato	20	0.02	0.37	0.13	0.09	0	LN99	0.66	0.8	Adequate *n* = 20.
Celery	8	0.26	2.4	0.81	0.42	0	Mean+3SD	3.33	4	There are too few samples for NAFTA calculation.
Tree nuts	11	0.02	0.25	0.08	0.05	0	LN99	0.29	0.5	There are too few samples for NAFTA calculation.
Hops (dry)	4	2.2	4.9	3.9	4.25	0	LN99	8.85	15	Very small data set. Known variability in hops residues.
Almond hulls	6	1.3	4.7	3.4	4.05	0	LN99	10.55	10	There are too few samples for NAFTA calculation.

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	Comment/ Explanation
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	
TEBUCONAZOLE (189)										
Pome fruit	13	< 0.05	0.47	0.21	0.19	2	LN, 99th	0.82	1	
Plums	22	< 0.02	0.12	0.06	0.06	5	LN, 99th	0.2	0.2	
Elderberries	4	0.32	0.73		0.37	0	NA		2	There are too few datapoints to usethe NAFTA calculation
Mango	8	< 0.05	<0.1		0.02	6	LN, 99th	0.24	0.1	Too few data points to use the SC 75% of the values < LOQ
Papaya	6	0.06	1.2	0.35	0.18	0	UPL Median 95th	2.07	2	There are too few datapoints to usethe NAFTA calculation
Leek	12	0.03	0.44	0.21	0.20	0	μ ± 3SD	0.5	1	There are too few datapoints to usethe NAFTA calculation
Garlic	7	< 0.02	0.06	0.03	0.02	4	μ ± 3SD	0.07	0.1	There are too few datapoints to usethe NAFTA calculation
Onions	11	< 0.02	0.06	0.04	0.05	8	μ ± 3SD	0.09	0.1	Too few data points to use the SC 73% of the values < LOQ
Brassicas	19	< 0.05	0.56	0.17	0.07	8	μ ± 3SD	0.66	1	42% of the values < LOQ
Melons	20	< 0.01	0.10	0.05	0.05	2	μ ± 3SD	0.12	0.2	There are too few datapoints to usethe NAFTA calculation
Watermelon	5	< 0.01	0.04	0.02	0.02	2	LN, 99th	0.08	0.1	There are too few datapoints to usethe NAFTA calculation
Sweet corn	4	< 0.01				4	NA		0.1	There are too few datapoints to usethe NAFTA calculation
Tomato	15	0.03	0.46	0.21	0.19	0	LN, 99th	1.06	1	
Head lettuce	8	0.18	3.2	1.21	0.98	0	UPL Median 95th	8.8	5	There are too few datapoints to usethe NAFTA calculation
Beans	8	0.12	1.2	0.51	0.49	0	LN, 99th	2.05	2	There are too few datapoints to usethe NAFTA calculation
Soya beans	28	< 0.01	0.06	0.03	0.02	7	μ ± 3SD	0.09	0.1	-
Carrot	13	< 0.1	0.22	0.14	0.12	3	LN, 99th	0.28	0.5	23% of the values < LOQ
Artichoke	6	< 0.05	0.32	0.18	0.15	1	LN, 99th	0.73	0.5	Too few data points to use the SC 16% of the values < LOQ
Barley	37	< 0.05	1.1	0.19	0.06	17	μ ± 3SD	1.08	2	46% of the values < LOQ

Commodity	No. of Trials	Min. Value (mg/kg)	Max Value (mg/kg)	Mean (mg/kg)	STMR (mg/kg)	No. ≤ LOQ	Statistical Calculation		JMPR	
							Distribution Type	Estimate (mg/kg)	MRL (mg/kg)	Comment/ Explanation
Rice	8	0.11	0.97	0.36	0.28	0	LN, 99th	1.5	2	There are too few datapoints to usethe NAFTA calculation
Maize	4	< 0.1					NA		0.1	There are too few datapoints to usethe NAFTA calculation
Peanut	19	< 0.01	0.08	0.04	0.04	13	μ ± 3SD	0.1	0.1	-
Rape seed	26	< 0.05	0.28	0.09	0.09	3	LN, 95th	0.39	0.5	There are too few datapoints to usethe NAFTA calculation
Coffee	5	0.02	< 0.1			3	NA		0.1	There are too few datapoints to usethe NAFTA calculation. 60% of the values < LOQ
Hops	8	5.8	21	11	9.65	0	LN, 95th	31.5	30	There are too few datapoints to usethe NAFTA calculation
Barley straw	36	0.16	19.3	3.6	2.5	0	LN, 95th	22.6	30	

[a] **95LN** is the 95% upper confidence bound on the point estimate of the 95th percentile.

99LN is the 99% point estimate.

UCL Median 95 is the 95th percentile of the upper confidence limit of the median value (50th percentile), assuming a coefficient of variation of 1 and a lognormal distribution. In such cases the 95th percentile is 3.9 times the median. The value is 3.9 times the upper confidence limit on the median.

Mean + 3 SD is the mean plus three standard deviations. According to the Chebychev Rule, at least 89% of measurements are within three standard deviations of the mean, and this is regardless of the shape of the frequency distribution.

Dw - dry weight, LOQ, limit of quantification; NA - NAFTA, SC – Statisical calculator, SD - Standard deviation

2.8 NATURE OF RESIDUE DATA POPULATIONS AND METHODS FOR COMBINING RESIDUE TRIAL DATA SETS

The JMPR estimates maximum residue levels (indicated with mrl to distinguish from the Codex MRL) for use as Codex MRLs.[16] The recommended maximum residue levels (mrl) are based on supervised trials reflecting the highest of the nationally recommended dosage and shortest pre-harvest intervals. The number of such trials is usually limited. In order to improve the reliability of the estimated supervised trial median residues (STMRs), the JMPR regularly combined those data sets which reflected similar use patterns and they appeared to come from similar residue populations, and verified the assumption with the Mann-Whitney U-test.[17] The JMPR has recently been exploring the approach of combining data sets for estimation of mrls.

Statistical methods of mrl estimation generally aim to estimate a prescribed percentile value (e.g., 95th percentile) for the underlying population based on the available data. This involves making assumptions regarding the underlying distribution and estimating the range of residues beyond the observed values. In particular, care is required in selection of data which should be:

- from a single population or the equivalent of a single population;
- a random sample (or equivalent such as stratified random) from the population;
- available in sufficient number to provide some assurance about the data distribution and to minimize the errors of extrapolation required to estimate high percentiles.

The NAFTA Working Group published the final version of a method for the statistically based estimation of the MRLs.[18] The Working Group stated that "when the sample size is 15 or larger, the calculated MRLs consistently provide narrower ranges", and "if the data set has less than 10 data points, the MRL calculations ... are not very precise".

An independent review of the NAFTA calculator noted that for small sample sizes the methods employed lead to "both poor theoretical grounding and poor simulation performance" which is "not surprising given the problem of extreme percentile of an unknown distribution based on a small sample is an extremely difficult one". It was suggested that "rather than trying to modify the appropriate tolerance limit calculation so that its performance in small samples is less variable (and thus less appropriate), it is more sensible to simply place a lower limit on the allowable size of

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[16] Codex Alimentarius Procedural Manual: Codex maximum limit for pesticide residues (MRLP) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:

(a) toxicological assessment of the pesticide and its residue; and

(b) review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices.

[17] In: Pesticide Residues in Food—2001. Report of the JMPR 2001, FAO Plant Production and Protection Paper, 167, p. 14

[18] http://www.pmra-arla.gc.ca/english/pdf/mrl/calc2-eng.xls

samples to be used in mrl setting." The review strongly recommended that no adopted methodology allow the setting of an MRL based on a sample of less than 15 observations.

The individual or combined residue data sets available for estimation of STMR or mrls typically vary from 3 to 50 or more (minimum of 1 to a maximum of 71). Figure 1 shows the frequency of the number of trials, from which the mrls were estimated by the JMPR from 2002 to 2007, excluding those trials with over 80% of non-detected residues.

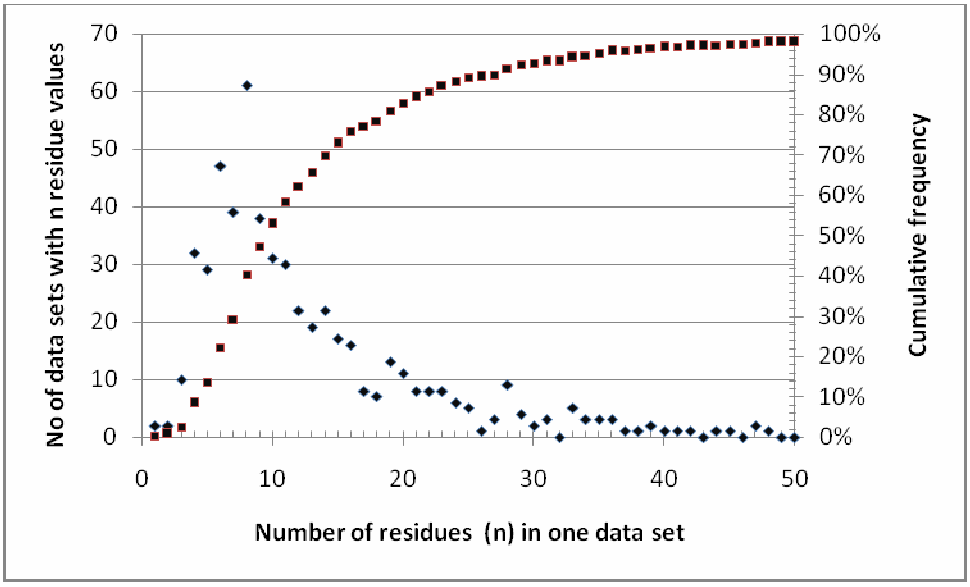

Figure 1 Frequency of occurrence of data sets consisting of *n* residue values used by JMPR between 2002 and 2007

The figure indicates that most frequently the STMR/mrl estimates were based on 8 (61), 6 (47) and 9 (38) supervised trials, and data sets consisting of 9 or less trials represented 47.2% of the 551 cases studied.

In the majority of cases (70%) less than 15 relevant residue trials were available to JMPR for estimating an mrl. The number of available trials reflects the requirements of national regulators. The use of combined sets of observations, from related, but not identical, field trials (i.e., deriving from similar GAPs) may allow more reliable use of statistical methods for estimating mrls, as they consist of larger number of observations than the individual ones. However, the validity of mrl estimates based on combined data sets is reliant on the comparability of the information from the individual trials. The various data sets derived from supervised trials carried out in various countries or on similar crops cannot be automatically pooled together. The distribution of residue data shall be carefully examined and only those which may be expected to form the same populations should be combined.

The proper evaluation of residue data requires the understanding of the nature of residue populations and the limitations of the estimations based on small samples.

1. Nature of residue data populations

1.1 Between fields variability of residues

Due to the large number of factors affecting the distribution and magnitude of the residues within a field trial, the variability of residues among field trials in composite samples of typical size of 12–25 units is large (typical co-efficient of variation (CV) values are in the range of 60 to 110%[19]).

Statistical analysis of supervised trial data sets with minimum 15 residue values, evaluated by the JMPR between 1997 and 2007, indicates that in many cases (70% of 144 data sets) log-normality of the data sets cannot be excluded. Although this should not be taken as evidence that the underlying populations conform to log-normal distributions, the following discussion will proceed on the assumption of log-normality for residue populations.

Figures 2 and 3 illustrate the hypothetical log normal distribution of residues simulating thousands of supervised trials where a crop has been harvested at different times after application at the same rate, say 1 kg ai/ha. Table 2 contains the parameters of the distributions used for constructing the figures.

Table 2 Parameters used to generate the lognormal curves of hypothetical residues.

PHI (days)	7	14	21	28	All data
Limited decline					
Mean ln(residue)[a]	-0.78	-0.88	-0.98	-1.08	
SD ln(residue) [a]	0.98	0.98	0.98	0.98	
Median [a]	0.46	0.42	0.38	0.34	0.39
95th percentile [a]	2.30	2.08	1.88	1.70	2.00
Moderate decline					
Mean ln(residue)	-0.78	-1.08	-1.38	-1.68	
SD ln(residue)	0.98	0.98	0.98	0.98	
Median	0.46	0.34	0.25	0.19	0.29
95th percentile	2.3	1.7	1.26	0.94	1.62

[a] Parameters of the hypothetical log-normal distribution

The graphs have been constructed to examine the case where the application rate is the same in two countries but the pre-harvest interval (PHI) is different, however the conclusions would equally apply to other situations (different application rate, same PHI; different application rate and different PHI).

The graphs can be thought of as the actual distribution of residues from which a small number of residue trial data are evaluated in MRL estimation. Although for each graph there is significant overlap in the distributions, each distribution has a different 95th percentile and could potentially lead to a different MRL recommendation for GAPs that have different PHI values.

In the first example (Figure 2) there is limited decline in residues with time, the median for residues at 7 days PHI is 0.46 mg/kg and at 28 days 0.34 mg/kg while the 95th percentiles are 2.3 and 1.7 mg/kg respectively. In the second example the decline in residues is moderate with median values of 0.46 mg/kg at 7 days and 0.19 mg/kg at 28 days while the 95th percentiles are 2.3 and 0.94 mg/kg respectively.

[19] Ambrus A., 2000. Measurement of uncertainty in pesticide residue analysis: implications in legal limits, Ital. J. Food Sci. N. 3 vol 12. 259-278.

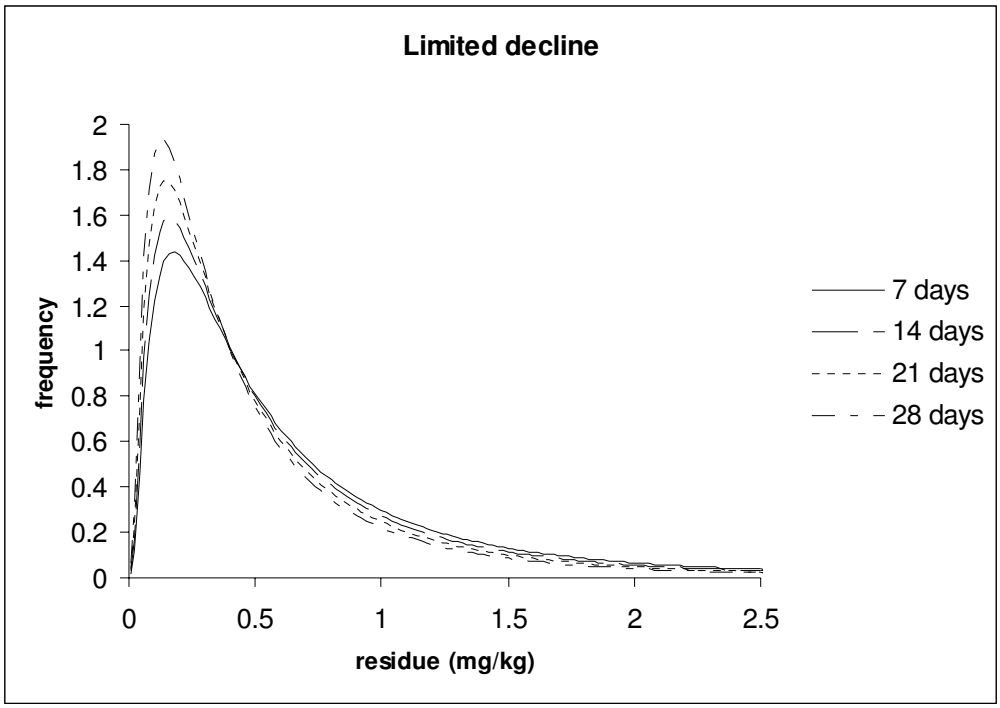

Figure 2 Distribution of residues at different PHIs following treatment with a pesticide with limited decline in time

Under practical conditions the true distribution of the residues is not known, we can only estimate them from a small number of samples.

We may assume that a set of trials conducted at maximum label conditions is equivalent to a random sample taken from a large residue population resulted from the pesticide application according to maximum GAP that occur in typical farming practice. The set of such trials is then considered as a stratified random sample representing the agriculture practice where the maximum amount of pesticides (dosage rate, number of applications) were used at shortest PHI permitted by the national GAP. Thus the residues indicate their upper concentration range that may be present in marketed commodities treated according to the particular GAP.

In reality, many crops are treated with longer PHIs and/or lower application rates resulting in residues lower than the MRLs, as indicated by the results of market place monitoring programmes, where only a very small proportion of the marketed commodities contains residues close or above the MRL.

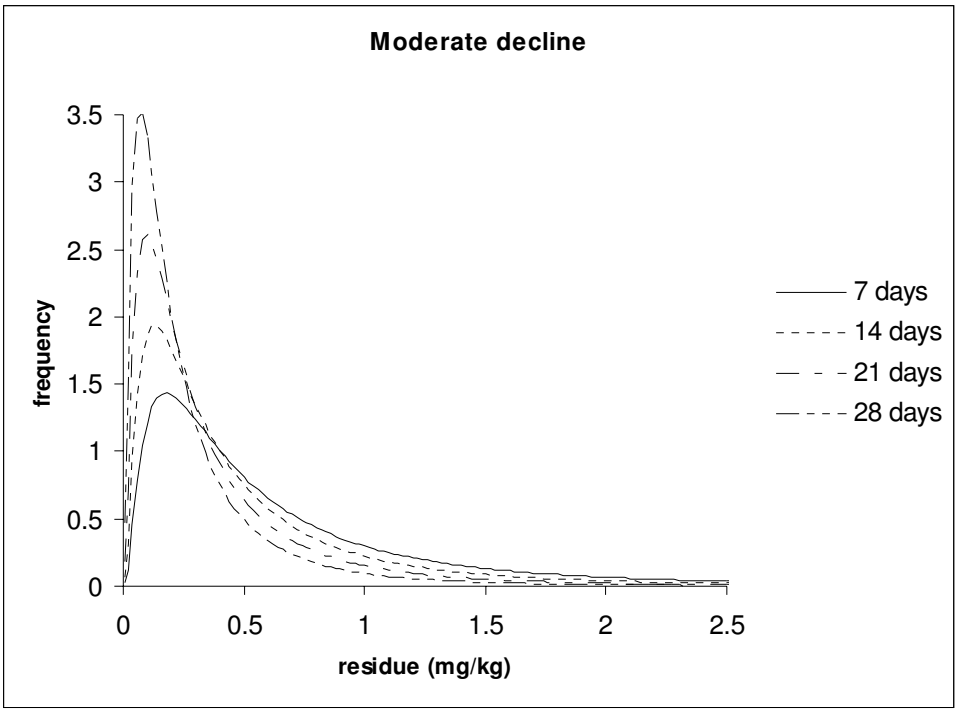

Figure 3 Distribution of residues at different PHIs following treatment with a pesticide with moderate decline in time

1.2 Variability of residues deriving from sampling

The inevitable variability of residues resulting from the wide dispersion of the residues within and among fields is illustrated with the results of random samples of size 4–50 drawn with replacement from a fixed parent population.

In the described process 1000 samples, consisting of either 50 or 30 residue values, were drawn with replacement from the parent population shown in the left column of Table 3. From the 1000 samples ordered according to their mean residue, the 975th (R0.975) and 25th (R0.025) samples were taken and their maximum, mean, median, minimum, CV and SD values were listed in the columns under R0.975 and R0.025. Similarly the parameters of samples ordered according to their median values are listed under columns P0.975 and P0.025.

Even when 1000 random samples, representing 50 and 30 residue trials (sample size), were drawn with replacement from a theoretical parent sample population with log-normal distribution and a CV value of 0.77, the characteristics of the populations showed substantial variation. The results are summarized in Table 3.

Table 3 Characteristic parameters of samples drawn with replacement from a log-normally distributed parent populations with a CV of 0.77

	Parent population	Sample populations (1000 samples of *n* trials)							
	n = 10 000	*n* = 50		*n* = 50		*n* = 30		*n* = 30	
Sample		R0.975[20]	R0.025	P0.975[21]	P0.025	R0.975	R0.025	P0.975	P0.025
Max	25.21	13.54	16.14	11.14	16.14	19.39	9.60	14.08	8.05
Mean	3.52	4.32	2.82	3.84	2.87	4.59	2.63	3.22	2.90
Min	0.20	0.52	0.73	0.73	0.56	0.73	0.73	0.44	0.52
Median	2.78	3.55	2.39	3.47	2.19	2.96	2.37	2.46	2.07
CV	0.77	0.69	0.83	0.59	0.94	1.04	0.75	0.87	0.72
SD	2.717	2.973	2.350	2.253	2.705	4.782	1.959	2.802	2.077

Notes: Parent population consists of residues in samples taken from 10 000 trials

Columns marked with R0.975 and R0.025 show the maximum, mean, median and minimum co-efficient of variation and standard deviation for the dataset representing the 97.5th and 2.5th percentile of residues in 1000 samples, each with *n* = 30 or 50 residue values, ordered according to their average residues. The columns P0.975 and P0.025 show the same parameters of samples ordered according to their median

The range of R0.025 and R0.975 encompasses the values obtained from samples corresponding to the 2.5% and 97.5% of the sample populations (covering the 95% centre portion of the of the sample population)

When small number of trials (4–10 data points) is sampled from the same parent population, the variability in individual sample mean, median, maximum and minimum residues is larger and show inverse relationship with the square root of sample size.

The expectable variation is demonstrated with the 66 trial data obtained with tolylfluanid on tomato.[22] As the range of residues measured as parent tolylfluanid and the sum of the parent compound and its metabolite (DMST) was very similar, for this example the 33 residue values for tolyfluanid have been combined with the 33 values for the sum of tolyfluanid and DMST, in order to obtain a reasonably large realistic data set used as parent population for simulation of sampling. Table 4 shows the individual residue values for samples that represent the 2.5th and 97.5th percentile of 1000 data sets ordered first according to their median residues and then sets having the same median values were ordered by their maximum residue values.

[20] R0.975 refers to the individual dataset that is at rank represented by the 97.5th percentile when datasets are ordered by average.

[21] P0.975 refers to the individual dataset that is at rank represented by the 97.5th percentile when datasets are by ordered median

[22] In: Pesticide Residues in Food—2002. Report of the JMPR 2002, FAO Plant Production and Protection Paper, 172.

Table 4 Residues in data sets obtained with random sampling from a parent population of 66 residue values

N	Percentile	Individual residues in the relevant data set									
4	P.025	0.05	0.05	0.19	0.49						
	P.975	0.18	0.4	1.27	1.4						
5	P.025	0.05	0.07	0.14	0.14	0.48					
	P.975	0.07	0.27	0.67	0.77	1.27					
6	P.025	0.07	0.15	0.15	0.18	0.27	0.56				
	P.975	0.05	0.42	0.47	0.77	0.77	0.99				
8	P.025	0.04	0.08	0.1	0.15	0.22	0.24	0.6	0.72		
	P.975	0.18	0.4	0.54	0.59	0.59	0.67	1.5	1.5		
10	P.025	0.05	0.07	0.15	0.15	0.16	0.23	0.47	0.5	0.54	0.67
	P.975	0.14	0.29	0.34	0.35	0.54	0.59	0.6	0.7	1.4	2.2

Table 5 includes the characteristic parameters of the original residue population (66 data points) called parent population and the samples covering the 95% range of sample populations (between 2.5th and 97.5th percentiles).

Comparing the estimated maximum residue levels based on the NAFTA and the traditional JMPR procedures indicates the uncertainty of the estimation based on small number of residue data points (samples). For instance, there is 95% probability that we may get random samples from the same 'true' parent data population leading to an estimated mrl ranging from 1–6 mg/kg for sample size of 5 or from 1.5–3.5 for sample size of 10 with NAFTA method and 0.5–2 and 1–3 with the JMPR procedure for the same samples.

The large inevitable variation of residues in small samples underlines the importance of proper selection of valid residue data which form the data base for the estimation of the mrls, especially in those cases where statistically based estimation of mrls is aimed, for instance, by applying the NAFTA calculation method.

Table 5 Characteristic values of original supervised residue data set and those of 1000 samples of size *n* withdrawn from the original residue data

n	Percentile	Residues in samples [a]				Estimated MRLs		
		Max	Med	Mean	Min	NAFTA		JMPR
66		2.20	0.370	0.452	0.040	1.8	2	3
4	P.025	0.49	***0.120***	0.195	0.050	1.3	1.5	0.7
	P.975	1.40	**0.835**	**0.813**	0.180	6	6	2
5	P.025	0.48	0.140	***0.176***	0.050	1	1	0.5
	P.975	1.27	0.670	0.610	0.070	6	6	2
6	P.025	0.56	0.165	0.230	0.070	1	1	0.7
	P.975	0.99	0.620	0.578	0.050	1.6	2	2
8	P.025	0.72	0.185	0.269	0.040	1.3	1.5	1
	P.975	1.50	0.590	0.746	0.180	3.5	3.5	2
10	P.025	0.67	0.195	0.299	0.050	1.3	1.5	1
	P.975	2.200	0.565	0.715	0.140	3.5	3.5	3

Notes: [a] The values presented represent the 95% range of the 1000 small samples

The maximum observed median and mean values of all data are indicated with bold and the minimum values are with bold-italics numbers

2. Principles of selection of residue data for estimation of mrls

2.1 Estimation based on the residues derived from the maximum (one) GAP

In accordance with the Codex definitions and general practice of the JMPR, the mrls are primarily estimated based on the GAP that leads to the highest residue (**ONE GAP**, the critical or **maximum GAP**), i.e., the trials represent the maximum residue anticipated when a pesticide is applied according to the one GAP (label directions, usually maximum permitted application rate, shortest PHI). The Codex Alimentarius definition (JMPR practice) implies that only the results of "supervised trials conducted at the highest nationally recommended, authorized or registered use" are included in mrl estimation (i.e., one maximum GAP per country, one of these is used to select data for mrl estimation).

The focus on one GAP allows for alternative GAP to be assessed if there is an identified dietary intake problem.

As a general precondition, for reliable estimation of maximum residue levels an adequate number of independent trials are required which reflect the national maximum GAP and conducted according to well designed protocols that consider geographical distribution and the inclusion of a number of different growing and management practices, and growing seasons.

Maximum residue level estimates may be based on an accepted/recognized extrapolation of trial data to cover commodities within a group which had shown similar residue pattern. Application should be made using equipment and spray volumes likely to give rise to the highest residues. As weather (not climate) is usually the major factor in determining the resultant residues for such trials, only one field trial would normally be selected per trial site if multiple plots/trials are conducted in parallel.

The decline rate of a pesticide may be different at various geographical locations depending on, among others, the weather, cultivation mode and soil conditions. Under practical conditions the number of trials which can be performed for a given commodity is limited. On the other hand, a larger data set *representing statistically not different residue population* provides more accurate estimation of the selected percentile than a small data set derived from trials representing the critical GAP but only if the data are not biased by missing a segment of the underlying population such as might occur if data were from a single season and from the same region, and consequently did not reflect the actual range of growing conditions and management practices.

Consequently, where only limited number of trial data is available from the 'ONE' GAP assumed to lead to the highest magnitude of residues, one approach is to consider those GAPs which may possibly lead to similar magnitude of residues, and this assumption can be confirmed based on prior experience and with suitable statistical methods described in section 3.

2.2 Consideration of all trials conducted at various maximum GAPs

As an alternative to the selection of the ONE GAP described in section 2.1, the other possibility would be to include all trials in the residue data set used for estimation of mrls provided that residues are derived from trials conducted with maximum dosage rate at shortest PHI permitted by any relevant national maximum GAP.

Though, from global trade prospective such an approach may better reflect the residue population in traded commodities, this method leads to two conceptual problems as it would include residue data with significantly lower median (mean) values, which would result in lower estimated daily intake than that obtained from the residues reflecting the highest GAP, and lower MRLs if the latter one would be calculated with the NAFTA procedure.

The effect of combining all residues deriving from any maximum GAP is illustrated with an example:

Lets assume that the data set A, showing lognormal distribution (0.050, 0.060, 0.070, 0.100, 0.130, 0.140, 0.140, 0.140, 0.160, 0.170, 0.210, 0.210, 0.230, 0.270, 0.270, 0.280, 0.290, 0.330, 0.340, 0.340, 0.380, 0.380, 0.410, 0.440, 0.490, 0.500, 0.570, 0.570, 0.680, 0.680, 0.730, 0.800, 0.840, 0.860, 0.900, 0.900, 0.900, 0.910, 0.920, 1.060, 1.070, 1.170, 1.210, 1.360, 1.430, 1.480, 1.800, 1.890, 1.990, 3.550) would be combined with additional low residue values (15×0.05 and 16×0.10) representing a different maximum GAP. The estimated maximum residues based on 95UCL calculation would be 3.51 mg/kg and 2.24 (based on California mean+3×SD), respectively, leading to mrl estimates of 4 mg/kg and 2.5 mg/kg, regardless that the maximum valid residue value is 3.55 mg/kg. The median values would be 0.5 mg/kg and 0.17 mg/kg, respectively.

Combination of such data is clearly inappropriate as the deterministic approach used for estimation of daily intake aims to identify the highest residue level, which a certain portion of the world populations might be exposed to.

The above approach would also contradict with one of the purposes of Codex MRLs as MRLs for trade and it would also be unfair to growers of a country with critical GAP if the estimated mrl would be much lower than the residues expected after applying the pesticide at maximum GAP.

It should be noted that:

1. there is a subtle difference in the two selection procedures and the mrl recommendations will differ. In scenario 1 with data set A, the residues at the high end of the distribution dominate and this leads to an estimation of a larger mrl value. In scenario 2, adding trials with low residues, as occurs when datasets are combined, gives a smaller estimate for the 95th percentile even though the highest residue remains the same;
2. the mrl estimated with the NAFTA method may also be different where similar data sets are combined due to the different calculation methods used depending on the size of the sample and the distribution of residues.
3. In special cases where residues do not show evidence of decline and do not scale with application rate, such as triadimefon/triadimenol in grapes (JMPR 2007) it may be appropriate to consider wider range of GAPs.

3. Statistical methods for deciding on the similarity of data sets

As it was shown in section 1, the inevitable sampling variation may lead to an inaccurate estimation of the true residue population resulted from the use of a pesticide according to maximum GAP. The NAFTA statistical procedure for estimation of mrls claimed to provide reasonable estimates based on samples larger than 15, and the estimation becomes more precise if it is based on larger residue data sets.

Under practical conditions such number of trials reflecting the critical GAP is rarely available; one approach is to combine similar data sets. While similarity of data is extremely difficult to assess statistically and should primarily be based on other scientific criteria, tools are available that can be used to ascertain if data sets come from populations characterized by similar median/mean and variance.

In view of the skewed distribution of residues and the difficulties of describing the residue distribution with parametric methods, distribution free statistical methods should be applied for testing the similarity of sample populations.

The JMPR routinely applied the Mann-Whitney U test for comparing two data sets before they were combined. However, there are cases where more than two data sets should be compared. In such cases the U-test is not applicable, and the so called Kruskal-Wallis H-test may be used. It assumes that the samples are taken from continuous populations of similar shape, the errors in individual residue values are independent. Thus, if the null hypothesis is rejected we do not know whether the median values, the shape or the variance of the tested populations are different. It is

applicable for ***k*** independent samples, provided that the data sets are not too small (≥ 4). For the purpose of the test, samples are independent if the supervised trials had been carried out at different sites.

The null hypothesis, H_0, is that the ***k*** independent sets of samples were taken from the same parent population. The calculation is illustrated in Table 5 with the example of deltamethrin residues in leafy vegetables (2002 JMPR) and performed as follows:

4. Mark, with different colours and or letters, the residue values belonging to the ***k*** data sets consisting of N_i residue values to enable the distinction of data sets from each other.
5. Combine the residues from the ***k*** data sets in one data set consisting of $N=\sum N_i$ residue data, and arrange the residues in ascending order.
6. Determine the rank number of individual residues (r_i) giving the same rank for the same residue values (ties) and calculate the sum of the ranks (R_i) for each data set.
7. Calculate the H statistics and the correction factor (C_f) for the ties.

$$H = \frac{12}{N(N+1)} \sum_{i=1}^{k} \left(\frac{R_i^2}{N_i} \right) - 3(N+1)$$

$$C_f = 1 - \frac{\sum_j T_j}{N^3 - N}$$

Where $T_j = t^3 - t$, and t is the number of ties. For instance the residue values of 0.03 occur twice, so t =2 and $T_j = 2^3 - 2 = 6$. The value of 0.1 occurs 5 times, so t = 5 and $T_j = 5^3 - 5 = 120$.

8. Calculate the corrected H_c value:

$$H_C = \frac{H}{C_f}$$

9. The H_c value follows χ^2 (chi square) distribution with ν = k-1 degrees of freedom. If $H_c \leq \chi 2_{0.05,\nu}$ the null hypothesis is retained, which indicates that the tested residue populations are not significantly different and can be combined for the estimation of mrls.

The critical $\chi^2_{0.05}$ values are:

ν	2	3	4	5	6
$\chi^2_{0.05}$	5.9915	7.8147	9.4877	11.0705	12.5916

Table 6 Illustration of the calculations for Kruskal-Wallis test for comparison of multiple independent samples

	Independent residue data sets			All residues	Corrected ranks	Corrected rank numbers for sample sets			Ties	T_j
	Curly kale	Lettuce	Spinach			Curly kale	Lettuce	Spinach		
No of data	8	10	16	34	34	8	10	16		
Sum of ranks, R_i					595	160	215.5	219.5		
R_i^3/N_i						3200	4644.02	3011.27		
	0.07	0.07	0.03	0.03	1.5			1.5	2	6
	0.08	0.12	0.03	0.03	1.5			1.5		
	0.1	0.13	0.04	0.04	3			3		
	0.11	0.15	0.06	0.06	4			4		
	0.32	0.18	0.08	0.07	5.5	5.5			2	6
	0.32	0.18	0.09	0.07	5.5		5.5			
	0.34	0.25	0.09	0.08	7.5	7.5			2	6
	0.39	0.26	0.1	0.08	7.5			7.5		
		0.29	0.1	0.09	9.5			9.5	2	6
		0.41	0.1	0.09	9.5			9.5		
			0.1	0.1	13	13			5	120
			0.14	0.1	13			13		
			0.17	0.1	13			13		
			0.2	0.1	13			13		
			0.5	0.1	13			13		
			1	0.11	16	16				
				0.12	17		17			
				0.13	18		18			
				0.14	19			19		
				0.15	20		20			
				0.17	21			21		
				0.18	22.5		22.5		2	6
				0.18	22.5		22.5			
				0.2	24			24		
				0.25	25		25			
				0.26	26		26			
				0.29	27		27			
				0.32	28.5	28.5			2	6
				0.32	28.5	28.5				
				0.34	30	30				
				0.39	31	31				
				0.41	32		32			
				0.5	33			33		
				1.0	34			34	17	156

The performance of the Kruskal-Wallis test is facilitated by an Excel template, which performs the calculations for 7 data sets after inserting the residues composing of the data sets and arranging the ranks corrected for ties for each sample set.

The ranks are corrected for ties accurately if the sum of corrected ranks is equal to the total number of samples.

4. Recommendations

The Meeting confirms the applicability of its current practice and emphasizes the importance of the following principles:

1. Only the results of "supervised trials conducted at the highest nationally recommended, authorized or registered uses" should be considered in mrl estimation (i.e., maximum GAP per country)
2. Where prior experience indicate that the agricultural practice and climatic conditions lead to similar residues the critical GAP of one country can be applied for the evaluation of supervised trials carried out in another country.
3. Statistical calculations in support for mrl estimation should only be used where the data are suitable for those data to yield valid conclusions. Considerations should include:
    - data from a single population or the equivalent of a single population;
    - the data should be from a random sample or stratified random sample from the population; and
    - sufficient data (≥ 15) should be available to minimize the errors of extrapolation to the required high percentile values;
    - the number of residue values below the LOQ and the residue distribution around LOQ;
    - no statistical test should be applied for excluding potential outliers; residue data should only be excluded if experimental evidence indicates that the data is invalid.
4. If a sufficient number of trials is available reflecting the maximum GAP of one country or geographical region, the mrl estimates should be based those residue data alone.
5. When considering combining different residue data, the distribution of residue data shall be carefully examined and only those datasets combined which may be expected to arise from the same parent populations based on comparable GAP. The expert judgement (see also point 6) could be assisted with appropriate statistical tests (e.g., Mann-Whitney U-test or Kruskal-Wallis H-test)
6. The focus on one GAP allows for alternative GAP to be assessed if there is an identified dietary intake problem. In such cases, where residue data permits, an alternative national GAP is considered and the supporting residue data sets are used for estimation of mrls which do not raise acute intake concern.
7. In cases, where only small number of residue data are available, mrl estimates should take into account:
    - the highest values, median value and approximate 75^{th} percentile value in the available data set of supervised residue trials;
    - residue levels resulting from application rates other than the label rate (for instance, using residues below LOQ in samples derived from double rate treatments to support no detectable residues following the application at maximum label rate, using highest residues from samples taken at longer intervals than PHI);
    - experience of typical distributions of residue data from supervised trials;
    - knowledge of residue behaviour from the metabolism studies (e.g., is it a surface residue, does it translocate from foliage to seeds, roots, etc.); and
    - knowledge of residue trials on comparable crops.
8. The Meeting does not consider it appropriate to combine residue data sets deriving from different GAPs without sufficient justification. This method would include residue data with

different median (mean) values, which would result in lower estimated daily intake and also lower mrls if the latter would be calculated with the NAFTA statistical calculator.

9. There may be some situations which are not covered by the general principles outlined in this section. Such cases require a casa-by-case consideration and expert judgement based on all available information and prior experience.

10. Principles used for the evaluation of data sets for one pesticide-commodity combination may be applied for evaluation of residues within one commodity group (e.g., application of 'one GAP' principle for estimating mrl for a group based on the highest residues data set obtained in one commodity).

2.9 EVALUATION FOR FOLLOW-UP CROPS

The JMPR 2006 recommended the CCPR to request member countries to provide information on how residues in follow crops are regulated at the national level. This information will be taken into account in making recommendations based on the evaluation of residues in follow crops.

In member countries which provided information (Australia, the EU, Japan and the United States) residues in follow crops are regulated either by setting specific MRLs for "other plant commodities or crop groups" according to the residue definition for primary treated crops or by setting label restrictions on the type of succeeding crops and/or the plant back interval after harvest. The Meeting recognized that neither approach is applicable for the JMPR, since label restrictions are limited to national authorisations and MRLs for "other plant commodities" are currently not supported by the Codex classification system for foods and animal feeds.

For an estimation of possible residues in follow crops the Meeting must rely on the information provided. In 2006 the JMPR emphasized that in cases where residues in follow crops may occur at levels above the LOQ, in addition to the minimum data requirements as specified in the *FAO Manual*, the data submitters should automatically provide information on metabolism in root or tuber vegetables, environmental fate studies and the results of field studies on follow crops carried out at various times after the application of the pesticide.

Field studies on follow crops in particular provide important information for an estimation of possible residues levels under more realistic conditions. By comparing these residues with results obtained from supervised residue trails on primary treated crops (if available) a decision can be made if the recommended maximum residue levels are also sufficient for commodities from follow crops including theoretical additional treatments with the same active substance in subsequent years.

More realistic maximum residues expected in succeeding crop groups (e.g., root and tuber vegetables, leafy vegetables or cereals) can be estimated based on an extrapolation from the representative follow crops used in the field studies. For such an extrapolation the metabolism in rotational crops as well as the aerobic metabolism in soil must be investigated sufficiently. The estimation of residues level must be based on the maximum annual application rate according to the labels provided, the residue definition for enforcement purposes proposed for plant commodities and the residue data for representative crops obtained from follow field studies. In addition the interval between last treatment and the crop rotation must be taken into account when considering the degradation rate in soil under field conditions, in order to estimate a realistic concentration of the active ingredient in the soil at the planting/sowing of the following crops.

As an example, chlorantraniliprole (5.6) evaluated by JMPR 2008 various studies on follow crops were provided to the Meeting conducted according to the maximum seasonal application rate.

For the leafy vegetables group investigated in lettuce, spinach and Swiss chard residues found were in the range of < 0.01 to 0.01 mg/kg. In comparison to the group maximum residue level

recommended for leafy vegetables of 20 mg/kg no significant contribution to total residues in these commodities by follow-crops is expected by the Meeting.

Root and tuber vegetables gave residues ranging from < 0.01 up to 0.01 mg/kg in turnip, beet and radish roots. Under consideration of the maximum residue level recommended for root and tuber vegetables of 0.01 mg/kg, the Meeting decided to combine residues from direct treatment and follow-crops to recommend a maximum residue level of 0.02 mg/kg and an STMR of 0.01 mg/kg for root and tuber vegetables.

Cereals are not registered for direct treatment using chlorantraniliprole according to the labels provided. In follow crop studies, residues in cereal grain, forage and straw/hay of up to < 0.01, 0.083 and 0.15 mg/kg were found, respectively. Based on this data the Meeting recommended maximum residue levels and STMR values of 0.02 and 0.01 mg/kg for cereal grain and 0.3 and 0.051 mg/kg (dry-weight based) for straw and fodder of cereal grain, respectively. For cereal straw and hay also a highest residue of 0.17 mg/kg (dry-weight based) was recommended. For cereal forage an STMR of 0.022 mg/kg and a highest residue of 0.083 mg/kg were used in the livestock animal's dietary burden.

For pulses only two data points from follow crop studies with detections below the LOQ of 0.01 mg/kg were available. The Meeting considered two trials on pulses to be inadequate for the purpose of estimating maximum residue levels.

No trials on residues in follow crops were available on brassica vegetables, stalk and stem vegetables, legume vegetables, bulb vegetables, oilseeds, grass/pasture and legume animal feeds. No recommendations were given for commodities of these crop groups.

In view of the purpose of these studies the Meeting pointed out that all information obtained is utilized in estimating the maximum residues in follow crop commodities after treatment of the primary crops according to the GAP. In most cases the data provided are not intended for an estimation of median residues in plant commodities used in the dietary risk assessment or livestock animal dietary burden resulting in an overestimation of the exposure.

The Meeting also noted that several special cases for residues in follow crops besides the normal agricultural farming exist. Examples may be the transfer of carbendazim from treated cereal straw used as substrate for fungi cultivation or clopyralid in manure and compost made from cattle excreta. In these special cases where an unexpected transfer into follow crops is observed, data submitters as well as member countries are encouraged to submit additional data suitable to assess residues in these commodities. Helpful data might be transfer studies for the individual scenario as well as monitoring data for commodities without authorizations for direct treatment.

2.10 SELECTION OF REPRESENTATIVE COMMODITIES WHEN ESTABLISHING COMMODITY GROUP MRLS

The Codex Classification of Foods and Animal Feeds is being revised by CCPR with one of the aims being to facilitate the establishment and interpretation of Codex MRLs.

In 2007, JMPR reported on 'Crop groups and commodity group MRLs'. The proposed draft revision of the Codex Classification of Foods and Animal Feeds was an agenda item of the 2008 session of the CCPR. The agenda item included a proposal for guidance on the selection of representative commodities.[23]

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[23] Codex Alimentarius Commission. *Report of the 40th Session of the Codex Committee on Pesticides Residues, 14–19 April 2008, Hangzhou, China*, (ALINORM 08/31/24). Draft document outlining the principles of and guidance on the selection of representative crops for the purpose of extrapolation of MRLs. The selection of representative commodities, principles and guidance. Addendum II to CX/PR 08/40/4.

The document (CX/PR 08/40/4) provided advice to JMPR about the use of representative crops and commodities for the purposes of residue extrapolation to commodity groups. Suggestions are based on practices from JMPR, USA, EU and Japan.

Ideally, groupings should be chosen so that members of the crop group, or sub-group, would be subject to the same GAP and the resultant commodities would form a group, or sub-group, with similar residue characteristics.

Representative crops and commodities should then be chosen according to their commercial importance and their residue characteristics.

The most important crop from a commercial perspective may not be the most important from a residue perspective. For example, Chilli peppers because of their size, normally have a higher residue than sweet peppers for the same GAP and are likely to drive a peppers MRL. However, a group MRL should not generally be established on the basis of data from a minor crop only.

The Meeting noted that the selection of representative crops and corresponding commodities for particular crop and commodity groups would be very valuable to proponents planning residue trials.

JMPR evaluates available data, whether on a 'representative' commodity or not. In estimating a group MRL, JMPR includes available data, if valid and sufficient, from all commodities whether potentially representative or not. Residue behaviour cannot always be predicted, and therefore the residue data driving the group MRL will not necessarily arise from suggested 'representative' commodities.

The Meeting looked forward to further progress with commodity grouping and representative commodities. Careful attention to grouping will assist the JMPR to propose group MRLs more often.

2.11 PROPORTIONALITY OF PESTICIDE RESIDUE CONCENTRATIONS AND APPLICATION RATES IN SUPERVISED TRIALS

JMPR often receives residue data from supervised trials on crops where the application rates in the trials do not match the GAP rate. Maximum residue level estimates are based on trials with application at the GAP rate. Applications at other rates are commonly used as additional evidence and context for the GAP trials. However, it would be advantageous to make more direct use of the data if possible.

The Meeting was aware of research work on 'proportionality', including the work reported at the IUPAC Congresses in 1998[24] and 2006.[25] Conclusions were drawn from JMPR residue data summaries. Also, side-by-side trials were initiated in USA. Until now, the data analysed have included only foliar uses of insecticides and fungicides.

Before the results of such work can be applied to residue evaluation, it is important to examine the conditions where proportionality is valid and where it is not. For example, proportionality may not apply to the use of herbicides or plant growth regulators on crops because the different application rates may have different effects on the crop.

Where proportionality is valid, the residues from trials other than the GAP rate could be adjusted to values equivalent to the GAP rate.

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[24] Banasiak U, Hohgardt K, Koinecke A, Plass R and Moll E. 1998. Extrapolation of residue data - based on the RUEDIS Information System. Abstract. IUPAC International Congress on Pesticide Chemistry, London, August 1998.

[25] Villanueva P and Hamilton DJ. 2006. Is the resulting residue proportional to pesticide application rate? Abstract. IUPAC International Congress on Pesticide Chemistry, Kobe, August 2006.

The Meeting invited research workers to publish their findings in the scientific literature and to describe the boundary conditions where ‘proportionality’ has been validated. This would provide a basis for JMPR and national authorities to make more use of non-GAP rate trials in residue evaluation.

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

3.1 CARBARYL (008)

The insecticide carbaryl was last evaluated by the 2002 JMPR within the periodic review programme. The Meeting concluded that the IESTI for children exceeded the ARfD (130–1100% for several crops). The 40th Session of the CCPR[26] reiterated the decision by the 39th CCPR (Para 42 of Alinorm 08/31/24) to return to Step 6 the draft MRLs for cherries; citrus fruits; citrus juice; citrus pulp, dry; dried grapes (=currants, raisins and sultanas); grape juice; grape pomace, dry; grapes and stone fruits, awaiting the outcome of the 2008 JMPR evaluation.

The Meeting noted that the 2002 JMPR did not report an intake concern for citrus fruits.

Updated GAP information was provided by The Netherlands and United States. The GAP from the Netherlands could not be matched with any trial data. The updated US GAP was the same as previously reported by the 2002 JMPR. The sponsor announced that no additional data would be submitted; the evaluation was then rescheduled to the 2008 JMPR.

Results of supervised residue trials on crops

Citrus fruits

The GAP in USA for citrus is up to 8 applications of 2.42 to 8.4 kg ai/ha, with a maximum of 22.4 kg ai/ha per season and 5 days PHI.

Supervised trials reported by the 2002 JMPR performed according to maximum GAP resulted in highest residues of 10, 5.5 and 6.8 mg/kg in orange, lemon and grapefruit, respectively. The calculated short-term intakes based on the highest residue of 1.16 mg/kg in pulp estimated by the 2002 JMPR for children and adults consuming orange and grapefruit are 40% and 20% of the ARfD of 0.2 mg/kg, respectively. Mandarin and lemon short-term intake for children was estimated as 20% and 10% of the ARfD.

Based on the available information the Meeting concluded that there was no need to consider an alternative GAP for citrus fruits and processed products prepared from them.

Cherries

For stone fruit including cherries, the available supervised trials were performed according to the maximum US GAP only. No alternative GAP or new trial data was made available.

Consequently the Meeting could make no new proposals for stone fruits or cherries.

Grapes

Similarly, trials performed in grapes reflected the maximum US GAP. No alternative GAP or trial data were made available to the Meeting. Consequently the Meeting could make no new proposal for grapes.

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[26] Codex Alimentarius Commission. *Report of the 40th Session of the Codex Committee on Pesticides Residues, 14–19 April 2008, Hangzhou, China*, (ALINORM 08/31/24)

3.2 LAMBDA-CYHALOTHRIN (146)

Background

At the 40th Session of the CCPR,[27] the delegation of the European Community (EC) raised concerns regarding the ADI and ARfD for lambda-cyhalothrin, established by JMPR in 2007 on the basis of neurotoxic effects.[28] The ADI and ARfD established by the EC were both lower than the values established by the JMPR.

Evaluation of lambda-cyhalothrin by the JMPR

In 2007, the JMPR established a group ADI for cyhalothrin and lambda-cyhalothrin of 0–0.02 mg/kg bw on the basis of neurotoxicity observed in a study of acute toxicity in rats given lambda-cyhalothrin orally (decreased motor activity), with a threshold dose of 0.5 mg/kg bw; and in repeat-dose studies with cyhalothrin and lambda-cyhalothrin in dogs treated orally (ataxia, tremors, occasionally convulsions) with a NOAEL of 0.5 mg/kg bw per day, using a safety factor of 25. Because lambda-cyhalothrin is relatively rapidly absorbed and excreted and the neurotoxic effects are rapidly reversible and dependent on C_{max}, the Meeting considered it appropriate to adjust the safety factor for the reduced variability in C_{max} compared with AUC.

In 2007 the JMPR established a group ARfD for cyhalothrin and lambda-cyhalothrin of 0.02 mg/kg bw on the basis of systemic neurotoxicity (decreased motor activity) observed in a study of acute toxicity in rats given lambda-cyhalothrin orally with a threshold dose of 0.5 mg/kg bw per day; and in repeat-dose studies with cyhalothrin and lambda-cyhalothrin in dogs treated orally, in which neurotoxic effects (ataxia, tremors, occasionally convulsions) occurred during the first week, within a few hours after treatment, with an overall NOAEL of 0.5 mg/kg bw per day, and using an safety factor of 25. For the same reasons as described above, the JMPR considered it appropriate to adjust the safety factor for the reduced variability in C_{max} compared with AUC.

Evaluation of lambda-cyhalothrin by the EC

The ADI established by the EC for lambda-cyhalothrin (0.005 mg/kg bw) was based on the NOAEL of 0.5 mg/kg bw per day, identified in 1-year and 26-week studies in dogs, on the basis of clinical signs of neurotoxicity observed at 3.5 mg/kg bw per day, and using a safety factor of 100.

In the EC evaluation, the ARfD for lambda-cyhalothrin (0.0075 mg/kg bw) was based on the NOAEL of 0.75 mg/kg bw per day, obtained from a 6-week study in dogs treated orally, on the basis of neurotoxicity observed at 1.5 mg/kg bw per day, and a safety factor of 100. For both the ADI and the ARfD, the EC considered that an extra safety factor could be necessary when undertaking a risk assessment for children.

Comment by the JMPR

The JMPR and the EC identified the same overall NOAEL for neurotoxicity as the basis for the ADI. The difference between the ADI established by the EC and that established by the JMPR is determined by the safety factor used. The EC used the default safety factor of 100, while the JMPR considered that it was appropriate and scientifically justified in this case to adjust the safety factor for these substances that are rapidly absorbed and excreted and have effects that are rapidly reversible

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[27] Codex Alimentarius Commission. *Report of the 40th Session of the Codex Committee on Pesticides Residues, 14–19 April 2008, Hangzhou, China*, (ALINORM 08/31/24).

[28] In: Pesticide Residues in Food—2007. Report of the JMPR 2007, FAO Plant Production and Protection Paper, 191. Lambda cyhalothrin (146), pp 91–98.

and dependent on C_{max}, compared with AUC.[29] Thus, the kinetic portion of the inter- and intraspecies safety factors was reduced by half, yielding an overall safety factor of 25 (see general item 2.6 of the present report)

The difference between the ARfDs established by the EC and by the JMPR can be explained by the different studies used as a basis for this decision and the different safety factors used. The ARfD established by the EC for lambda-cyhalothrin was based on a NOAEL of 0.75 mg kg bw per day identified on the basis of tremors observed at 1.5 mg/kg bw per day in a 6-week pilot study in dogs treated orally. JMPR noted that in this study each dosing group comprised only one male and one female. In view of this limitation, JMPR did not identify a NOAEL from this study and did not consider it to be appropriate to establish the ARfD on the basis of the results of this study. The studies that formed the basis for the ARfD established by the JMPR are described above.

The reasoning behind the choice of safety factor for the ARfD used by the JMPR was the same as for the ADI. The JMPR considered that there were no indications for increased sensitivity of children to acute or long-term oral exposure to lambda-cyhalothrin. Therefore, JMPR considered that the applied safety factor of 5 for intraspecies variation was adequate to protect all sensitive groups, including children.

3.3 FLUSILAZOLE (165)

Background

At the 40th Session of the CCPR, the delegation of the European Community (EC) raised concerns regarding the ARfD for flusilazole established by the JMPR in 2007 on the basis of developmental effects (Annex 5, reference *191*), the ARfD established by the EC differing from that established by JMPR

Evaluation of flusilazole by the JMPR

In 2007, the Meeting established an ARfD for flusilazole of 0.02 mg/kg bw based on the NOAEL of 2 mg/kg bw per day for skeletal variations in a study of developmental toxicity in rats treated orally, with a safety factor of 100. The lowest-observed-adverse-effect level (LOAEL) for embryo and fetal toxicity was identified as 10 mg/kg on the basis of a higher incidence of skeletal variations – extra cervical ribs. The incidence of rudimentary cervical ribs was slightly, but not statistically significantly, increased at 2 mg/kg bw per day (3 fetuses out of 3 litters, 4 fetuses out of 4 litters, 9 fetuses out of 6 litters, 27 fetuses out of 15 litters, and 141 fetuses out of 22 litters in the groups at 0, 0.5, 2, 10, 50 mg/kg bw per day, respectively).

Evaluation of flusilazole by the EC

The ARfD established by the EC, described in the EC review report as being relevant to women of childbearing age, was established on the basis of the same study of developmental toxicity in rats as used by the JMPR, but was based on a NOAEL of 0.5 mg/kg bw per day, resulting in an ARfD of 0.005 mg/kg bw. The EC considered that the non-statistically significant increase in rudimentary cervical ribs at 2 mg/kg bw per day was treatment-related and an adverse effect, as it represented the beginning of a dose–response relationship. The EC also identified two additional developmental effects at 2 mg/kg bw per day that the JMPR considered to be maternal effects, and not adverse effects at that dose. The first effect was an increase in red vaginal discharge (0, 0, 3, 12 and 22 out of

[29] In: Pesticide Residues in Food—2000. Report of the JMPR 2000, FAO Plant Production and Protection Paper, 163. Annex 5. page 198

25 rats at 0, 0.5, 2, 10 or 50 mg/kg bw per day, respectively) and the second was an increase in mean placental weight (0.54, 0.57, 0.67, 0.87 and 0.99 g at 0, 0.5, 2, 10 and 50 mg/kg bw per day, respectively). In both cases, statistical significance was achieved at doses of 2 mg/kg bw per day and above. The red vaginal discharge occurred late in gestation and was not associated with adverse reproductive outcomes in the three dams at 2 mg/kg bw per day.

Comment by the JMPR

The JMPR and the EC identified the same critical effects in the same study of developmental toxicity as being the basis for the ARfD. The primary differences in the JMPR and EC assessments were the identification of the NOAEL for skeletal variations and the inclusion by the EC of the placental weights and vaginal discharge as critical effects. The JMPR considered that vaginal discharge late in gestation and changes in placental weights at 2 mg/kg bw per day were not toxicologically significant effects, and were not the result of a single exposure. The identification of the NOAEL for skeletal variations by the JMPR was reconfirmed on the basis of the lack of statistical significance.

3.4 OXAMYL (126)

At the 40th Session of the CCPR, the delegation of Ireland raised concerns regarding the ARfD for oxamyl, established by the JMPR in 2002. The ARfD of 0.001 mg/kg bw established by the EC was based on a study in rats. This ARfD differed from that set by the JMPR, 0.009 mg/kg bw, which was based on a study in humans. The EC as a policy does not accept data from studies in humans as a basis for setting health-based guidance values (e.g., ARfD) for plant-protection products.

The difference in the respective ARfDs is due to differences in policy with respect to the use of data from studies in humans, not to any differences in the data evaluated or their interpretation. The Meeting reaffirmed the basis of the ARfD established by the JMPR in 2002.

Evaluation for Alternative GAP

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). However the 2002 Meeting noted that for dietary intake estimation, this definition could result in an overestimate of the dietary intake calculations because the only residue of toxicological concern was the parent compound (oxamyl).

The 2002 JMPR estimated short-term intakes that exceeded the ARfD of 0.009 mg/kg bw for apple, cucumber, grapefruit, lemon, mandarin, melons, oranges, peppers and tomato.

At the 39th Session of the CCPR in 2007, the Committee requested JMPR to consider using alternative GAPs to recommend lower MRLs for citrus; cucumber; melon and pepper and at the 40th Session the CCPR (2008) noted that additional data would be available to support an alternative GAP assessment for tomato.

Information on current and proposed GAPs, analytical methods and new supervised trials data were submitted to the 2008 JMPR for citrus fruits (orange and mandarin), cucurbits (cucumbers, courgettes, melons), peppers and tomatoes.

The Meeting noted that while the accepted residue definition included both the parent compound and its oxime metabolite, the method used in the new supervised trials reported only the parent compound (oxamyl).

Bridging studies were reported to the meeting on the relative concentrations of oxamyl (parent compound) and total oxamyl (i.e., oxamyl plus oxamyl-oxime) in sweet peppers and lettuce following drip irrigation treatments 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).

In the plant metabolism studies reviewed by the 2002 JMPR, relative concentrations of oxamyl and oxamyl-oxime were measured in a tobacco plant 3 weeks after being transplanted into soil treated with oxamyl (6 mg/kg). Residues of the oxamyl-oxime were present at about 70% of the oxamyl residues (i.e., a total oxamyl/oxamyl ratio of 1.7).

In the bridging studies on lettuce and sweet peppers following five soil drip irrigation treatments, the ratio of total oxamyl/oxamyl residues ranged from 1.1 to 2.6 in lettuce sampled 0–7 days after the last application and from 5.5 to 35 in peppers sampled 1–28 days after the last application.

The Meeting concluded that these studies were insufficient to extrapolate residue values for oxamyl alone to total oxamyl residues in citrus fruits, cucurbits, peppers and tomatoes and concluded there was insufficient data to support alternative GAP assessments for these commodities.

4. DIETARY RISK ASSESSMENT FOR PESTICIDE RESIDUES IN FOODS

At the present Meeting, compounds with recommended maximum residue levels and estimated STMRs were assessed for risks associated with long-term dietary intake. International estimated daily intakes (IEDIs) were calculated by multiplying the concentrations of residues (STMRs and STMR-Ps) by the average estimated daily per capita consumption for each commodity on the basis of the 13 GEMS/Food Consumption cluster diets.[30] IEDIs are expressed as a percentage of the ADI for a 55 kg or 60 kg person, depending on the cluster diet.

The percentages are rounded up to one whole number up to nine 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.

Hexythiazox was evaluated toxicologically at the current Meeting under the periodic re-evaluation programme, with the previous ADI confirmed. The long-term dietary risk assessment for this compound will be considered at a subsequent Meeting's periodic review of residues.

The assessment for boscalid was not conducted, as STMR values could not be estimated for plant commodities due to a lack of data on follow crops. Consequently a complete dietary risk assessment could not be performed.

The evaluations of bifenazate, carbaryl, chlorpropham, diphenylamine, oxamyl and spinosad performed at this Meeting do not supersede the long-term dietary assessments conducted by previous Meetings of the JMPR for these compounds.

An ADI for prothioconazole was established by the present Meeting. As this parent compound is present in food commodities at very low levels, the residue definition for dietary intake assessment is:

— prothioconazole-desthio metabolite only for plant commodities;

— prothioconazole-desthio plus its 3- and 4-hydroxy derivatives and their conjugates, expressed as prothioconazole-desthio in animal commodities.

Therefore, the long-term dietary risk assessment for prothioconazole was based on prothioconazole-desthio residues and the relevant ADI.

The triazole fungicide metabolites 1,2,4-triazole, 1,2,4-triazolyl-3-alanine and 1,2,4-triazole-1-yl- acetic acid have been considered by the present Meeting following recommendation from the 2007 Meeting of the JMPR (General Consideration 2.3). ADIs were established for 1,2,4-triazole and for 1,2,4-triazolyl-3- alanine/1,2,4-triazole-1-yl acetic acid. These ADIs are intended to provide future guidance in the event these metabolites are found as residues in food commodities. No long-term dietary risk assessment was performed.

A summary of the long-term dietary risk assessments conducted by the present Meeting is presented in Table 7. The detailed calculations of long-term dietary intakes are given in Annex 3. 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.[31]

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

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

Table 7 Summary of long-term dietary of risk assessments conducted by the 2008 JMPR

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI as % of maximum ADI
229	Azoxystrobin	0–0.2	2–10
173	Buprofezin	0–0.009	0–9
096	Carbofuran	0–0.001	20–70
230	Chlorantraniliprole	0–2	0
146	Cyhalothrin/lambda cyhalothrin	0–0.02	3–10
118	Cypermethrin (includes alpha and zeta cypermethrin)	0–0.02	5–20
027	Dimethoate	0–0.002	20–100
035	Ethoxyquin	0–0.005	0–40
206	Imidacloprid	0–0.06	1–5
049	Malathion	0–0.3	0–3
231	Mandipropamid	0–0.2	0–3
094	Methomyl	0–0.02	0–3
171	Profenofos	0–0.03	1–10
232	Prothioconazole [a]		
	Prothioconazole-desthio	0–0.01	0–1
233	Spinetoram	0–0.05	0–1
234	Spirotetramat	0–0.05	1–10
189	Tebuconazole [b]	0–0.03	1–8

[a] Based on prothioconazole-desthio

[b] The assessment includes residues at MRL level for some commodities

Assessment of risk from short-term dietary intake

Available consumption data was reviewed at the present Meeting to assess the risks associated with short-term dietary intake for compounds with estimated STMR and HR values and established acute reference doses (ARfDs). The procedures for calculating the short-term intake were defined primarily in 1997 at an FAO/WHO Geneva Consultation[32], then refined both at the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment sponsored by the Pesticide Safety Directorate, and at subsequent JMPR Meetings.

Data on the consumption of large portions were provided to GEMS/Food by the governments of Australia, France, The Netherlands, Japan, South Africa, Thailand, the UK and the USA. Data on unit weights and per cent edible portions were provided to GEMS/Food by the governments of Belgium, France, Japan, Sweden, the UK and the USA. The body weights of adults and children aged ≤ 6 years were provided to GEMS/Food by the governments of Australia, France, the Netherlands, South Africa, Thailand, the UK and the USA. The consumption, unit weight and body weight data used for the short-term intake calculation were compiled by GEMS/Food.[33] The documents are dated April, 2008 (large portions and body weights) and May, 2003 (unit weights). The procedures used for calculating the International Estimated Short-term Intake (IESTI) are described in detail in Chapter 3

[32] WHO (1997) Food consumption and exposure assessment of chemicals. Report of a FAO/WHO Consultation. Geneva, Switzerland, 10–14 February 1997, Geneva

[33] http://www.who.int/foodsafety/chem/acute_data/en/

of the 2003 Report of the JMPR. Detailed guidance on the setting of ARfD is described in Section 2.1 of the 2004 Report of the JMPR.[34]

On the basis of data received by the present or previous Meetings, JMPR considered the establishment of an ARfD to be unnecessary for azoxystrobin, bifenazate, boscalid, chlorantraniliprole, hexythiazox, mandipropamid, spinetoram, spinosad and the triazole fungicide metabolites 1,2,4-triazoyl-3-alanine and 1,2,4-triazole-1-yl-acetic acid. Therefore, it was not necessary to estimate the short-term intakes for these compounds.

An ARfD for 1,2,4-triazole was established by the present Meeting (0.3 mg/kg bw). This ARfD should provide guidance for future consideration when residues of this metabolite are found in traded food commodities. No short-dietary intake assessment was performed.

An ARfD for prothioconazole (only for women of childbearing age) was established by the present Meeting. However, as the residue definition for dietary intake does not include the parent compound (see previous section), the short-term dietary assessment was based on prothioconazole-desthio residues and that compounds ARfDs (see Table 8).

The evaluations of bifenazate, chlorpropham, diphenylamine and oxamyl performed at this Meeting do not supersede the short-term dietary intake assessments conducted by previous Meetings of the JMPR for these compounds.

The short-term intake of tebuconazole was estimated by the present Meeting, however the need for an ARfD has not yet been considered by the JMPR. Therefore, the short-term risk assessment for this compound could not be finalized.

The short-term intakes as percentages of the ARfDs for the general population and for children are summarized in Table 8. The detailed calculations of short-term dietary intakes are given in Annex 4.

Table 8 Summary of short-term dietary risk assessments conducted by the 2008 JMPR

				Percentage of ARfD	
CCPR code	Compound Name	ARfD (mg/kg bw)	Commodity	General population	Children aged ≤ 6 years
008	Carbaryl	0.2	All	3–20	10–40
096	Carbofuran	0.001	Banana Cucumber Cantaloupe Mandarins Milks Orange Potato Summer squash Sweet corn on the cob Other commodities	320 510 230 90 190 130 180 360 120 0–40	760 830 700 190 430 290 390 810 280 0–70
173	Buprofezin	0.5	All	0–1	0–3
05	Ethoxyquin	0.5	Pear	20	50
171	Profenofos	1	All	0–6	0–10
146	Cyhalothrin/ lambda cyhalothrin	0.02	All	0–40	0–60
118	Cypermethrin (includes alpha and zeta cypermethrin)	0.04	All	0–40	0–90

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

				Percentage of ARfD	
CCPR code	Compound Name	ARfD (mg/kg bw)	Commodity	General population	Children aged ≤ 6 years
027	Dimethoate	0.02	Sweet pepper and head lettuce	30–40	80
206	Imidacloprid	0.4	Tree nuts, root and tuber vegetables, berries, animal products	0–10	0–50
049	Malathion	2	Wheat and wheat processed commodities	0–7	0–10
094	Methomyl	0.02	All	0–50	0–100
232	Prothioconazole [a]	1	All	0	0–3
	(Prothioconazole desthio)	0.01 [b]	All	0–2 [b]	–
234	Spirotetramat	1	All	0–10	0–40

[a] Based on prothioconazole-desthio

[b] For women of childbearing age

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

5.1 AZOXYSTROBIN (229)

TOXICOLOGY

Azoxystrobin is the International Organization for Standardization (ISO) approved name for methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate, International Union of Pure and Applied Chemistry (IUPAC), for which the Chemical Abstracts Service (CAS) No. is 131860-33-8. Azoxystrobin is a β-methacrylate compound that is structurally related to the naturally occurring strobilurins, which are compounds derived from some fungal species. Azoxystrobin is a broad-spectrum, systemic fungicide that acts by inhibiting electron transport in pathogenic fungi. It has the ability to provide protection against the fungal diseases caused by *Ascomycota*, *Deuteromycota*, *Basidiomycota* and *Oomycota* groups.

Azoxystrobin has not been evaluated previously by JMPR and was evaluated by the present Meeting at the request of the 40th Session of the Codex Committee on Pesticide Residues (CCPR). All pivotal studies with azoxystrobin were certified as complying with good laboratory practice (GLP).

Biochemical aspects

In a autoradiography study in rats, groups of one male and one female were given azoxystrobin labelled with ^{14}C in either the cyanophenyl, pyrimidinyl or phenylacrylate ring as a single dose at 1 mg/kg bw by gavage. The results of this study indicated that the position of the radiolabel had no significant effect on the rates and routes of excretion or tissue distribution of azoxystrobin, therefore, further metabolism studies were conducted using azoxystrobin labelled in the pyrimidinyl position. In studies in rats given a single oral dose of radiolabelled azoxystrobin, 73–89% of the administered dose was recovered in the faeces and 9–18% in the urine (1 and 100 mg/kg bw) after 7 days. The extent of oral absorption at 1 mg/kg bw was nearly complete since no parent compound was found in the excreta. At least 74–81% of the administered dose was absorbed at 100 mg/kg bw, based on recoveries of radioactivity in the bile and urine. Between 82% and 96% of the administered dose was excreted within the first 48 h. Regardless of the dose administered, residues remaining in the carcass (including organs and tissues) were between 0.31% and 0.62% of the administered dose after 7 days. The highest concentrations were found in the liver (0.009–0.72 µg equivalents/g) and in the kidneys (0.023–1.12 µg equivalents/g) at 7 days. No significant quantities of radiolabel were detected in exhaled air. In a study of biliary excretion, about 57–74% of the administered dose was recovered in the bile within 48 h after administration of a single dose at 100 mg/kg bw by gavage. No parent compound was detected in the bile.

Systemically absorbed azoxystrobin was extensively metabolized. The mass balance for the metabolism study indicated that a substantial percentage (45.6–73.6%) of the radiolabel was unextracted, although the excretion studies showed a total recovery of 91.8–104%, with 72.6–89.3% being in the faeces. Fifteen metabolites were identified in the excreta and seven additional metabolites were detected but not identified (< 4.9% of the administered dose). The major metabolites of azoxystrobin in the bile, urine and faeces resulted from hydrolysis followed by glucuronide conjugation. Azoxystrobin was also hydroxylated at the 8 and 10 positions on the cyanophenyl ring, followed by glucuronide conjugation. A minor pathway involving the cleavage of the ether linkage was identified. Approximately 15–32% of the unchanged azoxystrobin was detected in the faeces of bile-duct cannulated rats and rats at the highest dose. Absorption, distribution, excretion and metabolite profiles were essentially similar in males and females, but sex-specific

differences in biotransformation were observed, with the number of metabolites produced being greater in females than in males.

Toxicological data

Azoxystrobin has low acute toxicity when administered by the oral, dermal or inhalation routes. The median lethal dose (LD_{50}) in rats treated orally was > 5000 mg/kg bw. The LD_{50} in rats treated dermally was > 2000 mg/kg bw. The median lethal concentration (LC_{50}) in rats treated by inhalation (nose only) was 0.7 mg/L. Azoxystrobin was slightly irritating to the eyes and skin of rabbits. Azoxystrobin was not a skin sensitizer as determined by the Magnusson & Kligman (maximization) test in guinea-pigs.

In short-term studies in rats and dogs and long-term studies in mice and rats, the major toxicological findings included decreased body weight and body-weight gains, often accompanied by decreased food consumption and utilization. The major target organs in rats were the liver, kidney and bile duct as shown by changes in organ weights, histopathology, and clinical chemistry parameters. Changes in liver weights, often accompanied by changes in clinical chemistry, were also observed in dogs and mice. Kidney-weight changes in mice were not accompanied by any histopathological findings.

In a 90-day dietary study of toxicity in rats, decreased body weights and body-weight gains were seen at 2000 ppm (equal to 221.0 mg/kg bw per day) and 4000 ppm (equal to 443.8 mg/kg bw per day). At 4000 ppm, decreased food consumption, food utilization, changes in clinical chemistry parameters, increased liver and kidney weights, hepatocellular hyperplasia and enlarged lymph nodes, and reduction in total urinary protein were seen in males. The no-observed-adverse-effect level (NOAEL) was 200 ppm, equal to 20.4 mg/kg bw per day.

In a 90-day and a 1-year study in dogs, clinical observations included increased salivation at dosing, and increased incidences of salivation, vomiting, regurgitation and fluid faeces, beginning in week 1 and occurring throughout the study in some cases. These signs were considered to be treatment-related; however, they were not considered to be relevant for establishment of a NOAEL for systemic toxicity because these effects were secondary to local gastrointestinal irritation/disturbances and bolus dosing (capsules). In a 90-day study of toxicity in dogs, decreases in body weights were observed in males and females at 250 mg/kg bw per day, the highest dose tested. Changes in liver weights and in clinical chemistry parameters were observed at the intermediate and the highest dose, indicating adverse effects on the liver and possibly on biliary function. The changes in the liver at 50 mg/kg bw per day were small and without histological correlates, therefore, the Meeting considered that they were not toxicologically relevant. In a 90-day study in dogs, the NOAEL was 50 mg/kg bw per day on the basis of alterations in clinical chemistry (cholesterol, triglycerides and alkaline phosphatase activity), and decreases in body weights seen at the lowest-observed-adverse-effect level (LOAEL) of 250 mg/kg bw per day, the highest dose tested. Similar findings were observed in a 1-year study of toxicity in dogs but were mainly confined to the highest dose of 200 mg/kg bw per day. In a 1-year study of toxicity in dogs, the NOAEL was 25 mg/kg bw per day on the basis of changes in clinical chemistry and increases in liver weights seen at 200 mg/kg bw per day. The overall NOAEL in dogs was 50 mg/kg bw per day on the basis of the similarity of effects in the two studies in dogs.

The carcinogenic potential of azoxystrobin was studied in mice and rats. In a study of carcinogenicity in mice, reduced body weights were observed at 2000 ppm, equal to 272.4 mg/kg bw per day. The NOAEL was 300 ppm, equal to 37.5 mg/kg bw per day. There were no treatment-related neoplastic findings in the bioassay in mice.

In a long-term combined study of toxicity and carcinogenicity in rats, the highest dose of 1500 ppm, equal to 108.6 mg/kg bw per day, was excessively toxic in males and was reduced to 750 ppm, equal to 34 mg/kg bw per day, after 1 year. Reduced body weights, food consumption, and food-conversion efficiency was observed in males and females at the highest dose tested. In the

common bile duct of males at the highest dose only, there were significant increases in the incidences of distension, cholangitis, thickening of the wall, and epithelial hyperplasia. The NOAEL was 300 ppm, equal to 18.2 mg/kg bw per day. There were no treatment-related neoplastic findings in rats.

Azoxystrobin gave a mixed response in a battery of tests for genotoxicity. It gave a weak positive response in two studies in mammalian cells (mouse lymphoma cells and human lymphocytes). The latter findings suggest that azoxystrobin has a clastogenic potential in vitro since the increased occurrence of small colonies observed in the mouse lymphoma-cell assay is considered to be indicative of chromosome aberrations rather than of point mutations. However, azoxystrobin has been shown to give negative results in assays for chromosomal damage in vivo (i.e., clastogenicity) and for general DNA damage at high doses of 2000 mg/kg bw or above. Therefore, the Meeting concluded that the clastogenic effects seen in vitro are not expressed in the whole animal.

The Meeting concluded that azoxystrobin is unlikely to be genotoxic.

In view of the lack of evidence for a genotoxic potential in vivo and the absence of carcinogenicity in rats and mice, the Meeting concluded that azoxystrobin is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats, reproductive parameters were not affected at the highest dose tested (1500 ppm, equal to 165.4 mg/kg bw per day). The NOAEL for parental systemic toxicity was 300 ppm, equal to 32.3 mg/kg bw per day, on the basis of reduced adjusted body weight, feed consumption, feed utilization, and an increase in liver weights and the frequency of histopathological findings in the liver (males only). Offspring toxicity was manifested as a decrease in pup body weights, and a decrease in adjusted mean liver weights was observed in pups of both generations at 1500 ppm, equal to 165.4 mg/kg bw per day. The NOAEL for offspring toxicity was 300 ppm, equal to 32.3 mg/kg bw per day.

In a study of developmental toxicity in rats, treatment at the highest dose (300 mg/kg bw per day) was terminated as this dose was toxic; at this dose, three rats died and one was killed in extremis after two doses. Clinical signs of diarrhoea, salivation and urinary incontinence were seen at 25 and/or at 100 mg/kg bw per day. The Meeting considered these effects to be treatment-related but not relevant for the identification of a NOAEL for systemic toxicity, being considered to be secondary to local gastrointestinal irritation/disturbances and dosing by gavage. There were no effects on fetuses at any doses tested. The NOAEL for maternal and developmental toxicity was 100 mg/kg bw per day, the highest dose tested.

Two studies of developmental toxicity in rabbits were conducted. The results of the first study were considered to be invalid because of the adverse effects of administration of high volumes of corn oil as a vehicle. Several special studies were conducted in pregnant and non-pregnant rabbits to evaluate the influence of the type and volume of vehicle used for administration by gavage. The results of these studies showed that corn oil at volumes greater than 2 mL/kg bw was harmful. The NOAEL for maternal toxicity in rabbits was 150 mg/kg bw per day (identified in the study using the lowest volume of corn oil for dosing) based on decreased body-weight gain seen at the LOAEL of 500 mg/kg bw per day. There were no effects on fetuses. The NOAEL for developmental toxicity in rabbits was 500 mg/kg bw per day, the highest dose tested.

Azoxystrobin was not embryotoxic, fetotoxic or teratogenic at doses of up to 300 and 500 mg/kg bw per day in rats and rabbits, respectively.

The Meeting concluded that azoxystrobin is not teratogenic.

In a study of acute neurotoxicity in rats, no treatment-related effects on motor activity parameters, brain measurements (weight, length and width) or neurohistopathology were observed at doses of up to and including 2000 mg/kg bw. Increased incidences of transient diarrhoea, tip-toe gait, hunched posture and landing-foot splay were observed in all groups receiving azoxystrobin, although

these effects were not dose-related. They were considered to be treatment-related but not relevant for identification of a NOAEL for systemic toxicity, being considered to be secondary to local gastrointestinal irritation/disturbances and bolus dosing by gavage. The NOAEL for systemic toxicity was 2000 mg/kg bw, the highest dose tested. In a short-term study of neurotoxicity in rats, no treatment-related changes in mortality, clinical signs, functional observational battery (FOB), motor activity, brain measurements (weight, length, and width), gross necropsy, or neurohistopathology were observed at doses of up to 2000 ppm, equal to 161 mg/kg bw per day, the highest dose tested. The NOAEL for systemic toxicity was 500 ppm, equal to 38.5 mg/kg bw per day, on the basis of decreased body weight and body-weight gain and food utilization in males and females seen at the LOAEL of 2000 ppm, equal to 161 mg/kg bw per day.

Azoxystrobin was not considered to be neurotoxic on the basis of the available data.

No significant adverse effects were reported in personnel working in plants producing azoxystrobin.

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

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.2 mg/kg bw based on a NOAEL of 300 ppm (equal to 18.2 mg/kg bw per day) in a 2-year study of carcinogenicity in rats, identified on the basis of reduced body weights, food consumption and food efficiency, and bile-duct lesions seen at 750 ppm (equal to 34 mg/kg bw per day) and above, and using a safety factor of 100.

The Meeting concluded that it was unnecessary to establish an acute reference dose (ARfD) for azoxystrobin because no toxicity could be attributable to a single exposure in the available database, including a study of developmental toxicity in rats and rabbits and a study of acute neurotoxicity in rats. The mortality seen in the study of developmental toxicity in pregnant rats at 300 mg/kg bw per day was associated with gross local gastrointestinal pathology and was not seen in pregnant rabbits. The Meeting considered that clinical signs observed in dogs and rats were related to local gastrointestinal effects seen after bolus dosing by gavage in rats or bolus dosing (capsules) in dogs, since these signs were not seen in the dietary studies. Therefore, the Meeting considered that these effects were not relevant for the establishment of an ARfD.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	104-week study of toxicity and carcinogenicity[a]	Toxicity	300 ppm, equal to 37.5 mg/kg bw per day	2000 ppm, equal to 272.4 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 272.4 mg/kg bw per day[c]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	300 ppm, equal to 18.2 mg/kg bw per day	750 ppm, equal to 34 mg/kg bw per day[c]
		Carcinogenicity	750 ppm, equal to 34 mg/kg bw per day[c]	—
	Multigeneration study of reproductive toxicity[a]	Parental toxicity	300 ppm, equal to 32.3 mg/kg bw per day	1500 ppm, equal to 165.4 mg/kg bw per day[c]
		Offspring toxicity	300 ppm equal to 32.3 mg/kg bw per day	1500 ppm, equal to 165.4 mg/kg bw per day[c]

Species	Study	Effect	NOAEL	LOAEL
	Developmental toxicity[b]	Maternal toxicity	100 mg/kg bw per day[c]	—
		Embryo and fetal toxicity	100 mg/kg bw per day[c]	—
Rabbit	Developmental toxicity[b]	Maternal toxicity	150 mg/kg bw per day	500 mg/kg bw per day[c]
		Embryo and fetal toxicity	500 mg/kg bw per day[c]	—

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.2 mg/kg bw per day

Estimate of acute reference dose

Unnecessary

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

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

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

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid and nearly complete absorption
Distribution	Widely distributed in tissues
Potential for accumulation	Low, no evidence of significant accumulation
Rate and extent of excretion	Approximately 82–90% (73–89% in faeces and 9–18% in urine) within 48 h
Metabolism in animals	Extensive; metabolic pathways include hydrolysis followed by glucuronide conjugation and minor pathway included cleavage of the ether
Toxicologically significant compounds (animals, plants and environment)	Azoxystrobin
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	0.7 mg/L , dust (4 h exposure, nose only)
Rabbit, dermal irritation	Slight irritation
Rabbit, ocular irritation	Slight irritation

Guinea-pig, dermal sensitization	Not a sensitizer (Magnusson & Kligman test)
Short-term studies of toxicity	
Target/critical effect	Body-weight effects
Lowest relevant oral NOAEL	20.4 mg/kg bw per day (90-day study in rats)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day; highest dose tested (21-day repeated dermal toxicity study in rat)
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	Unlikely to be genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver-weight increases and bile-duct lesions
Lowest relevant NOAEL	18.2 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Not carcinogenic in mice and rats
Reproductive toxicity	
Reproduction target/critical effect	No toxicologically relevant effects
Lowest relevant reproductive NOAEL	165.4 mg/kg bw per day (rats; highest dose tested)
Developmental target/critical effect	No developmental toxicity in rats and rabbits
Lowest relevant developmental NOAEL	100 mg/kg bw per day (rats; highest dose tested)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity	No sign of specific neurotoxicity
Mechanistic data	
	No studies were submitted
Medical data	
	No significant adverse health effects reported

Summary

	Value	*Study*	*Safety factor*
ADI	0–0.2 mg/kg bw per day	Rat, 2-year study of toxicity	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

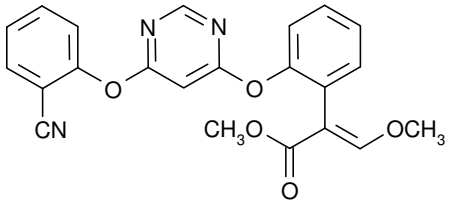
Azoxystrobin is a broad-spectrum fungicide belonging to the class of methoxyacrylates, which are synthetic analogues from the naturally-occurring strobilurin fungi. It exerts its fungicidal activity by inhibiting mitochondrial respiration in fungi. At the 39th Session[35] of the CCPR, azoxystrobin was scheduled for the evaluation as a new compound by the 2008 JMPR.

Chemical name

ISO common name: Azoxystrobin

IUPAC: Methyl (*E*)-2-{2 [6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate

CA: Methyl(*E*)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]-α-(methoxymethylene)benzeneacetate



Animal metabolism

The Meeting received results of animal metabolism studies in lactating goats and laying hens.

Lactating goats were dosed twice daily at each milking with either cyanophenyl-, pyrimidinyl, or phenylacrylate-[^{14}C]labelled azoxystrobin in gelatine capsules at a nominal rate of 25 ppm in the diet (on a dry weight basis) for seven consecutive days, corresponding to a daily dose of approximately 1 mg/kg bw. The actual dose rate was equivalent to 23–33 mg/kg in the diet. The majority (90–93%) of the administered radiolabelled doses were recovered. The primary route of excretion was via the faeces (62–72% of the administered doses). Excretion via the urine accounted for a further 18–24% of the administered doses, resulting in total of 83–92% of the administered doses being excreted in faeces and urine. The TRR in milk, muscle and fat were very low (0.004–0.025 mg/kg of azoxystrobin equivalents), corresponding to < 0.01% of the administered doses. Characterization of these radioactive residues by fractionation showed that they were unlikely to be attributed to any individual compound at a significant level. Radioactivity in milk reached a plateau of only 0.01 mg/L after 3–4 days of dosing.

In tissues and organs, most of the radioactivity was recovered in the liver (0.58–1.2 mg/kg) and kidney (0.18–0.25 mg/kg), corresponding to 0.2–0.4% and 0.06–0.08%, respectively, of the administered doses, reflecting the role of these organs in metabolism and excretion. In goat kidney, the major metabolites included 2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenylacetic acid (0.01–0.05 mg/kg, 6.9–20% TRR), a glucuronide conjugate of a phenylacrylate ring hydroxy-derivative of azoxystrobin (0.02–0.03 mg/kg, 8.2–16% TRR), and *(E)*-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid (0.005–0.02 mg/kg and 2.0–11% TRR). These metabolites were also present in goat liver but not as major metabolites (only 0.2–0.9, 0.5–1.9, and 0.7–1.9% TRR, respectively). The major metabolite detected in liver of goats dosed with [cyanophenyl-^{14}C]

[35] Codex Alimentarius Commission. *Report of the 40th Session of the Codex Committee on Pesticides Residues, 14–19 April 2008, Hangzhou, China*, (ALINORM 08/31/24)

labelled azoxystrobin was ring hydroxyl-derivative of S-(2-cyanophenyl)cysteine (compound L4: 0.35 mg/kg and 29% TRR), whereas 4-(2-cyanophenoxy)-6-hydroxypyrimidine was the major metabolite in liver of goats dosed with [pyrimidinyl-^{14}C] labelled azoxystrobin (0.13 mg/kg and 20% TRR). Compound L4 was not detected in kidney, and 4-(2-cyanophenoxy)-6-hydroxypyrimidine accounted for only 5.0% TRR in kidney of goats dosed with [pyrimidinyl-^{14}C] labelled azoxystrobin. Azoxystrobin parent was present at low levels in both the kidney (0.002–0.008 mg/kg and 0.8 to 2.0% TRR) and the liver 0.007–0.02 mg/kg and 0.6–1.8% TRR). In general, there was no significant difference in metabolism observed using the three different radiolabels.

Laying hens were dosed once daily with either cyanophenyl-, pyrimidinyl-, or phenylacrylate-[^{14}C] labelled azoxystrobin in gelatine capsules at a nominal rate of 1.5 mg/day for ten consecutive days, corresponding to a daily dose of approximately 0.75 mg/kg bw. The dose was equivalent to an intake of approximately 11–12 ppm in the diet.

The recovery of the administered radiolabelled dose was 93–98%. The majority of the administered dose was excreted in faeces (91–97%). The cage washings accounted for no more than 2.0% of the administered dose. Radioactive residues in tissues and eggs accounted for ≤ 0.2% of the dose. Residues in muscle, egg white, skin with underlying fat, and peritoneal fat were in the range of 0.004–0.039 mg/kg. The highest radioactive residues were in egg yolk (0.040–0.14 mg/kg) and liver (0.082–0.11 mg/kg), both of these representing ≤ 0.1% of the administered dose. The fractionation of these residues showed that no single organosoluble fraction exceeded < 0.01 mg/kg and aqueous or unextractable fractions represented < 0.05 mg/kg.

Residues in egg whites reached a plateau of only 0.008–0.011 mg/kg after 3–4 days of dosing. In egg yolks, the residues plateaued at 0.040–0.14 mg/kg after 6–8 days of the dosing. The Meeting noted that it typically takes up to ten days for an egg to form, therefore the egg yolk values can be used as representative of what is happening in the whole egg.

Azoxystrobin (< 0.001–0.006 mg/kg, 0.3–12% TRR) and 4-(2-cyanophenoxy)-6-hydroxypyrimidine (0.002–0.004 mg/kg of azoxystrobin equivalents and 1.8–8.4% TRR), were identified in egg yolk. A significant portion of the radioactivity (0.018 mg/kg and 15% TRR) in egg yolk from the hens dosed with [pyrimidinyl-^{14}C]azoxystrobin was due to the breakdown of azoxystrobin into small components, which were then incorporated through biosynthetic pathways into fatty acids.

Based on the results of the submitted studies, the Meeting concluded that, in goats and hens, azoxystrobin was rapidly metabolized and excreted in faeces and urine, with minimal retention of the parent and its metabolites in the tissues.

Plant metabolism

The Meeting received information on azoxystrobin metabolism, studied in wheat, grapes, peanuts, rice, and cotton.

Wheat was treated with radiolabelled azoxystrobin (labelled separately in each of the three rings) formulated as a suspension concentrate (250 g ai/L) and applied as a foliar spray twice (at BBCH 30–31 and 59–61) at a nominal rate of 0.5 kg ai/ha. The treated plants were harvested either as forage (a PHI of 13 days) or mature crop (a PHI of 61–62 days). The metabolic profile of azoxystrobin in wheat was very complex with at least 23 metabolites detected. Residues were mainly in the forage (TRR of 1.0–2.8 mg/kg) and straw (TRR of 3.1–9.4 mg/kg). The total radioactive residues in the grain were low (0.075–0.077 mg/kg).

In wheat grain, the only significant residue was the parent, azoxystrobin, (17–22% TRR and 0.013–0.017 mg/kg). No other discrete metabolite (12 compounds identified) was present at greater than 3.3% TRR (0.002 mg/kg). Naturally incorporated glucose comprised 9.7–21% TRR.

In the wheat straw and forage, 14 and 12 metabolites were identified, respectively. The major residue was azoxystrobin, representing 22–43% TRR (0.67–4.1 mg/kg) and 55–65% TRR (0.56–1.8 mg/kg) in the straw and forage, respectively.

Other significant components included:

- 4-(2-cyanophenoxy)-6-hydroxypyrimidine (a product of the cleavage of the ether linkage between the phenyacrylate ring and the pyrimidinyl ring), for which sum of free, conjugated and bound forms accounted for 8.2–10% TRR and 3.2–3.7% TRR in the straw and forage, respectively
- the *Z*-isomer of azoxystrobin (2.1–3.5% TRR in straw, 1.9–2.9% TRR in forage), which is the photo-isomerisation product of azoxystrobin
- (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid (3.0–3.4% TRR in straw, 0.7–0.8% in forage), which can be formed from azoxystrobin either by hydrolysis of the ester group or by oxidative de-alkylation.

The Meeting noted that the metabolic profile of the extractable residue of azoxystrobin in wheat was essentially the same in each analysed sample and very similar in each radiolabel, with the parent as the major residue accounting for 19–26%, 24–47%, and 59–68% of the extractable residue in grain, straw, and forage, respectively.

In an additional study, winter wheat was treated with [pyrimidinyl-^{14}C]azoxystrobin applied once as a 250 SC formulation at 250 g ai/ha as a late season treatment at BBCH 71 (a PHI of 28 days). The total radioactive residues in grain and straw were 0.066 and 2.5 mg/kg, respectively. The only relevant radioactive residue was the parent, azoxystrobin, which accounted for 31% TRR (0.020 mg/kg) in grain and 51% TRR (1.3 mg/kg) in straw. Other significant metabolites, including 4-(2-cyanophenoxy)-6-hydroxypyrimidine or the *Z*-isomer of azoxystrobin, did not account for more than 3.4% TRR each. The Meeting noted that the results of this study were consistent with those from the previous wheat metabolism study. In both studies, azoxystrobin was the major component of the residue in grain and straw, representing 44% and 60% of the extractable residue, respectively.

Grapes were treated with radiolabelled azoxystrobin (labelled separately in each of the three rings), which was applied as a 250 SC formulation to three grape vines (one vine for each radiolabel) as a foliar spray four times with application rates of 0.25, 1.0, 1.0, and 0.25 kg ai/ha. Grapes and leaves were harvested 21 days after the final application. The TRR in grapes were 0.38–1.4 mg/kg of azoxystrobin equivalents. The major residue for each radiolabel was the parent, azoxystrobin (35–65% TRR and 0.13–0.92 mg/kg). A total of nine metabolites were identified and the most significant were 2-hydroxybenzonitrile (5.7% TRR), 4-(2-cyanophenoxy)-6-hydroxypyrimidine (2.6–5.2% TRR), the *Z*-isomer of azoxystrobin (1.9–4.0% TRR), and methyl 2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-glycolate (2.5–3.9% TRR). Incorporation of radioactivity into naturally occurring sugars (glucose, fructose, and sucrose) indicated mineralization of [^{14}C]azoxystrobin in soil, with subsequent assimilation of $^{14}CO_2$ and the formation of ^{14}C-sugars via photosynthesis.

Peanuts were treated with radiolabelled azoxystrobin (labelled separately in each of the three rings), which was formulated as a 250 g ai/L suspension concentrate and applied three times as a foliar spray to peanut vines at 0.85, 0.85, and 0.3 kg ai/ha. Ten days after the last application, a portion of the vines was stored fresh and the remaining vines and pods (nut and hull intact) were dried. The radioactive residues were mainly in the hay (dried vine containing 39–47 mg/kg of azoxystrobin equivalent) and vine (16–21 mg/kg). Nuts and hulls contained only 0.24–0.65 mg/kg and 0.67–0.90 mg/kg, respectively. The most significant residues identified in the nutmeat were the fatty acids, oleic and linoleic, accounting for 28–32% TRR (0.074–0.21 mg/kg) and 11–16% (0.27–0.11 mg/kg), respectively. Natural incorporation of radioactivity into sugars sucrose (1.7–5.6% TRR), glucose (1.5–1.9% TRR), and fructose (1.4–2.2% TRR) indicated mineralization of [^{14}C]azoxystrobin in soil with subsequent assimilation of $^{14}CO_2$. Parent azoxystrobin was not detected in the nutmeat and no individual metabolite was present at a level greater than 1.0% TRR**.** In hay and hulls, the

major component of the radioactive residue was the parent, azoxystrobin, accounting for 33–44% TRR (13–20 mg/kg) and 13–14% TRR (0.088–0.11 mg/kg), respectively. A total of 10 and 11 metabolites were identified in hay and hull, respectively (residues in the vine were qualitatively similar to those in the hay), the most significant of which were 4-(2-cyanophenoxy)-6-hydroxypyrimidine (3.9% TRR in hay and 2.5–2.6% TRR in hulls) and its glucose conjugate (2.9–5.6% TRR in hay and 1.2-1.9% TRR in hulls).

Rice was treated with radiolabelled azoxystrobin (labelled separately in each of the three rings) in two separate experiments, one with a single foliar spray and the other with two granular paddy applications. For the foliar treatment, azoxystrobin was applied formulated as a suspension concentrate just after heading, at rates equivalent to a total field application of 0.36–0.55 kg ai/ha. For the paddy application, the compound was formulated as a granular product and applied twice to the paddy water to give a total seasonal application rate of 1.73–1.92 kg ai/ha. Crops were harvested at maturity after a PHI of 75–95 days for the foliar-treated plants and a PHI of 95–98 days after the second application for the granular treated rice plants.

The TRR (expressed as azoxystrobin) were 0.32–0.74 mg/kg and 5.7–11 mg/kg in grain and straw, respectively. In rice grain, the only significant residues from the granular application were radiolabelled sugars (43–58% TRR) and the parent compound (3.4–5.3% TRR). Similarly, the foliar application resulted mainly in the residues of the parent (36–72% TRR) and radiolabelled sugars (4.9–17% TRR). In rice straw, the major components from the granular application were the parent (3.3–5.6% TRR), isomers of methyl-2-{2-[6-(2-cyano-4-hydroxyphenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy acrylate (5.1–8.1%TRR), and (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid (3.6–6.7% TRR). In foliar application, the parent, azoxystrobin, was the single most abundant component (38–46% TRR), followed by 4-(2-cyanophenoxy)-6-hydroxypyrimidine (5.2–8.5% TRR). Similarly to rice grain, a portion of the radioactivity (up to 3.9% TRR) was identified as radiolabelled sugars.

Cotton grown in the USA was treated with [pyrimidinyl-^{14}C]azoxystrobin formulated as a suspension concentrate and applied at planting, as an in-furrow application, at a rate of 18 g ai/km (0.19 oz ai/1000 ft row), which was close to the US GAP for in-furrow application to cotton (19 g ai/km). The cotton was harvested both immature (forage) and mature (separated into seed, lint, and gin trash). Characterization of the residues was not carried out in seed, lint, and gin trash, in which the TRR were < 0.01 mg/kg. The TRR in forage was 0.085 mg/kg. The most significant residue in the forage was the parent, representing 15% TRR (0.013 mg/kg). At least eight unknowns were detected; not one representing > 0.01 mg/kg of parent equivalent. None of the unknowns co-chromatographed with any of the applied reference substances.

Based on the results of the submitted studies on wheat, grapes, peanut and cotton, the Meeting concluded that qualitatively similar metabolism occurred among these crops, with the parent, azoxystrobin, being the major component of the residue. In peanut meat, fatty acids (oleic and linoleic) accounted for most of the TRR. In cotton, no significant residues were detected in cottonseed after the in-furrow application at planting.

The Meeting noted that, in most of the studies, a significant portion of the radioactivity was identified as radiolabelled natural products such as sugars, starch, fatty acids, and amino acids. The presence of radioactivity in these natural products is believed to result from the mineralization of azoxystrobin in soil and subsequent incorporation of $^{14}CO_2$ via photosynthesis.

Environmental fate

The Meeting received information on aerobic and anaerobic degradation of azoxystrobin in soil; photolysis on soil surface; mobility in soil; field dissipation studies and azoxystrobin residues in rotational crops.

The aerobic and anaerobic degradation of radiolabelled azoxystrobin was studied in the dark at 20 °C in three soils (silt loam, sandy clay loam, and sandy loam) incubated for 120 days and one soil (sandy loam) incubated for 360 days.

Under aerobic conditions, azoxystrobin degraded with DT_{50} values between 56 and 279 days, depending on the amount of microbial biomass in this soil. No significant degradation was observed in sterile treatments, suggesting that the aerobic degradation was due to microbial activity. The major residue was azoxystrobin (31–55% and 33% of the applied radioactivity after 120 and 360 days, respectively). The only significant metabolite was (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid, accounting for 10–15% and 18% of the radioactivity after 120 and 360 days, respectively.

Under anaerobic conditions, the degradation was more rapid with DT_{50} of 49–181 days. Azoxystrobin accounted for 19–21% and 28% of the applied radioactivity after 120 and 360 days of incubation, respectively. (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid represented 57–59% and 49% of the radioactivity after 120 and 360 days, respectively.

Mineralization to CO_2 was significant with up to 27% detected after 120 days under aerobic conditions (only up to 5% under anaerobic conditions). The acid metabolite and other identified metabolites were also finally mineralized into CO_2.

Photodegradation of radiolabelled azoxystrobin was studied on the surface of sandy loam soil irradiated under conditions equivalent of up to 30 days Florida summer sunlight. Azoxystrobin underwent rapid degradation with a mean DT_{50} of 11 days Florida summer sunlight, which is equivalent to 11.5 days summer sunlight at 50 °North. A total of nine photolysis products were identified, of which the Z-isomer of azoxystrobin, 2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]benzoic acid, and 4-(2-cyanophenoxy)-6-hydroxypyrimidine accounted for up to 9%, 7.5%, and 5.7% of applied radioactivity, respectively. The only significant photodegradation product was $^{14}CO_2$, reaching up to 29% of the applied radioactivity.

The Meeting concluded that both photolytic and microbial degradation are important routes of degradation under field conditions, with both routes ultimately leading to formation of CO_2.

Mobility in soil was evaluated through adsorption/desorption and leaching studies, showing low to medium potential mobility of azoxystrobin in the tested soils.

Field dissipation studies on bare soil were performed in Northern and Southern Europe. The results showed a rapid degradation of azoxystrobin under field conditions (DT_{50} 3–39 days, DT_{90} 87–433 days). No measurable residues of azoxystrobin or its metabolites were determined below 10 cm. No measurable residues of the Z-isomer of azoxystrobin or (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid were determined in any samples from any trials, with the exception of detection of the acid metabolite in one trial in Northern Europe (0.03 mg/kg) in the 0–10 cm horizon. Residues of 4-(2-cyanophenoxy)-6-hydroxypyrimidine and 2-[6-(2-cyanophenoxy) pyrimidin-4-yloxy] benzoic acid ranged between < 0.01–0.03 and < 0.01–0.05 mg/kg, respectively, in the 0–10 cm horizon and declined to < 0.01 mg/kg by 28–195 days after application.

Residues in Rotational Crops

The Meeting received results of three greenhouse confined rotation studies conducted in the USA. In each study, radiolabelled azoxystrobin (different radiolabel each time) was applied directly to sandy loam soil at 2.2 kg ai/ha, which corresponds to the maximum seasonal application rate for azoxystrobin in the USA (maximum of six applications of a single rate of 0.37 kg ai/ha or maximum of eight applications of a single rate of 0.28 kg ai/ha), thus simulates a worst case scenario. Rotational crops (radish, lettuce, and wheat) were planted 30, 200, and 365 days after the treatment. Radish and lettuce were harvested at maturity while wheat was harvested at an immature stage (forage) and at maturity (grain and straw).

The TRR in the soil declined on average from 0.74–1.0 mg/kg at treatment to 88, 56, and 13% at 30, 200, and 365 days after treatment, respectively. The metabolism of azoxystrobin in rotational crops was complex with a large number of conjugated metabolites formed (mostly glucose or amino acid conjugates of the corresponding primary crop metabolites). The residues declined significantly at longer plant back intervals. Radioactive residues in the 365-day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17–44% TRR); with very low actual residue levels in the tested crops (< 0.01–0.08 mg/kg at 30 days and < 0.01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (to 0.02–0.05 and 0.06–0.12 mg/kg, respectively) and 365 days (to < 0.01 mg/kg). Azoxystrobin residues in wheat grain were < 0.01 mg/kg even in wheat planted 30 days after the treatment.

In the absence of field rotational studies, it was difficult to assess the uptake of rotational crops (such as cereals), from soil under realistic conditions. The Meeting noted that the greenhouse confined studies were conducted at an exaggerated application rate: the TRR in the soil declined rapidly, and the azoxystrobin residues resulting from direct applications on the rotational crops were significantly higher than those found (even at the shortest plantback interval of 30 days) in the confined rotational studies resulting from the uptake from the treated soil.

Water-sediment systems

The hydrolysis rate of [^{14}C]azoxystrobin was determined at 25 °C and 50 °C in buffered aqueous solutions at pH 5, 7 and 9 under sterile conditions in the dark for up to 31 days. At 25 °C, there was no significant hydrolysis (< 10%) at any pH. At 50 °C, there was no significant hydrolysis at pH 5 or 7. At 50 °C and pH 9, analysis showed significant hydrolysis (DT_{50}=12.56 days). The Meeting concluded that no significant hydrolysis of azoxystrobin is likely under realistic environmental conditions.

The aqueous photolysis of [^{14}C]azoxystrobin was studied at 25 °C in buffered aqueous solutions at pH 7 under sterile conditions over a period of approximately 30 days using an artificial light source. The half-life was calculated to be in the range of 11 and 17 days Florida summer sunlight (12–18 days summer sunlight at 50 °North). Azoxystrobin was the major component in all samples, accounting for up to 26% of the applied radioactivity at the final sampling interval. Only one photoproduct, the Z-isomer, was present at levels greater than 10% of the applied radioactivity during the study.

Degradation in the sediment/water systems was studied in two natural systems under laboratory conditions in the dark at 20 °C over 152 days. Throughout the incubation period, the majority of the radioactivity (44–75% of applied radioactivity) was found in the sediment layer. In water, azoxystrobin was rapidly dissipated with a half-life of less than seven days. After 152 days of incubation, the parent compound azoxystrobin represented 47–61% of the applied radioactivity in the water-sediment systems. (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid was the major metabolite, present at up to 20% of the applied activity 152 days after incubation, while up to 6% of the applied radioactivity had been mineralized to CO_2. Azoxystrobin reaching water would be quickly adsorbed onto sediment and subsequently degraded, thus unlikely to cause residues in crops.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for azoxystrobin in samples of plant and animal origin.

The described methods are mostly based on extraction with an organic solvent (usually acetonitrile or acetone); followed by a partition step, gel permeation chromatography (GPC) clean-up, and often also a silica, C18, alumina or Florisil solid-phase extraction (SPE) clean-up. The

determination step employs either capillary GC with nitrogen-phosphorus (GC-NPD) or mass spectrometric (GC-MS) detection or liquid chromatography with tandem MS detection (LC-MS/MS). The typical LOQ is 0.01 mg/kg for most plant and animal matrices, with mean recoveries typically ranging between 70–120%. Multiresidue methods, such as the German DFG S19, are available for azoxystrobin analysis in plant and animal matrices.

Adequate multi- and single-residue methods exist for both gathering data in supervised trials and other studies and for monitoring and enforcing azoxystrobin MRLs in samples of plant and animal origin.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of azoxystrobin in samples of plant and animal commodities freezer-stored at ≤ –18 °C. Fortified samples, typically at 0.1 mg/kg, of plant commodities (apples, orange oil, juice and pulp, peaches, grapes, wine, bananas, tomatoes, cucumbers, carrot root, lettuce leaf, oilseed rape, soya bean meal, corn grits, wheat straw, grain, and forage, peanuts, and pecans) were stored for up to 24 months. Fortified samples of processed commodities (peanut oil and meal, wheat bran and tomato juice and paste) were stored up to 12 months. Fortified samples of animal origin (beef muscle, liver, kidney, fat, milk and eggs) were stored up to ten months, which adequately covers the sample storage intervals in the livestock feeding studies.

No significant degradation of azoxystrobin was observed in the samples tested over the reported storage intervals. The uncorrected recoveries of azoxystrobin were > 70% during the storage intervals, except for one sample of orange pulp (56% recovery), for which the concurrent recovery was also low (69%).

Azoxystrobin is stable when stored frozen (≤ –18 °C) over the periods for which crop and animal tissue samples were stored, prior to the analysis in supervised trials, animal feeding and processing studies.

Residue definition

Azoxystrobin is extensively metabolized in animals and plants. Results of plant metabolism studies on wheat, rice, grapes, peanuts, and cottonseed indicate that azoxystrobin is rapidly metabolized and that portions of the molecule becomes associated with sugars and other natural plant constituents. The main residue remaining in the edible plant tissues at harvest is the parent compound, azoxystrobin. Although a number of metabolites were identified, all were at levels below 10% of the total recovered radioactive residue.

In ruminants (goats) and poultry (hen), azoxystrobin was rapidly metabolized with the majority of the administered dose excreted in the faeces and urine. The metabolism was quantitatively similar to rats. The total radioactive residues in goat milk, muscle, and fat were very low and characterization showed that the residues were unlikely to be attributed to any individual compound at a significant level. The residues were higher in kidney and liver, reflecting the role of these organs in metabolism and excretion. The major metabolites in the liver were not detected or found only at low levels in the kidney and vice versa. The parent, azoxystrobin, was present at low levels in both the kidney and liver. The hen metabolism showed very low transfer of radioactivity into tissues and eggs. The parent, azoxystrobin, was identified in the egg yolk (up to 12% TRR).

Based on the above, the Meeting agreed:

Definition of the residue in plant and animal commodities for estimation of dietary intake and for compliance with MRLs: *azoxystrobin.*

The log K_{ow} of azoxystrobin is 2.5 (at 20 °C, pH 7). In the cattle feeding study, azoxystrobin accumulated in cream when milk was processed to skimmed milk and cream (6.7 to 40-fold higher

azoxystrobin concentration in cream *vs.* skimmed milk), corresponding to 5–7.5 concentration factor for cream *vs.* whole milk. Also, even at the highest dosing level of 250 ppm, no measurable azoxystrobin residues (< 0.01 mg/kg) were found in cattle muscle, whereas azoxystrobin residues of 0.01–0.03 mg/kg were determined in fat. The Meeting noted that azoxystrobin represents a borderline case of fat solubility and concluded that the azoxystrobin residue is fat-soluble for the purpose of the residue definition.

Results of supervised residue trials on crops

The Meeting received supervised trials data for azoxystrobin on citrus fruits (post-harvest and foliar treatments), stone fruits (cherry, peach and plum), berries and small fruit (blackberry, blueberry, cranberry, grapes, raspberry and strawberry), tropical fruits with inedible peel (banana, mango and papaya), bulb vegetables (bulb onion, spring onion and leeks), brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower and kohlrabi), fruiting vegetables (cucumber, gherkin, melon, summer squash, pepper and tomato), lettuce, legume vegetables (beans and peas), pulses (soya beans), root and tuber vegetables (beetroot, carrot, chicory, potato, radish and sugar beet), stalk and stem vegetables (artichokes, asparagus, celery, witlof and chicory), cereal grains (barley, oat, rye, triticale, wheat, maize and rice), tree nuts (almonds, pecans and pistachios), oil seeds (cottonseed, peanuts and sunflower), herbs (basil, chives, parsley and mint), peanut hay, soya bean forage and hay, straw, fodder and forages of cereal grains (barley, oat, rye, triticale, wheat, maize and rice), sugar beet tops, dried herbs (basil, chives, parsley and hops), and almond hulls.

Citrus fruit

The Meeting received results from supervised trials with azoxystrobin used as post-harvest and foliar treatments on citrus fruits (grapefruit, orange, lemon, tangerine and mandarin) in the USA.

For the post-harvest treatment on citrus fruits, the GAP of the USA specifies a maximum of two treatments (for maximum decay control, once before storage and once after storage, just prior to marketing) that can be performed as a dip application with 0.12 kg ai/hL or a spray, drench, or flood application with 4 kg ai/ton fruit.

Ten trials were performed according to the GAP using two dip treatments (one with and one without a storage wax) at 0.12 kg ai/hL. Azoxystrobin residues in whole fruit were: 2.7 and 2.9 mg/kg for grapefruit, 2.1 and 2.2 mg/kg for orange, 2.6 and 4.2 mg/kg for tangerine, 3.4 and 6.2 mg/kg for mandarin, and 5.5 and 8.8 mg/kg for lemon. Three trials at the GAP using two spray treatments at 4 kg ai/ton fruit resulted in significantly lower azoxystrobin residues: 0.86 (grapefruit), 0.58 (orange) and 0.88 (lemon) mg/kg.

Eighteen other trials were performed at the GAP rate but only with a single application. Among these trials, the dip treatment with a storage wax resulted in the highest azoxystrobin residues (as compared to dip without wax or spray with or without wax), which were: 2.1 and 5.3 mg/kg for grapefruit, 1.6 and 4.0 mg/kg for orange, and 3.5 and 6.6 mg/kg for lemon.

In one post-harvest orange trial, involving a single dip without a storage wax, azoxystrobin residues in the whole fruit, pulp, and peel were analysed. Azoxystrobin residues were: 2.0 mg/kg in the whole fruit, 0.72 mg/kg in pulp, and 5.4 mg/kg in orange peel.

For the foliar treatment on citrus fruits, the GAP of the USA specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–21 day intervals) and a PHI of 0 days. Twenty-two trials were conducted at the GAP, with azoxystrobin residues in grapefruit (n = 6): 0.19, 0.20, 0.21, 0.25, 0.27, and 0.41 mg/kg; in orange (n = 11): 0.23, 0.26, 0.28, 0.30, 0.31, 0.32, 0.34, 0.37, 0.40, 0.41, and 0.53 mg/kg for orange; and for lemon (n = 5): 0.31, 0.52, 0.60, 0.65, and 0.74 mg/kg.

The Meeting noted that azoxystrobin residues from the foliar application were significantly lower as compared to the residues obtained in the post-harvest dip trials. The Meeting agreed to use

the post-harvest dip results with one and two applications on the smaller citrus fruits (lemon, tangerine, and mandarin) to support a "citrus fruit" maximum residue level. Azoxystrobin residues in whole citrus fruit, in ranked order, were (n = 8): 2.6, 3.4, 3.5, 4.2, 5.5, 6.2, 6.6 and 8.8 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in whole citrus fruit of 15 mg/kg and an STMR value of 4.9 mg/kg.

Stone fruit

The Meeting received results from supervised trials with azoxystrobin used as a foliar treatment on stone fruits (cherry, peach, and plum) in the USA.

The GAP of the USA for stone fruit specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–14 day intervals) and a PHI of 0 days.

Seven trials on sweet cherry were conducted at the GAP rate with eight applications. Azoxystrobin residues in cherry, in ranked order, were (n = 7): 0.20, 0.42 (2), 0.45, 0.50, 0.98, and 1.0 mg/kg.

Fourteen trials on peach were conducted at the GAP rate with eight applications. Azoxystrobin residues in peach, in ranked order, were (n = 14): 0.28, 0.38, 0.41, 0.60, 0.64, 0.72 (2), 0.73, 0.74, 0.83, 0.84, 0.86, 0.89, 0.94, and 1.4 mg/kg.

Eight trials on plum were conducted at the GAP rate with eight applications. Azoxystrobin residues in plum, in ranked order, were (8): 0.02, 0.09, 0.24 (2), 0.25, 0.30, 0.37, and 0.42 mg/kg.

The Meeting agreed that the data on cherry, peach, and plum complying with the US GAP for stone fruit could be used to support a commodity group maximum residue level. Based on the residues obtained on peach, the Meeting estimated a maximum residue level for azoxystrobin in stone fruit of 2 mg/kg and an STMR value of 0.74 mg/kg.

Berries and other small fruits

The Meeting received results from supervised trials from the USA where azoxystrobin was used as a foliar treatment on berries and other small fruits, i.e., blackberry, blueberry, cranberry, raspberry, grape, and strawberry.

Blackberry, raspberry and blueberry

The GAP of the USA for cane berries (including blackberry and raspberry) specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–14 day intervals) and a PHI of 0 days. One trial on blackberry was at the GAP rate with eight applications. Azoxystrobin residue was 3.6 mg/kg. Two trials on raspberry were according to the GAP (six or seven applications). Azoxystrobin residues were 0.71 and 2.4 mg/kg.

The GAP of the USA for bush berries (including blueberries) specifies a rate of 0.28 kg ai/ha with a seasonal total of 0.84 kg ai/ha (three applications at 7–14 day intervals) and a PHI of 0 days. Seven trials on blueberries were conducted at the GAP rate with six applications. Azoxystrobin residues, in ranked order, were (n =7): 0.52, 0.79, 0.86, 0.95, 1.1 (2), and 1.4 mg/kg.

The Meeting decided to use the data on blackberry, raspberry, and blueberry to support a "Berries and other small fruits, except cranberry, grapes, and strawberry" commodity group maximum residue level. Azoxystrobin residues, in ranked order (n = 10): 0.52, 0.71, 0.79, 0.86, 0.95, 1.1 (2), 1.4, 2.4, and 3.6 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in Berries and other small fruits, except cranberry, grapes, and strawberry of 5 mg/kg and an STMR value of 1.0 mg/kg.

Cranberry

The GAP of the USA for cranberry specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–14 day intervals) and a PHI of three days. Four trials were conducted according to the GAP. Azoxystrobin residues, in ranked order, were: 0.15, 0.19, 0.26, and 0.31 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in cranberry of 0.5 mg/kg and an STMR value of 0.23 mg/kg.

Grapes

The GAP of the USA for grapes specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 10–14 day intervals) and a PHI of 14 days. Fifteen trials on grapes were conducted according to the GAP with a PHI of 13–14 days. Azoxystrobin residues in grapes, in ranked order, were (n = 15): 0.11, 0.16, 0.24, 0.30, 0.33, 0.47 (2), 0.53 (3), 0.60, 0.62, 0.73, 0.76, and 0.80 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in grapes of 2 mg/kg and an STMR value of 0.53 mg/kg.

Strawberry

The GAP of the USA for strawberry specifies a rate of 0.28 kg ai/ha with a maximum seasonal total of 1.1 kg ai/ha (four applications at 7–10 day intervals) and a PHI of 0 days. Seven trials were conducted at the GAP rate with 6–7 applications. Azoxystrobin residues in strawberry in ranked order were (n = 7): 0.26, 0.28, 0.65, 1.3 (2), 4.3, and 4.5 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in strawberry of 10 mg/kg and an STMR value of 1.3 mg/kg.

Tropical fruits- inedible peel

Bananas

The Meeting received results from supervised trials with azoxystrobin used as a foliar treatment on bananas in the USA and as a post-harvest treatment in Central America (Costa Rica, Guatemala, and Mexico). The post-harvest trials were carried out according to the GAP of the USA.

For the foliar treatment on bananas and plantains, the GAP of the USA specifies a rate of 0.15 kg ai/ha with a maximum seasonal total of 1.2 kg ai/ha (eight applications at 12–14 day intervals) and a PHI of 0 days. Six trials were conducted according to the GAP. Azoxystrobin residues in whole fruit from bagged bunches were (n = 6): 0.01, 0.02 (2), 0.05 (2), and 0.15 mg/kg. Azoxystrobin residues in whole fruit from unbagged bunches were (n = 6): 0.10, 0.11, 0.17, 0.18, and 0.26 (2) mg/kg. Azoxystrobin residues in banana pulp were < 0.01 (4) and 0.01 (2) mg/kg for bagged bananas and < 0.01 (3), 0.02 (2), and 0.03 mg/kg for unbagged bananas.

For the post-harvest treatment on bananas and plantains, the GAP of the USA specifies a maximum of one application made as a spray, dip, or paint using 0.04 kg ai/hL. Six post-harvest trials on banana were conducted according to the GAP. Azoxystrobin residues in the whole fruit, in ranked order, were (n = 6): 0.58, 0.71, 0.82, 0.85, 0.98, and 1.1 mg/kg. Azoxystrobin residues in the pulp, in ranked order, were (n = 6): < 0.02, 0.02, 0.03 (2), 0.05, and 0.07 mg/kg.

The Meeting noted that the post-harvest trials resulted in higher residues, thus considered only the post-harvest results for maximum residue level and STMR estimations. Also, the Meeting agreed to extrapolate the results from bananas to plantains (the same GAP as bananas).

The Meeting estimated a maximum residue level for azoxystrobin in banana and plantain (whole fruit) of 2 mg/kg. Based on the pulp data, the Meeting estimated an STMR value of 0.03 mg/kg for banana and plantain pulp.

Mango

The Meeting received results from supervised trials on mango in Brazil, South Africa, and the USA.

In Brazil azoxystrobin is approved for use on mangoes at a spray rate of 0.008 kg ai/hL (0.06 kg ai/ha), with a maximum of six applications and a PHI of 2 days. From six trials in Brazil, at the GAP rate with six or eight applications residues of azoxystrobin, in whole fruit, were (n = 6): 0.03, 0.06 (2), 0.07, 0.08, and 0.13 mg/kg.

The GAP of South Africa specifies an application rate of 0.01 kg ai/hL, a maximum of two applications and a PHI of 21 days. Four trials complied with the GAP of South Africa, azoxystrobin residues, in whole fruit (n = 4), were: 0.02, 0.03, and 0.06 (2) mg/kg. The residues in flesh were < 0.01 mg/kg even at 200% GAP or in cases where fruit was harvested within the PHI of 21 days. In two trials at 100 and 200% of the GAP rate and a PHI of 0 days, azoxystrobin residues in flesh were 0.01 and 0.03 mg/kg and in whole fruit were 0.05 and 0.20 mg/kg, respectively, giving an average whole fruit/flesh residue concentration factor of 5.8.

The GAP of the USA (for tropical fruit) specifies a rate of 0.28 kg ai/ha with a maximum of six application (1.7 kg ai/ha seasonal total) and a PHI of 0 days. In three US trials, conducted according to the US GAP, residues of azoxystrobin in mango halves (stone removed) were: 0.09, 0.31, and 0.48 mg/kg. Using the stone/whole fruit weight factors of 0.10 and 0.09, based on the information provided in the South African trials for mango varieties Kent and Tommy Atkins, respectively, calculated residues of azoxystrobin in whole fruit were: (n = 3): 0.08, <u>0.28</u>, and 0.44 mg/kg.

Based on the results from the US trials, the Meeting estimated a maximum residue level for azoxystrobin in mango (whole fruit) of 0.7 mg/kg. Based on the whole fruit/flesh residue concentration factor of 5.8 and the median value in whole fruit of 0.28 mg/kg, the Meeting estimated an STMR value of 0.05 mg/kg for mango flesh.

Papaya

The Meeting received results from supervised trials with azoxystrobin used as a foliar treatment on papaya in Brazil and Malaysia.

The GAP of Brazil specifies a spray concentration 0.008 kg ai/hL (0.064 kg ai/ha), with a maximum of four applications and a PHI of 3 days. Four trials on papaya in Brazil involved six applications at 125% GAP rate. Azoxystrobin residues in the whole fruit were: 0.06, 0.09, 0.11, and 0.12 mg/kg. In two trials, papaya flesh was analysed, with azoxystrobin residues in flesh being 0.01 and 0.02 mg/kg at a PHI of three days. The whole fruit/flesh distribution data were also obtained for two trials at 250% GAP rate (PHIs of 0–14 days). The average whole fruit/flesh residue concentration factor was 5.8 (n = 18).

The GAP of Malaysia specifies a spray concentration 0.011 kg ai/hL (0.11 kg ai/ha), a maximum of two applications and a PHI of one day. Three trials on papaya in Malaysia were conducted according to the GAP. Azoxystrobin residues in the whole fruit were (n = 3): < 0.05 (2) and 0.15 mg/kg.

The Meeting decided to combine results obtained from supervised trials on papaya in Brazil and Malaysia for mutual support. Azoxystrobin residues in the whole fruit, in ranked order, were (n = 7): < 0.05 (2), 0.06, <u>0.09</u>, 0.11, 0.12 and 0.15 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in papaya (whole fruit) of 0.3 mg/kg. Based on the whole fruit/flesh residue concentration factor of 5.8 and the median value in whole fruit of 0.09 mg/kg, the Meeting estimated an STMR value of 0.02 mg/kg for papaya flesh.

Bulb vegetables

Leeks

The Meeting received results from supervised trials with azoxystrobin on leeks in France (Southern and Northern), Germany, Switzerland, and the UK.

The GAP of France specifies a rate of 0.25 kg ai/ha, with a maximum of three applications and a PHI of 50 days. The GAP of Germany specifies a rate of 0.25 kg ai/ha, a maximum of two applications and a PHI of 42 days. No trials were conducted according the GAP of France or Germany.

The GAP of the UK specifies a rate of 0.25 kg ai/ha, a maximum of four applications and a PHI of 21 days. The GAP of Switzerland specifies a rate of 0.25 kg ai/ha, a maximum of two applications (14-day interval), and a PHI of 14 days. The GAP of Italy specifies a rate of 0.25 kg ai/ha, a maximum of two applications (7–14 day interval) and a PHI of 15 days. Twelve trials in France (Southern and Northern), Germany, Switzerland, and UK were conducted according to the GAP of Switzerland or Italy. Azoxystrobin residues found were (n = 12): 0.06, 0.07, 0.10, 0.11, 0.13, 0.14 (2), 0.17, 0.19, 0.34, 0.64, and 1.2 mg/kg.

Onion bulb, dry

The Meeting received results from supervised trials with azoxystrobin used on bulb onions in the USA. The GAP of the USA (for bulb vegetables) specifies a rate of 0.28 kg ai/ha, a maximum of 6 applications (total seasonal rate of 1.7 kg ai/ha) and a PHI of 0 days.

Eight trials were conducted according to the GAP. Azoxystrobin residues, in ranked order, were (n = 8): < 0.01, 0.07, 0.15, 0.21, 0.31, 0.36, 0.51, and 0.66 mg/kg.

Spring onion

The Meeting received results from supervised trials with azoxystrobin on spring onions in the USA. The GAP of the USA (for bulb vegetables) specifies a rate of 0.28 kg ai/ha, a maximum of 6 applications (total seasonal application rate of 1.7 kg ai/ha) and a PHI of 0 days.

Six trials were conducted according to the GAP with six applications. It was also decided to include one trial that involved 11 applications as the Meeting considered that the last application was more likely to contribute the majority to the residue of azoxystrobin. Also, the resulting residue of 3.3 mg/kg falls within the population of residues from the trials with six applications. Azoxystrobin residues, in ranked order, were (n = 7): 0.67, 1.3, 1.4, 2.2, 2.6, 2.7, 3.3, and 6.3 mg/kg.

The Meeting decided that the data on leeks, onion bulb and spring onion could be used to support a “bulb vegetables” commodity group maximum residue level. Based on the results on spring onions obtained according to the US GAP for bulb vegetables, the Meeting estimated a maximum residue level for azoxystrobin in bulb vegetables of 10 mg/kg and an STMR value of 2.2 mg/kg.

Brassica vegetables

Broccoli

The Meeting received results from supervised trials with azoxystrobin on broccoli in Europe (Germany, the Netherlands, and Spain), Canada and the USA.

In Europe, the GAPs of France, Germany, the Netherlands, and the UK specify a rate of 0.25 kg ai/ha, a maximum of two applications with a PHI of 14 days. Eight trials in Europe were conducted according to GAP. Azoxystrobin residues were (n = 8): < 0.01 (2), 0.01, 0.04 (3), 0.11, and 0.58 mg/kg.

The GAP of the USA (for brassica vegetables, head and stem subgroup) specifies a rate of 0.28 kg ai/ha with a maximum of 6 applications (total seasonal application rate of 1.7 kg ai/ha) and a PHI of 0 days. Two trials in Canada and two trials in the USA were conducted according to the US GAP. Azoxystrobin residues were (n = 4): 0.25, 0.93, 1.5, and 2.3 mg/kg.

The Meeting noted that azoxystrobin residues in broccoli obtained in the trials in the USA and Canada were significantly higher than those obtained in the European trials.

Brussels sprouts

The Meeting received results from supervised trials with azoxystrobin on Brussels sprouts in Europe (Austria, Germany, France, the Netherlands, Spain, and the UK).

In Europe, the GAPs of France, Germany, Italy, the Netherlands, and the UK for Brussels sprouts specifies a rate of 0.25 kg ai/ha, a maximum of two applications (8 to14-day interval) with a PHI of 14 days.

Twelve trials in Europe were conducted according to GAP with either two or four applications. Azoxystrobin residues, in ranked order were, were (n = 12): 0.03, 0.04 (3), 0.05 (3), 0.06, 0.08, 0.14, and 0.18 (2) mg/kg.

Cabbage, head

The Meeting received results from supervised trials with azoxystrobin on cabbage in Europe (Austria, Germany, Italy, the Netherlands, and Spain), Canada and the USA.

In Europe, the GAPs of France, Germany, Italy, the Netherlands, and the UK, for Brussels sprouts, specify a rate of 0.25 kg ai/ha, a maximum of two applications (8 to14-day interval), with a 14 day PHI. Twelve trials in Europe were conducted according to GAP with either two or four applications. Azoxystrobin residues, in ranked order were, were (n = 12): < 0.01 (7), 0.01 (2), 0.07, 0.09, and 0.18 mg/kg.

The GAP of the USA (for brassica vegetables, head and stem subgroup) specifies a maximum of six applications at 0.28 kg ai/ha (seasonal total rate of 1.7 kg ai/ha) with a PHI of 0 days. Two trials in Canada and two trials in the USA were conducted according to the US GAP. Azoxystrobin residues were (n = 4): 0.32, 0.90, 1.8 and 2.0 mg/kg.

The Meeting noted that azoxystrobin residues in cabbage obtained in the trials in the USA and Canada were significantly higher than those obtained in the European trials.

Cauliflower

The Meeting received results from supervised trials with azoxystrobin on cauliflower in Europe (Austria, Germany, Spain, and the UK).

The GAP of Germany specifies a maximum of two applications at 0.25 kg ai/ha, (8 to12-day interval) with a PHI of 10 days. Eight trials in Germany, Austria, and the UK were conducted according to the German GAP with either two or four applications. Azoxystrobin residues were (n = 8): < 0.01 (2), 0.04 (2), 0.07, 0.17, 0.42, and 0.46 mg/kg.

The GAP of France and Italy for cauliflower specify a maximum of two applications (12 to14-day interval) at 0.25 kg ai/ha, and a PHI of 14 days. Four trials in Spain were conducted according to the GAP with either two or four applications. Azoxystrobin residues were (n = 4): < 0.01 (2), 0.03, and 0.44 mg/kg.

Kohlrabi

The Meeting received results from supervised trials with azoxystrobin used on kohlrabi in Germany. The GAP of Germany for kohlrabi specifies a maximum of two applications (8 to12-day interval) at 0.25 kg ai/ha, and a PHI of 14 days. Six trials were conducted according to the GAP. Azoxystrobin residues, in ranked order, were (n = 6): < 0.02, 0.03, 0.04, 0.05, 0.06, and 0.09 mg/kg.

The Meeting agreed that the data on broccoli, Brussels sprouts, cabbages (head), cauliflower and kohlrabi could be used to support a "Brassica vegetables" commodity group maximum residue level. The Meeting noted that azoxystrobin residues obtained on broccoli and head cabbage according to the same US GAP for brassica vegetables appear to be from similar populations and decided to combine them. Combined azoxystrobin residues, in ranked order median underlined, were (n = 8): 0.25, 0.32, 0.90, <u>0.93</u>, <u>1.5</u>, 1.8, 2.0, and 2.3 mg/kg.

Based on the data on broccoli and head cabbage, the Meeting estimated a maximum residue level for azoxystrobin in brassica vegetables of 5 mg/kg, an STMR value of 1.2 mg/kg and a highest residue value of 2.3 mg/kg.

Fruiting vegetables, Cucurbits

Cucumber

The Meeting received results from supervised trials with azoxystrobin on cucumber both indoors (glasshouse) in Europe (France, Germany, Greece, and the UK) and in the field in Europe (France, Italy, and Spain) and the USA.

The indoor and field trials in France, Germany, Greece, and the UK were conducted using a spray concentration of 0.02 kg ai/hL with 4–8 applications and a PHI of three days. The rate and PHI corresponds to the GAP of France (0.02 kg ai/hL, three applications, a PHI of three days), which can cover both southern and northern parts of Europe. The GAPs of Italy and Switzerland specify a maximum of 3 applications at 0.025 kg ai/hL with a PHI of three days, i.e., the trials were conducted at 80% of the GAP rate in these countries. Azoxystrobin residues from the indoor trials were (n = 6), 0.03, 0.13 (2), 0.20, 0.49, and 0.75 mg/kg. Azoxystrobin residues from the outdoors trials in Europe were (n = 5): 0.02, 0.04, 0.06, 0.07, and 0.12 mg/kg.

Only two indoor trials in Germany (listed above with residues of 0.13 and 0.13 mg/kg at a PHI of three days) matched the GAP of the Netherlands, which specifies 0.02 kg ai/hL, 3 applications, and a PHI of one day for indoor use. Azoxystrobin residues were (n = 2): 0.19 and 0.23 mg/kg.

The GAP of the USA for cucurbits specifies a maximum of six applications at 0.28 kg ai/ha (with a total seasonal rate of 1.7 kg ai/ha) and a PHI of one day. Nine trials were conducted outdoors in the USA according to US GAP. Azoxystrobin residues were (n = 9): 0.04, 0.05, 0.06 (2), 0.07, 0.09, 0.11, 0.35, and 0.40 mg/kg.

Gherkin

The Meeting received results from supervised trials with azoxystrobin on gherkins in Germany. The GAP of Germany for cucumber specifies a maximum of two applications at 0.25 kg ai/ha, (8 to12-day interval) and a PHI of three days. Four trials in Germany on gherkins were conducted at the GAP rate with four or six applications. Azoxystrobin residues were (n = 4): 0.04, 0.05, 0.06, and 0.15 mg/kg.

Melons

The Meeting received results from supervised trials with azoxystrobin on indoor melons, i.e., in a glasshouse or a poly-tunnel, in Europe (France, Greece, Italy, the Netherlands, and Spain) and in the field in Europe (France, Greece, Italy, and Spain) and the USA.

Most of the indoor and field trials in Europe were conducted using a spray concentration of 0.02 kg ai/hL with 5–8 applications and a PHI of three days. The rate and PHI corresponds to the GAP of the Netherlands for indoor use (0.02 kg ai/hL, three applications, a PHI of three days) and 80% GAP rate for indoor/field application in Italy and Switzerland (0.025 kg ai/hL, three applications, a PHI of three days). Azoxystrobin residues from the indoor trials were (n = 8): 0.03 (2), 0.08, 0.16, 0.17, 0.18, 0.29, and 0.40 mg/kg. Azoxystrobin residues from the field trials in Europe were (n = 8): 0.01, 0.04 (3), 0.06, 0.07, 0.08, and 0.38 mg/kg.

Two field trials on melons in southern France were conducted at 0.20 kg ai/ha, eight applications, and a PHI of three days, which corresponds to the GAPs of France, Italy and Spain for field treatment (0.20 kg ai/ha, three applications, a PHI of three days). Azoxystrobin residues were: 0.06 and 0.09 mg/kg.

In six of the European trials, melon pulp and skin were analysed, azoxystrobin residues found in pulp (n = 6) were: < 0.01, 0.01 (2), 0.02, 0.05, and 0.06 mg/kg.

The GAP of the USA for cucurbits specifies a maximum of six applications (7–14 day intervals) at 0.28 kg ai/ha (total seasonal rate of 1.7 kg ai/ha) and a PHI of one day. Seven field trials were conducted in the USA according to GAP. Azoxystrobin residues were (n = 7): 0.10 (2), 0.16, 0.17 (2), 0.20, and 0.26 mg/kg.

Summer squash

The Meeting received results from supervised trials with azoxystrobin used on summer squash in the USA.

The GAP of the USA for cucurbits specifies a maximum of six applications at 0.28 kg ai/ha (total seasonal rate of 1.7 kg ai/ha) and a PHI of one day. Five trials on summer squash in the USA were conducted according to the GAP. Azoxystrobin residues, in ranked order, were (n = 5): 0.06, 0.07, 0.09, 0.11, and 0.16 mg/kg.

The Meeting agreed that the results obtained on cucumber, gherkins, melons, and summer squash could be used to support a "Fruiting vegetables, Cucurbits" commodity group maximum residue level. The Meeting noted that the results from indoor trials on cucumber and melon in Europe according to the same GAP gave highest residues. The Meeting also noted that these data sets appear to be from similar populations and decided to combine them. Azoxystrobin residues, in ranked order, were (n = 14): 0.03 (3), 0.08, 0.13 (2), 0.16, 0.17, 0.18, 0.20, 0.29, 0.40, 0.49, and 0.75 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in fruiting vegetables, cucurbits of 1 mg/kg and an STMR value of 0.17 mg/kg. Based on the pulp data for melon, the Meeting estimated an STMR value of 0.02 mg/kg for cucurbits with inedible peel.

Fruiting vegetables, other than cucurbits

Peppers, sweet

The Meeting received results from supervised trials with azoxystrobin on sweet pepper grown in an indoor environment, i.e., in a glasshouse or a poly-tunnel, in Europe (France, Italy, and the Netherlands) and in the field (outdoor) in southern Europe (France, Italy, and Spain).

Seven field trials in southern Europe were conducted using a spray concentration of 0.025 kg ai/hL with six applications and a PHI of three days. The rate and PHI corresponds to the GAP of Italy for indoor/field application (0.025 kg ai/hL, three applications and a PHI of three days) and 125% GAP of Spain (0.020 kg ai/h, three applications and a PHI of three days). Azoxystrobin residues from the field trials were (n = 7), 0.04, 0.17, 0.18, 0.44, 0.45, 0.61, and 0.85 mg/kg.

Five indoor trials were conducted using a spray concentration of 0.025 kg ai/hL with six applications and a PHI of three days. These trials were conducted at the GAP rate of Italy. Azoxystrobin residues were (n = 5): 0.27, 0.35 (2), 0.62, and 1.4 mg/kg.

Two indoor trials in France were conducted at 0.25 kg ai/ha with six applications and a PHI of three days. These trials were conducted at the GAP rate of France (0.25 kg ai/ha, three applications and a PHI of 3 days). Azoxystrobin residues were (n = 2): 0.25 and 0.58 mg/kg.

Tomato

The Meeting received results from supervised trials with azoxystrobin on indoor grown tomatoes (in a glasshouse) in Europe (France, Italy, the Netherlands, and Spain) and in the field in southern Europe (France, Greece, Italy, and Spain).

The indoor and field trials on tomatoes were conducted using a rate of 0.23–0.26 kg ai/ha or a spray concentration of 0.025 kg ai/hL with six applications and a PHI of six days. The rate and PHI correspond to the GAP of France for indoor/field use (0.25 kg ai/ha, three applications and a PHI of three days) or the GAP of Italy for indoor/field use (0.025 kg ai/hL, three applications and a PHI of three days) and the GAP of Switzerland for indoor application (0.025 kg ai/hL, three applications and a PHI of three days).

Six field trials on tomatoes were conducted using a spray concentration of 0.025 kg ai/hL with six applications and a PHI of three days. Azoxystrobin residues were (n = 8): 0.08, 0.15, 0.16, 0.19, 0.39, and 0.41 mg/kg.

Two field trials on tomatoes were conducted using a rate of 0.23–0.26 kg ai/ha with six applications and a PHI of three days. Azoxystrobin residues were (n = 2): 0.31 and 0.40 mg/kg.

Six indoor trials on tomatoes were conducted using or a spray concentration of 0.025 kg ai/hL with six applications and a PHI of six days. Azoxystrobin residues were (n = 6): 0.08, 0.20, 0.29, 0.33, 0.54, and 0.86 mg/kg.

Five field trials on tomatoes were conducted using 0.24–0.26 kg ai/ha with six applications and a PHI of three days. Azoxystrobin residues were (n = 5): 0.14, 0.20, 0.49, 0.54, and 0.69 mg/kg.

The Meeting agreed that the data on sweet pepper and tomato could be used to support a "Fruiting vegetables, other than Cucurbits, except fungi and sweet corn" commodity group maximum residue level. The Meeting noted that indoor trials on sweet pepper and tomato (conducted according to the same GAP with a spray concentration of 0.025 kg ai/hL) gave the highest residues (as compared to the indoor trials at 0.25 kg ai/ha or the field trials). The Meeting also noted that the data on sweet peppers and tomatoes from these trials appear to be from a similar population and decided to combine them. Azoxystrobin residues, in ranked order, were (n = 11): 0.08, 0.20, 0.27, 0.29, 0.33, 0.35 (2), 0.54, 0.62, 0.86, and 1.4 mg/kg

The Meeting estimated a maximum residue level for fruiting vegetables, other than cucurbits, except fungi and sweet corn of 3 mg/kg and an STMR value of 0.35 mg/kg.

Using a default concentration factor of 10 for extrapolation from sweet peppers to dried chilli peppers, the Meeting estimated a maximum residue level for azoxystrobin in dried chilli pepper of 30 mg/kg and an STMR value of 3.5 mg/kg.

Lettuce

The Meeting received results from supervised trials with azoxystrobin on lettuce in France, Spain and the UK.

The GAPs of France, Germany, and the Netherlands for lettuce specifies a rate of 0.25 kg ai/ha, a maximum of three applications (two applications in Germany), and a PHI of 14 days. The GAP of Italy specifies 0.25 kg ai/ha, a maximum of three applications, and a PHI of seven days.

Twelve trials in northern Europe (northern France and the UK) were conducted at the GAP of France, Germany, or the Netherlands. Azoxystrobin residues from these trials were (n = 12): < 0.01 (5), 0.24, 0.25, 0.39, 0.49, 0.56, 1.2, and 1.6 mg/kg.

Eight trials in southern Europe (southern France and Spain) were conducted at the GAP of Italy. Azoxystrobin residues from these trials were (n = 8): 0.12 (2), 0.14, 0.31, 0.44, 0.85, 1.1, and 1.4 mg/kg.

The Meeting noted that the residues in lettuce from the trials in northern and southern Europe appear to be from a similar population (based on the Mann-Whitney U-test). Combined azoxystrobin residues in lettuce, in ranked order median underlined, were (n = 20): < 0.01 (5), 0.12 (2), 0.14, 0.24, <u>0.25</u>, <u>0.31</u>, 0.39, 0.44, 0.49, 0.56, 0.85, 1.1, 1.2, 1.4, and 1.6 mg/kg.

The Meeting estimated a maximum residue level for lettuce (head) and lettuce (leaf) of 3 mg/kg and an STMR value of 0.28 mg/kg.

Legume vegetables

The Meeting received results from supervised trials with azoxystrobin on succulent beans and peas in the USA. The GAP of the USA for legume vegetables specify a maximum of six applications at 0.28 kg ai/ha with total seasonal rate of 1.7 kg ai/ha and a PHI of 0 days.

Beans

Six trials in the USA were conducted on succulent beans according to GAP with 7–8 applications. In three trials, the beans were collected without the pods. Azoxystrobin residues in beans without pods were: 0.02, 0.07, and 0.08 mg/kg. In three trials where beans were collected and analysed with the edible pods, azoxystrobin residues were: 0.11, 0.48, and 1.5 mg/kg.

Peas

Six trials in the USA were conducted on succulent peas according to the GAP of the USA with seven applications. In three trials, the peas were collected without the pods. Azoxystrobin residues in peas without pods were: 0.03, 0.08, and 0.17 mg/kg. In three trials where the peas were collected and analysed with the edible pods azoxystrobin residues were: 0.87, 1.2, and 1.5 mg/kg.

The Meeting agreed that the data on beans and peas obtained from trials according to the same GAP for legume vegetables could be used to estimate a "legume vegetables" commodity group maximum residue level. The Meeting decided to use the higher residues found on beans and peas with pods, for the estimation. Azoxystrobin residues in beans and peas with pods, in ranked order median underlined, were (n = 6): 0.11, 0.48, <u>0.87</u>, <u>1.2</u>, and 1.5 (2) mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in legume vegetables of 3 mg/kg and an STMR value of 1.0 mg/kg.

Soya beans, dry

The Meeting received results from supervised trials with azoxystrobin on soya beans in the USA.

The GAP of the USA for soya beans (seeds) specifies a maximum of 6 applications at 0.28 kg ai/ha with a total sanctioned seasonal total rate of 1.7 kg ai/ha and a PHI of 14 days. Nineteen trials on soya beans in the USA were conducted at the US GAP rate with 5–7 applications and a PHI of 12–16 days. Azoxystrobin residues, in ranked order median underlined, were (n = 19): < 0.01, 0.02 (5), 0.03, 0.05, <u>0.06</u> (3), 0.07, 0.09, 0.12, 0.15, 0.18, 0.23, 0.24, and 0.33 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in soya beans, dry of 0.5 mg/kg and an STMR value of 0.06 mg/kg.

Root and tuber vegetables

The Meeting received results from supervised trials with azoxystrobin on beetroot, carrot, radish, and sugar beet in the USA, on chicory root in France and on potato in Europe.

The GAP of the USA for root vegetables specifies a maximum of six applications at 0.37 kg ai/ha with a total seasonal rate of 2.2 kg ai/ha (six applications) and a PHI of 0 days.

Beetroot

Four trials on beetroot (garden beet) were conducted in the USA using 0.28 kg ai/ha (76% US GAP rate) with a total seasonal application of 2.2 kg ai/ha (six applications) and a PHI of 0 days. Azoxystrobin residues in beetroot, in ranked order, were (n = 4): 0.18, 0.23, 0.32, and 0.34 mg/kg.

Carrot

Six trials on carrot were conducted in the USA according to the US GAP for root vegetables (one trial with eight applications). Azoxystrobin residues in carrot, in ranked order, were (n = 6): 0.03, 0.13, 0.14, 0.17, 0.26, and 0.30 mg/kg.

Chicory root

Five supervised trials with azoxystrobin used on chicory (endive) in France (see chicory and endive leaves for trial details) were conducted according to the GAP of France, which specifies a PHI of 21 days, maximum of three applications at 2.5 kg ai/ha for chicons (the edible part) production (treatment of plants) and 0.25 kg ai/ha for root production (treatment of parts).

Azoxystrobin residues in chicory roots (harvest of chicory leaves and roots at a PHI of 21 days), were (n = 5) 0.06, 0.07, 0.11, 0.25, and 0.46 mg/kg.

Potato

The Meeting received results from supervised trials with azoxystrobin used on potato as soil treatment (whole field or in-furrow) in France, Italy, the Netherlands, Spain, and the UK or as a foliar treatment in Spain and the UK.

For the pre or at planting soil treatment, the GAP of the Netherlands and the UK specify a single application at 1.5 kg ai/ha as an overall or incorporated treatment or a single application at 0.75 kg ai/ha as an in-furrow treatment. The resulting application rates at the actual planting sites of potatoes are comparable (about 1.5 kg ai/ha) because of the reduced field area sprayed in the in-furrow application, i.e., applied as a 50% 'band' treatment.

Six trials in the Netherlands and two trials in the UK were performed using 1.5–1.6 kg ai/ha as a single application. Azoxystrobin residues in potatoes from these trials were (n = 8): < 0.01 (4) and 0.01 (4) mg/kg. Twelve trials were conducted using the same rate (1.5–1.6 kg ai/ha) in Southern Europe (southern France, Italy, and Spain), with azoxystrobin residues being (n = 12): < 0.01 (6), 0.02 (2), 0.03 (3), and 0.07 mg/kg. No GAP was available for potatoes in the southern Europe.

Six trials in the Netherlands were conducted using 0.77–0.8 kg ai/ha as a single in-furrow treatment at planting. Azoxystrobin residues in potato from these trials were (n = 6): < 0.01 (3), 0.02 and 0.03 (2) mg/kg. Four trials in southern France were conducted using 0.37–0.39 kg ai/ha (about 50% GAP rate) as a single in-furrow treatment at planting, resulting in azoxystrobin residues of (n = 4): 0.02 and 0.03 (3) mg/kg.

For the foliar application, the GAP of Germany specifies 0.13 kg ai/ha, a maximum three applications, and a PHI of seven days. The GAP of the Netherlands specifies 0.063 kg ai/ha, a maximum of two applications, and a PHI of seven days. Two trials in the UK, two trials in the Netherlands, and four trials in Spain were conducted according to the GAP of Germany. In addition,

two trials in the UK and four trials in Spain were conducted at 200% GAP rate and two trials in the Netherlands were conducted at 50% of German GAP (100% of the GAP of the Netherlands). Azoxystrobin residues in potato in all these trials were < 0.01 (16) mg/kg.

Radish

Five trials on radish were conducted in the USA according to the US GAP for root vegetables. Azoxystrobin residues in radish, in ranked order, were (n = 5): 0.13, 0.16, 0.29, 0.38, and 0.45 mg/kg.

Sugar beet

Nine trials on sugar beet were conducted in the USA according to the US GAP for root vegetables. Azoxystrobin residues in sugar beet, in ranked order, were (n = 9): 0.04, 0.05, 0.06 (2), 0.09 (2), 0.10, 0.11, and 0.24 mg/kg.

The Meeting decided to use the data on beetroot, carrot, and radish according to the same US GAP to estimate a "root and tuber vegetables" commodity group maximum residue level. The Meeting noted that the results on beetroot, carrot, and radish appear to be from a similar population and decided to combine them. Azoxystrobin residues, in ranked order median underlined were (n = 5): 0.03, 0.13 (2), 0.14, 0.16, 0.17, 0.18, <u>0.23</u>, 0.26, 0.29, 0.30, 0.32, 0.34, 0.38, and 0.45 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in root and tuber vegetables of 1 mg/kg, an STMR value of 0.23 mg/kg, and a highest residue value of 0.45 mg/kg.

Stalk and stem vegetables

Artichoke, globe

The Meeting received results from supervised trials with azoxystrobin on artichokes in France, Spain, and the USA.

The GAP of France and Spain specify 0.25 kg ai/ha, a maximum three applications, and a PHI of seven days. Five trials in France and one trial in Spain were conducted according to the GAP of France and Spain. Azoxystrobin residues were (n = 6): 0.16, 0.24, 0.30, 0.42, 0.48, and 0.61 mg/kg.

The GAP of the USA for artichokes specifies a maximum of six applications at 0.28 kg ai/ha with total seasonal rate of 1.7 kg ai/ha and a PHI of 0 days. Three trials on artichokes in the USA were conducted according to the US GAP. Azoxystrobin residues were (n = 3): 1.6, <u>1.8</u>, and 2.4 mg/kg.

The Meeting noted that azoxystrobin residues from the US trials according to the US GAP were significantly higher that those from the European trials that were conducted at French GAP, which specifies a lower application rate and a longer PHI. The Meeting considered three trials acceptable for estimation of a maximum residue level for this minor crop.

The Meeting estimated a maximum residue level for azoxystrobin in artichoke, globe of 5 mg/kg and an STMR value of 1.8 mg/kg.

Asparagus

The Meeting received results from supervised trials with azoxystrobin on asparagus in France and the USA.

The GAP of France for asparagus specifies 0.25 kg ai/ha with a maximum of three applications (a PHI is not required). Four trials on asparagus in France were conducted according to

the GAP of France with four applications (PHI of 215–259 days). Azoxystrobin residues from these trials were < 0.01 (4) mg/kg.

The GAP of the USA for asparagus specifies six applications at 0.28 kg ai/ha with total seasonal rate of 1.7 kg ai/ha and a PHI of 100 days. Two trials on asparagus in the USA were conducted according to the US GAP with a PHI of 93 or 104 days. Azoxystrobin residues from both these trials were < 0.02 (2) mg/kg.

The Meeting estimated a maximum residue level for asparagus of 0.01 (*) mg/kg and an STMR value of 0.01 mg/kg.

Celery

The Meeting received results from supervised trials with azoxystrobin used on celery in Italy and the UK. Azoxystrobin residues were determined in trimmed and untrimmed celery.

The GAP of Italy for celery specifies a maximum of three applications at 0.25 kg ai/ha, and a PHI of seven days. Six trials in Italy were conducted at the GAP rate of Italy, with four applications and a PHI of 6–7 days. Azoxystrobin residues in trimmed celery were (n = 6): 0.12, 0.16, 0.19, 0.33, 0.41, and 0.73 mg/kg. Azoxystrobin residues in untrimmed celery were (n = 6): 0.19, 1.0, 1.4, 1.8, 2.0, and 2.5 mg/kg.

Eight trials on celery in the UK were conducted according to the GAP of Germany (0.25 kg ai/ha, two applications, a PHI of 14 days) with 4–7 applications. Azoxystrobin residues in trimmed celery were (n = 8): 0.05, 0.08, 0.09, 0.10, 0.11, 0.23, 0.26, and 0.33 mg/kg. Azoxystrobin residues in untrimmed celery were (n = 7): 0.23, 0.25, 0.28, <u>0.43</u>, 0.96, 2.9 and 3.2 mg/kg.

Based on the data on untrimmed celery in the UK, the Meeting estimated a maximum residue level for azoxystrobin in celery of 5 mg/kg and an STMR value of 0.43 mg/kg.

Witloof chicory (sprouts)

The Meeting received results from supervised trials with azoxystrobin used on witloof chicory in France. The GAP of France specifies a PHI of 21 days, maximum of three applications at 2.5 kg ai/ha for chicons (the edible part) production (treatment of plants) and 0.25 kg ai/ha for root production (treatment of parts).

In five trials, plants were treated twice at the rate of 0.25 kg ai/ha (at intervals of 20–22 days). Fourteen days after the second application mature plants were harvested, the leaves removed, and the roots stored in a climate controlled room.

After 14 days the roots were separated into two batches: the first set of roots were dipped in a solution containing 0.01 kg ai/hL and the second set were sprayed once at a rate of 2.5 kg ai/ha. Following the treatments, hydroponic forcing was performed on both sets of roots in dark climate-controlled rooms. Azoxystrobin residues in chicons from the second set (treatment according to the GAP of France), in ranked order, were (n = 5) 0.03 (2), <u>0.05</u>, 0.10, and 0.11 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in witloof chicory (sprouts) of 0.3 mg/kg and an STMR value of 0.05 mg/kg.

Cereal grains

The Meeting received results from supervised trials with azoxystrobin used on barley, oat, rye, triticale and wheat in Europe and on maize and rice in the USA.

Barley

The Meeting received results in barley grain from supervised trials with azoxystrobin in France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland, and the UK.

The GAP of France for barley specifies a maximum of two applications at 0.25 kg ai/ha, with a 42-day PHI. The GAP of Spain for barley specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands specify a maximum of two applications at 0.25 kg ai/ha, and a PHI of 35 days. The Meeting decided to consider all trials on barley in continental Europe that were conducted at the GAP rate (± 30%) of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Nineteen trials in France conducted at 72–104% GAP rate, with 2–3 applications and a PHI of 35–42 days (both the highest and lowest residues were obtained at a PHI of 42 days). Azoxystrobin residues, in ranked order, were (n = 19): 0.01 (3), 0.02 (2), 0.03 (2), 0.04 (2), 0.05, 0.08, 0.09, 0.11 (2), 0.12, 0.13 (3), and 0.19 mg/kg.

Two trials in Germany conducted at 100% GAP rate, with three applications, and a PHI of 35 days, resulted in azoxystrobin residues of 0.10 and 0.11 mg/kg. One trial in Germany carried out at 80% GAP rate, with two applications, and a PHI of 37 days resulted in an azoxystrobin residue of 0.02 mg/kg.

Two trials in Italy conducted at 100–104% GAP rate, with two applications, and a PHI of 36 days resulted in azoxystrobin residues of 0.08 and 0.10 mg/kg.

One trial in Netherlands conducted at 100% GAP rate, with two applications, and a PHI of 37 days resulted in azoxystrobin residues of 0.08 mg/kg.

Two trials in Spain conducted at 100% GAP rate, with two applications, and a PHI of 35 days resulted in azoxystrobin residues of 0.03 and 0.11 mg/kg. One trial in Spain carried out at 104% GAP, with two applications, and a PHI of 38 days resulted in an azoxystrobin residue of 0.28 mg/kg.

One trial in Sweden carried out 100% GAP rate, with two applications, and a PHI of 42 days resulted in an azoxystrobin residue of 0.20 mg/kg.

Two trials in Switzerland conducted at 104% GAP rate, with two applications, and a PHI of 36 days resulted in azoxystrobin residues of 0.02 and 0.04 mg/kg. Four trials in Switzerland carried out at 80% GAP, with two applications, and a PHI of 35 days resulted in azoxystrobin residues of 0.01, 0.02 (2) and 0.03 mg/kg.

The GAP of the UK for barley specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (BBCH growth stage 71). Three trials in the UK were conducted at 100% GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 38–54 days). Azoxystrobin residues in barley grain were 0.13, 0.14, and 0.23 mg/kg.

Combined azoxystrobin residues in barley grain from the trials in Europe (n = 38), in ranked order median underlined, were: 0.01 (4), 0.02 (6), 0.03 (4), 0.04 (3), 0.05, <u>0.08</u> (3), 0.09, 0.10 (2), 0.11 (4), 0.12, 0.13 (4), 0.14, 0.19, 0.20, 0.23, and 0.28 mg/kg.

Oat, rye, and triticale

The Meeting received results in oat, rye, and triticale grain from supervised trials with azoxystrobin in Germany. The GAP of Germany for oat, rye, and triticale specifies a maximum two applications at 0.25 kg ai/ha, and a PHI of 35 days.

Two trials on oat in Germany conducted at 100% GAP rate, with three applications, and a PHI of 35 or 36 days. Azoxystrobin residues were 0.01 and 0.06 mg/kg.

Two trials on rye in Germany conducted at 100% GAP rate, with three applications, and a PHI of 35 days. Azoxystrobin residues were 0.02 and 0.04 mg/kg.

Two trials on triticale in Germany conducted at 100% GAP rate, with three applications, and a PHI of 36 days. Azoxystrobin residues were < 0.01 and 0.02 mg/kg.

Wheat

The Meeting received results in wheat grain from supervised trials with azoxystrobin on wheat in France, Germany, Italy, Spain, Switzerland, and the UK.

The GAP of France for wheat specifies a maximum of two applications at 0.25 kg ai/ha, with a PHI of 42 days. The GAP of Spain for wheat specifies a maximum two applications at 0.25 kg ai/ha, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands for barley specify 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days. The Meeting decided to consider all trials on wheat in continental Europe that were conducted at the GAP rate (± 30%) of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Fourteen trials on wheat in France were conducted at 80–104% GAP rate, with 2–3 applications and a PHI of 35–42 days (the highest and lowest residues were obtained at a PHI of 38 and 35–42 days, respectively). Azoxystrobin residues, in ranked order, were: < 0.01 (5), 0.01 (4), 0.02, 0.03 (3), and 0.14 mg/kg.

Four trials in Germany were conducted at 80–100% GAP rate, with 2–3 applications, and a PHI of 35–42 days (both the highest and lowest residues were obtained at a PHI of 35 days). Azoxystrobin residues, in ranked order, were: < 0.01, 0.01, 0.02 and 0.04 mg/kg.

Two trials in Italy were conducted at 100–104% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were: < 0.01 and 0.02 mg/kg.

Three trials in Spain were conducted at 100% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues, in ranked order, were: < 0.01, 0.01, and 0.04 mg/kg.

Five trials in Switzerland were conducted at 80–108% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were: < 0.01 (5) mg/kg.

The GAP of the UK for wheat specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (BBCH growth stage 71). Three trials in the UK were conducted at 100% GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 40–59 days). Azoxystrobin residues in wheat grain were: 0.01, 0.02, and 0.03 mg/kg.

Combined azoxystrobin residues in wheat grain from the trials in Europe (n = 31), in ranked order median underlined, were: < 0.01 (13), <u>0.01</u> (7), 0.02 (4), 0.03 (4), 0.04 (2) and 0.14 mg/kg.

The Meeting decided to use the data on barley grain to extrapolate to oat and data on wheat grain to extrapolate to rye and triticale.

The Meeting estimated a maximum residue level for azoxystrobin in barley and oat grain of 0.50 mg/kg and an STMR value of 0.08 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in wheat, rye and triticale grain of 0.20 mg/kg and an STMR value of 0.01 mg/kg.

Maize

The Meeting received results in maize grain from supervised trials with azoxystrobin in the USA.

The GAP of the USA for maize specifies a maximum of eight applications at 0.28 kg ai/ha with a total seasonal application of 2.2 kg ai/ha and a PHI of seven days. Twenty trials in the USA

were conducted on maize according to the US GAP with a PHI of 6–7 days. Azoxystrobin residues in maize grains in these trials were (n = 20): < 0.01 (17), 0.01 (2), and 0.02 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in maize grain of 0.02 mg/kg and an STMR value of 0.01 mg/kg.

Rice

The Meeting received results in rice grain from supervised trials with azoxystrobin used on rice in the USA.

The GAP of the USA for rice specifies a rate of 0.34 kg ai/ha with a total seasonal rate of 0.78 kg ai/ha and a PHI of 28 days. Sixteen trials were conducted in the USA on rice, in accordance with the US GAP with a maximal seasonal application of 0.78 kg ai/ha (2×0.22 and 1×0.34 kg ai/ha) and a PHI of 26–28 days. Azoxystrobin residues in rice grain, in ranked order median underlined, were (n = 16): 0.07, 0.19, 0.29, 0.30 (2), 0.41, 0.43, 0.62, 0.74, 0.81, 0.89, 1.6, 2.3, 2.8, 3.0 and 3.3 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in rice grain of 5 mg/kg and an STMR value of 0.68 mg/kg.

Tree nuts

The Meeting received results from supervised trials with azoxystrobin used on almonds, pecans, and pistachios in the USA.

Almonds

The GAP of the USA for almonds specifies a maximum of six applications at 0.28 kg ai/ha with a total authorized seasonal rate of 1.7 kg ai/ha and a PHI of 28 days. Five trials in the USA were conducted on almonds according to the US GAP with a PHI of 28–29 days. Azoxystrobin residues in almonds were (n = 5): < 0.01 (4) and 0.01 mg/kg.

Pecans

The GAP of the USA for pecans specifies 0.22 kg ai/ha with total seasonal application of 1.3 kg ai/ha (six applications) and a PHI of 45 days. Six trials in the USA were conducted on pecans at the US GAP rate with six applications. In four trials with a PHI shorter than 45 days (24–42 days), azoxystrobin residues were < 0.01 (4) mg/kg. In two trials with a PHI of 20–25 days, azoxystrobin residues were 0.01 and 0.02 mg/kg.

Based on the data on almonds and pecans, the Meeting estimated a maximum residue level for azoxystrobin in tree nuts, except pistachios of 0.01 mg/kg and an STMR value of 0.01 mg/kg.

Pistachios

The GAP of the USA for pistachios specifies a rate of 0.28 kg ai/ha with a total seasonal rate of 1.7 kg ai/ha (six applications) and a PHI of seven days. Three trials in the USA were conducted on pistachios according to the US GAP. Azoxystrobin residues were 0.25, 0.44, and 0.48 mg/kg. The Meeting considered three trials acceptable for estimation of a maximum residue level for this minor crop.

The Meeting estimated a maximum residue level for azoxystrobin in pistachios of 1 mg/kg and an STMR value of 0.44 mg/kg.

Oilseeds

Cotton seed

The Meeting received results from supervised trials with azoxystrobin used on cotton as in-furrow and foliar treatments in the USA.

For in-furrow treatment, the GAP of the USA specifies 0.019 kg ai/km of row (0.20 oz ai/1000 row feet), which corresponds to the maximum of 0.34 kg ai/ha (for 22-inch rows). Twelve trials were conducted in the USA according to the US GAP for in-furrow treatment immediately before planting. In all these trials, azoxystrobin residues in cottonseed, taken at normal harvest, (PHI of 121–186 days) were < 0.01 (12) mg/kg.

For foliar application, the GAP of the USA for cotton specifies 0.17 kg ai/ha with total seasonal application rate of 0.5 kg ai/ha (three applications) as a foliar spray and a PHI of 45 days. Twelve trials in the USA were conducted with a combined in-furrow application at the planting (0.17 kg ai/ha) and three foliar applications at 0.17 kg ai/ha with a PHI of 45 days. Azoxystrobin residues from these trials, in ranked order, were (n = 12): < 0.01 (5), 0.01 (2), 0.02, 0.03 (3), and 0.54 mg/kg.

Based on the trials with combined foliar and in-furrow (at-planting) application, the Meeting estimated a maximum residue level for azoxystrobin in cotton seed of 0.7 mg/kg and an STMR value of 0.01 mg/kg.

Peanuts

The Meeting received results from supervised trials with azoxystrobin used on peanuts in the USA.

The GAP of the USA for peanuts specifies a rate of 0.45 kg ai/ha with a seasonal total of 0.9 kg ai/ha (two applications) with a PHI of 14 days. Eleven trials on peanuts in the USA were conducted according to the US GAP with a PHI of 13–14 days. Azoxystrobin residues, in ranked order, were (n = 11): < 0.01 (5), 0.01 (4), 0.06, and 0.13 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in peanut of 0.2 mg/kg and an STMR value of 0.01 mg/kg.

Sunflower seed

The Meeting received results from supervised trials with azoxystrobin used on sunflower in the USA.

The GAP of the USA for sunflower specifies a rate of 0.28 kg ai/ha with a seasonal total of 0.5 kg ai/ha and a PHI of 30 days. Six trials on sunflower in the USA were conducted according to the US GAP with a seasonal application of 0.5 kg ai/ha (three applications of 0.12, 0.26, and 0.12 kg ai/ha) and a PHI of 28–30 days. Azoxystrobin residues, in ranked order, were (n = 6): 0.01, 0.03 (2), 0.05, 0.08, and 0.24 mg/kg.

The Meeting estimated a maximum residue level for sunflower seed of 0.5 mg/kg and an STMR value of 0.04 mg/kg.

Herbs

The Meeting received results from supervised trials with azoxystrobin used on basil, chives, mint, and parsley in the USA.

The GAP of the USA for herbs (including basil, chives, parsley) specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications) and a PHI of 0 days.

Three trials on basil were conducted according to the GAP of the USA for herbs with 5–6 applications. Azoxystrobin residues in fresh basil were: 23, 25, and 48 mg/kg. Four trials on chives

were conducted according to the US GAP. Azoxystrobin residues in fresh chives were 1.1, 2.7, 4.2, and 7.3 mg/kg. Two trials on parsley were conducted according to the US GAP with five or six applications. Azoxystrobin residues in fresh parsley were 17 and 20 mg/kg.

The GAP of the USA for mint specifies 0.28 kg ai/ha with maximal seasonal application of 1.7 kg ai/ha (six applications) and a PHI of 0 days for fresh mint and a PHI of seven days for mint intended for processing. Two trials in the USA were conducted on fresh mint according to the US GAP with a PHI of 0 days. Azoxystrobin residues in fresh mint were 21 and 25 mg/kg. Five trials were conducted on mint intended for processing according to the US GAP with a PHI of seven days (one trial with a PHI of six days). Azoxystrobin residues in the trials with a PHI of seven days were 4.8, 5.48, 8.0, and 12 mg/kg. Azoxystrobin residue from the trial with a PHI of six days was 17 mg/kg.

The Meeting noted that significantly higher residues were obtained in basil, parsley, and mint (with a critical PHI of 0 days) as compared to chives. Also, the residues in basil, mint, and parsley appear to be from a similar population, were obtained using the same US GAP rate and PHI, and could be used to support an "herbs, fresh" commodity maximum residue level. Azoxystrobin residues in fresh herbs, in ranked order, were (n = 7): 17, 20, 21, 23, 25 (2), and 48 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in herbs, (fresh) of 70 mg/kg and an STMR value of 23 mg/kg.

Legume animal feeds

Peanut fodder

The Meeting received results in peanut hay from supervised trials with azoxystrobin on peanuts in the USA.

The GAP of the USA for peanuts specifies an application rate of 0.45 kg ai/ha with a seasonal total of 0.9 kg ai/ha (two applications) and a PHI of 14 days. Eleven trials on peanuts in the USA were conducted according to the US GAP with a PHI of 13–14 days. Azoxystrobin residues, in ranked order, were (n = 11): 1.5, 3.0, 3.1, 3.3, 4.0, 4.3, 4.7, 8.3, 8.9, 9.3, and 13 mg/kg. On dry-weight basis (DM=85%), azoxystrobin residues in peanut hay, in ranked order, were (n = 11): 1.8, 3.5, 3.6, 3.9, 4.7, 5.1, 5.5, 9.8, 10, 11, and 15 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in peanut fodder of 30 mg/kg, an STMR value of 5.1 mg/kg and a highest residue value of 15 mg/kg.

Soya bean fodder and forage

The Meeting received results in soya bean forage and hay from supervised trials with azoxystrobin used on soya beans in the USA.

The GAP of the USA for soya bean forage and hay specifies 0.28 kg ai/ha, one application and a PHI of 0 days. Nineteen trials on soya beans forage were conducted according to the US GAP. A portion of forage was dried for hay.

Azoxystrobin residues in soya bean forage (n = 19), in ranked order, were: 4.6, 6.8, 7.1, 7.2, 7.4, 7.6, 7.7, 8.3, 8.5, 9.4, 9.5, 9.9, 10, 11, 12 (2), 18, 20, and 23 mg/kg.

Azoxystrobin residues in soya bean hay, in ranked order, were (n = 19): 6.8, 16 (2), 22 (2), 24, 27 (2), 28, 31, 33 (2), 34, 37, 38 (2), 43, 51 and 53 mg/kg. On dry-weight basis (DM=85%), azoxystrobin residues in soya bean hay were (n = 19): 8.0, 19 (2), 26 (2), 28, 32 (2), 33, 36, 39 (2), 40, 44, 45 (2), 51, 60, and 62 mg/kg.

The Meeting estimated an STMR value of 9.4 mg/kg and a highest residue value of 23 mg/kg for azoxystrobin in soya bean forage and a maximum residue level for azoxystrobin in soya bean

fodder (dry-weight basis) of 100 mg/kg, an STMR value of 36 mg/kg, and a highest residue value of 62 mg/kg.

Straw and fodder (dry) of cereal grains

The Meeting received results in cereal straw from supervised trials with azoxystrobin used on barley, oat, rye, triticale and wheat in Europe and rice in the USA. The Meeting also received results in maize fodder from supervised trials with azoxystrobin used on maize in the USA.

Barley straw

The Meeting received results in barley straw from supervised trials with azoxystrobin used on barley in France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland, and the UK.

The GAP of France for barley specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 42 days. The GAP of Spain for barley specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands for barley specify 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days. For barley straw, the Meeting decided to consider all trials on barley in continental Europe that were conducted at the GAP rate (± 30%) of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Seventeen trials in France were conducted at 72–100% GAP rate, with 2–3 applications and a PHI of 35–42 days (both the highest and lowest residues were obtained at a PHI of 42 days). Azoxystrobin residues, in ranked order, were: 0.53, 0.65, 0.67, 0.72, 0.82, 0.84, 0.91 (2), 1.2, 1.3 (3), 1.6 (2), 2.9, 3.6 and 3.7 mg/kg.

Two trials in Germany were conducted at the GAP rate, with three applications, and a PHI of 35 days, resulting in azoxystrobin residues of 2.2 and 2.9 mg/kg. One trial in Germany was carried out at 80% GAP rate, with two applications, and a PHI of 37 days. Azoxystrobin residue was 0.58 mg/kg.

Two trials in Italy were conducted at 100–104% GAP rate, with two applications, and a PHI of 36 days. Azoxystrobin residues were 2.3 (2) mg/kg.

One trial in Netherlands was conducted at the GAP rate, with two applications, and a PHI of 37 days. Azoxystrobin residue was 1.5 mg/kg.

One trial in Spain was conducted at the GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residue was 1.2 mg/kg. One trial in Spain was carried out at 104% GAP, with two applications, and a PHI of 38 days. Azoxystrobin residue was 5.5 mg/kg.

One trial in Sweden was carried out the GAP rate, with two applications, and a PHI of 42 days. Azoxystrobin residue was 5.3 mg/kg.

Two trials in Switzerland were conducted at 104% GAP rate, with two applications, and a PHI of 36 days. Azoxystrobin residues were 0.39 and 0.48 mg/kg. Four trials in Switzerland were carried out at 80% GAP, with two applications, and a PHI of 35 days. Azoxystrobin residues were 0.50, 0.61, 0.71, and 0.94 mg/kg.

The GAP of the UK for barley specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (growth stage 71). Three trials in the UK were conducted at the GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 38–54 days). Azoxystrobin residues in barley straw were 1.6, 3.4, and 4.5 mg/kg.

Combined azoxystrobin residues in barley straw from the trials in Europe (n = 35), in ranked order, were: 0.39, 0.48, 0.50, 0.53, 0.58, 0.61, 0.65, 0.67, 0.71, 0.72, 0.82, 0.84, 0.91 (2), 0.94, 1.2 (2), 1.3 (3), 1.5, 1.6 (3), 2.2, 2.3 (2), 2.9 (2), 3.4, 3.6, 3.7, 4.5, 5.3, and 5.5 mg/kg.

On dry-weight basis (DM=89%), azoxystrobin residues in barley straw were (n = 35): 0.44, 0.54, 0.56, 0.60, 0.65, 0.69, 0.73, 0.75, 0.80, 0.81, 0.92, 0.94, 1.0 (2), 1.1, 1.3 (2), 1.5 (3), 1.7, 1.8 (3), 2.5, 2.6 (2), 3.3 (2), 3.8, 4.0, 4.2, 5.1, 6.0, and 6.2 mg/kg.

Maize fodder

The Meeting received results in maize fodder from supervised trials with azoxystrobin used on maize in the USA.

The GAP of the USA for maize specifies 0.28 kg ai/ha with maximal seasonal application of 2.2 kg ai/ha (eight applications) and a PHI of seven days. Twenty trials in the USA were conducted on maize according to the US GAP with a PHI of 6–7 days. Azoxystrobin residues in maize fodder, in ranked order, were (n = 20), 0.88, 1.1, 2.5, 2.6 (2), 2.9, 3.1, 3.2, 3.5, 4.0, 4.4, 4.7, 5.2, 5.3, 7.8, 8.7 (2), 9.3, 16, and 21 mg/kg.

On dry-weight basis (DM=83%), azoxystrobin residues in maize fodder were (n = 20), 1.1, 1.3, 3.0, 3.1 (2), 3.5, 3.7, 3.9, 4.2, 4.8, 5.3, 5.7, 6.3, 6.4, 9.4, 10 (2), 11, 19, and 25 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in maize fodder (dry-weight basis) of 40 mg/kg, an STMR value of 5.0 mg/kg, and a highest residue value of 25 mg/kg.

Oat, rye and triticale straw

The Meeting received results in oat, rye, and triticale straw from supervised trials with azoxystrobin in Germany. The GAP of Germany for oat, rye, and triticale specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days.

Two trials on oat in Germany were conducted at the GAP rate, with three applications, and a PHI of 35 or 36 days. Azoxystrobin residues were 1.0 and 1.5 mg/kg. On dry-weight basis (DM=90%), azoxystrobin residues in oat straw were (n = 2), 1.1 and 1.6 mg/kg.

Two trials on rye in Germany were conducted at the GAP rate, with three applications, and a PHI of 35 days (higher residues were obtained at 42 and 44-day PHIs). Azoxystrobin residues were 2.0 and 2.7 mg/kg. On dry-weight basis (DM=88%), azoxystrobin residues in rye straw were (n = 2) 2.3 and 3.1 mg/kg.

Two trials on triticale in Germany were conducted at the GAP rate, with three applications, and a PHI of 36 days. Azoxystrobin residues were 1.4 and 1.5 mg/kg. On dry-weight basis (DM=90%), azoxystrobin residues in triticale straw were (n = 2), 1.6 and 1.7 mg/kg.

Rice straw

The Meeting received results in rice straw from supervised trials with azoxystrobin used on rice in the USA.

The GAP of the USA for rice specifies 0.34 kg ai/ha with maximal seasonal application of 0.78 kg ai/ha and a PHI of 28 days. Sixteen trials in the USA were conducted on rice according to the US GAP with a maximal seasonal application of 0.78 kg ai/ha (2×0.22 and 1×0.34 kg ai/ha) and a PHI of 26–28 days. Azoxystrobin residues in rice straw (n = 16), in ranked order, were: 0.59, 0.62, 0.78, 0.84, 0.91, 1.9, 2.6, 2.7, 3.2, 4.1, 4.2 (2), 5.0, 6.4, 6.9, and 10 mg/kg.

On dry-weight basis (DM=90%), azoxystrobin residues in rice straw were (n = 16): 0.66, 0.69, 0.87, 0.93, 1.0, 2.1, 2.9, 3.0, 3.6, 4.6, 4.7 (2), 5.6, 7.1, 7.7, and 11 mg/kg.

Wheat straw

The Meeting received results in wheat straw from supervised trials with azoxystrobin used on wheat in France, Germany, Italy, Spain, Switzerland, and the UK.

The GAP of France for wheat specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 42 days. The GAP of Spain for wheat specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands for barley specify 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days. The Meeting decided to consider all trials on wheat in continental Europe that were conducted at the GAP rate (± 30%) of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Thirteen trials on wheat in France were conducted at 80–104% GAP rate, with 2–3 applications and a PHI of 35–42 days. Azoxystrobin residues in wheat straw, in ranked order, were: 0.36, 0.73, 0.75, 0.81, 0.83, 1.7, 1.8, 2.3, 2.4, 2.5, 3.2, 3.5, and 6.2 mg/kg.

Four trials in Germany were conducted at 80–100% GAP rate, with 2–3 applications, and a PHI of 35–42 days (both the highest and lowest residues were obtained at a PHI of 35 days). Azoxystrobin residues, in ranked order, were: 0.36, 0.50, 1.2, and 1.7 mg/kg.

Two trials in Italy were conducted at 100–104% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were 1.6 and 3.8 mg/kg.

Three trials in Spain were conducted at the GAP rate, with two applications, and a PHI of 35 and 41 days (the 41-day PHI gave the highest residue). Azoxystrobin residues, in ranked order, were: 1.2, 1.9, and 3.5 mg/kg.

Five trials in Switzerland were conducted at 80–108% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were: 0.22, 0.41 (2), 0.46, and 0.58 mg/kg.

The GAP of the UK for wheat specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (BBCH growth stage 71). Three trials in the UK were conducted at the GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 40–59 days). Azoxystrobin residues in wheat straw were 1.6, 2.3, and 5.7 mg/kg.

Combined azoxystrobin residues in wheat straw from the trials in Europe (n = 30), in ranked order, were: 0.22, 0.36 (2), 0.41 (2), 0.46, 0.50, 0.58, 0.73, 0.75, 0.81, 0.83, 1.2 (2), 1.6 (2), 1.7 (2), 1.8, 1.9, 2.3 (2), 2.4, 2.5, 3.2, 3.5 (2), 3.8, 5.7, and 6.2 mg/kg.

On dry-weight basis (DM=88%), azoxystrobin residues in wheat straw were (n = 30): 0.25, 0.41 (2), 0.47 (2), 0.52, 0.57, 0.66, 0.83, 0.85, 0.92, 0.94, 1.4 (2), 1.8 (2), 1.9 (2), 2.0, 2.2, 2.6 (2), 2.7, 2.8, 3.6, 4.0 (2), 4.3, 6.5, and 7.0 mg/kg.

The Meeting agreed that the data on barley, oat, rice, rye, triticale, and wheat straw appear to be from a similar population and could be combined to estimate a "Straw and fodder (dry) of cereal grains, except maize" commodity group maximum residue level. On dry-weight basis, azoxystrobin residues, in ranked order median underlined, were (n = 87): 0.25, 0.41 (2), 0.44, 0.47 (2), 0.52, 0.54, 0.56, 0.57, 0.60, 0.65, 0.66 (2), 0.69 (2), 0.73, 0.75, 0.80, 0.81, 0.83, 0.85, 0.87, 0.92 (2), 0.93, 0.94 (2), 1.0 (3), 1.1 (2), 1.3 (2), 1.4 (2), 1.5 (3), 1.6, <u>1.7</u> (3), 1.8 (5), 1.9 (2), 2.0, 2.1, 2.2, 2.3, 2.5, 2.6 (4), 2.7, 2.8, 2.9, 3.0, 3.1, 3.3 (2), 3.6 (2), 3.8, 4.0 (3), 4.2, 4.3, 4.6, 4.7 (2), 5.1, 5.6, 6.0 6.2, 6.5, 7.0, 7.1, 7.7, and 11 mg/kg.

On dry-weight basis, the Meeting estimated a maximum residue level for straw and fodder (dry) of cereal grains, except maize of 15 mg/kg, an STMR value of 1.7 mg/kg, and a highest residue value of 11 mg/kg.

Forage of cereal grains

The Meeting received results in cereal forages from supervised trials with azoxystrobin used on barley, oat, rye, triticale and wheat in Europe and on maize in the USA.

Barley, oat, rye, triticale and wheat forage

The Meeting received results in barley and wheat forage from supervised trials with azoxystrobin applied to barley and wheat in France, Germany, Italy, the Netherlands (barley only), Spain, Switzerland, and the UK. The Meeting also received results in oat, rye, and triticale forage from supervised trials in Germany.

The GAPs in Europe do not specify a PHI for cereal forage. In the case of livestock grazing, it is assumed that animals are unlikely to be foraging within seven days of the application of the fungicide. Therefore, the Meeting decided to consider all trials conducted at ± 30% of the GAP rate available in Europe (0.25 kg ai/ha), with 2–3 applications and with forage data obtained at a PHI of seven days.

Azoxystrobin residues in barley forage (n = 10), in ranked order, were: 0.54, 0.73, 0.75, 1.1, 1.6, 1.8, 1.9, 3.8, 3.9, and 4.0 mg/kg.

Azoxystrobin residues in wheat forage (n = 10), in ranked order, were: 0.61, 1.4, 1.6 (2), 1.8, 1.9, 2.9, 3.2, 4.0, and 5.4 mg/kg.

For oat, rye, and triticale, the Meeting received residue data in forage for days 0 and 20–23 from seven trials.

The Meeting decided to use the data on barley forage to extrapolate to oat forage and data on wheat forage to extrapolate to rye and triticale forage. The Meeting estimated an STMR value of 1.7 mg/kg and a highest value of 4.0 mg/kg for azoxystrobin in barley and oat forage. The Meeting estimated an STMR value of 1.9 mg/kg and a highest residue value of 5.4 mg/kg for azoxystrobin in wheat, rye and triticale forage.

Maize forage

The Meeting received results in maize forage from supervised trials of azoxystrobin applied to maize in the USA.

In the 20 maize trials, harvested for grain and fodder, in the USA (conducted according to the US GAP of 0.28 kg ai/ha with a seasonal total rate of 2.2 kg ai/ha), forage was harvested at the milk stage, 6–7 days after the sixth application (out of eight applications for fodder and grain) of azoxystrobin. Azoxystrobin residues in maize forage (n = 20), in ranked order, were: 0.49, 0.58, 0.65, 0.83, 0.94, 1.0, 1.1, 1.2 (2), 1.5, 1.7, 2.4, 2.7, 2.8 (3), 2.9, 3.6, 3.8, and 7.2 mg/kg.

The Meeting estimated an STMR value of 1.6 mg/kg and a highest residue value of 7.2 mg/kg for azoxystrobin in maize forage.

Sugar beet leaves and tops

The Meeting received results in sugar beet tops from supervised trials with azoxystrobin in the USA. The GAP of the USA for root vegetables (both for leaves and root) specifies a rate of 0.37 kg ai/ha with a seasonal total of 2.2 kg ai/ha (six applications) and a PHI of 0 days.

Nine trials on sugar beet were conducted in the USA according to the US GAP for root vegetables. Azoxystrobin residues in sugar beet tops, in ranked order, were: 5.8, 8.7, 9.5, 11, 16 (2), 22, 25, and 44 mg/kg.

The Meeting estimated an STMR value of 16 mg/kg and a highest residue value of 44 mg/kg for azoxystrobin in sugar beet tops.

Dried herbs

The Meeting received results in dried herbs from supervised trials with azoxystrobin used on basil, chives, and parsley in the USA and on hops in Germany and the UK.

Basil, chives and parsley, dry

The GAP of the USA for herbs (including basil, chives, parsley) specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications) and a PHI of 0 days.

Two trials on basil were conducted in the USA according to the US GAP. Azoxystrobin residues in dried basil were 139 and 235 mg/kg.

Three trials on chives were conducted in the USA according to the US GAP. Azoxystrobin residues in dried chives were 27, 31, and 45 mg/kg.

Two trials on parsley were conducted in the USA according to the US GAP with five or six applications. Azoxystrobin residues in dried parsley were 135 and 165 mg/kg.

The Meeting decided to use the results on dried basil and parsley for the estimation of a maximum residue level for dried herbs, except dry hops. Azoxystrobin residues were (n = 4), 135, 139, 165, and 235 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in dried herbs, except dry hops of 300 mg/kg and an STMR value of 152 mg/kg.

Hops, dry

The GAP of Germany for hops specifies a rate of 0.19 kg ai/ha up to BBCH 37, 0.25 kg ai/ha up to BBCH 55, and 0.4 kg ai/ha above BBCH 55, with a total seasonal rate of 0.8 kg ai/ha and a PHI of 28 days.

Four trials on hops in the UK were carried out using six applications of 0.4 kg ai/ha and a PHI of 28 days or two applications at 0.20 kg ai/ha, followed by two applications at 0.30 kg ai/ha and two applications at 0.40 kg ai/ha, with a PHI of 27–28 days. Azoxystrobin residues were (n = 4) 0.83, 1.1, 1.3, and 2.2 mg/kg.

Four trials on hops in Germany were carried out using two applications at 0.23–0.25 kg ai/ha, followed by two applications at 0.30–0.36 kg ai/ha and two applications at 0.40–0.46 kg ai/ha, with a PHI of 26–28 days. Azoxystrobin residues were (n = 4): 5.7, 11 (2), and 12 mg/kg.

Based on the data from the German trials, the Meeting estimated a maximum residue level for azoxystrobin in hops, dry of 30 mg/kg and an STMR value of 11 mg/kg.

Almond hulls

The Meeting received results in almond hulls from supervised trials with azoxystrobin on almonds in the USA.

The GAP of the USA for almonds specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications) and a PHI of 28 days. Five trials in the USA were conducted on almonds according to the US GAP. Almonds were harvested slightly immature (PHI of 28–29 days) and mature (PHI of 43–44 days). In each trial, azoxystrobin residues in hulls of the mature almonds were higher than those in slightly immature almonds (a PHI specified in the US GAP). Azoxystrobin residues in hulls of mature almonds, in ranked order, were (n = 5): 0.69, 1.5, 1.9, 2.1, and 3.0 mg/kg.

On dry-weight basis (DM=90%), azoxystrobin residues in almond hulls, in ranked order, were (n = 5): 0.77, 1.7, 2.1, 2.3, and 3.3 mg/kg.

On dry-weigh basis, the Meeting estimated a maximum residue level for azoxystrobin almond hulls of 7 mg/kg and an STMR value of 2.1 mg/kg.

Fate of residues during processing

The Meeting received information on the fate of azoxystrobin residues during processing of oranges, grapes, plums, tomato, barley, corn, rice, wheat, soya beans, sunflower, and peanuts and on azoxystrobin fate under hydrolysis conditions simulating commercial food processing.

In a high-temperature hydrolysis study, 97–101% of radiolabelled azoxystrobin remained under conditions simulating industrial processing (temperatures ranging from 90–120 °C; pH 4–6). Therefore, azoxystrobin can be considered stable to simulated pasteurization, baking, brewing, boiling and sterilization.

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

Raw agricultural commodity			Processed commodity			
Name	STMR (mg/kg)		CCN	Name	Processing factor [a]	STMR-P (mg/kg)
Orange [b]	4.9		JF 0004	Orange juice	< 0.08	0.39
				Orange oil, cold-pressed	4.8	24
			AB 0001	Citrus pulp, dry	1.9	9.3
Grapes	0.53			Distillate	< 0.04	0.02
			DF 0269	Dried grapes (raisins)	0.45	0.24
			JF 0269	Grape juice	0.36	0.19
				Grape must	0.52	0.28
			AB 0269	Grape pomace, dry	5.0	2.7
				Grape pomace, wet	3.1	1.6
				Pasteurized wine	0.54	0.29
				Spirit	< 0.04	0.02
				Wine	0.67	0.36
Plum [c]	0.74		DF 0014	Prunes	0.19	0.14
Tomato [d]	0.44			Tomato conserve	< 0.12	0.05
			JF 0448	Tomato juice	0.36	0.16
				Tomato ketchup	0.47	0.21
			VW 0448	Tomato paste	2.6	1.1
				Tomato pomace, dry	24	11
				Tomato pomace, wet	9.2	4.0
				Tomato puree	0.8	0.35
Barley	0.08			Barley malt	0.10	0.01
				Barley roots	0.45	0.04
				Barley spent grain	0.15	0.01
				Beer	0.03	0.002
Maize	0.01		CF 1255	Maize flour	0.73	0.01
				Maize grits	0.27	0.003
			CF 0645	Maize meal	0.55	0.01
			OR 0645	Maize oil, refined (dry milling)	0.64	0.01
			OR 0645	Maize oil, refined (wet milling)	6.1	0.06

Raw agricultural commodity			Processed commodity			
Name	STMR (mg/kg)		CCN	Name	Processing factor [a]	STMR-P (mg/kg)
				Maize starch	< 0.09	0.001
Rice	0.68		CF 0649	Rice bran, processed	1.2	0.82
			CM 1205	Rice grain, polished	0.09	0.06
			CM 1207	Rice hulls	4.8	3.3
Wheat	0.01		CF 0654	Wheat bran	0.38	0.004
			CP 1211	Wheat bread, white	0.13	0.001
			CP 1212	Wheat bread, wholemeal	< 0.13	0.001
			CF 1210	Wheat flour, low grade	0.25	0.003
			CF 1210	Wheat flour, patent	0.25	0.003
			CF 1212	Wheat flour, wholemeal	0.25	0.003
				Wheat shorts	0.13	0.001
Soya beans	0.06		AB 0541	Soya bean hulls	2.2	0.13
			AB 1265	Soya bean meal	0.09	0.01
			OR 0541	Soya bean oil, refined	0.77	0.05
Sunflower	0.04			Sunflower meal	< 0.08	0.003
			OR 0702	Sunflower oil, refined	0.15	0.01
Peanuts	0.01			Peanut meal	1.0	0.01
			OC 0697	Peanut oil, crude	4.0	0.04
			OR 0697	Peanut oil, refined	3.0	0.03

[a] Processing factors were mostly obtained in a single study on each crop, except for grapes (4 studies, but a single study for raisins) and tomato (3 studies), in which case a median processing factor was calculated.

[b] STMR and HR values for citrus fruit commodity group.

[c] STMR and HR values for stone fruit commodity group.

[d] STMR and HR values for fruiting vegetables, other that cucurbits, except fungi and sweet corn commodity group.

Based on the STRM-P value of 0.06 mg/kg, the Meeting estimated a maximum residue level of 0.1 mg/kg for azoxystrobin in maize oil, refined.

Farm animal dietary burden

The Meeting estimated the dietary burden of azoxystrobin in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from the 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.

The table below shows estimated maximum and mean dietary burdens for beef cattle, dairy cattle, broilers, and laying poultry based on the animal diets from the United States/Canada, the European Union, and Australia. The calculations are provided in Annex 6.

		Azoxystrobin, Animal dietary burden (ppm of dry matter diet)		
		US-Canada	EU	Australia
Beef cattle	Maximum	34	55	58
	Mean	15	19	32 [a]
Dairy cattle	Maximum	33	72 [b]	39
	Mean	16	27 [c]	20
Poultry - broiler	Maximum	0.44	0.62	0.59
	Mean	0.44	0.40	0.59
Poultry - layer	Maximum	0.44	23 [d]	0.59
	Mean	0.44	9.1[e]	0.59

[a] Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian meat.

[b] Highest maximum cattle dietary burden suitable for MRL estimates for milk and 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 information on lactating dairy cow and laying hen feeding studies.

Fifteen lactating cows were randomly assigned among five dosing groups of three animals each: one control group and four groups dosed at one of three azoxystrobin feeding levels each (5, 25, 75 and 250 ppm based on measured feed intake). All groups were fed for 30 consecutive days. Milk samples were taken twice a day and the daily production bulked into one single sample per cow. Samples of milk collected on days 21–23 were processed into cream and skimmed milk. Average fat contents in the whole milk and cream were 3.7% and 55%, respectively.

Azoxystrobin residues in whole milk, skimmed milk, milk cream and tissues obtained at the 5, 25, 75 and 250 ppm dosing levels in the diet are summarized in the table below.

Matrix	Dose (ppm)	Highest residue, mg/kg	Mean residue, mg/kg
Whole milk	5	0.003	0.002
	25	0.006	0.002
	75	0.004	0.002
	250	0.009	0.004
Skimmed milk	5	< 0.001	< 0.001
	25	< 0.001	< 0.001
	75	0.001	0.001
	250	0.003	0.002
Milk cream	5	< 0.01	< 0.01
	25	< 0.01	< 0.01
	75	0.02	0.01
	250	0.04	0.03
Muscle	5	< 0.01	< 0.01
	25	< 0.01	< 0.01
	75	< 0.01	< 0.01
	250	< 0.01	< 0.01
Liver	5	< 0.01	< 0.01
	25	0.01	0.01
	75	0.05	0.03
	250	0.07	0.05
Kidney	5	< 0.01	< 0.01
	25	< 0.01	< 0.01

Matrix	Dose (ppm)	Highest residue, mg/kg	Mean residue, mg/kg
	75	0.01	0.01
	250	0.02	0.02
Fat[a]	5	< 0.01	< 0.01
	25	< 0.01	< 0.01
	75	0.03	0.02
	250	0.03	0.02

[a] Residues in peritoneal fat, which were higher than residues obtained in subcutaneous fat.

The azoxystrobin residues in muscle were lower than in fat. Also, azoxystrobin accumulated in the cream when whole milk was processed to skimmed milk and cream.

In a hen feeding study, forty eight laying hens were divided into four groups and each group was divided into three pens holding four birds each. Each group was fed for 28 consecutive days with a nominal dose rate of 0, 6, 18, or 60 ppm of azoxystrobin in the diet. Eggs were collected twice daily and the total daily production for each group bulked. On day 21, the eggs were separated into egg yolk and egg white.

At the 60 ppm dosing level in the diet, azoxystrobin residues in eggs (whole egg, egg white, egg yolk) and tissues (muscle, liver, and fat) were < 0.01 mg/kg in all analysed samples. No analyses were carried out on the samples from the lower dose rate groups.

Animal commodity maximum residue levels

The dietary burdens for the estimation of maximum residue levels for azoxystrobin in animal commodities are 72 ppm for cattle and 22 ppm for poultry. The dietary burdens for the estimation of STMR values for animal commodities are 32 ppm for beef cattle, 27 ppm for dairy cattle and 9.1 ppm for poultry.

In the table below, dietary burdens for cattle are shown in round brackets (), feeding levels and resulting residue concentrations in square brackets [], and estimated azoxystrobin concentration related to the dietary burdens are shown without brackets.

Dietary burden (ppm) Feeding level [mg/kg]	Milk	Cream	Muscle	Liver	Kidney	Fat
MRL Cattle	Mean	Mean	Highest	Highest	Highest	Highest
(72) [25, 75]	0.002 [0.002, 0.002]	0.01 [< 0.01, 0.01]	< 0.01 [< 0.01,< 0.01]	0.048 [0.01, 0.05]	0.01 [< 0.01, 0.01]	0.029 [< 0.01, 0.03]
STMR Beef Cattle			Mean	Mean	Mean	Mean
(32) [25, 75]			< 0.01 [< 0.01, < 0.01]	0.013 [0.01, 0.03]	0.01 [< 0.01, 0.01]	0.01 [< 0.01, 0.02]
STMR Dairy Cattle	Mean	Mean				
(27) [25, 75]	0.002 [0.002, 0.002]	0.01 [< 0.01, 0.01]				

Maximum dietary burden of 72 ppm for cattle is very close to the 75 ppm dosing level in the cattle feeding study. The residues in muscle were significantly lower (all < 0.01 mg/kg even at the dosing level of 250 ppm) than in fat. Based on the highest residues at the dosing levels of 25 and 75

ppm, the interpolated (estimated) highest residues for the dietary burden of 72 ppm were 0.048 mg/kg in liver, 0.01 mg/kg in kidney, and 0.029 mg/kg in fat.

Based on the mean residues for the dosing levels of 25 and 75 ppm, the interpolated (estimated) mean residues for the beef cattle dietary burden of 32 ppm were 0.013 mg/kg in liver, < 0.01 mg/kg in kidney, and 0.01 mg/kg in fat.

On the fat basis, the Meeting estimated a maximum residue level of 0.05 mg/kg for meat (fat) from mammals (other than marine mammals) and an STMR value of 0.01 mg/kg. Based on the liver results, the Meeting estimated a maximum residue level of 0.07 mg/kg for mammalian edible offal and an STMR value of 0.01 mg/kg.

Based on the mean residues for the dosing levels of 25 and 75 ppm, the interpolated (estimated) mean residues for the dairy cattle dietary burdens of 72 ppm and 27 ppm were in both cases 0.002 mg/kg in milk and 0.01 mg/kg in cream. Based on the average fat content in the cream (55 in the feeding study), the calculated mean residue in milk fats would be 0.018 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in whole milk of 0.01 mg/kg and an STMR value of 0.01 mg/kg. The Meeting estimated a maximum residue level for azoxystrobin in milk fats of 0.03 mg/kg and an STMR value of 0.03 mg/kg.

For poultry, the maximum dietary burden of 22 ppm is lower that the dose level of 60 ppm in the hen feeding study, which resulted in azoxystrobin residues < 0.01 mg/kg in eggs and tissues. The Meeting estimated maximum residue levels of 0.01 (*) mg/kg and STMR value of 0 mg/kg for poultry meat (fat), poultry edible offal, and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of azoxystrobin based on STMR and STMR-P values estimated for 82 commodities or commodity groups for the thirteen GEMS/Food regional diets were 2–10% of the maximum ADI (0.2 mg/kg bw). The results are shown in Annex 3 of the Report. The Meeting concluded that the long-term dietary intake of azoxystrobin residues 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 dietary intake of azoxystrobin is unlikely to present a public health concern.

5.2 BIFENAZATE (219)

RESIDUE AND ANALYTICAL ASPECTS

Bifenazate was evaluated by JMPR as a new compound in 2006. Trials on citrus fruits, eggplant, and tea had been provided for evaluation by the 2006 JMPR in summary form only and therefore could not be evaluated. Translations of the original Japanese reports on these commodities and the Japanese label have been submitted to the 2008 JMPR for evaluation.

Methods of analysis

The analytical methods used in the supervised trials in Japan either determined bifenazate and bifenazate-diazene together or separately. In the first case, the samples were extracted with acetonitrile/hydrochloric acid solution and the converting bifenazate-diazene metabolite was converted to bifenazate by 1% ascorbic acid. The concentrated extract was sequentially cleaned on three columns and detected with HPLC fluorescence. In the second case the residue components were separated with column chromatography. Bifenazate or bifenazate-diazene residues were determined by HPLC with fluorescence detection. The concentration of bifenazate-diazene was calculated as parent compound equivalent based on molecular mass ratios. The recoveries at the spiking levels of 0.5 mg/kg for citrus pulp, 1 mg/kg for citrus peel, 0.5 mg/kg for eggplant, and 2.5 mg/kg for tea were within the acceptable range (70–110%). The reported LOQs were 0.01 mg/kg for citrus pulp and eggplant, 0.02 mg/kg for citrus peel and 0.05 mg/kg for tea leaves. Data were not provided for validation of the reported LOQs.

Results of supervised residue trials on crops

The translations of supervised trials conducted in Japan on citrus fruits (mandarins, natsudaidai and limes), eggplant and tea were submitted to the Meeting.

Citrus fruits

A total of six supervised trials on citrus fruits, two on mandarins, two on natsudaidai (shaddock or pomelo subgroup) and two on limes were conducted with a 200 SC formulation of bifenazate in different experimental stations in Japan during 1997, according to the Japanese GAP (0.02 kg ai/hL, 7-day PHI). Samples were taken at 7, 14, 30 and 45 days after a single treatment to each plot. Duplicate samples were analysed for the combined residues of bifenazate and bifenazate-diazene, and also for the individual residue components. The results obtained with the two methods were found to be comparable.

The largest residue value, expressed on a whole fruit basis from each site, were 0.46 and 0.69 mg/kg for mandarin, 0.23 and 0.31 mg/kg for natsudaidai, and 0.26 and 0.3 mg/kg for lime.

The corresponding residues in the pulp of mandarins and natsudaidai were 0.01, 0.02, 0.02, and 0.01 mg/kg. In lime pulp residues were not measured.

The trial results demonstrate that the residues are primarily concentrated in the peel of citrus fruits. For mandarins and natsudaidai the median of ratios of residues in whole fruit and pulp and whole fruit and peel were 0.0315 and 3.655, respectively.

The Meeting noted that the residues on different citrus commodities were similar regardless of the size of the fruits. However, six trials in total were considered insufficient to estimate maximum residue levels and STMR values for the citrus group.

Eggplant

Supervised trials on eggplant were conducted at two experimental stations in Japan in 1997 and in 2000 complying with Japanese GAP (one application at 0.02 kg ai/hL and a 1-day PHI). The highest residues from duplicate analyses obtained by the two laboratories were 0.53 and 0.55 mg/kg. The 2006 JMPR evaluated residues in tomatoes, bell and non-bell peppers, but was not able to estimate a group MRL due to marked differences in residue levels for the different commodities. The present Meeting concluded that two additional residue trials on eggplants were insufficient to estimate maximum residue level or STMR values alone or for recommending a group MRL.

Tea, dry

Supervised trials on tea were conducted during 1998 at two experimental stations in Japan, following the Japanese GAP (one application with 0.02 kg ai/hl and 14-day PHI). The residues declined rapidly. The largest residue values in dried tea leaves reported from the two sites at day 14 were 0.47 and 0.82 mg/kg.

The Meeting concluded that data from two trials was insufficient for the estimation of maximum residue level and STMR values.

Fate of residues during processing

A study on brewing tea from dried treated tea was provided for evaluation.

Tea was prepared by mixing 6 g dried leaves with 360 mL of 100 °C water for 5 minutes. The tea extract did not contain detectable residues above 0.05 mg/L.

The median transfer factor calculated from the individual residue data is 0.216 mg/kg.

5.3 BOSCALID (221)

RESIDUE AND ANALYTICAL ASPECTS

Boscalid was first evaluated by the 2006 JMPR which established an ADI of 0-0.04 mg/kg bw and proposed maximum residue levels for a number of commodities.

Results of additional supervised trials on banana, kiwi and hops were evaluated by the present Meeting.

Results of supervised residue trials on crops

New registrations have been obtained for banana, kiwi and hops. Trials conducted complying with the registered uses were evaluated and the relevant residues considered for the estimation of maximum residue level and STMR values.

Banana

The 2006 JMPR evaluated and reported the results of 12 trials on banana, were performed in accordance with the recently registered uses in Colombia and Ecuador (0.15 kg as/ha, 0 day PHI). The banana whole fruit samples which were bagged and all pulp samples both bagged and unbagged did not contain any boscalid residue above the limit of quantification of 0.05 mg/kg.

In the 2006/07 growing season, a bridging study with six trials was conducted, according to the GAP in Costa Rica and Colombia, comparing a WG formulation (BAS 510 01 F) with a SC formulation (BAS 510 05 F). Immediately after and one following the last application, fruit from both bagged and unbagged treatments were sampled. Banana whole fruit, pulp and peel samples were then analysed.

The results show that of all bagged samples only two whole fruit samples contained detectable boscalid residues at 0.06 and 0.07 mg/kg. These values were selected for the estimation of a maximum residue level as they were higher than the residues in unbagged bananas. The residue in/on peel confirmed there was no difference between residues derived from the WG and SC formulations.

As the magnitude of residues was similar on day 0 and day 1, regardless of which formulation was used (the WG or SC), the highest residue was selected from each trial carried out at one site. The residues found in rank order were: < 0.05, < 0.05, 0.05, 0.06, 0.07, 0.08, 0.08, 0.09, 0.12, 0.18, 0.19 and 0.42 mg/kg.

The residues from the trials in 2004 were: < 0.05 (4), 0.05, 0.07, 0.07, 0.09, 0.10, 0.10, 0.11, and 0.18 mg/kg.

The two data sets are not statistically different and can be combined for the estimation of a maximum residue level. The combined data (24) in rank order were: < 0.05 (6), 0.05 (2), 0.06, 0.07 (3), 0.08 (2), 0.09 (2), 0.10 (2), 0.11, 0.12, 0.18 (2), 0.19 and 0.42 mg/kg.

Banana pulp contained residues below the LOQ of 0.05 mg/kg in all but one of 18 trials, where the residue was found to be 0.08 mg/kg.

Based on the residue data available, the Meeting confirmed its previous recommendation for an STMR value of 0.05 mg/kg for banana pulp, withdrew its previous recommendation for a maximum residue level of 0.2 mg/kg and proposed a value of 0.6 mg/kg for bagged and unbagged bananas.

Kiwi fruits

In kiwifruit, boscalid is used as a post-harvest treatment applied as a dip treatment at a rate of 0.0375 kg ai/hL. Four Italian trials were conducted according to GAP.

Kiwi fruits were sampled directly after the application and again at about 60 days thereafter. Kiwi whole fruit, as well as peel and pulp were analysed. The average of the procedural recoveries for boscalid was between 101 and 106%.

The residues in whole fruits 59–60 days after the post-harvest treatment were 0.80, 1.16, 1.32, and 2.38 mg/kg.

The pulp contained residues of 0.055, 0.063, 0.083 and 0.142 mg/kg.

The Meeting took into account that post harvest treatment normally produces more uniform residue distributions than foliar applications, and estimated a maximum residue level of 5 mg/kg and an STMR of 0.073 mg/kg for kiwi fruits.

Hops

Boscalid is approved for use on hops in the USA (US GAP: maximum of 3 applications per season at 0.5 kg/ha with a total maximum seasonal application rate of 1482 g ai/ha and a PHI of 14 days).

Three trials were conducted in the USA according to the registered use pattern. The cones were dried and analysed with a method providing 98% recovery and an LOQ of 0.05 mg/kg.

In addition eight trials were carried out in Germany corresponding to the target rate specified in a pending registration (three foliar applications of maximum 504 g ai/ha each with a maximum seasonal application rate of 1512 g ai/ha and a PHI of 21 days). These results were reported by the 2006 JMPR. As the product is not registered in Germany or other countries with comparable growing practice, those results could not be used for estimation of maximum residue levels.

The US trials were conducted with application volumes of 750 and 1420 L/ha. The treatments with the lower spray volume resulted in higher residues, and therefore were considered. The residues determined at 14 day PHI in the two trials were: 29.4 and 31.1 mg/kg.

The Meeting concluded that two trials were insufficient for the estimation of a maximum residue level.

DIETARY RISK ASSESSMENT

Long-term intake

The 2006 JMPR could not recommend STMR values for a large number of follow crops in which residue may be present above the LOQ, the Meeting decided that the estimation of the long-term intake would not be realistic.

Therefore no long-term intake calculations could be carried out by this Meeting.

5.4 BUPROFEZIN (173)

TOXICOLOGY

Buprofezin is the ISO approved name for (*EZ*)-2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one (IUPAC), CAS No. 69327-76-0. Buprofezin is an insecticide that acts by the inhibition of chitin synthesis.

Buprofezin was previously evaluated by the JMPR in 1991 when an ADI of 0–0.01 mg/kg bw per day was established based on a NOAEL of 0.9 mg/kg bw per day identified in a 2-year study in rats and with a safety factor of 100. The JMPR in 1999 considered that the establishment of an ARfD was unnecessary. Buprofezin was re-evaluated by the present Meeting as part of the CCPR periodic re-evaluation programme. New studies not previously evaluated by the Meeting included several studies of acute oral toxicity, irritation, sensitization and genotoxicity, metabolism studies in rats and a two-generation study in rats.

The more recent studies complied with GLP, but many of the older reported studies were performed before the widespread use of GLP.

Biochemical aspects

Studies with [phenyl-^{14}C]buprofezin showed that the radiolabel was absorbed with a C_{max} at 9 h and was rapidly excreted (> 60% in 24 h and > 80% in 48 h) in male and female rats given doses of 10 and 100 mg/kg bw. In males and females, urinary (22–25%) and faecal (70–74%) cumulative excretion at 10 and 100 mg/kg bw was similar after 4 days. In a study in bile-duct cannulated rats, oral absorption after 24 h was low (40–45%) in both sexes; of the administered dose, 30–38% was found in bile, 3–6% in the urine and about 5% in the liver and carcass (not including the gastrointestinal tract). The difference in urinary excretion between bile-duct cannulated and non-cannulated rats suggests that buprofezin excreted in the bile undergoes gastrointestinal re-circulation. The radiolabel was distributed within 2 h to the organs and tissues and after 7 days the highest concentrations were found in erythrocytes, the thyroid and the liver. The total amount of radiolabel recovered in the body accounted for less than 0.7% of the administered dose.

In a 24-week feeding study, no evidence for accumulation was observed. The metabolism of buprofezin was studied in rat liver homogenates and in vivo. Hydroxylation and subsequent methylation of the phenyl ring, oxidation of sulfur with subsequent ring-opening of the thiadiazinane ring and conjugation reactions with sulfate and glucuronic acid were the main metabolic routes. Buprofezin, 4-hydroxybuprofezin (BF2), tert-butylhydroxy-buprofezin (BF4), dione metabolite (BF9), buprofezin sulfoxide (BF10), phenylbiuret (BF11), isopropylphenylurea (BF12), 4-hydroxyisopropylphenylurea (BF13), dimethoxy buprofezin (BF20), 4-aminophenol (BF22), 4-hydroxyacetanilide (BF23), thiobiuret (BF25), hydroxy-methoxy-buprofezin (BF27), 2-[3-isopropyl-3-[methylsulfonylmethyl, (phenyl)carbamoyl]ureido]-2-methylpropionic acid (BF28) and dihydroxy buprofezin (C) were identified in the metabolism study in rats.

The results suggested that there are no significant differences between males and females in toxicokinetic parameters and metabolic profiles over a dose range of 10 to 100 mg/kg bw.

Toxicological data

Buprofezin was of low to moderate toxicity when administered orally, with an LD_{50} of 1635–3847 mg/kg bw in rats, LD_{50} > 5000 mg/kg bw in rabbits and LD_{50} > 10 000 mg/kg bw in mice and hamsters. By the dermal, subcutaneous and intraperitoneal routes, the LD_{50}s were > 10 000 mg/kg bw in mice and rats, and the inhalation LC_{50} was > 4.57 mg/L. In rabbits, buprofezin was not irritating to the skin and only very slightly irritating to the eye. In a Magnussen & Kligman maximization test in

guinea-pigs, buprofezin gave equivocal results suggesting a very slight potential for delayed contact hypersensitivity, while the results of a local lymph-node assay with buprofezin in mice were negative.

In short-term studies in rats and dogs, the main effects were liver-weight increases accompanied by histological changes; in dogs, behaviour was also affected.

In a 13-week feeding study in rats, the feed intake in males at 200 ppm and above and in females at 5000 ppm was low after 1 or 2 weeks, resulting in lower body weights in the groups at 5000 ppm at study termination. At 200 ppm and above, slight changes in clinical chemistry parameters, including decreased glucose and triglyceride concentrations and increased cholesterol, phospholipid, urea nitrogen and albumin and globulin concentrations were observed. In males and females at 5000 ppm, liver and thyroid weights were increased and spleen weights were decreased. The increases in liver weight were accompanied by hypertrophic and necrotic changes and, in the thyroid, by hypertrophic and hyperplastic changes. The NOAEL was 40 ppm, equal to 3.4 mg/kg bw per day, on the basis of changes in clinical chemistry parameters in rats at 200 ppm.

In a 13-week study in dogs fed capsules containing buprofezin, transiently subdued behaviour was observed 1 h after dosing at 50 mg/kg bw per day and above. This observation was predominantly made in the first few days of treatment, but also at other time-points throughout the study, although with a lower incidence. At 300 mg/kg bw per day, slight ataxia was shown by virtually all dogs 1 h after dosing and persisting for about 5 h. This effect was seen in females only in the first few days of the study, but persisted for 9 weeks in one male. Male and female dogs at the highest dose had significantly lowered body-weight gains, increased liver, kidney and thyroid weights and two- to three-fold increases in the activity of alkaline phosphatase (ALP). Increased liver weights were also seen in both sexes at 50 mg/kg bw per day. The NOAEL was 10 mg/kg bw per day.

In a 2-year study in dogs given capsules containing buprofezin, which was performed before the 13-week study, no behavioural effects were reported at up to the highest dose of 200 mg/kg bw per day. Increased liver weights were seen in all females receiving buprofezin and in males at 200 mg/kg bw per day. Thyroid weights were high in males and females at 200 mg/kg bw per day. At 20 mg/kg bw per day and above, ALP activity was significantly increased from week 4 onwards and higher incidences of hepatocellular hypertrophy, bile-duct and mammary hyperplasia were found. The NOAEL was 2 mg/kg bw per day.

Since it was not clear whether the observation scheme used in the 2-year study could have detected putative behavioural changes 1 h after treatment, an overall NOAEL for behavioural changes could not be identified. The overall NOAEL for systemic toxicity in the 13-week and the 2-year studies in dogs was 10 mg/kg bw per day on the basis of hepatocellular hypertrophy and bile-duct and mammary hyperplasia at 20 mg/kg bw per day in the 2-year study in dogs.

The long-term toxicity and carcinogenicity of buprofezin has been investigated in mice and rats. The liver was identified as the main target of toxicity.

In the 2-year study in mice, body weights in both sexes were slightly (5–10% in females and about 5% in males) but statistically significantly reduced in the group at the highest dose at 5000 ppm from week 6 (males) and week 9 (females) onwards. A very slight trend towards reduced body weight was also observed at 2000 ppm in males and females. At the highest dose of 5000 ppm, males and females had higher platelet counts at study termination and females had transiently lower erythrocyte counts and lower concentrations of haemoglobin. In males and females, liver weights were increased at 2000 ppm and above at 52 weeks; liver weights were statistically significantly increased at study termination only in males at 5000 ppm. Histologically, higher incidences of hepatocellular hypertrophy were seen at 2000 ppm and above. Hyperplastic changes were increased in the livers of males at 5000 ppm and of females at 200 ppm and above, without a clear dose–response relationship in females. In females at 2000 or 5000 ppm, slightly increased incidences of liver adenoma were close to the upper bound of the range for historical controls but without a dose–response relationship. The NOAEL for toxicity was 200 ppm, equal to 17.4 mg/kg bw per day, on the basis of

hepatocellular hypertrophy at 2000 ppm. The NOAEL for carcinogenicity was 5000 ppm, equal to 481 mg/kg bw per day, the highest dose tested.

In the 2-year study in rats, terminal body weights were decreased in females at the highest dose of 2000 ppm. Males at 2000 ppm showed lowered activities of alanine aminotransferase (ALT) and aspartate aminotransferase (AST). Males and females at 2000 ppm had elevated liver weights at 26, 52 and 104 weeks. In the first year of the study, rats had higher thyroid weights that were statistically significant only in females. Treatment-related histological changes were restricted to the liver and the thyroid. Since the criteria for histopathological diagnosis had substantially changed since the release of the study report in 1982, the original histology slides for livers and thyroids were re-examined in 1995. At 2000 ppm, males and females had higher incidences for centrilobular hepatocellular and diffuse hypertrophy and females also had more eosinophilic foci than did the controls. A slight and statistically not significant increase in the incidence of liver adenoma was observed at 2000 ppm in females but not in males. Males at 200 ppm and males and females at 2000 ppm showed higher incidences of thyroid F-cell hypertrophy. The NOAEL for toxicity was 20 ppm, equal to 0.9 mg/kg bw per day, on the basis of higher incidences of thyroid F-cell hypertrophy at 200 ppm and the NOAEL for carcinogenicity was 2000 ppm, equal to 89.46 mg/kg bw per day, the highest dose tested.

Buprofezin was not carcinogenic in mice and rats.

Buprofezin was tested for genotoxicity in an adequate range of studies in vitro and for induction of micronucleus formation in vivo. In the submitted studies, there was no evidence for genotoxicity in vitro; however, in a published non-GLP study, micronucleus formation was induced in cultured cells by an aneugenic mechanism, rather than by chromosomal breakage. In assays for micronucleus formation in immature erythrocytes of mouse bone marrow in vivo, conflicting results have been obtained. One study reported statistically significantly increased incidences in two experiments, but the numerical results were very different and were not fully supported by equivocal results from an earlier study in which the administered doses were five times higher. Furthermore, the suggestion of an aneugenic effect in vitro in the published study was not confirmed in vivo.

The Meeting concluded that there was equivocal evidence that buprofezin might be genotoxic.

On the basis of clearly negative results in assays for genotoxicity in vitro and equivocal results in assays for genotoxicity in vivo and the absence of carcinogenicity, the Meeting concluded that buprofezin is unlikely to pose a carcinogenic risk to humans.

The reproductive toxicity of buprofezin has been investigated in two two-generation studies and one one-generation study in rats. In none of the three studies were there any effects on the fertility of males or females or on reproductive performance. In one study, minor increases in liver and kidney weights, without histological correlates, were seen in parental males at 1000 ppm. Pup body weights at birth were not affected by treatment with buprofezin in any of the three studies, but pup body-weight gains were lower at 1000 ppm from postnatal day 4 to postnatal day 21. At postnatal day 21, the body weights of pups at 1000 ppm were 10–18% lower than those of the controls. The NOAEL for parental toxicity was 100 ppm, equal to 6.46 mg/kg bw per day, on the basis of very slight changes in organ weights. The NOAEL for reproductive effects was 1000 ppm, equal to 66.0 mg/kg bw per day, the highest dose tested. The NOAEL for effects in offspring was 100 ppm, equal to 6.46 mg/kg bw per day, on the basis of reduced pup body-weight gain during lactation at 1000 ppm.

Developmental toxicity with buprofezin had been investigated in rats and rabbits. In rats at the highest dose of 800 mg/kg bw per day, clinical signs of intoxication were observed from day 10 of gestation onwards, dams had lower body-weight gains and lower feed intake from day 7 of gestation onwards and four total litter losses occurred. Additionally, postimplantation losses were increased and fetal body weights were low in this group. At this, the highest dose, there were also more fetuses with a space between body-wall and organs, subcutaneous oedema and retarded

ossification. The NOAEL for maternal toxicity and fetal toxicity was 200 mg/kg bw per day on the basis of lower body-weight gains and litter losses in dams and retarded ossification in fetuses at 800 mg/kg bw per day.

In the study of developmental toxicity in artificially inseminated rabbit dams given pooled semen, body-weight gain and feed intake were lowered from the first days of treatment in the group given the highest dose of 250 mg/kg bw per day. One rabbit at 50 mg/kg bw per day aborted and two rabbits at 250 mg/kg bw per day showed total litter losses. Since the frequency of total litter loss was within the range for historical controls, a relationship to treatment is questionable. One fetus from the group at 50 mg/kg bw per day and one fetus from the group at 250 mg/kg bw per day showed unilateral agenesis of one kidney. Because this finding is occasionally observed and might be related to carrier males, its toxicological significance is questionable. Additionally, enlarged aortic arches were observed in one fetus in each of two litters of the group at the highest dose. Although the incidence of this finding was very low it was above the range for historical controls and was thus considered to be treatment-related. The NOAEL for maternal and fetal toxicity was 50 mg/kg bw per day on the basis of lowered body-weight gain and feed intake in dams and increased incidence of enlarged aortic arches in fetuses.

The Meeting concluded that buprofezin was developmentally toxic only at doses that were maternally toxic and did not induce structural changes in fetuses.

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

The Meeting considered that buprofezin is not neurotoxic on the basis of the available data.

In mechanistic studies on thyroid function in rats, buprofezin at a dose of 1000 ppm, equivalent to 68.5 mg/kg bw per day, did not affect serum concentrations of triiodothyronine (T3) and thyroxine (T4). At higher doses, T4 was lowered at the beginning of dosing only and recovered thereafter. At doses of 500 mg/kg bw per day administered by gavage for 15–60 days, thyroid weights increased and concentrations of T4 decreased, but the activity of thyroid peroxidase did not change markedly. The Meeting concluded that the mechanistic studies did not explain the thyroid changes in studies in rats and dogs.

In studies with the rat metabolite BF4, no mortalities were observed in rats given a single oral dose at 300 mg/kg bw, but all rats died at 2000 mg/kg bw. BF4 gave negative results in the Ames test. In studies with the rat metabolite BF11, no mortalities were observed in rats given a single oral dose at 2000 mg/kg bw. BF11 gave negative results in the Ames test. In studies with the rat metabolite BF25, no mortalities were observed in rats given a single oral dose at 300 mg/kg bw, but all rats died at 2000 mg/kg bw. BF25 gave negative results in the Ames test. The plant metabolite BF26 did not induce mortalities in rats given a single oral dose at 50 mg/kg bw, but all animals died at 300 mg/kg bw. BF26 BF4 gave negative results in the Ames test.

No health effects related to exposure were reported among personnel involved in the synthesis and manufacture of buprofezin.

Toxicological evaluation

The Meeting established an ADI of 0–0.009 mg/kg bw based on a NOAEL of 0.9 mg/kg bw per day in the 2-year study in rats, identified on the basis of increases in the incidence of thyroid F-cell hypertrophy at 8.71 mg/kg bw per day. A safety factor of 100 was applied. The difference between the current ADI and the previous ADI of 0.01 mg/kg bw per day is due to rounding of the figures; both ADIs were based on the same NOAEL from the same study.

The Meeting established an ARfD of 0.5 mg/kg bw based on a NOAEL of 50 mg/kg bw identified on the basis of ataxia at 300 mg/kg bw per day in a 13-week feeding study in dogs. A safety factor of 100 was applied. This ARfD would also be protective against the finding of enlarged aortic arches in rabbit fetuses, although this effect is unlikely to be the result of 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	200 ppm, equal to 17.4 mg/kg bw per day	2000 ppm, equal to 190 mg/kg bw per day
		Carcinogenicity	5000 ppm, equal to 481 mg/kg bw per day[c]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	20 ppm, equal to 0.9 mg/kg bw per day	200 ppm, equal to 8.71 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 89.46 mg/kg bw per day[c]	—
	Two-generation study of reproductive toxicity[a,d]	Reproductive toxicity	1000 ppm, equal to 66.0 mg/kg bw per day[c]	—
		Parental toxicity	100 ppm, equal to 6.46 mg/kg bw per day	1000 ppm, equal to 66.0 mg/kg bw per day
		Offspring toxicity	100 ppm, equal to 6.46 mg/kg bw per day	1000 ppm, equal to 66.0 mg/kg bw per day
	Developmental toxicity[b]	Maternal toxicity	200 mg/kg bw per day	800 mg/kg bw per day
		Embryo and fetal toxicity	200 mg/kg bw per day	800 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
		Embryo and fetal toxicity	50 mg/kg bw per day	250 mg/kg bw per day
Dog	13-week and two-year study of toxicity[b, e]	Toxicity	10 mg/kg bw per day	20 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

[d] The results for three studies were combined.

[e] The results for two studies were combined.

Estimate of acceptable daily intake for humans

0–0.009 mg/kg bw

Estimate of acute reference dose

0.5 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 buprofezin

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, 40–45%
Dermal absorption	—
Distribution	Extensive, highest levels in erythrocytes, thyroid, liver
Potential for accumulation	Low, no evidence of accumulation
Rate and extent of excretion	Rapid, > 80% within 48 h, mainly via bile
Metabolism in animals	Extensive, primarily via oxidations, thiadiazinane ring opening and conjugation
Toxicologically significant compounds (animals, plants and environment)	Buprofezin, rat metabolite BF25, plant metabolite BF26
Acute toxicity	
Rat, LD_{50}, oral	1635–3847 mg/kg bw
Rat, LD_{50}, dermal	> 10 000 mg/kg bw
Rat, LC_{50}, inhalation	4.57 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization (test method used)	Not a sensitizer (Magnusson & Kligman and local lymph node assay)
Short-term studies of toxicity	
Target/critical effect	Feed intake, clinical chemistry (rat) liver weight increase with histological changes (dog)
Lowest relevant oral NOAEL	3.4 mg/kg bw per day (13-week study in rats)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day, highest dose tested (24-day study in rats)
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	Equivocal evidence of genotoxicity
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Increases in liver weight with histological changes (mouse, rat) and thyroid changes (rat)
Lowest relevant NOAEL	20 ppm, equal to 0.9 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Not carcinogenic
Reproductive toxicity	
Reproduction target/critical effect	No reproductive effects; reduced body-weight gain in pups during lactation
Lowest relevant reproductive NOAEL	1000 ppm, equal to 66 mg/kg bw per day (rat)

Lowest relevant offspring NOAEL	100 ppm; equal to 6.46 mg/kg bw per day (rat)
Developmental target/critical effect	Enlarged aortic arches (rabbit), retarded ossification (rat)
Lowest relevant developmental NOAEL	50 mg/kg bw per day (rabbit)
Neurotoxicity/delayed neurotoxicity	
	No evidence in conventional studies
Other toxicological studies	
	Rat metabolites BF4 and BF25 and plant metabolite BF26 had moderate acute oral toxicity; the rat metabolite BF11 was of low acute oral toxicity. All metabolites were not genotoxic.
Medical data	
	Medical surveillance of workers in a plant producing buprofezin did not reveal any adverse health effects.

Summary

	Value	*Study*	*Safety factor*
ADI	0–0.009 mg/kg bw	Rat, 2-year study	100
ARfD	0.5 mg/kg bw	Dog, 13-week study	100

RESIDUE AND ANALYTICAL ASPECTS

The insecticide buprofezin was evaluated by the JMPR for residues in 1991, 1995 and 1999. Toxicology was reviewed in 1991. Buprofezin was listed within the periodic re-evaluation programme at the 40th Session of the CCPR for periodic review by the 2008 JMPR for toxicology and residues.

The Meeting received information on identity, metabolism, storage stability, residue analysis, use patterns, fate of residue during processing, livestock feeding studies and residues resulting from supervised trials on oranges, mandarins, lemons, grapes, apples, pears, persimmons, custard apples, mangoes, cucumbers, eggplants and tomatoes. The Meeting also received information on use patterns from Japan and Australia.

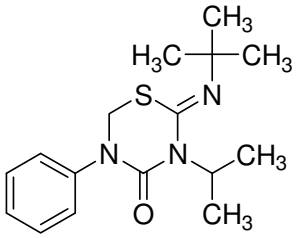
Chemical name

ISO common name: buprofezin

IUPAC: 2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one

CA: (Z)-2-[(1,1-dimethylethyl)imino]tetrahydro-3-(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one

Structural formula:



Metabolites referred to in the appraisal were addressed by their common names, except reverse Schiff base which refers to 3-isopropyl-5-phenyl-1,3,5-thiadiazinan-2,4-dione and the allophanate degradate which refers to 2-amino-2-methylpropyl-2-methylethyl-4-phenyl-allophanate.

Animal metabolism

The Meeting received results of animal metabolism studies in a lactating cow and in laying hens. Experiments were carried out using uniformly [^{14}C]phenyl labelled buprofezin.

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2008. Studies with [^{14}C]phenyl buprofezin showed that radioactivity was rapidly absorbed (C_{max} at 9 h) and rapidly excreted (> 60% in 24 h and > 80% in 48 h) in male and female rats at 10 and 100 mg/kg bw. The metabolism of buprofezin was studied in rat liver homogenates and in vivo. Hydroxylation with consecutive methylation of the phenyl ring, hydroxylation of the t-butyl moiety, oxidation of sulfur with consecutive ring opening of the thiadiazinane ring and conjugation reactions with sulfate and glucuronic acid were the main metabolic routes. Buprofezin, buprofezin sulfoxide, isopropylphenylurea, 4-hydroxybuprofezin, dihydroxybuprofezin, hydroxy-methoxybuprofezin, 4-aminophenol, 4-hydroxyacetanilide, dimethoxybuprofezin, reverse Schiff base, 4-hydroxyisopropylphenylurea, 2-[3-isopropyl-3-[methylsulfonylmethyl(phenyl)carbamoyl]ureido]-2-methylpropionic acid tert-butylhydroxy-buprofezin, biuret and thiobiuret were identified in the rat metabolism.

A lactating cow, orally treated twice daily for 7 consecutive days with [^{14}C]phenyl-buprofezin at a calculated dose rate of 27 ppm in the dry weight feed (equivalent to 0.38 mg ai/kg bw/d), was sacrificed 15 hours after the last dose. Most of the radioactivity was excreted: with 46% of the administered dose found in the faeces and 19% in the urine. Tissues contained only 1.6%, while milk contained 0.087% of the administered dose. The radioactivity in the tissues ranged from 1.21 mg/kg in the liver and 0.41 mg/kg in the kidney to 0.020 mg/kg in the fat and 0.018 mg/kg buprofezin equivalents in muscle. Radioactivity in milk reached a plateau on the fifth day of dosing at an average level of 0.026 mg/kg buprofezin equivalents. Radioactivity in the milk was distributed between cream and whey in a ratio of approximately 2:1.

Radioactivity was characterized in cow liver, kidney and milk. Metabolites were only identified after hydrolysis of the organic extracts with β-glucuronidase and sulfatase, indicating that the metabolites identified were conjugates.

No buprofezin was detected in the liver or kidney. The major metabolite in liver and kidney was 4-hydroxybuprofezin at 11% and 18% of the total radioactivity, respectively. Isopropylphenylurea, 4-hydroxyisopropylphenylurea and 4-hydroxyacetanilide were identified as minor metabolites at levels up to 8% of the total radioactivity. In milk 2.2% of the total radioactivity was identified as buprofezin. The principal milk metabolite was 4-hydroxyacetanilide at 14% of the total radioactivity with minor amounts of 4-hydroxybuprofezin and isopropylphenylurea at levels up to 4% of the total radioactivity. The major part of the residue in liver, kidney and milk remained unidentified (67–81% of the total radioactivity), but was characterized as organic soluble compounds (10–12% of the total radioactivity) comprising each less than 6% of the total radioactivity, as a mixture of highly polar metabolites (15–28% of the total radioactivity) or as unextractable residue

(20–55% of the total radioactivity). Most of the unextractable residue could be released by proteinase treatment (16–36% of the total radioactivity) indicating that residues were incorporated in animal tissues.

Six laying hens, orally treated twice daily for 14 consecutive days with [^{14}C]phenyl-buprofezin at a calculated dose rate of 12 ppm in the dry weight feed (equivalent to 0.80 mg ai/kg bw/d), were sacrificed 13–14 h after the last dose. The largest amount of radioactivity was found in the excreta, which contained 80% of the administered dose. Tissues contained only 0.2%, while eggs contained less than 0.1% of the administered dose. The radioactivity in the tissues ranged from 0.15 mg/kg in liver and 0.14 mg/kg in kidney to 0.035 mg/kg in fat and 0.019 mg/kg buprofezin equivalents in muscle. Radioactivity in egg yolks reached a plateau on the 12th day of dosing at an average level of 0.11 mg/kg buprofezin equivalents; radioactivity in egg whites reached a plateau on the 3rd day of dosing at an average level of 0.012 mg/kg buprofezin equivalents.

Radioactivity was characterized in hen liver, egg yolk and egg white. Metabolites could only be identified following hydrolysis of the organic extracts with dioxane/hydrochloric acid and sodium hydroxide under severe conditions, indicating that metabolites identified must be considered as conjugates.

Buprofezin was detected at trace amounts in liver, egg yolks and egg whites (0.3–0.9% of the total radioactivity). In addition, the reverse Schiff base, isopropylphenylurea, and 4-hydroxyisopropylphenylurea were identified as minor metabolites at levels up to 4% of the total radioactivity. The major part of the residue in liver, egg yolks and egg whites remained unidentified (90–95% of the total radioactivity), but was characterized as organic soluble compounds (9–31% of the total radioactivity) comprising each less than 9% of the total radioactivity, as aqueous soluble highly polar metabolites (11–39% of the total radioactivity) or as unextractable residue (45–56% of the total radioactivity). Residue released from solids was also characterized as a mixture of highly polar metabolites.

It was found that [^{14}C]buprofezin was efficiently eliminated from cattle and hens. The absorbed dose was extensively metabolized and conjugated as demonstrated by the wide range of solvent polarities required to extract and partition radioactivity from the tissues, the necessity for acid or enzyme hydrolysis to release identifiable metabolites and also the large amount of minor unidentifiable and bound metabolites.

The metabolic pathways have been found to be virtually identical for cattle and hens. Two basic metabolic pathways are proposed. The first is hydroxylation at the para position of buprofezin to form 4-hydroxybuprofezin, followed by cleavage of the thiadiazinane ring and loss of the $–CH_2$-S-C=N-C$(CH_3)_3$ group to leave 4-hydroxyisopropylphenylurea which is degraded to 4-hydroxyacetanilide. The second proposed route consists of a reverse Schiff base reaction followed by cleavage of the thiadiazinane ring with loss of $–CH_2$-S-C=O to form isopropylphenylurea which is hydroxylated and metabolized by multiple steps also to the 4-hydroxyacetanilide.

The metabolic pathway proposed for ruminants and hens is consistent with that for rats, though rats have some additional metabolic routes, i.e., double hydroxylation at the phenyl ring, hydroxylation of the tert-butyl moiety and formation of the buprofezin sulfoxide. These additional rat metabolic routes were evaluated in livestock, with the aid of reference standards, and were not found; the Meeting therefore concluded that these additional metabolic routes are specific to rats.

Plant metabolism

The Meeting received plant metabolism studies for buprofezin in fruit (citrus), fruiting vegetables (tomato), leafy vegetables (lettuce) and oilseeds (cotton). Experiments were carried out using uniformly [^{14}C]phenyl labelled buprofezin.

Greenhouse grown tomato plants were sprayed to run-off with [^{14}C]buprofezin four times at 14 day intervals at a dose rate of 0.0075 kg ai/hL. Tomato fruit were harvested 0, 1, 3 and 7 days after

the last application. Total radioactive residues declined from 0.49–0.67 mg/kg to 0.32–0.37 mg/kg buprofezin equivalents from 0 to 7 days. Washing with water released 16% to 4% of the total radioactivity from 0 to 7 days, while washing with ethanol released 61% to 26% of the radioactivity.

Fruit of greenhouse grown tomato plants were treated topically with [^{14}C]buprofezin at a dose rate equivalent to 0.062 kg ai/hL with the treated tomatoes harvested 0, 1, 3 and 7 days after the last application. The applied radioactivity on the day 7 tomato fruit was 36% surface residue, 33% in the peel and 11% in the fruit pulp, while 20% of the applied radioactivity was lost. Autoradiography of the day 7 tomato fruit indicated that a large part of the radioactivity was still present in the peel, although diffusion into the pulp had started. Total radioactive residues varied between 0.28 to 0.72 mg/kg buprofezin equivalents for day 0 to 7 samples. Of the total radioactivity in the day 7 tomato fruits, 93% was identified as unchanged buprofezin.

Fruit from greenhouse grown lemon trees, treated with [^{14}C]buprofezin, were harvested 75 days after a single foliar treatment of 1.0 kg ai/ha (0.05 kg ai/hL), 14 days after a double foliar treatment with a 75 day interval at 1.0 kg ai/ha (0.05 kg ai/hL) each or 30 days after a single foliar treatment of 3.5 kg ai/ha (0.17 kg ai/hL). Total radioactive residues were 0.40, 0.94 or 3.8 mg/kg buprofezin equivalents, respectively. The vast majority of the total radioactive residue from the fruit (90–98%) was recoverable by an ethanol surface wash and a solvent extraction of the peel, indicating surface residue, with 2–9% non-extractable. In the lemons treated two times at 1.0 kg ai/ha and a pre-harvest interval of 14 days, 79% of the total residue was identified with the aid of acid hydrolysis indicating conjugation of residues. Buprofezin was the major residue (66%) of which the majority remained on the surface of the fruit as unconjugated compound (64%). Reverse Schiff base (6.0%), isopropylphenylurea (1.7%), and allophanate degradate (5.7%) were identified as minor metabolites in the extractable and fibre bound residue with the aid of acid hydrolysis indicating conjugation. Levels of other unidentified metabolites individually did not exceed 3.6% of the total radioactivity (0.03 mg/kg eq). In the lemons treated once at 1.0 kg ai/ha and at a longer pre-harvest interval of 75 days, 68% of the total residue was identified. The metabolite profile was similar, but the levels of buprofezin had decreased (18% of total residue) and levels of conjugated metabolites had increased (7.3–34% of total residue).

Lemon twigs and leaves from greenhouse grown trees were treated topically with [^{14}C]buprofezin at 2.0 kg ai/ha (0.1 kg ai/hL) and adjacent fruits were harvested 28 days later. Fruits contained only 0.03–1.2% of the applied dose and total radioactive residues in the fruits were less than 0.01 mg/kg buprofezin equivalents. This translocation study indicates that buprofezin does not move systemically through the plant.

Field-grown leaf lettuce was sprayed with [^{14}C]buprofezin two times at an interval of 12 days at a dose rate of 0.86 kg ai/ha. The lettuce was then harvested 14 days after the last treatment. Average total radioactive residue was 43 mg/kg eq. The majority of the radioactive residues were removable by ethanol surface wash (89%) indicating that the residue resides primarily on the surface. The remainder of the residue was extractable with organic solvents and water (10%), while 1.1% was non-extractable. Buprofezin was the major component of the residue (89%) with the majority remaining on the leaf surface as unconjugated compound (89%). Reverse Schiff base (0.2%), isopropylphenylurea (0.4%), and allophanate degradate (0.6%) were identified as minor metabolites in the extractable and fibre bound residue with the aid of acid and base hydrolysis indicating conjugation. Levels of other unidentified metabolites individually did not exceed 1% TRR (0.52 mg/kg eq).

Field-grown cotton was sprayed with [^{14}C]buprofezin twice at an interval of 42 days at a dose rate of 0.85 kg ai/ha. The cotton was harvested 27 days after the last treatment and separated into seeds and gin trash. Average total radioactive residue was 16 and 0.37 mg/kg buprofezin equivalents in gin trash and cotton seeds, respectively. A large part of the radioactive residues were removable by ethanol surface wash (45–68%) indicating surface residues. The remainder of the residue was extracted with organic solvents and water (17–44%), while 13–14% was non-extractable. Approximately 76% and 62% of the total radioactive residue was identified in gin trash and cotton

seeds, respectively. Buprofezin was the major residue (59%) of which the majority remaining as unconjugated compound on the surface of the gin trash (46%) or cotton seeds (53%). With the aid of acid hydrolysis reverse Schiff base (1.4–5.8%), isopropylphenylurea (1.5–5.7%), and allophanate degradate (0.4–6.1%) were identified as minor metabolites in the extractable and fibre bound residue. Levels of other unidentified metabolites individually did not exceed 7.5% TRR (1.1 mg/kg eq).

In each commodity tested, buprofezin was found to be the major residue (59–89% of the total radioactivity), staying primarily on the surface of the treated crop as unconjugated compound. The remainder of the residue was identified as reverse Schiff base, isopropylphenylurea, and allophanate degradate as free or conjugated compound albeit at very low levels (less than 7% of the total residue). No single unidentified metabolite comprised more than 7.5% TRR in either crop tested (0.03–1.1 mg/kg eq, depending on the commodity).

Two metabolic pathways are proposed for buprofezin residues that penetrate the surface of plants. The first proposed route consists of a reverse Schiff base reaction followed by cleavage of the thiadiazinane ring with loss of $–CH_2$-S-C=O to form isopropylphenylurea. The second proposed route consists of chemical rearrangements and cleavage of the thiadiazinane ring to form allophanate degradate followed by formation of isopropylphenylurea or formation of reverse Schiff base followed by formation of isopropylphenylurea.

Other than the allophanate degradate, plant metabolites were also found in the rat. The unconjugated form of the allophanate degradate was only found in cotton seeds at trace levels (0.4% of the total residue). Conjugated forms of the allophanate degradate were found at levels of up to 5.7% of the total residue in lemons treated 14 days prior to harvest, while the levels increased to 34% of the total residue in lemons treated 75 days prior to harvest. Only trace levels of the allophanate degradate could be released from lemon by mild enzyme hydrolysis (ß-glucuronidase, ß-glucosidase, cellulase, 20 h at 37 °C), quantifiable amounts were released by a more forcing acid hydrolysis (dioxane:concentrated HCl, 5:2, v/v, 16 h at 50 °C). Additional analysis of the lemon residues indicated that the allophanate degradate most likely originated from hydrolysis of tert-butylhydroxy-buprofezin linked to a non-glucose hexose. The unconjugated tert-butylhydroxy-buprofezin could not be isolated from the lemon residues, but acid hydrolysis of a solution of tert-butylhydroxy-buprofezin (1 M HCl, 90 °C, 1 h) resulted in the formation of allophanate degradate, isopropyl-phenylurea and reverse Schiff base, which were the same metabolites as found in plants.

Environmental fate

The Meeting received information on the hydrolysis and photolysis of buprofezin in sterile water. Experiments were carried out using uniformly [^{14}C]phenyl labelled buprofezin.

Buprofezin is hydrolytically stable in sterile water at pH 7 and 9 but hydrolyses at pH 5 with a half life of 51 days. The proposed route for hydrolysis in water involves opening of the thiadiazinane ring to form thiobiuret followed by amide cleavage to produce isopropylphenylurea or replacement of the sulfur with oxygen to form biuret followed by amide cleavage to produce isopropylphenylurea.

The hydrolysis products thiobiuret and biuret were not found in or on crops treated with a foliar spray of buprofezin.

Three photolysis studies were conducted involving either artificial sunlight or natural sunlight, with, in each case, the light equivalent to 30 days of natural sunlight. Half lives ranged from 33 days (Study 2) and 38 days (Study 3) to 106–140 days (Study 1) for natural sunlight in summer. The major route is either a reverse Schiff base reaction or cleavage of the thiadiazinane ring to form thiobiuret followed by further degradation to isopropylphenylurea, phenylurea and the major photodegradate formanilide or formation of biuret. Minor photodegradation products found were des-isopropyl buprofezin, buprofezin sulfoxide, and 4-hydroxybuprofezin.

The photodegradation products 4-hydroxybuprofezin, des-isopropyl buprofezin, thiobiuret, biuret, phenylurea, formanilide and buprofezin sulfoxide were not found in or on crops treated with a foliar spray of buprofezin, despite buprofezin persisting for a long time on plant surfaces. Reference standards for phenylurea and formanilide were not available in the metabolism study on lettuce.

Methods of analysis

The Meeting received description and validation data for analytical methods for enforcement-monitoring of buprofezin and residue analytical methods used in the various study reports for buprofezin and its metabolites.

Multi-residue method DFG S19 is a post-registration monitoring and enforcement method for parent buprofezin in crops. The Meeting considered the method sufficiently validated for commodities with high water content, commodities with high acid content, commodities with high fat content and dried commodities. No enforcement-monitoring method was available for animal commodities.

The methods reported to the Meeting and used in the supervised residue trials, processing studies and storage stability studies on crops, determined parent buprofezin and in some cases also the metabolite 4-hydroxybuprofezin or the metabolites reverse Schiff base and isopropylphenylurea. Macerated samples were extracted with acetone or ethyl acetate. The extract was cleaned up by solvent partition and/or column chromatography and/or solid phase extraction, if necessary. The final residue could then be determined by GC-NPD, GC-MS, HPLC-UV or HPLC-MS-MS. Determination of 4-hydroxybuprofezin generally required acetylation. LOQs were in the 0.005–0.1 mg/kg range for buprofezin and 4-hydroxybuprofezin, and in the 0.01–0.05 mg/kg range for reverse Schiff base and isopropylphenylurea.

The methods reported to the Meeting and used in the feeding studies and storage stability studies on animal commodities, determined parent buprofezin and/or the metabolites 4-hydroxybuprofezin, isopropylphenylurea or 4-hydroxyacetanilide. Macerated samples were typically extracted with acetonitrile. The extract was cleaned up by solvent partition and/or solid phase extraction. The final residue could then be determined by GC-NPD or GC-MS. The analytical method has a reported limit of quantification of 0.01 mg/kg in milk and 0.05 mg/kg in tissues for each analyte, but suffers from matrix interferences, thereby increasing the valid limit of quantification to levels of 0.04 mg/kg for 4-hydroxyacetanilide in milk, 0.07 mg/kg buprofezin in beef fat, and 0.1 mg/kg in beef liver.

The Meeting noted that conjugated forms of buprofezin and its metabolites are unlikely to be detected by the analytical methods described for plant and animal commodities because of the simple extraction methods used.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of buprofezin, 4-hydroxybuprofezin, reverse Schiff base and isopropylphenylurea in samples stored frozen.

Parent buprofezin was stable when stored frozen for up to 32 months in crops with high water content (32 months lettuce, 30 months tomatoes, 5 months cucumbers), up to 12 months in crops with high acid content (12 months citrus, 4 months grapes), up to 6 months in dry tomato pomace and tomato juice, and 6 months in tomato paste.

Metabolites reverse Schiff base and isopropylphenylurea were stable when stored frozen for 32 months in crops with high water content (32 months lettuce, 30 months tomatoes), 12 months in crops with high acid content (citrus), and 6 months in dry tomato pomace, tomato juice, and tomato paste. 4-Hydroxybuprofezin is stable when stored frozen for 12 months in crops with high acid content (12 months citrus) and 5 months in crops with high water content (5 months tomato and 3 months cucumber).

Parent buprofezin was stable when stored frozen at –10 °C for 10 months in beef fat and 10 months in milk (degraded at 12 months). Storage stability results for beef liver could not be interpreted because of the high variability in the analytical results.

The Meeting extrapolated 32 months of storage stability for apple, pear, persimmon, custard apple, mango and eggplant samples from crops with high water content. Samples in selected supervised residue trials on mandarins, oranges were stored for periods up to 3 years (mandarin) or 2 years (oranges) which is longer than the maximum storage period tested of 12 months for crops with high acid content. Because pH for tomatoes (4.3–4.5) is similar to pH for oranges (3.7–4.3) or mandarins, the Meeting considered the storage stability for citrus to be sufficiently covered. Storage stability data for orange juice, orange pomace, wine, grape juice and raisins were not available, although the samples were stored for a period of up to 2 years. Processed tomato samples were stored for periods of up to 8 months, longer than the maximum storage period tested at 6 months for tomato juice and 6 months for tomato paste. The Meeting considered the storage stability for processed commodities to be adequately covered by the storage stability data on the raw commodities.

Residue definition

In the metabolism studies [^{14}C]buprofezin was efficiently eliminated from cattle and hens. The absorbed dose was extensively metabolized and conjugated as indicated by the wide range of solvent polarities required to extract and partition radioactivity from the tissues, the necessity for acid or enzyme hydrolysis to release identifiable exocons and also the large amount of minor unidentifiable and bound metabolites. Based on the metabolism studies significant residues were not identified in animal commodities.

However, the Meeting noted that in a feeding study on lactating cows, where the dose rate was 6 times higher than in the metabolism study, residues of up to 0.02 and 0.12 mg/kg buprofezin were found in milk and beef fat, respectively. Taking into account the residues found in this feeding study, the residue is defined as buprofezin (no metabolites) for enforcement in animal products as well as for dietary risk assessment.

The log K_{ow} of 3.7 for buprofezin suggests fat solubility. The fat solubility of buprofezin was indicated in a poultry metabolism study where buprofezin levels (as mg/kg) in egg yolk were higher by a factor of 2 than in egg whites and by a feeding study in cows where buprofezin concentrated by a factor of 4 in cream as compared to whole milk. Buprofezin, however, was not detected in the fat of cows or poultry and could be removed easily by washing with water from plants surfaces. As a consequence, the Meeting considers the residue to be not soluble in fat.

Based on the available comparative plant metabolism studies, parent buprofezin is the major component (59–89% of the total residue) of the crops tested at short pre-harvest intervals (14–27 days). The Meeting concluded that parent buprofezin is a suitable analyte in plant commodities for enforcement purposes.

The remainder of the residue was identified, principally after hydrolysis, as reverse Schiff base, isopropylphenylurea, and the allophanate degradate, albeit at very low levels (less than 7% of the total residue). The reverse Schiff base and isopropylphenylurea were found in rat, but the allophanate degradate was not. Based on toxicological data the Meeting considered the allophanate degradate toxicologically relevant.

Since unconjugated forms of allophanate degradate were only available at trace levels in cotton seeds, and the allophanate degradate could only be identified using strong acid hydrolysis conditions (dioxane:concentrated HCl, 5:2, v/v, 16 h 50 °C). The Meeting considered the allophanate degradate an artefact resulting from strong hydrolysis. No analytical methods were available to quantify free or conjugated allophanate degradate.

Although the allophanate degradate is, and some of the other metabolites might be, of toxicological relevance, the levels are so low that the Meeting agreed that they should be excluded from the residue definition for risk assessment.

The Meeting recommended the following as the residue definition for buprofezin:

Definition of the residue for compliance with the MRL or for estimation of the dietary intake for plants and animals: *buprofezin*

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for buprofezin on lemons, mandarins, oranges, apples, pears, grapes, persimmons, custard apples, mangoes, cucumbers, egg plants and tomatoes.

Citrus fruits

Supervised field trials involving lemons were performed in New Zealand. GAP for citrus in New Zealand is for 2–4 applications at 0.013 kg ai/hL (PHI 14 days). In trials matching New Zealand GAP (2× 0.012 kg ai/hL, PHI 14 days), buprofezin residues in whole fruit were 0.22 mg/kg (n = 1). Buprofezin residues in lemon pulp were not available.

GAP for citrus in Australia is for 1–2 spray applications at 0.013–0.026 kg ai/hL (PHI 28 days) and in trials from New Zealand matching this GAP (2× 0.025 kg ai/hL, PHI 28 days), buprofezin residues in whole fruit were 0.40 mg/kg (n = 1). Buprofezin residues in lemon pulp were not available.

The Meeting agreed that the data corresponding to the New Zealand and Australian GAP were insufficient to estimate a maximum residue level for lemon.

Field trials involving mandarins were performed in Spain, Australia and Japan.

GAP for citrus in Spain is for 1 spray application at 0.013–0.025 kg ai/hL (PHI 7 days). In trials from Spain matching this GAP (1× 0.025 kg ai/hL, PHI 6–7 days), buprofezin residues in whole fruit were 0.11, 0.22, 0.23 (3), 0.41, 0.45, 0.46 mg/kg (n = 8). Buprofezin residues in mandarin pulp in these trials were < 0.01, 0.03, 0.04, 0.04, 0.05, 0.06 (3) mg/kg (n = 8).

GAP for citrus in Australia is for 1–2 spray applications at 0.013–0.026 kg ai/hL (PHI 28 days) and in trials from Australia matching this GAP (1–2× 0.024–0.026 kg ai/hL, PHI 28 days), buprofezin residues in whole fruit were 0.05, 0.33, 0.69 mg/kg (n = 3). Buprofezin residues in mandarin pulp in these trials were < 0.01 (2), 0.084 mg/kg (n = 3).

GAP for mandarin in Japan is for 1–3 spray applications at 0.017-0.025 kg ai/hL (PHI 14 days). In trials from Japan matching this GAP (2–3× 0.025 kg ai/hL, PHI 14 days), buprofezin residues in whole fruit were 0.07 (3) and 0.08 mg/kg (n = 4). Buprofezin residues in mandarin pulp in these trials were < 0.01 (3) and 0.02 mg/kg (n = 4).

The Meeting noted that the datasets from Australia and Japan were too small to estimate a maximum residue level. The Meeting agreed to use the dataset from Spain.

Field trials involving oranges were performed in Spain, USA, and Australia.

GAP for citrus in Spain is for 1 spray application at 0.013–0.025 kg ai/hL (PHI 7 days). In trials from Spain matching this GAP (1× 0.025 kg ai/hL, PHI 7–8 days), buprofezin residues in whole fruit were 0.17 (2), 0.19, 0.21 (2), 0.23, 0.32, 0.37 mg/kg (n = 8). Buprofezin residues in orange pulp in these trials were 0.03, 0.04 (4), 0.05, 0.10 mg/kg (n = 7).

Trial data from the USA did not match the available GAP for that country.

GAP for citrus in Australia is for 1–2 spray applications at 0.013–0.026 kg ai/hL (PHI 28 days) and in trials from Australia matching this GAP (2× 0.025 kg ai/hL, PHI 29 days), buprofezin

residues in whole fruit were 0.05, 0.067, 0.12 mg/kg (n = 3). Buprofezin residues in orange pulp in these trials were < 0.01, 0.011, 0.021 mg/kg (n = 3).

GAP for citrus in New Zealand is for 2–4 spray applications at 0.013 kg ai/hL (PHI 14 days) and in trials from Australia matching this GAP (2× 0.012 kg ai/hL, PHI 14 days), buprofezin residues in whole fruit were 0.051 and 0.11 mg/kg (n = 2). Buprofezin residues in orange pulp in these trials were 0.011 and 0.030 mg/kg (n = 2).

The Meeting noted that the individual datasets from Australia and New Zealand were too small to estimate a maximum residue level. The Meeting agreed to use the dataset from Spain.

The Meeting noted that GAPs for mandarin and orange were the same and that the datasets were from similar populations and could be combined. Buprofezin residues in whole fruit in ranked order were: 0.11, 0.17, 0.17, 0.19, 0.21, 0.21, 0.22, 0.23, 0.23, 0.23, 0.23, 0.32, 0.37, 0.41, 0.45, 0.46 mg/kg (n = 16). Buprofezin residues found in the pulp were: < 0.01, 0.03 (2), 0.04 (6), 0.05 (3), 0.06 (3), 0.10 mg/kg (n = 16).

The Meeting agreed that the mandarin and orange data could be used to support a citrus fruit commodity group maximum residue level and estimated a maximum residue level of 1 mg/kg for buprofezin on citrus fruit and estimated an STMR of 0.04 mg/kg and an HR of 0.10 mg/kg for buprofezin in the edible portion of citrus fruit. For purposes of calculating residues in processed citrus commodities an STMR of 0.23 mg/kg and an HR of 0.46 mg/kg was estimated based on whole fruit orange.

The Meeting withdrew its previous recommendation of 0.5 mg/kg for oranges, sweet and sour.

Pome fruits

Field trials involving apples were performed in New Zealand. Trials performed in New Zealand did not match with the available GAP for New Zealand or Australia.

The Meeting agreed that there was insufficient data to estimate a maximum residue level for apples.

Field trials involving pears were performed in Australia.

GAP for pears in Australia is for 2 spray applications at 0.013–0.026 kg ai/hL (PHI 56 days) and in trials from Australia matching this GAP (2–3× 0.026 kg ai/hL, PHI 52–62 days), buprofezin residues in whole fruit were 0.02, 0.04, 0.05, 0.05 mg/kg (n = 4).

GAP for pome fruit in New Zealand is for 3 spray applications at 0.013 kg ai/hL (PHI 56 days) and in trials from Australia matching this GAP (2–3× 0.013 kg ai/hL, PHI 52–62 days), buprofezin residues in whole fruit were < 0.01 (2), 0.02, 0.03 mg/kg (n = 4).

The Meeting noted that the individual datasets from Australia and New Zealand were too small to estimate a maximum residue level. As the GAPs were different, data could not be combined. The Meeting agreed that there was insufficient data to estimate a maximum residue level for pears.

Berries and other small fruits

Trials involving field-grown grapes were performed in Germany, France, Italy, USA, and Australia. Trials involving greenhouse-grown grapes were performed in Japan.

Trials performed in Germany, France and Italy did not match available GAPs for Switzerland or Italy.

Trials performed in the USA did not match the available GAP for the USA.

GAP for grapes in Australia consists of 2 applications at 0.013–0.026 kg ai/hL (PHI 56 days) and in field trials from Australia matching this GAP (2–3× 0.026 kg ai/hL, PHI 56–57 days), buprofezin residues in grapes were 0.02, 0.03, 0.07, 0.09, 0.19 mg/kg (n = 5).

GAP for grapes in New Zealand is for 2 spray applications at 0.013 kg ai/hL (no PHI, pre-flowering applications only) and in field trials from Australia matching this GAP (3× 0.013 kg ai/hL, pre-flowering), buprofezin residues found in grapes were < 0.01 (2) mg/kg (n = 2).

GAP for grapes in Japan is for 1–2 spray applications at 0.007–0.020 kg ai/hL (PHI 30 days) and in greenhouse trials from Japan matching this GAP (2× 0.013-0.020 kg ai/hL, PHI 30–31 days), buprofezin residues found in grapes were 0.18, 0.22, 0.28, 0.29 mg/kg (n= 4).

The Meeting noted that the individual datasets from Australia, New Zealand and Japan were too small to estimate a maximum residue level. As the GAPs were substantially different, the meeting decided that the data sets could not be combined. The Meeting therefore agreed that there was insufficient data available to estimate a maximum residue level for grapes.

Persimmons

Field trials involving persimmons were performed in Australia. GAP for persimmons in Australia is for 1–2 applications at 0.026 kg ai/hL (PHI 28 days) and in field trials from Australia matching this GAP (2× 0.026 kg ai/hL, PHI 28 days), buprofezin residues in whole fruits were 0.44 and 0.46 mg/kg (n = 2). The analytical method used to determine the residue values was insufficiently described and validated.

The Meeting agreed that there was insufficient data available to estimate a maximum residue level for persimmons.

Assorted tropical and subtropical fruits – inedible peel

Custard apple

Field trials involving custard apples were performed in Australia. GAP for custard apples in Australia is for 1–2 spray applications at 0.013–0.026 kg ai/hL (PHI 14 days) and in field trials from Australia matching this GAP (2× 0.024 kg ai/hL, PHI 14 days, buprofezin residues in whole fruits were 0.04 and 0.05 mg/kg (n = 2). Buprofezin residues in custard apple pulp were not available.

The Meeting agreed that there was insufficient data available to estimate a maximum residue level for custard apples.

Mangoes

Field trials involving mangoes were performed in Australia. GAP for mangoes in Australia is for 1–2 applications at 0.026 kg ai/hL (PHI 28 days) and in field trials from Australia matching this GAP (2× 0.025 kg ai/hL, PHI 28 days), buprofezin residues in whole fruits were < 0.01, < 0.01, 0.01, 0.03, 0.045 mg/kg (n = 5). Buprofezin residues determined in mango pulp from three of these trials were < 0.01, < 0.01, < 0.01 mg/kg (n = 3).

The Meeting estimated a maximum residue level of 0.1 mg/kg for buprofezin in mango whole fruit and estimated an STMR of 0.01 mg/kg and HR of 0.01 mg/kg for buprofezin in mango pulp.

Cucumbers

Trials involving field-grown cucumbers were performed in Spain, Greece and the USA. Trials involving indoor-grown cucumbers were performed in the UK, France, Italy, Spain, Australia and Japan.

Trials on field-grown cucumbers performed in Spain and Greece did not match the available GAPs from Spain, Greece, Italy and Portugal.

Trials on field-grown cucumbers performed in the USA did not match the available GAP from the USA.

GAP for cucumbers in Hungary is for applications at 0.25 kg ai/ha (PHI 3 days) and in indoor trials from the UK, France, Italy, and Spain matching this GAP (2× 0.20–0.28 kg ai/ha, PHI 3 days), buprofezin residues in whole fruit were < 0.01, 0.03 (3), 0.04 (2), 0.06, 0.09 mg/kg (n = 8) for SC formulations, and < 0.01, 0.03, 0.04, 0.10 mg/kg (n = 4) for WP formulations at the same locations. The Meeting noted that the residue populations corresponding to SC and WP formulations were from similar populations and as they were from the same location should be treated as replicates, i.e., only one residue should be selected per location. The Meeting therefore agreed to use only the dataset corresponding to the highest residue from each location. This resulted in the following dataset: < 0.01, 0.03, 0.03, 0.03, 0.04, 0.04, 0.06, 0.10 mg/kg (n = 8).

GAP for glasshouse cucumbers in Australia and New Zealand did not match with the indoor trials performed in Australia.

GAP for cucumbers in Japan is for 1–3 spray applications at 0.025 kg ai/hL (PHI 1 day) and in indoor trials from Japan matching this GAP (3× 0.020 kg ai/hL, PHI 1 day), buprofezin residues in whole fruit were 0.34 and 0.44 mg/kg (n = 2).

The Meeting noted that the dataset from Japan was too small to estimate a maximum residue level and agreed to use the dataset corresponding to Hungarian GAP.

The Meeting estimated a maximum residue level of 0.2 mg/kg for buprofezin in cucumber and estimated an STMR of 0.035 mg/kg and HR of 0.10 mg/kg for buprofezin in cucumber.

The Meeting withdrew its previous recommendation of 1 mg/kg for cucumber.

Fruiting vegetables other than cucurbits

Eggplant

Trials involving indoor-grown eggplants were performed in Spain.

GAP for eggplants in France is for spray applications at 0.13 kg ai/ha (PHI 5 days) and in trials from Spain matching this GAP (1× 0.14 kg ai/ha, PHI 4 days), buprofezin residues in whole fruit were 0.05 mg/kg (n = 1).

The Meeting agreed that the data were insufficient to estimate a maximum residue level for egg plants.

Tomatoes

Trials involving field-grown tomatoes were performed in Spain, Greece, France and the USA. Trials involving indoor-grown tomatoes were performed in the UK, France, Italy, Spain, New Zealand, and Japan.

Trials on field-grown tomatoes performed in Spain, Greece and France did not match the available GAPs from Spain, Greece, France, Italy and Portugal.

The GAP for tomatoes in the USA is for 1–2 applications at 0.28–0.43 kg ai/ha (PHI 7 days) and in trials on field-grown tomatoes from the USA matching this GAP (2× 0.42-0.43 kg ai/ha, PHI 7 days), buprofezin residues in whole fruit were 0.031 mg/kg (n = 1).

The GAP for tomatoes in Hungary is for spray applications at 0.13–0.25 kg ai/ha (PHI 3 days) and the GAP for Poland is for 2–4 spray applications at 0.012–0.025 kg ai/hL (PHI 3 days). In indoor trials from UK, France, Italy, and Spain matching this GAP (3× 0.23–0.27 kg ai/ha = 3×

0.025 kg ai/hL, PHI 3 days), buprofezin residues in whole fruit were 0.05, 0.12, 0.16, 0.17, 0.30, 0.35, 0.52 (2) mg/kg (n = 8) for the SC formulations and 0.13, 0.17, 0.24 mg/kg (n = 3) for the WP formulations applied at the same locations. The Meeting noted that the residue populations corresponding to SC and WP formulations were from similar populations and as they were from the same location should be treated as replicates, i.e., only one residue should be selected per location. The Meeting therefore agreed to use only the dataset corresponding to the highest residue from each location. This resulted in the following dataset: 0.05, 0.12, 0.16, 0.17, 0.30, 0.35, 0.52 (2) mg/kg (n = 8).

GAP for glasshouse tomatoes in New Zealand is for 1–2 applications at 0.013 kg ai/hL (PHI 3 days) and in indoor trials from New Zealand matching this GAP (0.012 kg ai/hL, PHI 4 days), buprofezin residues in whole fruit were 0.14 mg/kg (n = 1).

GAP for tomatoes in Japan is for 1–3 spray applications at 0.013–0.025 kg ai/hL (PHI 1 day) and in indoor trials from Japan matching this GAP (3× 0.025 kg ai/hL, PHI 1 day), buprofezin residues in whole fruit were 0.31 and 0.40 mg/kg (n = 2).

The Meeting noted that the individual datasets from New Zealand and Japan were too small to estimate a maximum residue level and agreed to use the dataset corresponding to Hungarian and Polish GAP.

The Meeting estimated a maximum residue level of 1 mg/kg for buprofezin in tomatoes and estimated an STMR of 0.24 mg/kg and HR of 0.52 mg/kg for buprofezin in tomatoes.

The Meeting confirmed its previous recommendation of 1 mg/kg for tomatoes.

Fate of residues in storage

Not applicable.

Fate of residues during processing

The Meeting received information on the fate of buprofezin under simulated processing conditions and on the fate of incurred residues of buprofezin during the processing of oranges, grapes, and tomatoes.

An aqueous solution of [phenyl-^{14}C]buprofezin was treated for 20 min at 90 °C at pH 4 (pasteurization), 60 minutes at 100 °C at pH 5 (brewing/baking/boiling), or for 20 minutes at 120 °C at pH 6 (sterilization). Degradation proceeded in the order pH 4 > pH 5 > pH 6 and 28.2%, 30.5%, 76% of the applied radioactivity remained as unchanged buprofezin after processing. Degradation proceeded via opening of the thiadiazinane ring to form thiobiuret (6.6–43%) followed by amide cleavage to produce isopropylphenylurea (5.3–31%) and aniline (7.2–18.9%) or replacement of the sulfur with oxygen to form biuret (< 4%).

The degradation products formed during simulated processing conditions are identical to the degradation products formed during hydrolysis in sterile water at low pH (pH 5), except that hydrolysis during simulated processing conditions proceeds further to aniline.

The degradation products isopropylphenylurea, biuret and thiobiuret were found in the rat metabolism study, but the degradation product aniline was not. Aniline is considered toxicologically relevant, but can come from sources other than buprofezin and could not therefore be included in a residue definition for risk assessment. Additional toxicological studies were available for biuret and thiobiuret and the Meeting considered these degradates toxicologically relevant.

In a processing study on tomatoes, where tomatoes were treated at 1× and 3× rate (3× 0.25 and 3× 0.75 kg ai/ha), biuret was not be detected in any samples. Thiobiuret was not be detected in the majority of samples, but was found in the 3× rate treatment at 0.02 mg/kg in two juice and two puree samples and at 0.01 mg/kg in one wet pomace and one canned tomato sample. The

concentration ratios buprofezin: isopropylphenylurea: thiobiuret were 14:0.5:1.0 and 6.5:1.0:1.0 for the juices sample, 26:10:1.0 and 20:13:1.0 for the puree samples, 110:14:1.0 for the wet pomace sample and 11:1.0:1.0 for the canned tomato sample. The ratios in juice and canned tomatoes resemble the ratios found in the simulated processing study at pH 6. Since biuret was not detected and the concentration level of thiobiuret was at maximum six times lower than the parent compound, the Meeting concluded that the residue definition for plant commodities is also suitable for the residues in processed plant commodities.

In the processed tomato commodities the isopropylphenylurea degradate was always present at levels lower than the parent. This was not the case in the processing study provided on grapes, where isopropylphenylurea was found at levels higher than the parent in white wine and grape juice. Since the level of isopropylphenylurea might be indicative for increased levels of thiobiuret, the Meeting considers additional quantitative data on thiobiuret in other processed commodities desirable.

Two processing studies were undertaken in which field treated oranges were processed into juice and wet or dry pomace. Calculated processing factors for buprofezin parent were 0.56, 0.58 for orange juice, 1.5 and 2.0 for wet pomace and 4.5 and 6.0 for dry pomace.

Fifteen processing studies were undertaken in which field treated grapes were processed into juice, white wine, red wine and raisins. Several processing studies were disregarded because residue levels in the raw agricultural commodity were near or below the LOQ and relevant processing factors could not be calculated. Calculated processing factors for buprofezin parent were 0.31 and 0.35 for grape juice, 0.51, 0.56, 0.69 and 0.78 for white wine, 0.52 for red wine, 1.0 and 1.7 for raisins.

Four processing studies were undertaken in which field or indoor treated tomatoes were processed into juice, canned tomatoes, puree, ketchup and wet/dry pomace. Calculated processing factors for buprofezin were 0.18, 0.2, 0.2, 0.21, 0.22, 0.22, 0.31, 0.42, 0.38, 0.75 for pasteurized tomato juice, 0.03, 0.09, 0.1, 0.11, 0.17, 0.19, 0.19, 0.2, 0.26, < 0.3 for canned whole tomatoes, 0.5, 0.71, 0.8, 0.81, 0.89, 0.9, 0.91, 0.95, 0.96, 1.0, 2.0 for tomato puree, 0.45, 0.47, 0.5, 0.5, 0.52, 0.67, 0.67, 0.69, 0.88, 1.2 for tomato ketchup, 2.3, 3.8, 4.1, 4.2, 5.2, 7.5 for wet tomato pomace, and 9.0, 15, 19, 20, 24, 40 for dry tomato pomace.

The Meeting considered the appropriate HR-P and STMR-P to be used in the livestock dietary burden calculation or dietary intake calculation. In the table below, relevant processing factors for citrus and tomatoes are summarized. The Meeting decided to extrapolate the processing factor for orange juice to citrus juice, to extrapolate the processing factor for canned tomatoes to peeled tomatoes and to extrapolate the processing factor for tomato puree to tomato paste.

Using the HR for tomatoes (0.52 mg/kg), the Meeting estimated HR-Ps for their processed commodities as listed below. Furthermore, using the STMRs for citrus whole fruit and tomatoes (0.23, 0.24 mg/kg, respectively), the Meeting estimated STMR-Ps for these commodities as listed below.

Codex Code	Commodity	Processing factors	Processing factor (median or best estimate)	STMR-P	HR-P
-	Citrus juice	0.56, 0.58	0.57	0.13	not applicable
AB0001-	Citrus pulp, dry	4.5, 6.0	5.25	1.2	not applicable
JF0448	Tomato juice	0.18, 0.2, 0.2, 0.21, 0.22, 0.22, 0.31, 0.42, 0.38, 0.75	0.22	0.053	not applicable
-	Tomato paste	0.5, 0.71, 0.8, 0.81, 0.89, 0.9, 0.91, 0.95, 0.96, 1.0, 2.0	0.9 [a]	0.22	not applicable

Codex Code	Commodity	Processing factors	Processing factor (median or best estimate)	STMR-P	HR-P
-	Tomato, peeled	0.03, 0.09, 0.1, 0.11, 0.17, 0.19, 0.19, 0.2, 0.26, < 0.3	0.17 [b]	0.041	0.088

[a] extrapolated from tomato puree

[b] extrapolated from canned tomatoes

The Meeting estimated an MRL of 2 mg/kg on a dry weight basis for Citrus pulp, dry.

Farm animal dietary burden

The Meeting estimated the dietary burden of buprofezin residues in farm animals from the diets listed in the Table of OECD Feedstuffs as published in Annex 6 of the 2006 JMPR Report[36]. Orange dry pomace was the only feedstuff identified as relevant to cattle. Poultry were not exposed to buprofezin through pesticide treated feed that was evaluated by the Meeting. A mean and maximum dietary burden of 0.40 ppm of dry matter diet was estimated for beef and dairy cattle in Australia as is shown in the table below.

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

	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
beef cattle	0.13	0.13	0.07	0.07	0.40 [a]	0.40 [a]
dairy cattle	0.13	0.13	0.26	0.26	0.40 [a]	0.40

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

Farm animal feeding studies

The Meeting received a feeding study on lactating cows. Four groups of three lactating Holstein cows were dosed twice daily via gelatin capsules at levels of 0.0–5.0–15–50 ppm dry weight feed for 28 consecutive days. Taking the average body weight of 544 kg, this dose was equivalent to 0.0–0.22–0.66–2.2 mg ai/kg bw/d. Milk was collected throughout the study on days 2, 4, 7, 10, 14, 17, 21, 24 and 28 and tissues were collected on day 29 within 24 h after the last dose.

Residues of up to 0.02 mg/kg buprofezin were found in milk and residues of up to 0.12 mg/kg buprofezin were found in beef fat from cows dosed at the highest level.

Animal commodity maximum residue levels

In a feeding study where lactating cows were dosed at 5.0 and 15 ppm dry feed, no parent buprofezin residues were detected in tissues and milk. Therefore, no residues are to be expected in tissues and milk at the mean and maximum calculated dietary burden of 0.40 ppm.

The Meeting estimated a maximum residue level for buprofezin of 0.01* mg/kg for milks and 0.05* mg/kg for meat from mammals other than marine mammals and mammalian edible offal. The Meeting estimated STMRs and HRs of 0 mg/kg in milk, muscle, and edible offal of mammals.

[36] identical to OECD, series on testing and assessment number 64, series on pesticides number 32, ENV/JM/MONO(2006)32

FURTHER WORK OR INFORMATION

None required.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for buprofezin was calculated from recommendations for STMRs for raw commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

The International Estimated Daily Intakes (IEDI) of in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 0–9% of the maximum ADI of 0.009 mg/kg bw. The Meeting concluded that the long-term intake of residues of buprofezin from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for buprofezin was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The residue value for citrus was entered separately for orange, lemon, mandarin, and grapefruit. The results are shown in Annex 4.

The International Estimated Short-term Intake (IESTI) varied from 0–1% of the ARfD (0.5 mg/kg bw) for the general population. The IESTI varied from 0–3% of the ARfD for children 6 years and below. The Meeting concluded that the short-term intake of residues of buprofezin from uses considered by the Meeting is unlikely to present a public health concern.

5.5 CARBOFURAN (096)

TOXICOLOGY

Carbofuran is the ISO approved common name for 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate, a broad spectrum *N*-methyl carbamate insecticide and nematicide that acts by inhibiting acetylcholinesterase activity in nervous tissues. Carbofuran was previously evaluated by the Joint Meeting in 1976, 1979, 1980, 1982, 1996, and 2002. In 1996, an ADI of 0–0.002 mg/kg bw was established based on the NOAEL for inhibition of erythrocyte acetylcholinesterase at 0.22 mg/kg bw per day in a 4-week dietary study in dogs, and using a safety factor of 100. In 2002, an ARfD of 0.009 mg/kg bw was established based on the NOAEL of 0.22 mg/kg bw per day in a 4-week study in dogs, and using a safety factor of 25, as the relevant toxic effects of carbofuran are dependent on the C_{max}.

The present Meeting evaluated newly submitted studies of acute toxicity in rats (adults and pups) and a newly submitted study in human volunteers (conducted in 1976), and re-examined relevant data from short-term studies of toxicity in dogs, which had been considered by previous Meetings. All pivotal studies were certified as complying with GLP or an approved quality assurance programme.

Toxicological data

Carbofuran is highly toxic after a single oral dose; the LD_{50} values in rats range from 6 to 18 mg/kg bw and in various other species (including mouse, guinea-pig, rabbit, cat and dog) from 3 to 19 mg/kg bw. The clinical signs of toxicity observed were typical of acetylcholinesterase inhibition. In rats, clinical signs were observed starting at about 5 min after administration, and mortality generally occurred within 1 h after dosing.

Two studies of the time course of inhibition of acetylcholinesterase activity were carried out in adult rats and pups aged 11 days (postnatal day 11). In the first study, after a single dose of 0.6 mg/kg bw of carbofuran, the time of maximum incidence and severity of clinical signs and of maximum inhibition of brain acetylcholinesterase was at 15 min after dosing for adults and pups. Recovery of brain acetylcholinesterase activity was achieved in adult males and females within 360 or 240 min after dosing, respectively, while the pups had not fully recovered by 360 min after dosing. In the second study, after a single dose of carbofuran at 0.1 mg/kg bw, no clinical signs were observed, and the time of maximum inhibition of brain acetylcholinesterase activity was at 30 min after dosing for adult rats and at 60 min after dosing for pups aged 11 days. Recovery of brain acetylcholinesterase activity was achieved in adults and in the pups within 240 min after dosing.

Two studies of acute toxicity were conducted to compare acetylcholinesterase inhibition in pups aged 11 days (postnatal day 11) and adult rats, and two range-finding studies of acute toxicity were carried out in rats aged 11 days given carbofuran at doses ranging from 0.03 to 1.0 mg/kg bw. In these studies, a spectrophotometric assay for cholinesterase activity was used. While data on erythrocyte acetylcholinesterase were considered to be unreliable because of unfavourable experimental conditions that led to significant spontaneous enzyme reactivation, the data on brain acetylcholinesterase were considered to be suitable for use in risk assessment because the degree of inhibition of acetylcholinesterase activity agreed with that obtained using the more reliable radiometric assay for cholinesterase activity (see below). Clinical signs (tremors) were observed at doses of 0.3 mg/kg bw and above. On the basis of inhibition of acetylcholinesterase activity in brain (pups, 35–47%; adults, 20–32%) at 0.1 mg/kg bw and above, the overall NOAEL for pups and adults was 0.03 mg/kg bw.

In two studies of acute toxicity designed to compare inhibition of acetylcholinesterase activity in pups (postnatal day 11 or postnatal day 17) and adult rats given carbofuran at doses

ranging from 0.1 to 1.5 mg/kg bw and using a radiometric assay for cholinesterase activity, the overall NOAEL for pups (both postnatal day 11 and postnatal day 17) was < 0.1 mg/kg bw on the basis of inhibition of acetylcholinesterase activity in brain (28–40%) and erythrocytes (50–53%) at 0.1 mg/kg bw and above. The overall NOAEL for adult rats was 0.1 mg/kg bw on the basis of inhibition of acetylcholinesterase activity in brain (28–33%) and erythrocytes (25–49%) at 0.3 mg/kg bw and above.

Using the data from three studies in rat pups aged 11 days, the estimated oral dose resulting in 10% inhibition of brain acetylcholinesterase activity (benchmark dose, BMD_{10}) was 0.04 mg/kg bw, while the lower 95% confidence limit for the BMD_{10} ($BMDL_{10}$) was 0.03 mg/kg bw.

In the latter two studies, inhibition of erythrocyte acetylcholinesterase activity appeared to be a more sensitive end-point than did inhibition of brain acetylcholinesterase activity. In the absence of data on inhibition of acetylcholinesterase activity in peripheral target tissues, the use of data on erythrocyte acetylcholinesterase activity might thus be considered as surrogate for data on the peripheral nervous system. However, given the quantitative dose–response correlation between clinical signs of cholinergic toxicity and inhibition of brain acetylcholinesterase activity by a range of *N*-methyl carbamates including carbofuran, the Meeting concluded that the current data support the use of inhibition of brain acetylcholinesterase activity rather than the surrogate measure of erythrocyte acetylcholinesterase activity as the end-point for the risk assessment of carbofuran.

In a 13-week dietary study in dogs, which was evaluated by the Joint Meeting in 1996 and 2002 and re-evaluated by the present Meeting, the LOAEL was 10 ppm, equal to 0.43 mg/kg bw per day. A NOAEL was not identified since significant inhibition of erythrocyte acetylcholinesterase activity and clinical signs were seen on the first day of dosing at the lowest dose. The data on brain acetylcholinesterase activity in this study were not reliable owing to significant recovery of acetylcholinesterase activity at the time-point of necropsy. In a supplementary 4-week study in male dogs, which was evaluated by the Joint Meeting in 1996 and re-evaluated by the present Meeting, brain acetylcholinesterase activity was not examined. The NOAEL for clinical signs and inhibition of erythrocyte acetylcholinesterase activity was 5 ppm in the diet, equal to 0.22 mg/kg bw per day, the highest dose tested. However, since a spectrophotometric assay for cholinesterase activity was used in both studies in dogs and it was not clear whether the experimental conditions were appropriate to minimize reactivation of the enzyme, the reliability of the data on erythrocyte acetylcholinesterase activity is questionable. The Meeting noted that, on the basis of the data on acute toxicity, dogs are not expected to be more sensitive than other species.

In a study in human volunteers, which met the ethical standards prevalent at the time when the research was conducted (1976), groups of two to four men received carbofuran as a single oral dose at 0.05, 0.1 or 0.25 mg/kg bw, while one man received placebo only. At 0.05 mg/kg bw, erythrocyte acetylcholinesterase activity was inhibited by 22% in one of two subjects; at 0.1 mg/kg bw, erythrocyte acetylcholinesterase activity was inhibited by 31–33% in both subjects; and erythrocyte acetylcholinesterase activity was inhibited by 46–63% and treatment-related clinical signs were seen in all four subjects at 0.25 mg/kg bw. Owing to the small sample size, the study could not be used for identification of a NOAEL or LOAEL, but provided information that was useful for the interspecies comparison of sensitivity for the risk assessment.

Toxicological evaluation

The Meeting established an ARfD of 0.001 mg/kg bw based on the overall NOAEL of 0.03 mg/kg bw per day identified on the basis of inhibition of brain acetylcholinesterase activity in rat pups aged 11 days (postnatal day 11) and a safety factor of 25. This NOAEL was supported by the $BMDL_{10}$ of 0.03 mg/kg bw extrapolated from data on inhibition of brain acetylcholinesterase activity in rat pups aged 11 days (postnatal day 11) in a second study. A safety factor of 25 was considered to be appropriate because the acute toxic effects of carbofuran are dependent on C_{max} rather than area under the curve of concentration–time (AUC) and data indicated that the sensitivity of humans and laboratory animals (rats, dogs) to inhibition of acetylcholinesterase activity by carbofuran was similar

(see general item: *Safety factors for acute C_{max}-dependent effects; specific considerations with respect to carbamates such as carbofuran*). Given the apparent higher sensitivity of younger animals, the ARfD was considered to be adequately protective of infants and children since it was based on the NOAEL from a study in pups aged 11 days.

The Meeting noted that this ARfD was lower than the current ADI of 0–0.002 mg/kg bw. This is plausible in view of the toxicological characteristics of inhibition of acetylcholinesterase activity by carbofuran, which shows very rapid recovery; long-term exposure can thus be likened to a series of acute exposures. The Meeting therefore concluded that the ADI and ARfD for carbofuran should be based on the same NOAEL and revised the ADI to 0–0.001 mg/kg bw based on the overall NOAEL of 0.03 mg/kg bw from the new studies of acute toxicity in rats and using a safety factor of 25.

An addendum to the toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Rat	Acute study of toxicity (pups aged 11 days and adults) [a, b]	Inhibition of pup brain acetylcholinesterase activity	0.03 mg/kg bw [c]	0.1 mg/kg bw
		Clinical signs	0.1 mg/kg bw	0.3 mg/kg bw

[a] Gavage administration.

[b] Results of several studies combined.

[c] Supported by a $BMDL_{10}$ of 0.03 mg/kg bw, based on inhibition of brain acetylcholinesterase activity in pups aged 11 days (postnatal day 11).

Estimate of acceptable daily intake for humans

0–0.001 mg/kg bw

Estimate of acute reference dose

0.001 mg/kg bw

Information that would be useful for continued evaluation of the compound

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

Summary

	Value	*Study*	*Safety factor*
ADI	0–0.001 mg/kg bw	Rat, study of acute toxicity	25
ARfD	0.001 mg/kg bw	Rat, study of acute toxicity	25

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for carbofuran is 0–0.001 mg/kg bw. The International Estimated Daily Intakes (IEDI) for carbofuran was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by previous Meetings. The results are shown in Annex 3. The IEDI ranged from 20–70% of the maximum ADI. The Meeting 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.

Short-term intake

The ARfD for carbofuran is 0.001 mg/kg bw. The International Estimated Short-term Intake (IESTI) was calculated for 22 commodities for which STMRs, HRs had been estimated by previous Meetings and for which consumption data was available. The results are shown in Annex 4.

For the general population, the IESTI was higher than the ARfD for banana, cucumber, cantaloupe, milks, orange, potato, summer squash and sweet corn on the cob (from 120 to 510% ARfD). For children, the IESTI was higher than the ARfD also for mandarins (from 280 to 810% ARfD). The information provided to the JMPR precludes an estimate that the short-term intake of residues of carbofuran from the consumption of the above listed commodities will be below the ARfD.

The short-term intake of residues of carbofuran from other uses considered by the JMPR is unlikely to present a public health concern.

5.6 CHLORANTRANILIPROLE (230)

TOXICOLOGY

Chlorantraniliprole is the ISO approved common name for 3-bromo-*N*-[4-chloro-2-methyl-6-(methylcarbamoyl)phenyl]-1-(3-chloropyridin-2-yl)-1*H*-pyrazole-5-carboxamide). Chlorantraniliprole (CAS No. 500008-45-7) is an insecticide that operates by a highly specific biochemical mode of action. It binds and activates ryanodine receptors, resulting in depletion of intracellular calcium stores and leading to muscle paralysis and death. Comparative studies have demonstrated that differential selectivity of chlorantraniliprole for insect receptors is more than 350-fold that for mammalian receptors.

Chlorantraniliprole is being evaluated for the first time by the present Meeting at the request of CCPR. The present JMPR review was based on a global assessment of the substance, which was performed in 2007 by 10 countries under the auspices of the Organization for Economic Co-operation and Development (OECD).

All critical studies complied with GLP.

Biochemical aspects

After oral administration, the extent of absorption of chlorantraniliprole is dependent on the dose administered. At a single dose of 10 mg/kg bw, absorption was about 73–85%, with 18–30% being excreted in the urine and 49–53% being excreted in the bile within 48 h. At a single dose of 200 mg/kg bw, absorption was about 14%, with 4% and 5–7% of the dose excreted in the urine and bile, respectively, within 48 h. Excretion in expired air was insignificant. Plasma half-lives were 38–43 h in males and 78–82 h in females. After multiple doses (10 mg/kg bw per day for 14 days) with chlorantraniliprole, peak plasma concentrations in males and females were about two and seven times higher than after a single dose at 10 mg/kg bw, respectively. Distribution in tissues was extensive, with 0.8% and 3% remaining in the tissues of males and females, respectively, 168 h after a single dose at 10 mg/kg bw.

Chlorantraniliprole is extensively metabolized through tolyl methyl and *N*-methyl carbon hydroxylation, followed by *N*-demethylation, nitrogen-to-carbon cyclization with loss of a water molecule resulting in the formation of the pyrimidone ring, oxidation of alcohols to carboxylic acids, amide-bridge cleavage, amine hydrolysis, and *O*-glucuronidation. The potential for hydroxylation of the tolyl methyl and *N*-methyl carbon groups was greater in males than in females. After a single dose at 200 mg/kg bw, excretion of the parent compound in the urine and faeces (78.9–85.5%) was 12 to16-fold that at 10 mg/kg bw (4.9–7.3%). The profile of metabolites after a single dose at 200 mg/kg bw or after repeated doses at 10 mg/kg bw per day was similar to the profile after a single dose at 10 mg/kg bw.

Toxicological data

The acute toxicity of chlorantraniliprole is low (oral and dermal LD_{50}, > 5000 mg/kg bw; inhalation LC_{50}, > 5.1 mg/L). Apart from ocular and nasal discharge observed in a study in which chlorantraniliprole was administered by inhalation, no clinical signs of toxicity were observed in studies of acute toxicity. Chlorantraniliprole is not irritating to the skin and eyes, and is not a skin sensitizer (Magnussen & Kligman test in guinea-pigs; local lymph node assay in mice).

Chlorantraniliprole shows low toxicity after repeated doses. Occasionally, reductions in body-weight gain were observed in studies with repeated doses. However, these reductions often did not occur on consecutive weeks but were seen sporadically, were not dose-related and were not

consistently found in different studies at similar or higher doses. Therefore, the incidental changes in body-weight gain were not considered to be a compound-related effect.

In short-term studies with chlorantraniliprole administered orally (gavage or diet), no adverse effects were observed at any dose tested, i.e., up to 7000 ppm, equal to 1443 mg/kg bw per day, in feeding studies in mice, up to 20 000 ppm, equal to 1188 mg/kg bw per day, in a feeding study in rats, and up to 40 000 ppm, equal to 1164 mg/kg bw per day, in a 1-year feeding study in dogs.

In an 18-month feeding study in mice, the NOAEL was 1200 ppm, equal to 158 mg/kg bw per day, on the basis of presence of eosinophilic foci in the liver, accompanied by hepatocellular hypertrophy and increased liver weight at 7000 ppm, equal to 935 mg/kg bw per day, in males only. No information on the chemical-specific mechanism of action was available to evaluate the relevance of liver foci to exposure of humans. However, the Meeting noted that this is a possible species- and sex-specific response that is of questionable toxicological significance and relevance, and thus the NOAEL of 158 mg/kg bw per day on the basis of these end-points is likely to be conservative.

In a 2-year feeding study in rats, the NOAEL was 20 000 ppm, equal to 805 mg/kg bw per day, the highest dose tested.

No treatment-related changes in the incidence of tumours were observed.

The Meeting concluded that chlorantraniliprole is not carcinogenic in rodents.

Chlorantraniliprole was tested for genotoxicity in adequate range of studies of genotoxicity in vitro and in vivo. No evidence for genotoxicity was observed in any test. The Meeting concluded that chlorantraniliprole 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 chlorantraniliprole is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity with chlorantraniliprole in rats, the NOAEL for parental, offspring and reproductive toxicity was 20 000 ppm, equal to 1199 mg/kg bw per day, the highest dose tested.

In a study of developmental toxicity in rats, the NOAEL for maternal and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested. In a study of developmental toxicity in rabbits, the NOAEL for maternal and fetal toxicity was 1000 mg/kg bw per day, the highest dose tested.

In a study of acute neurotoxicity in rats given chlorantraniliprole orally by gavage, the NOAEL was 2000 mg/kg bw per day, i.e., the highest dose tested. In a 90-day dietary study of neurotoxicity in rats, the NOAEL was 20 000 ppm, equal to 1313 mg/kg bw per day, the highest dose tested.

In a dietary study of immunotoxicity in mice, the NOAEL was 7000 ppm, equal to 1144 mg/kg bw per day, the highest dose tested. In a dietary study of immunotoxicity in rats, the NOAEL was 20 000 ppm, equal to 1494 mg/kg bw per day, the highest dose tested.

To date, chlorantraniliprole has only been produced on a pilot scale. In the limited number of workers involved with the synthesis of this compound to date, no illnesses have been attributed to exposure associated with the handling, testing, or manufacturing of chlorantraniliprole.

The rat metabolite 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-3,8-dimethyl-4(3*H*)-quinazolinone (IN-EQW78) was also a significant metabolite in soil, water, and sediment. The substances 2,6-dichloro-4-methyl-11*H*-pyrido[2,1-*b*]quinazolin-11-one (IN-ECD73) and 3-bromo-*N*-methyl-1*H*-pyrazole-5-carboxamide (IN-F6L99) were metabolites only observed at low concentrations in soil and as degradates in studies of high-temperature food processing. In studies of acute toxicity, these three chlorantraniliprole metabolites had LD_{50}s of > 2000 mg/kg bw. These metabolites gave negative results in a test for reverse mutation.

The Meeting concluded that the existing database on chlorantraniliprole is sufficient to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI for chlorantraniliprole of 0–2 mg/kg bw on the basis of eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight in mice in an 18-month feeding study for which the NOAEL was 158 mg/kg bw per day, and using a safety factor of 100. There was no available information on the chemical-specific mechanism of action with which to evaluate the relevance of the liver foci to exposure of humans. The Meeting noted, however, that this is a possible species- and sex-specific response that is of questionable toxicological significance and relevance, and thus the NOAEL of 158 mg/kg bw per day (and consequently the ADI) identified on the basis of these end-points is likely to be conservative.

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

A toxicological monograph was prepared.

Levels relevant for risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month study of toxicity and carcinogenicity[a]	Toxicity	1200 ppm, equal to 158 mg/kg bw per day	7000 ppm, equal to 935 mg/kg bw per day
		Carcinogenicity	7000 ppm, equal to 935 mg/kg bw per day[c]	—[c]
Rat	2-year study of toxicity and carcinogenicity[a]	Toxicity	20 000 ppm, equal to 805 mg/kg bw per day	—[c]
		Carcinogenicity	20 000 ppm, equal to 805 mg/kg bw per day[c]	—[c]
	Two-generation study of reproductive toxicity[a]	Parental	20 000 ppm, equal to 1199 mg/kg bw per day	—[c]
		Offspring toxicity	20 000 ppm, equal to 1199 mg/kg bw per day	—[c]
		Reproductive toxicity	20 000 ppm, equal to 1199 mg/kg bw per day	—[c]
	Developmental toxicity[b]	Maternal toxicity	1000 mg/kg bw per day	—[c]
		Foetotoxicity	1000 mg/kg bw per day	—[c]
	Acute neurotoxicity[b]	Neurotoxicity	2000 mg/kg bw per day	—[c]
	90-day neurotoxicity[a]	Neurotoxicity	20 000 ppm, equal to 1313 mg/kg bw per day	—[c]
Rabbit	Developmental toxicity[b]	Maternal toxicity	1000 mg/kg bw per day	—[c]
		Foetotoxicity	1000 mg/kg bw per day	—[c]
Dog	1-year study[a]	Toxicity	40 000 ppm, equal to 1164 mg/kg bw per day	—[c]

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

0–2 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 exposures

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of absorption	Rapid, incomplete and dose-dependent oral absorption (73–85% at 10 mg/kg bw; 14% at 200 mg/kg bw).
Distribution	Extensive (rats)
Potential for accumulation	Low in males, moderate in females (rats)
Rate and extent of excretion	Plasma half-lives: males, 38–43 h; females, 78–82 h
	At 10 mg/kg bw: 18–30% in urine, 49–53% in bile, within 48 h.
	At 200 mg/kg bw: 4% in the urine, 5–7% in bile, within 48 h.
Metabolism in animals	Extensive, through tolyl methyl and *N*-methyl carbon hydroxylation, followed by *N*-demethylation, nitrogen-to-carbon cyclization, formation of a pyrimidone ring, oxidation of alcohols to carboxylic acids, amide-bridge cleavage, amine hydrolysis, and *O*-glucuronidation.
Toxicologically significant compounds (animals, plants and environment)	Chlorantraniliprole
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.1 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Dermal sensitization	Not sensitizing (Magnussen & Kligman test in guinea-pigs; local lymph node assay in mice)
Short-term studies of toxicity	
Target/critical effect	None
Lowest relevant oral NOAEL	1443 mg/kg bw per day (mice), 1188 mg/kg bw per day (rats), 1164 mg/kg bw per day (dogs); highest doses tested
Lowest relevant dermal NOAEL	1000 mg/kg bw per day. i.e., highest dose tested (rat)

Lowest relevant inhalatory NOAEC	No data available
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver: eosinophilic foci, hepatocellular hypertrophy, increased liver weight (mice)
Lowest relevant NOAEL	1200 ppm, equal to 158 mg/kg bw per day (mice)
Carcinogenicity	Not carcinogenic (mice, rats)
Genotoxicity	
	Not genotoxic in vitro or in vivo
Reproductive toxicity	
Reproduction target/critical effect	No reproductive effects (rats)
Lowest relevant reproductive NOAEL	20 000 ppm, equal to 1199 mg/kg bw per day, i.e., highest dose tested (rats)
Developmental target	No developmental effects (rats, rabbits)
Lowest relevant developmental NOAEL	1000 mg/kg bw per day i.e., highest dose tested (rats, rabbits)
Neurotoxicity/delayed neurotoxicity	
Neurotoxicity	No neurotoxic effects
Lowest relevant oral NOAEL	2000 mg/kg bw, i.e., highest dose tested (acute toxicity in rats treated by gavage)
	1313 mg/kg bw per day i.e., highest dose tested (90-day dietary study in rats)
Other toxicological studies	
Immunotoxicity	Not immunotoxic
Lowest relevant oral NOAEL	7000 ppm, equal to 1144 mg/kg bw per day, i.e., highest dose tested (28-day study in mice)
	20 000 ppm, equal to 1494 mg/kg bw per day i.e., highest dose tested (28-day study in rats)
Medical data	
	No adverse effects observed in workers involved with the synthesis of this compound

Summary

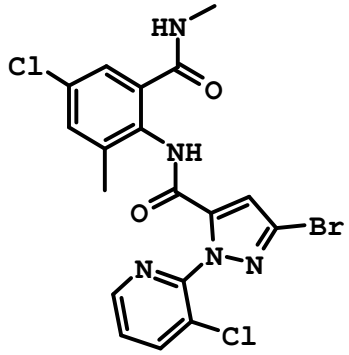
	Value	*Study*	*Safety factor*
ADI	0–2 mg/kg bw	Mouse, 18-month study	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

Chlorantraniliprole was considered for the first time by the present Meeting. The Meeting received information on chlorantraniliprole metabolism and environmental fate, methods of residue analysis, freezer storage stability, national registered use patterns, supervised residue trials, farm animal feeding studies and fate of residues in processing.

The 2008 JMPR established an ADI and ARfD for chlorantraniliprole of 0-2 mg/kg bw/day and not required respectively.

Chlorantraniliprole is 3-bromo-*N*-[4-chloro-2-methyl-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide.



The following abbreviations are used for the metabolites discussed below:

IN-DBC80	3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxylic acid
IN-EQW78	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-3, 8-dimethyl-4(3*H*)-quinazolinone
IN-ECD73	2,6-dichloro-4-methyl-11*H*-pyrido[2,1-b]quinazolin-11-one
IN-F9N04	*N*-[2-(Aminocarbonyl)-4-chloro-6-methylphenyl]-3-bromo-1-(3-chloro-2-pyridinyl)1*H*-pyrazole-5-carboxamide
IN-F6L99	5-Bromo-*N*-methyl-1*H*-pyrazole-3-carboxamide
IN-GAZ70	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-methyl-4(3*H*)-quinazolinone
IN-H2H20	3-Bromo-*N*-[4-chloro-2-[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide
IN-HXH44	3-Bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide
IN-L8F56	2-Amino-5-chloro-3-[(methylamino)carbonyl]benzoic acid
IN-LEM10	2-[5-Bromo-2-(3-chloro-pyridin-2-yl)-2*H* pyrazol-3-yl]-6-chloro-3,4-dihydro-3-methyl-4-oxo-8-quinazolinecarboxylic acid
IN-K9T00	3-Bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[[(hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-

	pyrazole-5-carboxamide
IN-K3X21	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-(hydroxymethyl)-3-methyl-4(3*H*)-quinazolinone
IN-K7H29	2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]-6-chloro-8-(hydroxymethyl)-4(3*H*)-quinazolinone
IN-KAA24	2-[[[3-Bromo-1-(3-chloro-2-pyridinyl)-1*H*-pyrazol-5-yl]carbonyl]amino]-5-chloro-3-[(methylamino)carbonyl]benzoic acid

Animal metabolism

Radiolabelled chlorantraniliprole (separately [^{14}C]labelled at the benzamide-carbonyl and pyrazole-carbonyl positions) was used in the metabolism and environmental studies. The metabolism of laboratory animals was qualitatively the same as for farm animals though some species related differences were noted. The proposed major route of chlorantraniliprole metabolism in livestock is via (i) hydroxylation of the N-methyl group (to IN-H2H20) or hydroxylation of the tolyl methyl group (to IN-HXH44); (ii) cyclization with loss of water to a quinazolinone derivative (IN-EQW78); and (iii) N-demethylation via IN-H2H20 to IN-F9N04.

Lactating goats were orally dosed with a 1:1 mixture of [benzamide carbonyl-^{14}C] and [pyrazole carbonyl-^{14}C]chlorantraniliprole at 0.36 mg/kg bw for 7 consecutive days equivalent to 10 ppm in the feed.

The majority of the administered dose was recovered in excreta (79% in faeces, 11% in urine) with an additional 3.9% recovered from the cage wash. Radioactivity retained in tissues, bile or secreted in milk accounted for approximately 1.3% of the administered dose. Overall 95% of administered radioactivity was accounted for.

Radiocarbon content in various tissues were highest in liver (0.64 mg/kg) followed by kidney (0.076 mg/kg), fat (0.07 mg/kg) and muscle (0.016 mg/kg) while in milk residues were 0.067 mg/kg for a composite sample from 1 through 7 days of the study. Chlorantraniliprole was the major component of the extracted radioactivity identified in kidney (19%), muscle (41%), and fat (35–75%) samples and was also present in liver (4%) where IN-L8F56 was the major component (7.5%). In milk chlorantraniliprole (24% TRR), IN-K9T00 (26% TRR) and IN-HXH44 (27% TRR) were the major components identified.

Laying hens were orally dosed with a 1:1 mixture of [benzamide carbonyl-^{14}C] and [pyrazole carbonyl-^{14}C]chlorantraniliprole at 0.8 mg/kg bw/day for 14 days. The majority of the administered radioactivity was excreted (98% over the 14 day dosing period), with 5% recovered from cage wash and approximately 3% in eggs (white and yolks). In tissues, the highest concentrations of radioactivity were in liver (0.52 mg/kg), followed by fat (0.052 mg/kg) and muscle (0.022 mg/kg). Chlorantraniliprole (25–30%) and IN-GAZ70 (29–37%) were the major components of the radioactivity in eggs with a large number of metabolites individually present at < 10% TRR, principally IN-K7H29, IN-H2H20, IN-EQW78 and IN-F9N04. In liver and muscle, no single component (unchanged parent compound or metabolite) was present at levels > 10% TRR with chlorantraniliprole present at only 2.2–3.7% TRR. Chlorantraniliprole formed the major component of the residue in skin with fat at 18% TRR. No other metabolite exceeded 9% TRR in skin and fat.

Plant metabolism

The Meeting received information on the fate of [^{14}C]chlorantraniliprole after foliar application to apple, tomato, lettuce and cotton and as a soil drench to rice.

Metabolism studies in apples, tomato, lettuce and cotton demonstrated that following foliar application, chlorantraniliprole was not metabolized to any great extent. With up to three consecutive foliar applications of chlorantraniliprole to apples (3×100 g ai/ha), tomatoes (3×100 g ai/ha) and lettuce (3×100 g ai/ha), and following a single application to cotton (1×150 g ai/ha), parent compound was the major component of the radioactive residues at 85%, 92%, 89% and 57% of the TRR respectively for apples, tomatoes, lettuce and cotton seed. When applied as a soil drench to rice crops (1×300 g ai/ha), the metabolism was complex due to uptake of degradates in water through the roots. Parent compound was the major component of the TRR in grain at harvest (51% TRR). For straw, numerous metabolites were identified in addition to parent compound. IN-GAZ70 (0.049 mg/kg) and IN-EQW78 (0.039 mg/kg) were two major metabolites in the rice straw but were present at less than 7% of the TRR. Minor metabolites (< 0.035 mg/kg) identified in rice straw included IN-KAA24, IN HXH40, IN H2H20, IN-HXH44, and IN-F6L99.

Environmental fate

Hydrolysis in water is pH dependent. Chlorantraniliprole is considered stable at pH 4 and 7 but is hydrolysed at pH 9 with a half-life of < 10 days. At pH 9, chlorantraniliprole undergoes cyclization followed by irreversible dehydration to form IN-EQW78. Abiotic hydrolysis is unlikely to contribute significantly to the degradation of chlorantraniliprole residues in aquatic systems unless the pH is high.

The aerobic degradation of chlorantraniliprole in soil is primarily by abiotic cyclization followed by dehydration to form IN-EQW78, with subsequent demethylation forming IN-GAZ70. Alternative pathways include abiotic rearrangement followed by cleavage to form IN-F6L99 and IN-ECD73. Ultimately mineralisation to $^{14}CO_2$ occurs. The half-life for degradation of chlorantraniliprole in soil is estimated to be >100 days and sometimes > 1000 days. The degradation is sometimes limited by sequestration (or aging) of the compound in soil. The sequestration of chlorantraniliprole in soil makes the compound more difficult to extract and protects the compound from degradation, while limiting mobility. Chlorantraniliprole is considered to be persistent.

The log Kow of chlorantraniliprole (log Kow 2.86, pH 7) and the results of the rice metabolism study suggests chlorantraniliprole may be translocated in plants. In confined and field rotational crop studies, residues of chlorantraniliprole were found in leafy vegetables, root vegetables and cereal grain. Residues of chlorantraniliprole and metabolites were also detected in forage and fodder. It is concluded that rotational crops may contain significant residues of chlorantraniliprole.

Methods of Analysis

Several different analytical methods have been reported for the analysis of chlorantraniliprole and selected metabolites/degradates in plant material (IN-EQW78, IN-ECD73, IN-F6L99) and animal commodities (IN-K9T00, IN-HXH44, IN-GAZ70, IN-EQW78). The basic approach employs extraction by homogenisation with acetonitrile:water, and column clean-up using SPE (hydrophilic-lipophilic balanced polymer and strong anion exchange in sequence). Residues are determined by gas chromatography with an electron capture detector or liquid chromatography with mass spectra detection.

The analytical methods for chlorantraniliprole and selected metabolites have been extensively validated with numerous recoveries on a wide range of substrates with LOQs of 0.01 mg/kg for each analyte.

German official multi-residue method (DFG-S19) with LC-MS/MS detection was validated for chlorantraniliprole in plant and chlorantraniliprole, IN-K9T00, IN-HXH44, IN-GAZ70 and IN-EQW78 in animal commodities. LOQs were 0.01 mg/kg for each analyte.

Stability of pesticide residues in stored analytical samples

Freezer storage stability was tested for a range of representative substrates. Residues of chlorantraniliprole were stable in fortified sample crops and their processed products for the duration of the studies. Chlorantraniliprole was stable in homogenized samples stored frozen for at least 24 months for apple, grape, tomato, lettuce, cauliflower, potato, wheat grain, wheat straw, alfalfa hay and cotton seed. Chlorantraniliprole and metabolites (IN-EQW78, IN-ECDW73 and IN-F6L99) were stable for at least 12 months, the period of frozen storage studied for the processed commodities tomato ketchup, raisin, cotton seed meal, cotton seed oil, and apple juice. Residues of chlorantraniliprole and the metabolites IN-K9T00, IN-HXH44, IN-GAZ70 and IN-EQW78 were stable in bovine liver, kidney, muscle, fat and milk stored frozen for at least 12 months.

Residue definition

The residue following use of chlorantraniliprole on crops following foliar application is predominantly chlorantraniliprole. Similarly, chlorantraniliprole is the major component of the residue in rotational crops.

In the lactating goat metabolism study, chlorantraniliprole is the major component of the residue in edible tissues while in milk IN-HXH44 and IN-K9T00, and in eggs from the laying hen study IN-GAZ70, were present at slightly higher levels than chlorantraniliprole. Residues of chlorantraniliprole and metabolites decline rapidly on removal of exposure sources. None of the metabolites were identified by the 2008 JMPR as being of toxicological concern. Chlorantraniliprole and metabolites are considered to have low toxicity. At low doses the metabolites IN-HXH44 and IN-K9T00 are detected in milk in the absence of parent compound in the lactating dairy cow feeding study.

The Meeting recommended that the residue definition for plant and animal commodities, for compliance with MRLs and for estimation of dietary intake should be chlorantraniliprole.

The log Kow of chlorantraniliprole (log Kow 2.86, pH 7) suggests that chlorantraniliprole might be borderline fat soluble. The ratio of chlorantraniliprole residues in muscle and fat observed in the livestock metabolism and feeding studies (lactating goat: 1:3.7–1:7.8; lactating cow 1:4.7, laying hen 1:12) and ratio of residues in whole milk to cream (1:5.4) support the conclusion that chlorantraniliprole is fat soluble.

The Meeting recommended that chlorantraniliprole be described as fat-soluble

Proposed definition of the residue (for compliance with MRL and for estimation of dietary intake): *chlorantraniliprole*.

The residue is fat-soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of chlorantraniliprole on numerous crops: apples, pears, apricots, peaches, nectarines, plums, cherries, grapes, strawberries, Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower and Chinese cabbage), peppers, tomatoes, lettuce, spinach, mustard greens, celery, potatoes, cotton, almonds and pecans.

Residue trial data was made available from Argentina, Australia, New Zealand, Canada, member states of the European Union and the USA. As information on GAP of Australia, New Zealand and members states of the European Union were not supplied, trials from these countries were not considered in estimating maximum residue levels, however, the results are summarized in the 2008 JMPR Monograph.

Apples and pears

Data were available from supervised trials on apples in several countries including Argentina, Canada and the USA for which GAP information was available.

In Argentina chlorantraniliprole is permitted to be used on apples with a maximum of two foliar sprays at a spray concentration of 4 g ai/hL and a PHI of 14 days. Three trials complied with the GAP of Argentina with residues of < 0.06, 0.12 and 0.19 mg/kg.

The GAPs of Canada and the USA are similar and the GAP of the USA was used to evaluate trials on pome fruit from the two countries (USA GAP: 111 g ai/ha, PHI 14 days with a maximum seasonal application of 224 g ai/ha).

Residues of chlorantraniliprole in apples from 16 trials in Canada and the USA complying with GAP of the USA were: 0.010, 0.012, 0.022, 0.030, 0.038, 0.045, 0.056, 0.061, 0.072, 0.073, 0.078, 0.088, 0.088 and 0.093, 0.11 and 0.23 mg/kg.

Nine of eleven trials on pears from Canada and the USA complying with GAP of the USA had residues of chlorantraniliprole of: 0.016, 0.026, 0.033, 0.059, 0.070, 0.085, 0.10, 0.12 and 0.13 mg/kg.

The Meeting noted that the use patterns for apple and pears in the USA were the same and that the residues populations for each crop could be used to support the other. The Meeting decided to combine the data for apples and pears to increase the database for the purposes of estimating a maximum residue level, STMR and HR and to make a recommendation for pome fruit.

Residues in rank order (n = 25), median underlined, were: 0.010, 0.012, 0.016, 0.022, 0.026, 0.030, 0.033, 0.038, 0.045, 0.056, 0.059, 0.061, 0.070, 0.072, 0.073, 0.078, 0.085, 0.088, 0.088, 0.093, 0.10, 0.11, 0.12, 0.13 and 0.23 mg/kg.

The Meeting estimated maximum residue level and STMR values for chlorantraniliprole in pome fruit of 0.4 and 0.07 mg/kg respectively.

Stone fruit

Data were available from supervised trials on stone fruit in Argentina, Australia, member states of the European Union, Canada and the USA. GAP information was only available for Argentina, Canada and the USA.

In Argentina chlorantraniliprole is permitted to be used on peaches with a maximum of two foliar sprays at a spray concentration of 5 g ai/hL and a PHI of 7 days. No trials complied with GAP of Argentina.

The GAPs of Canada and the USA are similar and the GAP of the USA was used to evaluate trials on stone fruit from the two countries (USA GAP: 111 g ai/ha, PHI 10 days with a maximum seasonal application of 224 g ai/ha). The USA GAP advises against the use of adjuvants when spraying cherries. As GAP of Canada does not advise against the use of adjuvants for cherries, where trials were conducted at the same location with and without adjuvants, the value from the trial plot with the highest residue was selected for estimating maximum residue levels. As there were no restrictions for other stone fruit, data were also selected from the plot at a trial location with the highest residue that complied with GAP.

Residues of chlorantraniliprole in cherries from eight trials in Canada and the USA complying with GAP of the USA were: 0.056, 0.11, 0.18, 0.19, 0.21, 0.26, 0.45 and 0.57 mg/kg.

Residues of chlorantraniliprole in peaches from 17 trials in Canada and the USA complying with GAP of the USA were: 0.072, 0.090, 0.092, 0.10, 0.10, 0.11, 0.12, 0.12, 0.13, 0.13, 0.14, 0.14, 0.16, 0.18, 0.25, 0.26 and 0.31 mg/kg.

Eleven trials on plums from Canada and the USA complied with GAP of the USA with residues of: < 0.01 (4), 0.011, 0.015, 0.026, 0.029, 0.066, 0.067 and 0.076 mg/kg. The STMR for plums is 0.015 mg/kg.

The use pattern in the USA is for stone fruit and the residues populations for each crop could be used to support a crop group recommendation. The Meeting decided to use the data on the crop with the highest residues, cherries, in estimating a maximum residue level and STMR for stone fruit.

The Meeting estimated maximum residue level and, STMR values for chlorantraniliprole in stone fruit of 1 and 0.20 mg/kg respectively.

Grapes

Data were available from supervised trials on grapes in Australia, member states of the European Union, Canada and the USA. GAP information was only available for Canada and the USA.

The GAPs of Canada and the USA are similar. The GAP of Canada was used to evaluate trials on grapes from the two countries (Canada GAP: 111 g ai/ha, PHI 14 days with a maximum seasonal application of 224 g ai/ha) as GAP of Canada does not advise against the use of adjuvants for grapes. The Meeting noted that the residue populations corresponding to treatments with and without adjuvants were from similar populations and where they were from the same location should be treated as replicates with the value from the trial plot with the highest residue selected for estimating maximum residue levels.

Residues of chlorantraniliprole in grapes from 17 trials in Canada and the USA, complying with GAP of the USA, were (in rank order, median underlined): 0.015, 0.042, 0.044, 0.044, 0.083, 0.091, 0.093, 0.11, 0.119, 0.18, 0.20, 0.26, 0.32, 0.34, 0.46, 0.48 and 0.52 mg/kg.

The Meeting estimated maximum residue level and STMR values for chlorantraniliprole in grapes of 1 and 0.119 mg/kg respectively.

Brassica vegetables

Chlorantraniliprole is registered in the USA for use on Brassica vegetables at 73 g ai/ha, PHI of 3 days and a maximum application per season of 224 g ai/ha. Trials were available from Canada and the USA in which crops were treated twice at three day intervals at 112 g ai/ha with harvest 3 days after the last spray. The trials did not comply with GAP of Canada and the USA and could not be used to estimate a maximum residue level.

Fruiting vegetables, Cucurbits

Trials on cucurbits were reported from Canada and the USA (USA GAP: 100 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues on cucumbers in seven trials from the USA matching GAP in rank order were: < 0.01, 0.011, 0.012, 0.015, 0.017, 0.076 and 0.076 mg/kg.

Residues on melons (cantaloupe, muskmelon) in seven trials from the USA matching GAP in rank order were: 0.010, 0.027, 0.052, 0.065, 0.081, 0.090 and 0.10 mg/kg. Data on residues in the edible portion for melons in trials complying with USA GAP were not available.

Chlorantraniliprole residues on summer squash (including zucchini) in six trials from the USA matching GAP, in rank order were: 0.017, 0.023, 0.040, 0.054, 0.076 and 0.081 mg/kg.

The use-pattern in the USA is for fruiting vegetables, cucurbits and the Meeting decided to use the data on the crop with the highest residues (melons) to estimate a maximum residue level for the group.

The Meeting estimated a maximum residue level and an STMR value for chlorantraniliprole in fruiting vegetables, cucurbits of 0.3 and 0.065 mg/kg respectively.

Fruiting vegetables, other than Cucurbits

Trials on tomatoes were reported from Canada and the USA (USA GAP: 110 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in twenty trials from the USA matching GAP in rank order (median underlined) were: 0.018, 0.032, 0.032, 0.040, 0.040, 0.044, 0.051, 0.059, 0.061, 0.070, 0.071, 0.082, 0.092, 0.095, 0.10, 0.11, 0.14, 0.14, 0.14 and 0.18 mg/kg.

Trials on peppers were reported from the USA (GAP: 110 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in eleven trials on peppers (Bell) from the USA matching GAP in rank order (median underlined) were: 0.013, 0.019, 0.022, 0.024, 0.069, 0.090, 0.11, 0.11, 0.13, 0.14 and 0.18 mg/kg.

Chlorantraniliprole residues in chilli peppers in nine trials from the USA matching GAP in rank order were (median underlined): 0.019, 0.035, 0.059, 0.063, 0.066, 0.069, 0.13, 0.21 and 0.41 mg/kg.

The Meeting decided that the trials in tomatoes, sweet and chilli peppers could be used to support a crop group maximum residue level for fruiting vegetables, other than Cucurbits except mushrooms and sweet corn. The Meeting decided to use the data on the crop with the highest residues (chilli peppers) to estimate a maximum residue level for the group.

The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in fruiting vegetables other than cucurbits (except mushrooms and sweet corn) of 0.6 and 0.066 mg/kg respectively.

Leafy vegetables

Trials on lettuce, spinach and mustard greens were reported from Canada and the USA (GAP: 110 g ai/ha, PHI of 1 day and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in fourteen trials on lettuce from Canada and the USA matching GAP in rank order were: < 0.01, 0.012, 0.43, 0.55, 1.3, 2.2, 2.4, 3.2, 3.9, 3.9, 4.0, 4.5, 5.3 and 6.2 mg/kg.

Chlorantraniliprole residues in seven trials on spinach from Canada and the USA matching GAP in rank order were: 3.4, 5.6, 6.8, 7.3, 7.4, 8.6 and 8.9 mg/kg.

Mustard greens are classified as a brassica vegetable in the US crop classification system and as a leafy vegetable according to the Codex classification. In considering trials on mustard greens and as explained for Brassica vegetables, the Meeting considered the trials did not comply with GAP of the USA.

The Meeting noted that the registered use of chlorantraniliprole in the USA is for leafy vegetables and decided to recommend a group MRL. The Meeting decided to use the data on the crop with the highest residues (spinach) to estimate a maximum residue level for the group. The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in leafy vegetables of 20 and 7.3 mg/kg respectively.

Celery

Chlorantraniliprole residues in seven trials on celery from Canada and the USA matching GAP (same as for leafy vegetables) in rank order were (median underlined): 0.99, 1.4, 2.1, 2.1, 2.6, 3.6 and

3.6 mg/kg. The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in celery of 7 and 2.1 mg/kg respectively.

Potatoes

Trials on potatoes were reported from Canada and the USA (US GAP: 49–74 g ai/ha, PHI of 14 days and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in twenty-seven trials from the USA matching GAP in rank order were (median underlined): < 0.01 (27) mg/kg.

Uptake of persistent residues from soil may also give rise to residues in potatoes tubers. Maximum residue levels and the potential for residues in succeeding and/or rotational crops are discussed under rotational crops below.

Tree nuts

Trials were available from the USA on residues of chlorantraniliprole in almonds and pecans but were unable to be evaluated as no relevant GAP existed at the time of evaluation.

Cotton seed

Trials on cotton were reported from the USA (GAP: 110 g ai/ha, PHI of 21 days and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues in thirteen trials from the USA matching GAP in rank order were (median underlined): < 0.01, 0.016, 0.022, 0.029, 0.031, 0.047, 0.049, 0.054, 0.081, 0.082, 0.083, 0.13 and 0.25 mg/kg.

The Meeting estimated a maximum residue level and STMR value for chlorantraniliprole in cotton seed of 0.3 and 0.049 mg/kg respectively.

Animal feedstuffs

Cotton gin-trash

Chlorantraniliprole field trials on cotton were made available to the Meeting from the USA (GAP: 110 g ai/ha, PHI of 21 days and a maximum application per season of 224 g ai/ha).

Chlorantraniliprole residues on cotton gin-trash were 1.1, 2.4, 3.3, 4.1, 6.4, 12 and 13 mg/kg (fresh weight basis). The Meeting estimated an STMR value for chlorantraniliprole in cotton gin-trash of 4.1 mg/kg.

Almond hulls

The trial data could not be evaluated as no GAP was available.

Rotational crops

Residues of chlorantraniliprole are persistent in soil and may be taken up by following crops. In the USA the total seasonal application rate for crops is 220 g ai/ha. Studies of residues in rotational crops were made available to the meeting where in confined rotational crop studies soil was treated at 300–900 g ai/ha and in field studies bare soil and preceding crops were treated at 200–600 g ai/ha and 220 g ai/ha respectively.

Residues in leafy vegetables were < 0.01 (5) and 0.010 mg/kg in lettuce, < 0.01 (2) and 0.010 mg/kg in spinach and < 0.01 (4) mg/kg in Swiss chard. The levels in leafy vegetables from

rotational crops are adequately covered by the recommendation for leafy vegetables of 20 mg/kg. Similarly residues of chlorantraniliprole in leaves/tops of turnips were < 0.01 (3) mg/kg, in beets < 0.01 (3), 0.015 and 0.034 mg/kg and in radish tops < 0.01, 0.010, 0.030, 0.068, 0.070 and 0.16 mg/kg and are also covered by the recommendation for leafy vegetables.

Residues in root and tuber vegetables grown as follow-crops were < 0.01 (3) mg/kg for turnip roots, < 0.01 (5) mg/kg for beet roots and < 0.01 (5) and 0.010 mg/kg for radish roots. Residues were observed at levels between the LOD and LOQ of the analytical method. Trials on root vegetables for foliar application according to GAP only supported a maximum residue level recommendation for potatoes of 0.01 mg/kg; no data on residues in potatoes grown as follow crops or on the combined effect of potatoes grown in soils containing residues (follow crops) and foliar application were made available to the Meeting. Residues in other root vegetables at harvest after planting as follow-crops were: < 0.01 (13) and 0.010 mg/kg.

Noting the residue data on follow-crops, the Meeting decided to recommend a maximum residue level for root and tuber vegetables of 0.02 mg/kg and an STMR of 0.01 mg/kg. The estimated maximum residue level for residues taken up from soil would accommodate residues arising from foliar application to potatoes.

Residues in follow-crop cereal grains were < 0.01 (3) mg/kg for oats and < 0.01 (8) mg/kg. As residues were observed in grain at levels above the LOD but below the LOQ of the analytical method, the Meeting decided to combine the data on follow-crop cereal grains and recommend maximum residue level and STMR values of 0.02 and 0.01 mg/kg respectively for cereal grain.

Corresponding residues in cereal forage (oat and wheat) were: < 0.01, 0.013, 0.016, 0.020, 0.022, 0.022, 0.031, 0.039, 0.043, 0.052 and 0.083 mg/kg. The Meeting decided to combine the data on forage of follow-crop cereals and recommend STMR and highest residue values of 0.022 and 0.083 mg/kg respectively for forage of cereals.

Residues in cereal hay (oat and wheat) were: < 0.01, 0.015, 0.017, 0.031, 0.043, 0.045, 0.051, 0.058, 0.10, 0.14 and 0.15 mg/kg. The estimated STMR and highest residue values for hay of cereals are 0.045 (or 0.051 mg/kg on a dry weight basis) and 0.15 mg/kg (or 0.17 mg/kg on a dry weight basis) respectively.

Residues in cereal straw (oat and wheat) were: < 0.01, 0.011, 0.014, 0.018, 0.030, 0.032, 0.039, 0.061, 0.078, 0.082 and 0.12 mg/kg. The estimated STMR and highest residue values for straw of cereals are 0.032 (or 0.036 mg/kg on a dry weight basis) and 0.12 mg/kg (or 0.136 mg/kg on a dry weight basis) respectively.

Residues in hay were higher than straw and the Meeting decided to use the hay data on follow-crop cereals and recommend a maximum residue level, STMR and highest residue for straw and hay of cereals of 0.3, 0.051 and 0.17 mg/kg respectively.

Two trials on residues in pulses (soya bean) with residues in seed of < 0.01 (2) mg/kg were available. Residues in forage were 0.027 and 0.041 mg/kg while residues in hay were 0.037 and 0.055 mg/kg. The Meeting considered two trials on pulses grown as rotational crops to be inadequate for the purposes of estimating maximum residue levels, STMRs and highest residues.

No trials on residues in follow-crops were available brassica vegetables, stalk and stem vegetables, legume vegetables, bulb vegetables, pulses, oilseeds, grass/pasture and legume animal feeds.

Fate of residues during processing

The fate of chlorantraniliprole residues has been examined in apples, grapes, plum and cotton processing studies. Processing of tomatoes into purée and paste showed a slight increase of chlorantraniliprole residues in the processed commodities when compared to the RAC. Whilst there was a decrease in residues found in the corresponding juice and ketchup. Apples and grapes showed a

decrease in residues found in the juice, but an increase in pomace, raisins and apple peel. There was a concentration into the hulls of cottonseed. Estimated processing factors and STMR-Ps are summarised below.

Summary of processing factors for chlorantraniliprole residues.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	PF (Mean, median or best estimate)	RAC-STMR (mg/kg)	STMR-P(mg/kg)
Apple	Pomace, dry	9.3 11 12 13	11.5	0.07	0.805
	Juice	< 0.06 < 0.09 < 0.19 < 0.19	< 0.14		< 0.0098
	Purée	0.09 0.09 < 0.19 < 0.19	0.09		< 0.0063
	Sauce	< 0.09 < 0.19 < 0.19 0.27	0.27		0.0189
	Preserves, canned	< 0.06 < 0.09 < 0.19 < 0.19	< 0.14		< 0.0098
Plum	Prune	1.9	1.9	0.015	0.0285
Grape	Pomace dry	6.1 12	9	0.119	1.07
	Juice	0.43 0.46 1.0 1.7	0.73		0.0869
	Raisin	2.7 2.9 4.0 7.1	3.45		0.411
	White wine	< 0.15 < 0.29	< 0.22		0.0262
	Red wine	0.76 1.6	1.18		0.140
Tomato	Canned tomatoes	< 0.2 0.23 0.33 0.65	0.28	0.066	0.0197
	Juice	0.57 0.78 0.89 1.1	0.835		0.0589
	Ketchup	0.72 0.74 1.2 1.6	0.98		0.0691
	Purée	1.2 1.4 1.5 1.7	1.45		0.102
	Paste	0.61 1.1 2.0 2.4	1.55		0.109
	Pomace, wet	1.2 1.4	1.3		0.0916
Cotton	Hulls	2.1	2.1	0.049	0.103
	Meal	0.75	0.75		0.0368
	Oil, refined	0.25	0.25		0.0122

Chlorantraniliprole concentrated in prunes, fruit pomace (apple, grape and tomato), raisins, cotton seed meal and hulls. As the estimated residues for the processed commodities raisins, cotton seed hulls and meal in the table above, are below the maximum residue levels proposed for the raw agricultural commodities the Meeting decided it was not necessary to make recommendations for maximum residue levels for these processed commodities.

The Meeting decided to estimate a maximum residue for chilli pepper (dried) of 5 mg/kg following application of a default dehydration factor of 7 to the estimated maximum residue level of 0.6 mg/kg for chilli pepper (7×0.6 = 4.2 mg/kg).

Farm animal dietary burden

The Meeting estimated the dietary burden of chlorantraniliprole in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values 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 as dry weight.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the animal diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

		Animal dietary burden, chlorantraniliprole, ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	0.45	0.18	0.67[a]
	mean	0.35	0.11	0.48[c]
Dairy cattle	max	0.25	0.15	0.63[b]
	mean	0.09	0.074	0.47[d]
Poultry - broiler	max	0.012	0.007	0.007
	mean	0.012	0.007	0.007
Poultry - layer	max	0.011	0.057[e]	0.007
	mean	0.011	0.020[f]	0.007

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

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

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

The chlorantraniliprole dietary burdens for animal commodity MRL and STMR estimation (residue levels in animal feeds expressed on dry weight) are: beef cattle 0.67 and 0.48 ppm, dairy cattle 0.63 and 0.47 ppm and poultry 0.057 and 0.020 ppm.

Farm animal feeding studies

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were dosed with chlorantraniliprole for 28 days at the equivalent of 1, 3, 10 and 50 ppm in the diet. Average residues of chlorantraniliprole in milk for the 3 ppm dose group were < 0.01 (3) mg/kg. Chlorantraniliprole residues in liver and fat were higher than in other tissues. Average residues for tissues for the 3 ppm dosing level (3 animals per dose group) were all < 0.01 mg/kg for liver, fat, kidney and muscle.

The Meeting also received information on the residue levels arising in tissues and eggs when laying hens were dosed with [^{14}C]chlorantraniliprole for 14 days at the equivalent of 10 ppm in the diet. Residues in eggs were 0.308 mg/kg. Of tissues, residues of chlorantraniliprole were highest in liver at 0.0193 mg/kg, followed by skin and fat at 0.0093 mg/kg and muscle 0.0008 mg/kg at 23 h after the last dose.

Animal commodity maximum residue levels

The maximum dietary burden for beef and dairy cattle is 0.67 and 0.63 ppm respectively, so the levels of residues in tissues can be obtained from the 1 ppm feeding level. Maximum residues expected in tissues are: fat, muscle, liver and kidney are 0.0067 mg/kg (0.01×0.67/1) and the mean residue for milk 0.0063 mg/kg. At the 3 ppm dose level, average residues of chlorantraniliprole were 0.015 mg/kg in cream and < 0.01 mg/kg in whole milk (0.025 and 0.005 mg/kg respectively for cream and whole milk for the 10 ppm dose level at day 14). Expected residues in cream are 5× the residues in whole milk or 5×0.0063 = 0.0315 mg/kg. The fat content of cream is 40–60% and the Meeting estimated the mean residue for milk fat to be 2×0.0315 = 0.063 mg/kg.

The Meeting estimated maximum residue levels for meat (from mammals other than marine mammals) 0.01* mg/kg (fat); edible offal (mammalian) 0.01* mg/kg; milks 0.01* mg/kg and 0.01* mg/kg for milk fat.

As no residues are expected at the maximum dietary burden, estimated STMRs are 0 mg/kg for meat (from mammals other than marine mammals), fat (from mammals other than marine mammals), edible offal mammalian, milk and 0.047 mg/kg for milk fat.

The maximum dietary burden for poultry is 0.057 ppm. Maximum residues expected at 23 h after last feeding are: muscle, skin/fat, liver and eggs are 0.0000016, 0.000019, 0.000039 and 0.000616 mg/kg.

The maximum residue levels for poultry meat 0.01* mg/kg (fat); poultry offal 0.01* and eggs 0.01* mg/kg.

The mean dietary burden for poultry is 0.02 ppm. No residues are expected in poultry tissues and eggs of birds at the mean dietary burden. STMRs for poultry meat, skin/fat, edible offal and eggs are all 0 mg/kg.

FURTHER WORK OR INFORMATION

Desirable

Information on residues in follow crops, especially for brassica vegetables, stalk and stem vegetables, legume vegetables, bulb vegetables, pulses, oilseeds, grass/pasture and legume animal feeds.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of chlorantraniliprole has resulted in recommendations for MRLs and STMRs for raw and processed commodities. Consumption data were available for 19 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 0% (0–0.3%) of the maximum ADI of 2 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of chlorantraniliprole from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

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

5.7 CHLORPROPHAM (201)

RESIDUES IN MILK AND MILKFAT

The CCPR at its 38th Session advanced the MRL for cattle milk, 0.0005 (*) F mg/kg, to Step 8 and also requested the JMPR to review the basis for setting the cattle milk MRL. Chlorpropham was evaluated by JMPR in 1965(T), 2000(T), 2001(R) and 2005 (T). It was listed for review by 2008 JMPR at the 39th Session of the CCPR for MRLs for whole milk and milk fat.

Chlorpropham is designated fat soluble.

Relevant studies on analytical method, livestock metabolism, and livestock feeding were supplied to the 2001 JMPR. All studies were considered during the periodic re-evaluation of chlorpropham (2001 Report of the JMPR). No new data was made available.

The 2001 JMPR reported results from a 28-day dosing study in which lactating cows were given chlorpropham, by capsule, at a level equivalent to 0, 322, 955 or 3111 ppm in the feed (dry weight basis). Only minor concentrations of chlorpropham residues (< 0.01–0.06 mg/kg) were found in whole milk that did not scale with dose level. At the lowest dose level, maximum average residues for milk produced on any single day were 0.043 mg/kg at day 18 of dosing. Chlorpropham residues could not be detected in skim milk, but in cream the concentrations were 0.02–0.03 mg/kg at the lowest dose level and 0.18–0.64 mg/kg at the highest dose level.

Following the revised policy of JMPR of estimating maximum residue levels for both whole milk and milk fat when data are available, the Meeting re-evaluated the transfer of residues to milk. The same dietary burden as used by the 2001 JMPR of 63 ppm for lactating dairy cows was employed for estimating both the maximum residue level, HR and STMR.

Residues in milk did not show a consistent pattern with duration of dosing and the Meeting decided to estimate residues based on residues in milk for the day that produced the highest residues. Maximum average residues, in a single day's production, were 0.043 mg/kg for day 18 for the 322 ppm group. The Meeting estimated maximum residues in whole milk of 0.0085 mg/kg (0.043 mg/kg ×63 ppm/322 ppm).

Data on residues in cream can be used to estimate residues in milk fat noting cream contains 40–60% fat. Residues in cream were only reported for day 14 of dosing for which residues in whole milk were < 0.01 mg/kg. Average residues in cream at day 14 were 0.027 mg/kg and assuming cream contains 50% milk fat, residues in milk fat would be 0.054 mg/kg. Scaling the anticipated milk fat residue to a feed level of 63 ppm gives a highest residue of 0.011 mg/kg (0.054 mg/kg× 63 ppm/322 ppm).

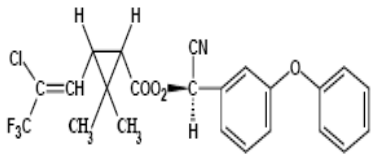
The Meeting estimated maximum residue levels for chlorpropham in milks (=whole milk) of 0.01* mg/kg and for milk fat of 0.02 mg/kg and highest residues of 0.0085 and 0.011 mg/kg respectively. In estimating STMR values the Meeting noted that on most days residues in milk were < 0.01 mg/kg for the 322 ppm dose group and therefore estimated STMRs for whole milk and milk fat of 0.00195 mg/kg (< 0.01 mg/kg ×65 ppm/322 ppm).

5.8 LAMBDA-CYHALOTHRIN (146)

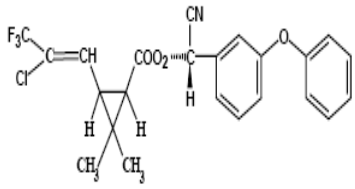
RESIDUE AND ANALYTICAL ASPECTS

Lambda-cyhalothrin was scheduled as a priority compound under the periodic re-evaluation programme at the 34th Session of the CCPR as a replacement for cyhalothrin. The toxicological evaluation for lambda-cyhalothrin was conducted at JMPR 2007. The isomeric mixture cyhalothrin was evaluated several times by JMPR for residues (1984, 1986 and 1988) and once for toxicology (1984). The Meeting received information on lambda-cyhalothrin metabolism and environmental fate, methods of residue analysis, freezer storage stability, national registered use patterns, supervised residue trials, farm animal feeding studies and fate of residues in processing.

Although cyhalothrin and lambda-cyhalothrin are isomers, only lambda-cyhalothrin is supported by the manufacturer and therefore intended as a replacement for cyhalothrin. For cyhalothrin as a mixture of all isomers only limited information on the metabolism and the environmental fate were submitted. No information on registered uses and/or supervised residue trial data was available to the Meeting.



lambda-cyhalothrin (R) (Z)-(1S)-cis-isomer



lambda-cyhalothrin (S)-(Z)-(1R)-cis-isomer

The following abbreviations are used for the metabolites discussed below:

cyhalothrin	3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyano(3-phenoxyphenyl)methyl cyclopropanecarboxylate
lambda-cyhalothrin	1:1 mixture of (S)-α-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl) -2,2-dimethylcyclopropane carboxylate and (R)-α-cyano-3-phenoxybenzyl (Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane carboxylate
Compound Ia	(Z)-3-(2-chloro-3,3,3-trifluoro-propenyl)-2,2-dimethylcyclo-propane carboxylic acid
Compound Ib	(1RS)-trans-3-(2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethyl-cyclopropane carboxylic acid
Compound III	(RS)-α -cyano-3-phenoxy-benzyl alcohol
Compound IV	3-phenoxybenzaldehyde
Compound V	3-phenoxybenzoic acid
Compound IX	(RS)-3-phenoxymandelamide
Compound XI	3-(2-chloro-3,3,3-trifluoro-prop-1-enyl)-2-hydroxy-methyl-2-methyl-cyclo-

	propane carboxylic acid
Compound XV	(RS)-α -cyano-3-(4-hydroxy-phenoxy)benzyl (Z)-(1RS)-cis-3-(2- chloro-3,3,3-trifluoro-propenyl)-2,2-dimethyl-cyclopropane carboxylate
Compound XXIII	3-(4'-hydroxy)-phenoxy-benzoic acid
R157836	enantiomeric pair A, cis 1RαR and cis 1SαS enantiomers of cyhalothrin

Animal metabolism

The Meeting received animal metabolism studies with cyhalothrin in rats and lambda-cyhalothrin in laying hens and lactating goats. In these studies lambda-cyhalothrin was [^{14}C]labelled at the acid moiety in most cases. Additional information on the metabolism of cypermethrin in cows and laying hens was submitted which shares the structure of the alcohol moiety with lambda-cyhalothrin and has only a slightly lower log K_{ow} of 5.3–5.6 compared to the log K_{ow} of 7.0 for lambda-cyhalothrin. Corresponding to lambda-cyhalothrin the cleavage of the ester bond is the first metabolism step resulting in a comparable alcohol-moiety metabolite which follows a similar pathway subsequently.

In general lambda-cyhalothrin is cleaved at the ester bond as the first step of metabolism followed by hydroxylation at various sites of both breakdown products. These products are further conjugated with sulfate or glucose and excreted via the urine. Parent lambda-cyhalothrin is fat-soluble (log K_{ow} = 7.0) since residue concentrations in fat are approximately 5 to 10 times higher than in the muscle. While unchanged parent compound contributed most to fatty tissues radioactivity, the residues found in liver and kidney at comparable TRR-levels consisted of cleaved and conjugated metabolites of higher polarity.

In rats oral doses of cyhalothrin were readily but incompletely absorbed (30–40% of radiolabel was recovered in urine). Most (70%) of the administered material was excreted in the faeces and urine within 24 h. After 7 days, 2–3% of the cyhalothrin administered persisted as unchanged residue in fat. Metabolism in rats involved initial cleavage of the molecule at the ester bond. In rats dosed with cyhalothrin, major metabolites identified in urine were the sulfate conjugate of compound XXIII and glucuronide conjugate of compound Ia. Minor metabolites identified were the unconjugated compound XXIII and compound V. (See the toxicology report for more details of laboratory animal metabolism)

For lactating goats dosed orally with [cyclopropyl-^{14}C]lambda-cyhalothrin at a rate equivalent to 10.8 mg/kg in the total diet for seven consecutive days, about 71% of the TRR was excreted (faeces 29.3%, urine 41.7%). Residues in milk reached a maximum after five days at a level of 0.27 mg/kg, mostly consisting of lambda-cyhalothrin (> 95%). Muscle gave relatively low total radioactive residues of 0.024–0.028 mg/kg compared to fat ranging from 0.13 to 0.44 mg/kg (0.32 mg/kg in average). Most of the radioactivity (> 88%) was identified as unchanged parent compound. In liver and kidney residues at a level of 0.34 and 0.2 mg/kg respectively were found. Lambda-cyhalothrin contributed to less than 7% of the TRR. Most of the residue was identified as the labelled cleavage metabolite Ia and its hydroxylated form (compound XI).

To investigate the fate of the alcohol-moiety, cows (non-lactating) were dosed orally with [benzyl-^{14}C-cypermethrin at a rate equivalent to 10 mg/kg of total diet for seven consecutive days. In liver and kidney the investigated radioactivity showed that analogous to lambda-cyhalothrin in goats the cleavage of the molecule is the initial breakdown reaction. The labelled alcohol-moiety fragment (compound V) was the dominant residue at levels of about 60% of the TRR, followed by its hydroxylation product compound XXIII at levels of 3.6 to 16% of the TRR (kidney and liver respectively). Due to the low total radioactivity in muscle no further identification was conducted while in fat more than 80% of the TRR consisted of unchanged [benzyl-^{14}C]cypermethrin.

In laying hens dosed orally with [cyclopropyl-^{14}C]lambda-cyhalothrin at a rate equivalent to 10.8 mg/kg of total diet for 14 consecutive days more than 98% of the administered dose was recovered from the excreta. In muscle tissues no TRR above 0.01 mg/kg was found and no further characterisation was possible. In the fat radioactive residues were between 0.17 to 0.46 mg/kg with unchanged lambda-cyhalothrin contributing more than 80% of the radioactivity. In the liver extensive metabolism occurred resulting mainly in the cleavage product compound Ia (51% of the TRR) and its hydroxylated product compound XI (9.5% of the TRR). No parent lambda-cyhalothrin was found in the liver of laying hens. In egg yolk about 60% of the TRR consisted of unchanged parent compound. Further radioactivity was characterized in the polar and hexane fraction amounting less than 10% of TRR. Unextractable residues were at 12.6% of the TRR.

For laying hens dosed orally with [phenoxy-^{14}C]labelled cypermethrin at a rate equivalent to approximately 10 mg/kg in the total diet (1.52 mg per bird and day) for 14 consecutive days similar results to the study with lambda-cyhalothrin were obtained. The labelled alcohol-moiety cleavage product compound V and its hydroxylated products compound XXIII were the main metabolites identified in liver. A subsequent transfer of these metabolites into other animal tissues or the eggs was observed in small amounts only (compound V in egg yolk at 1.2% of the TRR).

Plant metabolism

The Meeting received plant metabolism studies with [^{14}C]cyhalothrin and [^{14}C]lambda-cyhalothrin in apples, cabbage, wheat, cotton and soya beans. Parent substance labelled either as [cyclopropyl-^{14}C]- (cotton, wheat, soya beans), [phenyl-^{14}C]- (wheat) or [benzyl-^{14}C]lambda-cyhalothrin (cotton, soya beans) as well as [cyclopropyl-^{14}C]cyhalothrin (apples, cabbage) were used in the metabolism studies.

In general, the metabolism of cyhalothrin is limited to a few transformation steps. The cleavage of the ester bond is normally the first step followed by hydroxylation of the breakdown products. Translocation of the radioactivity within the plants investigated was not observed.

In the study on wheat both labelled test substances were applied at rates of 0.22 kg ai/ha. The wheat was treated in three variations: two treatments with a PHI of 14 days, two treatments with a PHI of 85 days or three treatments with a PHI of 30 days. Depending on the treatment, TRR values in grain differed significantly.

For two treatments with a PHI of 14 days only minor total residues were detected in wheat grain ranging from 0.002–0.007 mg/kg. Wheat grain with a PHI of 85 days (treated twice) also gave relatively low TRR values, i.e., from 0.005 to 0.018 mg/kg. An investigation of the radioactivity gave detectable residues of unchanged lambda-cyhalothrin, but these residues were below the LOQ of 0.001 mg/kg. The majority of the radioactivity was present in the water soluble phase but could not be further identified. For three applications and a PHI of 30 days the highest residues of the study were detected in the grain, which ranged from 0.112 to 0.131 mg/kg. More than 75% of the TRR was identified as lambda-cyhalothrin. Depending on the label the first products of the cleavage of the ester bond (compound Ia and V) were the only metabolites identified at levels below the LOQ.

For wheat foliage only the samples obtained from short PHIs (14 and 30 days) were analysed. After two treatments and a PHI of 14 days TRR values for both labels of 0.45 to 1.8 mg/kg were found. Three treatments and a PHI of 30 days led to higher radioactive residues ranging from 7.95 up to 10 mg/kg. In all samples, unchanged parent lambda-cyhalothrin was the main residue at levels > 80% of the TRR. Again the initial products of the ester bond cleavage and their hydroxylated metabolites were the only metabolites found at levels < 2% of the TRR each.

In soya beans both labels were applied as two treatments at rates of 0.02 kg ai/ha each. Samples of leaves and soya beans were taken 39 and 51 days after the last treatment respectively. In soya beans very low total radioactive residues ranging from 0.003 to 0.01 mg/kg were found. No further characterisation or identification of the radioactivity was achieved. In soya bean plants residues were higher (TRR 1.2–1.9 mg/kg). About half of the radioactivity was identified as lambda-

cyhalothrin (43–52% of the TRR). For the [cyclopropyl-^{14}C]-label compound Ia was the major metabolite with 25% of the TRR. Further breakdown products were the hydroxylated cleavage products at levels below 7% of the TRR.

Two cotton studies were conducted to investigate the residues of lambda-cyhalothrin in leaves and seeds. After three applications of 0.066 kg ai/ha, cotton leaves were sampled at a PHI of 80 days and analysed. Total radioactive residues were quite comparable for both labels ranging from 2.9 to 4.1 mg/kg. Depending on the label, 37–52% of the TRR was identified as unchanged lambda-cyhalothrin. Further metabolites were identified as the initial cleavage products and their hydroxylated metabolites. Except compound Ia (17.6% of the TRR) all metabolites were at levels below 10% of the total radioactivity in the cotton leaves.

In the second experiment cotton was either sprayed three times at rates of 0.066 kg ai/ha each with a PHI of 101 days or the cotton seeds were directly treated using a syringe with a PHI of 14 days. After the direct treatment the analysis of the radioactivity showed that all of the lambda-cyhalothrin applied remained unchanged. No degradation on the parent substance was observed. Following foliar application, residues in the seeds were relatively low ranging from 0.01 to 0.027 mg/kg. No further identification of the radioactivity was performed.

Metabolism on cabbage was investigated using cyhalothrin. The cabbage plants were directly spotted with a [^{14}C]cyhalothrin solution. Treated leaves were removed from these plants at intervals of 2, 4, 5, 6 and 7 weeks. Two additional plants were sprayed either four or eight times at rates of 0.055 kg ai/ha with a PHI of 7 days.

The cabbage leaves spotted with [^{14}C]cyhalothrin showed a steady decrease of the parent compound. At 2 weeks after the treatment more than 80% of the TRR was identified as cyhalothrin. This percentage dropped to 54% after 5–6 weeks. The leaves harvested after 6 weeks were further analysed and indicated both isomers of the initial cleavage products compound Ia and Ib as metabolites identified at levels of 4% of the TRR each.

After eight spray applications and a PHI of 7 days cabbage leaves showed total radioactive residues of 0.44 mg/kg. Most of the residues were located on the outer leaves (1.13 mg/kg) while only minor residues could be found within the cabbage head (0.003 mg/kg). In total about 80% of the TRR consisted of unchanged cyhalothrin. Again both isomers of the initial cleavage products (compound Ia and Ib) were identified as metabolites (3.0% and 0.8% of the TRR respectively).

In apples the metabolism was also investigated using the isomeric mixture of cyhalothrin labelled at the cyclopropyl-moiety. Ten apples were directly treated with the active ingredients and exposed to sunlight. At intervals of 0, 7, 14, 28 and 56 days two apples were harvested and analysed for radioactive residues. The results obtained from 0 to 28 days indicated that only very little degradation of cyhalothrin occurred. More than 97% of the TRR was identified as unchanged parent. After 56 days approximately 89% of the remaining TRR was cyhalothrin. Minor amounts of the isomers compound Ia and Ib were detected (< 3% of the TRR). The rest of the radioactivity was characterized as water soluble or unextractable.

Environmental fate in soil

The Meeting received information on aerobic soil metabolism and soil photolysis of lambda-cyhalothrin as well as studies on the behaviour in crop rotations. Due to the fact that mostly acid-labelled lambda-cyhalothrin was used in the aerobic soil metabolism study, additional information on the aerobic soil metabolism of alcohol-labelled cypermethrin was submitted.

The photolysis study conducted with [cyclopropyl-^{14}C]- and [phenyl-^{14}C]lambda-cyhalothrin at a rate of 40 g ai/ha showed no accelerated decrease in the residues under irradiation. The levels of parent compound in the samples were at comparable levels to the dark control samples.

In the aerobic soil metabolism studies conducted with [cyclopropyl-^{14}C]lambda-cyhalothrin at rates of 100–500 g ai/ha, DT_{50} values ranging from 22 to 83 days were reported. After 26 weeks a

significant mineralisation was observed (up to 70% evolved $^{14}CO_2$). The main metabolites found after 90 to 181 days were the hydroxylated parent compound (compound XV) and the labelled cleavage products compound Ia, each accounted for less than 12% of the initial dose.

In comparable studies using [benzyl-^{14}C]-cypermethrin compounds III, IV and IX were the predominant metabolites. After the cleavage of the initial molecule into the labelled compound III subsequent oxidation into compound IV and conjugation appear to be the typical reaction pathways in soil.

Rotational crop studies using [cyclopropyl-^{14}C] and [phenyl-^{14}C]lambda-cyhalothrin were conducted on wheat, lettuce and carrots with plant back intervals of 30, 60 and 120 days. After treatment with approximately 0.47 kg ai/ha, samples from each commodity were taken and analysed for the total radioactivity for the phenyl-label and additionally for the nature of residue for the cyclopropyl-label.

The samples grown in soil treated with the phenyl-label gave very low residues overall, ranging from 0.002 mg/kg for carrot roots up to the highest concentration of 0.035 mg/kg in wheat straw. Due to the low level of radioactivity no further investigation of the radioactivity was performed.

For the cyclopropyl-label residues were higher ranging from 0.003 mg/kg in carrot roots up to 0.85 mg/kg in wheat straw. The characterisation of the radioactivity showed negligible residues of parent lambda-cyhalothrin in all matrices (< 0.5% of the TRR). Most of the radioactivity was identified as the first cleavage product compound Ia at 40–60% of the TRR. The remaining radioactivity was included in unidentified polar fractions or not extractable.

Methods of analysis

The Meeting received information on analytical methods for the determination of residues of the active substance cyhalothrin, lambda-cyhalothrin (enantiomeric pair B, cis 1RαS and cis 1SαR enantiomers of cyhalothrin), R157836 (enantiomeric pair A, cis 1RαR and cis 1SαS enantiomers of cyhalothrin) and for some metabolites in target crops and animal products (milk, meat, kidney, liver, fat and eggs).

In the methods the macerated samples are typically extracted with acetone:hexane (50:50 v/v) and the extract is cleaned by a solid phase clean-up either with a silica or Florisil column. The final residue is determined by GLC with ECD or MS detection. LOQs are at 0.01 mg/kg for all plant and animal matrices.

Analytical recovery data were satisfactory for cyhalothrin, lambda-cyhalothrin, its epimer R157836 and several metabolites for numerous commodities. Residue methods were tested by independent laboratories unfamiliar with the analysis and were found to have satisfactory recoveries and no background interferences.

Stability of residues in stored analytical samples

Information was received on the freezer storage stability of lambda-cyhalothrin residues in plant and animal commodities. For some commodities the stability for the epimer of lambda-cyhalothrin (R157836) was also investigated.

Lambda-cyhalothrin residues were stable in the commodities apple and cabbage for 16 months and were stable for 26 months in apple, peach, cabbage, pea, potato, rape seeds, wheat grain, sugar beet roots and cotton seed. R157836 was stable in apples and cabbages for at least 16 months.

In animal commodities lambda-cyhalothrin residues were stable for 3 months (bovine muscle, kidney, liver, fat and milk) and 26 months (poultry muscle, liver fat and eggs).

Residue definition

The residue following use of lambda-cyhalothrin on crops is predominantly lambda-cyhalothrin. Epimerisation of lambda-cyhalothrin was measurable, but only at very low levels. Methods are available that can measure cyhalothrin as well as the individual diastereoisomers and epimers.

The ratio of lambda-cyhalothrin to major metabolites differed in the ruminant metabolism and feeding studies. In the feeding study, lambda-cyhalothrin is the major component of the residue in kidney and liver while in metabolism studies conducted with labelled material only minor amounts of the parent substance were detected. In muscle, fat, milk and eggs, lambda-cyhalothrin was the dominant residue.

Based on the actual residue measured (lambda-cyhalothrin), the Meeting recommended that the residue definition for plant and animal commodities for compliance with MRLs and for estimation of dietary intake should be lambda-cyhalothrin. The log K_{ow} of lambda-cyhalothrin of 7.0 and the animal metabolism and feeding studies suggest that lambda-cyhalothrin should be described as fat-soluble. In the ruminant and poultry metabolism studies lambda-cyhalothrin residues were approximately 5–10 times greater in fat than muscle.

For cyhalothrin, sum of isomers MRLs for animal commodities were established by JECFA in 2004. In addition the evaluation for lambda-cyhalothrin in by JMPR 2007 identified all isomers of cyhalothrin to be of toxicological concern in relation to dietary intake. In harmony with the JECFA MRLs established and the toxicological properties of cyhalothrin, a residue definition based on all isomers is recommended.

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

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trials data for lambda-cyhalothrin on citrus fruits (mandarins and oranges), pome fruits (apples and pears), stone fruits (cherries, peaches and plums), grapes, small berries (currants, gooseberries, raspberries and strawberries), olives, mangoes, onions, brassica vegetables (broccoli, cauliflower and cabbage), spinach, fruiting vegetables cucurbits (cucumbers, courgettes and melons), fruiting vegetables other than cucurbits (bell peppers, tomatoes and sweet corn), legume vegetables (beans, peas and immature soya beans), pulses (beans, peas, soya beans), root and tuber vegetables (carrots and potatoes), stem vegetables (asparagus and leek), cereals (wheat, oats, barley, maize, rice, rye, triticale and sorghum), sugarcane, tree nuts (almonds and pecan) and oilseeds (oilseed rape, sunflowers, cotton and peanuts).

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the sample with the higher residue was taken as the best estimate of the residue from the plot. All residue data refers to lambda-cyhalothrin residues as measured.

Labels (or translation of labels) were available from Australia, France, Italy, Portugal, Spain, Thailand and the United States describing the registered uses of lambda-cyhalothrin.

Citrus fruits

Lambda-cyhalothrin is registered in Portugal and Spain for use on citrus fruits at 0.001 and 0.002 kg ai/hL respectively with a PHI of 7 days. Supervised residue trials conducted in Southern Europe on mandarins and oranges according to the Spanish GAP were submitted. For whole mandarin fruits residues were (n = 10): 0.02, 0.03, 0.04, 0.05, 0.05, 0.06, 0.06, 0.07, 0.11 and 0.16 mg/kg. The corresponding residues in mandarin pulp were < 0.01(10) mg/kg. For whole orange fruits residues were (n = 5): 0.04(4) and 0.05 mg/kg and in the orange pulp < 0.01(6) and 0.01 mg/kg.

The Meeting decided to combine the trials in the mandarins and oranges for the purposes of estimating a maximum residue level, an HR and a STMR. Residues for whole citrus fruit in rank order were: (*n* = 15): 0.02, 0.03, 0.04(5), 0.05(3), 0.06, 0.06, 0.07, 0.11 and 0.16 mg/kg. Residues in citrus pulp in rank order were: < 0.01(16) and 0.01 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in citrus fruit of 0.2 (whole fruit), 0.01(pulp) and 0.01 mg/kg (pulp) respectively.

Pome fruit

Lambda-cyhalothrin is registered in France for use on apple, pear, nashi pear and quinces and in Spain for the use on fruit trees at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe on apples according to the French GAP were submitted. The apple fruit residues were (*n* = 8): < 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.04 and 0.04 mg/kg.

In the USA lambda-cyhalothrin is registered on apples, pears and quinces at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US on apples and pears according to the US GAP were submitted. In apples fruits a residue level of 0.09 mg/kg was found. The pear fruit residues were (*n* = 7): 0.05, 0.05, 0.06, 0.07, 0.09, 0.1 and 0.1mg/kg.

The Meeting decided to combine the trials for apples and pears conducted according to the comparable US GAP for the purpose of estimation a maximum residue level, an HR and an STMR for pome fruits. Residues for fruits in rank order were (*n* = 8) 0.05, 0.05, 0.06, 0.07, 0.09, 0.09, 0.1 and 0.1 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in pome fruits of 0.2, 0.08 and 0.1 mg/kg respectively.

Stone fruit

Lambda-cyhalothrin is registered in the US for use on cherries at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to the US GAP were submitted. In cherry fruits residues were (*n* = 10): 0.05, 0.07, 0.07, 0.09, 0.11, 0.14, 0.15, 0.16, 0.18 and 0.18 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in cherries of 0.3, 0.125 and 0.18 mg/kg respectively.

In France lambda-cyhalothrin is registered on peaches, apricots and nectarines at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in France according to the French GAP were submitted. In peaches residues were (*n* = 3): 0.02, 0.02 and 0.03 mg/kg.

In Italy the registration on peaches, apricots and nectarines is for 0.004 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to the Italian GAP were submitted. In peaches residues were (*n* = 6): 0.01, 0.02, 0.03(3) and 0.05 mg/kg.

Lambda-cyhalothrin is registered in the US for use on peaches, apricots and nectarines at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to the US GAP were submitted. In peach fruits residues were (*n* = 14): 0.02, 0.04, 0.05, 0.06, 0.08, 0.09, 0.09, 0.11, 0.11, 0.13, 0.14, 0.14, 0.2 and 0.33 mg/kg.

The Meeting decided to extrapolate the residue data for peaches to apricots and nectarines. Based on the GAP from the US the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in peaches, apricots and nectarines of 0.5, 0.1 and 0.33 mg/kg respectively.

In France lambda-cyhalothrin is registered on plums at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in France according to the French GAP were submitted. In plums residues were (*n* = 2): < 0.01 and 0.01 mg/kg.

Lambda-cyhalothrin is registered in the US for use on plums at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to the US GAP were submitted. In plums residues were (n = 12): < 0.01, < 0.01, 0.01, 0.01, 0.02(3), 0.03, 0.04, 0.06, 0.07, 0.1 mg/kg.

Based on the GAP from the US the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in plums, except prunes of 0.2, 0.02 and 0.1 mg/kg respectively.

Berries and other small fruits

Lambda-cyhalothrin is registered in France for use on currants at 0.002 kg ai/hL with a PHI of 21 days. Supervised residue trials conducted in Northern Europe according to the French GAP were submitted. In currants residues were (n = 4): 0.02, 0.02, 0.06 and 0.07 mg/kg.

In Spain lambda-cyhalothrin is registered on currants at 0.02 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in Southern Europe according to the Spanish GAP were submitted. In currants residues were (n = 9): < 0.01, < 0.01, 0.02, 0.03(3), 0.04, 0.06 and 0.07 mg/kg.

For gooseberries supervised residue trial data was submitted, but the only available GAP from Italy for small berries and other fruits is registered at a 50% higher application rate.

In Portugal lambda-cyhalothrin is registered on grapes at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to the Portuguese GAP were submitted. In grapes residues were (n = 11): < 0.01(4), 0.02(4), 0.03, 0.04 and 0.06 mg/kg.

In Italy and Spain lambda-cyhalothrin is registered on grapes at 0.003 kg ai/hL with a PHI of 7 days. One supervised residue trial conducted in Southern France according to these GAPs was submitted. In grapes residues were: 0.01 mg/kg.

Lambda-cyhalothrin is registered in France for use on raspberries at 0.002 kg ai/hL with a PHI of 14 days. Supervised residue trials conducted in France and the UK according to the French GAP were submitted. In raspberries residues were (n = 4): < 0.01, 0.01, 0.02 and 0.04 mg/kg.

In France lambda-cyhalothrin is registered on strawberries at 0.013 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in France (North and South), Italy and the UK according to the French GAP were submitted. In strawberries residues were (n = 14): < 0.01(6), 0.01, 0.02(3), 0.03, 0.03, 0.04 and 0.06 mg/kg.

In Spain lambda-cyhalothrin is registered on strawberries at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Southern Europe according to the Spanish GAP were submitted. In strawberries residues were (n = 16): 0.01(3), 0.02(6), 0.03(3), 0.05, 0.07, 0.08 and 0.09 mg/kg.

The Meeting noted that residues in berries and other small fruits are of the same magnitude and decided to extrapolate the data population based on the use of lambda-cyhalothrin in strawberries according to Spanish GAP to a group maximum residue recommendation. The estimated maximum residue level, STMR value and HR value for lambda-cyhalothrin in berries and other small fruits were 0.2, 0.02 and 0.09 mg/kg respectively.

Olives

Lambda-cyhalothrin is registered in France for use on olive trees at 0.002 kg ai/hL with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to the French GAP were submitted. In olives residues were (n = 12): 0.03, 0.05, 0.06, 0.06, 0.09, 0.12, 0.13, 0.18, 0.25, 0.25, 0.41 and 0.42 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in olives of 1, 0.125 and 0.42 mg/kg respectively.

Mangoes

Lambda-cyhalothrin is registered in Thailand for use on mango trees at 1.25 g ai/hL with a PHI of 8 days. Supervised residue trials conducted in Thailand according to this GAP were submitted. In mango fruits residues were (n = 5): 0.01, 0.02, 0.03, 0.04 and 0.07 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in mango of 0.2, 0.03 and 0.07 mg/kg respectively.

Bulb vegetables

Lambda-cyhalothrin is registered in France for use on leek at 0.008 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in Northern France and the United Kingdom according to this GAP were submitted. In leek plants residues were (n = 8): 0.02, 0.03, 0.04, 0.05, 0.05, 0.1, 0.1 and 0.11 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on bulb onions at 0.034 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In dry onions residues were (n = 9): < 0.01(4), 0.01, 0.04, 0.05, 0.06 and 0.06 mg/kg.

The Meeting decided to extrapolate the data for leek to support a group maximum residue level for the group of bulb vegetables. The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in bulb vegetables of 0.2, 0.05 and 0.11 mg/kg, respectively.

Flowerhead brassica

Lambda-cyhalothrin is registered in the United States for use on broccoli at 0.034 kg ai/ha with a PHI of 1 day. Supervised residue trials conducted in the US according to this GAP were submitted. In broccoli residues were (n = 10): 0.04, 0.05, 0.09, 0.18, 0.2, 0.23, 0.27, 0.28, 0.3 and 0.3 mg/kg.

In Spain lambda-cyhalothrin is registered on broccoli at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Spain according to the GAP were submitted. In broccoli residues were (n = 4): 0.06, 0.08, 0.08 and 0.09 mg/kg.

Lambda-cyhalothrin is registered in Spain for use on cauliflower at 0.02 kg ai/ha with a PHI of 7 days. One supervised residue trial conducted in Spain according to the GAP was submitted. In cauliflower residues were (n = 1): 0.02 mg/kg.

The Meeting noted that the data for flowerhead brassica from Spain is not sufficient for a proposal. Based on the US GAP for broccoli the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in flowerhead brassicas of 0.5, 0.215 and 0.3 mg/kg, respectively.

Head cabbages

Lambda-cyhalothrin is registered in the United States for use on head cabbage at 0.034 kg ai/ha with a PHI of 1 day. Supervised residue trials conducted in the US according to this GAP were submitted. In cabbage residues were (n = 6): 0.36, 0.41, 0.46, 0.52, 0.55 and 0.67 mg/kg.

In Spain lambda-cyhalothrin is registered on cabbage at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Southern Europe according to the GAP were submitted. In cabbage residues were (n = 6): 0.01, 0.02, 0.08, 0.08, 0.13 and 0.17 mg/kg.

Based on the more critical US GAP the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in head cabbages of 1, 0.49 and 0.67 mg/kg, respectively. The IESTI calculation indicates that the consumption of head cabbage at the HR level of 0.67 mg/kg coming from trials according this GAP would lead to an exceedance of the ARfD by

160%. Consequently, the Meeting used the prospective alternative GAP approach and selected residue data according to the Spanish GAP for the maximum residue level estimation.

Based on the Spanish GAP the Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in head cabbages of 0.3, 0.08 and 0.17 mg/kg, respectively.

Spinach

Lambda-cyhalothrin is registered in France for use on spinach at 0.006 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in France according to this GAP were submitted. In spinach residues were (n = 2): 0.04 and 0.08 mg/kg.

The Meeting decided that the residue data submitted for spinach is not sufficient to recommend a maximum residue level, an STMR and an HR value for spinach.

Fruiting vegetables – Cucurbits

Lambda-cyhalothrin is registered in Spain for use on cucurbits (outdoor and protected) at 0.02 kg ai/ha with a PHI of 3 days. Supervised residue trials conducted in Spain and Italy according to this GAP were submitted.

In cucumbers grown indoors residues were (n = 4): < 0.01(4) mg/kg.

For courgettes grown in field residues were (n = 7): < 0.01, < 0.01, 0.01(5) mg/kg.

In France lambda-cyhalothrin is registered on melons (outdoor and protected) at 0.02 kg ai/ha with a PHI of 3 days. Supervised residues trials conducted in Northern France according to the GAP were submitted for the indoor and outdoor application.

In whole melon fruits grown in field residues were (n = 6): < 0.01(6) mg/kg. The corresponding residue values in melon pulp (outdoor melons) were (n = 6): < 0.01(6) mg/kg.

In whole melon fruits grown under protection residues were (n = 5): < 0.01(4) and 0.02 mg/kg. The corresponding residue values in melon pulp (protected melons) were (n = 5): < 0.01(5) mg/kg.

The Meeting decided to combine the trials for cucumbers, courgettes and melons for mutual support for the purpose of estimating a maximum residue level, an HR and a STMR. Residues for fruiting vegetables, cucurbits in rank order were (n = 22) < 0.01(16), 0.01(5) and 0.02 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in fruiting vegetables, cucurbits of 0.05, 0.01 and 0.02 mg/kg, respectively.

Fruiting vegetables other than cucurbits, except mushrooms

Lambda-cyhalothrin is registered in the United States for use on sweet peppers at 0.034 kg ai/ha with a PHI of 5 days. Supervised residue trials on bell pepper conducted in the US according to this GAP were submitted. In bell pepper residues were (n = 8): 0.01, 0.02(3), 0.05, 0.05, 0.12 and 0.15 mg/kg.

For the purpose to extrapolate to dry Chilli pepper the Meeting estimated an STMR value and an HR value for lambda-cyhalothrin in sweet peppers of 0.035 and 0.15 mg/kg, respectively.

For tomatoes lambda-cyhalothrin is registered in the United States at 0.034 kg ai/ha with a PHI of 5 days. Supervised residue trials conducted in the US according to this GAP were submitted. In tomatoes residues were (n = 23): < 0.01(4), 0.01, 0.01, 0.02(4), 0.03(3), 0.04(5), 0.06, 0.08, 0.09, 0.13 and 0.15 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on sweet corn at 0.034 kg ai/ha with a PHI of 1 days. Supervised residue trials conducted in the US according to this GAP were submitted. In sweet corn (on the cob) residues were (n = 6): < 0.01(4), 0.14 and 0.18 mg/kg.

The Meeting decided to combine all data for mutual support to recommend a group MRL for fruiting vegetables other than cucurbits, except fungi. The corresponding reside data was (n = 37): < 0.01(8), 0.01(3), 0.02(7), 0.03(3), 0.04(5), 0.05, 0.05, 0.06, 0.08, 0.09, 0.12, 0.13, 0.14, 0.15, 0.15 and 0.18 mg/kg. Based on the combined data for lambda-cyhalothrin the Meeting estimated a maximum residue level, an STMR value and an HR value of 0.3, 0.03 and 0.18 mg/kg, respectively.

Applying the default concentration factor of 10 for sweet pepper to dried chilli pepper and an HR value of 0.15 mg/kg for sweet pepper the Meeting estimated a maximum residue level, an STMR and an HR value of 3, 0.35 and 1.5 mg/kg for lambda-cyhalothrin in dried chilli pepper, respectively.

Legume vegetables

Lambda-cyhalothrin is registered in the United States for use on green beans as legume vegetables at 0.034 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In beans with pods (fresh) residues were (n = 6): 0.02(4), 0.03 and 0.03 mg/kg.

For green beans lambda-cyhalothrin is registered in Spain at 0.02 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to this GAP were submitted. In beans with pods (fresh) residues were (n = 5): 0.01, 0.02, 0.02, 0.03 and 0.04 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on peas as legume vegetables at 0.034 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In peas without pods (fresh) residues were (n = 3): 0.01, 0.05 and 0.11 mg/kg.

For fresh peas lambda-cyhalothrin is registered in Spain at 0.02 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in Southern Europe according to this GAP were submitted. In peas without pods (fresh) residues were (n = 5): < 0.01(5) mg/kg.

For immature soya beans lambda-cyhalothrin is registered in Thailand at 0.016 kg ai/ha with a PHI of 8 days. Supervised residue trials conducted in Thailand according to this GAP were submitted. In whole pods with immature soya bean seeds residues were (n = 4): 0.05, 0.06, 0.07 and 0.08 mg/kg.

The Meeting decided to combine the trials for beans with pods and peas without pods according to US GAP for the purpose of estimating a maximum residue level, an HR and an STMR for the group of legume vegetables. Residues in rank order were (n = 9): 0.01, 0.02(4), 0.03, 0.03, 0.05 and 0.11 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in legume vegetables of 0.2, 0.02 and 0.11 mg/kg, respectively.

Pulses

Lambda-cyhalothrin is registered in the United States for use on beans and peas as pulses at 0.034 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted on beans and peas in the US according to this GAP were submitted. In bean seeds (dry) residues were (n = 9): < 0.01(9) mg/kg. In pea seeds (dry) residues were (n = 5): < 0.01(4) and 0.05mg/kg.

For soya beans lambda-cyhalothrin is registered in the US at 0.034 kg ai/ha with a PHI of 30 days for ground and aerial application. Supervised residue trials conducted in the US according to this GAP were submitted. In soya bean seeds (dry) residues were (n = 19): < 0.01(19) mg/kg.

The Meeting decided to combine the trials for beans, peas and soya beans as pulses according to US GAP for the purpose of estimation a maximum residue level, an HR and a STMR. Residues for pulses in rank order are (n = 33): < 0.01(32) and 0.05 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in pulses of 0.05 and 0.01 mg/kg, respectively.

Root and tuber vegetables

Lambda-cyhalothrin is registered in Italy for use on carrots at 0.013 kg ai/ha with a PHI of 3 days. Supervised residue trials conducted in Southern Europe with exaggerated rates of 0.025 kg ai/ha were submitted. In carrot roots residues were (n = 7): < 0.01(7) mg/kg.

Lambda-cyhalothrin is registered in Italy for use on potatoes at 0.013 kg ai/ha with a PHI of 15 days. Supervised residue trials conducted in Southern Europe with exaggerated rates of 0.025 kg ai/ha were submitted. In potato tubers residues were (n = 8): < 0.01(8) mg/kg.

The Meeting decided to combine the data available for the group of root and tuber vegetables based on the residue data for carrots and potatoes. The combined residues derived from supervised residue trials at exaggerated rates were (n = 15): < 0.01(15) mg/kg. The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in root and tuber vegetables of 0.01*, 0 and 0 mg/kg, respectively.

Asparagus

Lambda-cyhalothrin is registered in Thailand for use on asparagus at 0.018 kg ai/ha with a PHI of 3 days. Supervised residue trials conducted in Thailand according to this GAP were submitted. In asparagus sticks residues were (n = 6): 0.01(6) mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in asparagus of 0.02, 0.01 and 0.01 mg/kg, respectively.

Barley grain

In France lambda-cyhalothrin is registered on barley at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on barley conducted in Southern Europe according this GAP were submitted. In barley grain residues were (n = 29): < 0.01(3), 0.01(8), 0.02(5), 0.03(4), 0.04(4), 0.05, 0.06, 0.07, 0.08 and 0.33 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in barley grain of 0.5 and 0.02 mg/kg, respectively.

Maize grain

Lambda-cyhalothrin is registered in the United States for use on maize at 0.034 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In maize grain residues were (n = 19): < 0.01(18) and 0.01 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in maize grain of 0.02 and 0.01 mg/kg, respectively.

Oats, rye, triticale and wheat grain

Lambda-cyhalothrin is registered in the France for use on oats at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on oats conducted in Germany according to this GAP were submitted. In oats grain residues were (n = 5): < 0.01(4) and 0.02 mg/kg.

In France lambda-cyhalothrin is registered on rye at 0.008 kg ai/ha with a PHI of 28 days. One supervised residues trials on rye conducted in Germany according to this GAP was submitted. In rye grain residues were (n = 1): 0.01 mg/kg.

In France lambda-cyhalothrin is registered on triticale at 0.008 kg ai/ha with a PHI of 28 days. One supervised residues trials on triticale conducted in Germany according to this GAP was submitted. In triticale grain residues were (n = 1): < 0.01 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on wheat at 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials conducted in the US according to this GAP were submitted. In wheat grain residues were (n = 24): < 0.01(19), 0.01, 0.01, 0.02, 0.02 and 0.03 mg/kg.

In France lambda-cyhalothrin is registered on wheat at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on wheat conducted in Germany according to this GAP were submitted. In wheat grain residues were (n = 2): < 0.01 and 0.01 mg/kg.

The Meeting decided to extrapolate the data for wheat grain according to US GAP to make recommendation for oats, rye and triticale grain. The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in oats, rye, triticale and wheat grain of 0.05 and 0.01 mg/kg, respectively.

Rice grain

In the US lambda-cyhalothrin is registered on rice at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In rice grain residues were (n = 16): 0.06, 0.14, 0.15, 0.19, 0.2, 0.2, 0.24, 0.27, 0.32, 0.35, 0.42, 0.47, 0.48, 0.51, 0.66 and 0.79 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for lambda-cyhalothrin in rice grain of 1 and 0.295 mg/kg respectively.

Sorghum grain

Lambda-cyhalothrin is registered in the United States for use on sorghum at a maximum of 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials from the US were conducted at lower application rates of 0.022 kg ai/ha using ground and aerial application as well as furrow irrigation. None of these residue trials matched the maximum GAP submitted for sorghum.

The Meeting decided that the data submitted was not sufficient for an evaluation for the use of lambda-cyhalothrin in sorghum grain.

Sugar cane

Lambda-cyhalothrin is registered in the United States for use on sugar cane at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In sugar cane residues were (n = 9): < 0.01, < 0.01, 0.01, 0.02(5) and 0.03 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in sugar cane of 0.05, 0.02 and 0.03 mg/kg, respectively.

Tree nuts

Lambda-cyhalothrin is registered in the United States for use on almonds at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In almond nutmeat residues were (n = 5): < 0.01(5) mg/kg.

For pecans lambda-cyhalothrin is also registered in the US at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In pecan nutmeat residues were (n = 8): < 0.01(8) mg/kg.

Due to the fact that lambda-cyhalothrin is non-systemic and is mainly located on the surface of the commodities the Meeting decided to combine the data for almond and pecan nutmeat for mutual support to extrapolate to the whole group of tree nuts. The combined residues are: < 0.01(13) mg/kg

The Meeting estimated a maximum residue level, an STMR value and an HR value for lambda-cyhalothrin in tree nuts of 0.01*, 0.01 and 0.01 mg/kg, respectively.

Oilseeds

Lambda-cyhalothrin is registered in the United States for use on oilseed rape at 0.034 kg ai/ha with a PHI of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In rape seeds residues were (n = 7): < 0.01(3), 0.01, 0.02, 0.05 and 0.05 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on sunflowers at 0.034 kg ai/ha with a PHI of 45 days either with ground or with aerial application. Supervised residue trials conducted in the US according to these GAPs were submitted. In sunflower seeds residues following ground application were (n = 11): < 0.01(6), 0.01, 0.01, 0.03, 0.04 and 0.15 mg/kg. After aerial application residues in the seeds were (n = 5): < 0.01(4) and 0.03 mg/kg.

The Meeting decided that the data for sunflower seeds from ground and aerial application were from the same data population and can be combined. The combined residues were (n = 16): < 0.01(10), 0.01, 0.01, 0.03, 0.03, 0.04 and 0.15 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on cotton at 0.045 kg ai/ha with a PHI of 21 days either with ground or with aerial application. Supervised residue trials conducted in the US according to the GAP for aerial application were submitted. In cottonseeds residues following aerial application were (n = 4): < 0.01(4) mg/kg

Lambda-cyhalothrin is registered in the United States for use on peanuts at 0.034 kg ai/ha with a PHI of 14 days either with ground or with aerial application. Supervised residue trials conducted in the US according to the GAP for both application techniques were submitted. In peanut nutmeat residues following ground application were (n = 6): < 0.02(6) mg/kg. After aerial application residues in the nutmeat were (n = 2): < 0.02 and < 0.02 mg/kg.

The Meeting decided that the data for peanut nutmeat from ground and aerial application were from the same data population and can be combined. The combined residues are (n = 8): < 0.02(8) mg/kg.

Based on the use on sunflowers the Meeting decided to recommend a group maximum residue level for lambda-cyhalothrin in oilseeds. The estimated maximum residue level and STMR value for lambda-cyhalothrin in oilseeds were 0.2 and 0.01 mg/kg, respectively.

Peanut hay

Lambda-cyhalothrin is registered in the United States for use on peanuts at 0.034 kg ai/ha with a PHI of 14 days either with ground or with aerial application. Supervised residue trials conducted in the US according to the GAP for both application techniques were submitted, but only data after ground treatment is available for peanut hay. In peanut hay residues following ground application were (n = 5): 0.35, 0.65, 1.3, 1.3 and 2.2 mg/kg.

The Meeting estimated an STMR value and a highest residue value for lambda-cyhalothrin in peanut hay of 1.3 and 2.2 mg/kg respectively.

Soya bean fodder

For soya beans lambda-cyhalothrin is registered in the US at 0.034 kg ai/ha with a PHI of 30 days for ground and aerial application. One supervised residue trial conducted in the US according to the GAP for ground treatment was submitted. In soya bean fodder residues were: 0.3 mg/kg.

The Meeting concluded that the data submitted on soya bean fodder is not sufficient for an estimation of STMR and highest residue values.

Barley, oats, rye, sorghum and wheat forage

Due to the low degradation rate of lambda-cyhalothrin in plant metabolism studies no significant decline related to the dry matter content was anticipated by the Meeting. Therefore, the highest residue up to the PHI specified for grain harvesting was used for forage commodities unless specific limitations for grazing and/or forage were given on the label.

Lambda-cyhalothrin is registered in the United States for use on wheat at 0.034 kg ai/ha with a PHI for grazing and forage of 7 days. Supervised residue trials conducted in the US according to this GAP were submitted. In wheat forage residues were (n = 23): < 0.01, < 0.01, 0.19, 0.26, 0.27, 0.29, 0.3, 0.3, 0.31, 0.33, 0.35, 0.35, 0.37, 0.38, 0.43, 0.43, 0.51, 0.59, 0.65, 0.71, 0.75. 0.91 and 1.2 mg/kg.

In France lambda-cyhalothrin is registered on wheat at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on wheat conducted in Germany according to this GAP were submitted. In wheat forage residues were (n = 4): 0.04, 0.04, 0.05 and 0.06 mg/kg.

In Italy lambda-cyhalothrin is registered on barley at a rate of 0.015 kg ai/ha without a specified PHI for forage or grazing. Supervised residues trials conducted in Southern Europe according to this GAP were submitted. In barley forage residues after 0 to 18 days were (n = 12): 0.18, 0.24, 0.24, 0.28, 0.42, 0.42, 0.55, 0.72, 0.86, 0.92, 1.1 and 1.4 mg/kg.

In France lambda-cyhalothrin is registered on barley at 0.008 kg ai/ha without a specified PHI for forage or grazing. Supervised residues trials on barley conducted in Germany according to this GAP were submitted. In barley forage residues were (n = 5): 0.07, 0.15, 0.46, 0.52 and 0.88 mg/kg.

Lambda-cyhalothrin is registered in the France for use on oats at 0.008 kg ai/ha without a specified PHI for forage or grazing. Supervised residues trials on oats conducted in Germany according to this GAP were submitted. In oats forage after 0 days residues were (n = 5): 0.08, 0.17, 0.24, 0.24 and 0.3 mg/kg.

In France lambda-cyhalothrin is registered on rye at 0.008 kg ai/ha without a specified PHI for forage or grazing. One supervised residues trials on rye conducted in Germany according to this GAP was submitted. In rye forage after 0 days residues were (n = 1): 0.15 mg/kg.

In France lambda-cyhalothrin is registered on triticale at 0.008 kg ai/ha without a specified PHI for forage or grazing. One supervised residues trials on triticale conducted in Germany according to this GAP was submitted. In triticale forage after 0 days residues were (n = 1): 0.16 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on sorghum at 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials conducted in the US according to this GAP were submitted. In sorghum forage residues after 30 days within 30% of the GAP were (n = 10): 0.06, 0.08, 0.09, 0.09, 0.1, 0.11, 0.14, 0.16, 0.18 and 0.22 mg/kg.

The Meeting decided to estimate STMR and highest residue values for barley, oats, rye, sorghum and wheat forage on basis of the highest data population for barley according to the GAP from Italy. The corresponding STMR and highest residue values for lambda-cyhalothrin in barley, oats, rye, sorghum and wheat forage were 0.49 and 1.4 mg/kg (fresh-weight basis), respectively.

Maize forage

Lambda-cyhalothrin is registered in the United States for use on maize and sweet corn at 0.034 kg ai/ha with a PHI of 1 day for grazing. Supervised residue trials conducted in the US according to this GAP were submitted. In maize forage residues were (n = 6): 1.2, 1.4, 1.7, 2.0, 2.3 and 2.8 mg/kg.

The Meeting estimated an STMR value and a highest residue value for lambda-cyhalothrin in maize forage of 1.85 and 2.8 mg/kg (fresh-weight basis) respectively.

Straw and fodder of cereal grains

In Italy lambda-cyhalothrin is registered on barley at a rate of 0.015 kg ai/ha with a PHI of 30 days. Supervised residues trials conducted in Southern Europe according to this GAP were submitted. In barley straw residues were (n = 34): 0.06, 0.08, 0.09(3), 0.11, 0.11, 0.12, 0.13, 0.14, 0.14, 0.15, 0.15, 0.16, 0.16, 0.18, 0.19, 0.21, 0.23, 0.25, 0.28, 0.3, 0.3, 0.31, 0.32, 0.35, 0.4, 0.44, 0.48, 0.51, 0.65, 0.7, 0.82 and 1.2 mg/kg (fresh-weight basis). On a dry weight basis (DM 89%) residues were: 0.07, 0.09, 0.1(3), 0.12, 0.12, 0.13, 0.15, 0.16, 0.16, 0.17, 0.17, 0.18, 0.18, 0.2, 0.21, 0.24, 0.26, 0.28, 0.31, 0.34, 0.34, 0.35, 0.36, 0.39, 0.45, 0.49, 0.54, 0.57, 0.73, 0.79, 0.92 and 1.4 mg/kg.

In France lambda-cyhalothrin is registered on barley at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on barley conducted in Germany according to this GAP were submitted. In barley straw residues were (n = 5): 0.15, 0.25, 0.34, 0.41 and 0.43 mg/kg (fresh-weight basis). On a dry weight basis (DM 89%) residues were: 0.17, 0.28, 0.38, 0.46 and 0.48 mg/kg.

For the use on maize and sweet corn as fodder lambda-cyhalothrin is registered in the United States at 0.034 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In maize fodder residues were (n = 20): < 0.01, < 0.01, 0.05, 0.1, 0.12, 0.13(3), 0.15, 0.18, 0.19, 0.19, 0.2, 0.22, 0.23, 0.23, 0.24, 0.28, 0.34 and 0.4 mg/kg (fresh-weight basis). On a dry weight basis (DM 83%) residues were: < 0.01, < 0.01, 0.06, 0.12, 0.14, 0.16(3), 0.18, 0.22, 0.23, 0.23, 0.24, 0.26, 0.28, 0.28, 029, 0.34, 0.41 and 0.48 mg/kg.

Lambda-cyhalothrin is registered in France for use on oats at 0.008 kg ai/ha with a PHI of 28 days. Supervised residues trials on oats conducted in Germany according to this GAP were submitted. In oat straw residues were (n = 4): 0.04, 0.06, 0.06 and 0.25 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.04, 0.07, 0.07 and 0.28 mg/kg.

In the USA lambda-cyhalothrin is registered on rice at 0.045 kg ai/ha with a PHI of 21 days. Supervised residue trials conducted in the US according to this GAP were submitted. In rice straw residues were (n = 16): 0.15, 0.22, 0.23, 0.23, 0.42, 0.43, 0.45, 0.49, 0.49, 0.52, 0.65, 0.85, 0.87, 1.2, 1.4 and 1.4 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.17, 0.24, 0.26, 0.26, 0.47, 0.48, 0.5, 0.54, 0.54, 0.58, 0.72, 0.94, 0.97, 1.3, 1.6 and 1.6 mg/kg.

In France lambda-cyhalothrin is registered on rye at 0.008 kg ai/ha with a PHI of 28 days. One supervised residue trial on rye conducted in Germany according to this GAP was submitted. In rye straw residues were (n = 1): 0.1 mg/kg (fresh-weight basis). On a dry weight basis (DM 88%) residues were: 0.11 mg/kg.

In France lambda-cyhalothrin is registered on triticale at 0.008 kg ai/ha with a PHI of 28 days. One supervised residue trial on triticale conducted in Germany according to this GAP was submitted. In triticale straw residues were (n = 1): 0.06 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.07 mg/kg.

Lambda-cyhalothrin is registered in the United States for use on wheat at 0.034 kg ai/ha with a PHI of 30 days. Supervised residue trials conducted in the US according to this GAP were submitted. In wheat straw residues were (n = 24): 0.19, 0.21, 0.23, 0.24, 0.26, 0.27, 0.28, 0.29, 0.3, 0.31, 0.33, 0.35, 0.35, 0.36, 0.44, 0.47, 0.5, 0.52, 0.53, 0.7, 0.7, 0.84, 0.92 and 1.3 mg/kg (fresh-weight basis). On a dry weight basis (DM 88%) residues were: 0.21, 0.24, 0.26, 0.27, 0.29, 0.3, 0.31, 0.33, 0.34, 0.35, 0.37, 0.39, 0.39, 0.4, 0.49, 0.53, 0.56, 0.58, 0.6, 0.79, 0.79, 0.94, 1.0 and 1.5 mg/kg.

In France lambda-cyhalothrin is registered on wheat at 0.008 kg ai/ha with a PHI of at least 28 days. Supervised residues trials on wheat conducted in Germany according to this GAP were submitted. In wheat straw residues were (n = 9): 0.1, 0.11, 0.16, 0.2, 0.26, 0.34, 0.41, 0.42 and 0.61 mg/kg (fresh-weight basis). On a dry weight basis (DM 88%) residues were: 0.11, 0.12, 0.18, 0.22, 0.29, 0.38, 0.46, 0.47 and 0.69 mg/kg.

The Meeting noted that residues in cereal straw and fodder crops were of the same magnitude and decided to make recommendations for the whole group of straw and fodder of cereal grains. From the data population for rice straw according to US GAP that resulted in the highest residues, the

Meeting estimated a maximum residue level, an STMR value and a highest residue value for lambda-cyhalothrin in straw and fodder of cereal grains (dry-weight bases) of 2, 0.54 and 1.6 mg/kg respectively.

Almond hulls

Lambda-cyhalothrin is registered in the United States for use on almonds at 0.045 kg ai/ha with a PHI of 14 days. Supervised residue trials conducted in the US according to this GAP were submitted. In almond hulls residues were (n = 5): 0.29, 0.34, 0.38, 0.49 and 1.0 mg/kg (fresh-weight basis). On a dry weight basis (DM 90%) residues were: 0.32, 0.38, 0.42, 0.54 and 1.1 mg/kg.

The Meeting estimated a maximum residue level and a STMR value for lambda-cyhalothrin in almond hulls (dry-weight bases) of 2 and 0.42 mg/kg respectively.

Fate of residues during processing

The Meeting received information on the fate of lambda-cyhalothrin residues during processing of oranges, apples, peaches, plums, strawberries, currants, grapes, olives, tomatoes, spinach, beans, wheat, sorghum, rice sugarcane, soya beans and cotton seeds. Also information was provided on hydrolysis studies of lambda-cyhalothrin to assist with identification of the nature of the residue during processing. Processing factors presented below have been calculated for lambda-cyhalothrin for all commodities relevant to trade and/or the dietary intake estimation. Further data on processed commodities are presented in the evaluation for this active substance.

Lambda-cyhalothrin was stable under the hydrolysis condition (pH, temperature, time) representing the food processes pasteurisation, baking, brewing, boiling and sterilisation.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Oranges	juice	< 0.14, < 0.33	< 0.33
	wet pomace	1.6, 2	1.8
	dry pomace	3.9, 6.3	5.2
Apples	juice	< 0.1	<1
	wet pomace	< 1, 8.1	8.1
Grapes	raisins	3, 3	3
	wet pomace (white wine)	3.5	3.5
	wet pomace (red wine)	5.5	5.5
	dry pomace (white wine)	11	11
	dry pomace (red wine)	15	15
	young wine (white & red wine)	< 0.5, < 0.5	< 0.5
	juice (white & red)	< 0.5, < 0.5	< 0.5
Olives	virgin oil	0.46, 1	0.73
Tomatoes	juice	0.06	0.06
	paste	0.31	0.31
Wheat	bran	4.5	4.5
	middlings	1.0	1.0
	shorts & germs	1.5	1.5
	patent flour	0.5	0.5
	grain dust (< 420µ)	98	98
Rice	polished rice	< 0.01	< 0.01
	hulls	6.5	6.5
	bran	0.22	0.22

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Sugarcane	molasses	< 0.05	< 0.05
	refined sugar	< 0.05	< 0.05
Soya beans	hulls	< 1	< 1
	meal	< 1	< 1
	refined oil	< 1	< 1
Cottonseed	delinted seed	0.1	0.1
	hulls	0.1	0.1
	meal	< 0.1	< 0.1
	refined oil	0.1	0.1

Oranges were processed into juice and wet and dry pomace. Processing factors were < 0.33, 1.8 and 5.2 respectively. Based on the median residue of 0.05 mg/kg for whole oranges STMR-P values for lambda-cyhalothrin residues were 0.0165 mg/kg in orange juice, 0.09 mg/kg in wet pomace and 0.26 mg/kg in dry pomace.

Apples were processed into juice and wet pomace. Processing factors were < 0.1 for juice and 8.1 for wet pomace. Based on the STMR value of 0.08 mg/kg for pome fruit STMR-P values for lambda-cyhalothrin residues were 0.008 mg/kg for apple juice and 0.65 mg/kg for wet pomace.

Grapes were processed into wine, juice, raisins and wet and dry pomace. Processing factors were 0.5 for wine and juice (red and white combined), 3 for raisins and 5.5 and 15 for wet and dry pomace (based on red wine) respectively. Based on the STMR value of 0.02 for grapes STMR-P values were 0.01 mg/kg for wine and juice (red and white combined), 0.06 mg/kg for raisins and 0.11 mg/kg and 0.3 mg/kg for wet and dry pomace, respectively.

Based on the HR of 0.09 mg/kg estimated for grapes and the processing factor of 3 for raisins, the Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.06 and an HR of 0.27 mg/kg for lambda-cyhalothrin in dried grapes, respectively.

Olives were processed into virgin oil. The processing factor was 0.73. Based on the STMR value of 0.125 mg/kg for olives STMR-P value was 0.091 mg/kg for virgin oil.

Tomatoes were processed into juice and paste. Processing factors were 0.06 for juice and 0.31 for paste, respectively. Based on the STMR value of 0.03 mg/kg for tomatoes STMR-P values were 0.002 mg/kg for tomato juice and 0.007 mg/kg for paste, respectively.

Wheat was processed into bran, middlings, patent flour and grain dust. Processing factors were 4.5 for bran, 1 for middlings, 0.5 for flour (patent flour) and 98 for grain dust. Based on the STMR value of 0.01 mg/kg for wheat grain STMR-P values were 0.045 mg/kg for bran, 0.01 mg/kg for middlings, 0.005 mg/kg for flour and 0.98 mg/kg for grain dust.

Based on the STMR found in wheat grain of 0.01 mg/kg and a processing factor of 4.5 for wheat bran the Meeting estimated a maximum residue level of 0.1 mg/kg for wheat bran.

Rice was processed into polished rice, hulls and bran. Processing factors were < 0.01, 6.5 and 0.22 respectively. Based on the STMR value of 0.295 mg/kg for rice grain STMR-P values were 0.003 mg/kg for polished rice, 1.9 mg/kg for rice hulls and 0.065 mg/kg for rice bran.

Sugarcane was processed into molasses and refined sugar. Processing factors were < 0.05 and < 0.05, respectively. Based on the STMR value of 0.02 mg/kg for sugar cane STMR-P values were 0.001 mg/kg for molasses and refined sugar.

Soya beans were processed into hulls, meal and refined oil. In all cases the processing factors were < 1. Specific STMR-P values for lambda-cyhalothrin in soya beans can not be estimated.

Cottonseed was processed into delinted seed, hulls, meal and refined oil. Processing factors were 0.1 for delinted seeds, 0.1 for hulls, < 0.1 for meal and 0.1 for refined oil. Based on the STMR value of 0.01 mg/kg for cottonseeds STMR-P values were 0.001 for delinted seeds, 0.001 for hulls, 0.001 for meal and 0.001 for refined oil.

Farm animal dietary burden

The Meeting received lactating dairy cow feeding studies which provided information on likely residues resulting in animal tissues and milk from lambda-cyhalothrin residues in the animal diet.

Lactating dairy cows

Lactating Friesian dairy cows between four and nine years old were fed for up to 30 days on diets containing approximately 1, 5 and 25 ppm lambda-cyhalothrin. The lambda-cyhalothrin was incorporated into molasses, which was added to the concentrate feed at each of the twice-daily milking times. Each feeding group contained at least three cows; the 25 mg/kg group contained five cows. At the lowest dose level of 1 ppm no residues above the LOQ of 0.01 mg/kg were detected in meat. Liver and kidney gave small measurable residues at 0.03 mg/kg and 0.02 mg/kg respectively. Most of the residue was found in fat, ranging up to 0.5 mg/kg.

In the 5 ppm dose group comparable results were obtained. Residues in muscle, liver and kidney were in the range of 0.01 to 0.07 mg/kg. In fatty tissues lambda-cyhalothrin accumulated to a level up to 1.8 mg/kg. At the highest dose rate of 25 mg/kg residues were relatively high. Meat contained lambda-cyhalothrin resides up to 0.4 mg/kg. In liver lower residues compared to kidney were detected (0.08 mg/kg and 0.4 mg/kg respectively). Most of the residue was found in fat ranging from 1.3 up to 7.2 mg/kg.

Tissues from cows in the 25 mg/kg group that were allowed a recovery period on untreated diet of one week contained significantly lower residues of < 0.01–0.05 mg/kg (meat), < 0.01 mg/kg (liver), 0.10–0.20 mg/kg (kidney) and 0.03–2.6 mg/kg (fat).

In the milk residues reached a plateau after a dosing period of 10 to 12 days in all dose groups. For the feeding levels of 1, 5 and 25 ppm average residues in milk were 0.03, 0.1 and 0.83 mg/kg, respectively. No separation between cream and skim milk was conducted.

In a second study lactating Holstein dairy cows between four and six years old were fed for 28 days on diets containing approximately 8, 25 and 60 ppm lambda-cyhalothrin (administered as gelatine capsules). Each feeding group contained at least four cows. At the lowest dose group of 8 ppm lambda-cyhalothrin in the diet, residues were relatively low (< 0.01–0.09 mg/kg for liver and 0.02–0.08 mg/kg in kidney). Over the whole dosage interval up to 60 mg/kg in the diet, an increase in the residue up to 0.09 mg/kg in liver and 0.3 mg/kg in kidney was observed. Residues levels of compound Ia were comparable to lambda-cyhalothrin.

Estimated maximum and mean dietary burdens of farm animals

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 and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, lambda-cyhalothrin, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Beef cattle	4.07	2.83	5.93	4.03	6.12	4.05
Dairy cattle	4.55	3.1	4.79	3.27	6.12[a]	4.07[b]
Poultry - broiler	0.65	0.65	0.25	0.25	0.40	0.40
Poultry - layer	0.65	0.65	1.09	0.74	0.40	0.40

a Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat and milk

b Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat and milk

Animal commodities, MRL estimation

For MRL estimation, the residues in the animal commodities are lambda-cyhalothrin. The residue is fat-soluble.

Cattle

For MRL estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden (6.12 ppm) between the relevant feeding levels (5 and 25 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups. Only the feeding study conducted at rates of 1, 5 and 25 ppm was used for the estimation, since the second study available has a lowest dose of 8 ppm, which is higher than the maximum dietary burden for beef and dairy cattle.

The STMR values for the tissues were calculated by interpolating the mean dietary burden (4.07 ppm) between the relevant feeding levels (1 and 5 ppm) and using the mean tissue concentration from each feeding group.

In the table below, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding studies are shown in square brackets [] and estimated concentrations related to the dietary burden are shown without brackets.

Dietary burden (ppm) Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
MRL					
	mean	highest	highest	highest	highest
MRL beef or dairy cattle (6.12) [5, 25]	0.12 [0.1, 0.57]	0.1 [0.07, 0.4]	0.02 [0.01, 0.08]	0.09 [0.07, 0.4]	2.2 [1.8, 7.2]
STMR					
	mean	mean	mean	mean	mean
STMR beef or dairy cattle (4.07) [1, 5]	0.08 [0.03, 0.1]	0.04 [0.01, 0.05]	0.008 [0.03, 0.01]	0.03 [0.01, 0.04]	1.0 [0.25, 1.3]

The data from the cattle feeding study were used to support mammalian meat and milk MRLs.

The Meeting estimated a maximum residue level for lambda-cyhalothrin in whole milk of 0.2 mg/kg. No information was available on the distribution of residue between fat and non-fat milk fractions.

The residue arising from a dietary burden of 6.12 ppm was 2.2 mg/kg in the fat. Since the target tissue for lambda-cyhalothrin residues in animal tissues is fat, the Meeting recommended a maximum residue level of 3 mg/kg for meat (on a fat basis) and fat.

For kidney and liver the interpolation between the 5 and 25 ppm dose group lead to estimates of 0.09 mg/kg and 0.02 mg/kg respectively. On basis of the estimates, the Meeting recommended maximum residue levels of 0.2 mg/kg for kidney and 0.05 mg/kg for liver. All maximum residue levels recommended for animal commodities represent higher values as compared to those currently established in the Codex system by JECFA.

For dietary risk assessment, the STMR values are 0.08 mg/kg for whole milk, 1.0 mg/kg for meat/fat, 0.04 mg/kg for muscle, 0.03 mg/kg for kidney and 0.008 mg/kg for liver. The estimated HR values were 2.2 mg/kg for meat/fat, 0.1 mg/kg for muscle, 0.09 mg/kg for kidney and 0.02 mg/kg for liver. For liver residue data did not scale according to the dosing level in the feed. The Meeting decided to use the values for the dose level of 5 ppm as a basis for the estimation instead of the values at 1 ppm, since the residue data from higher dose rates seem to reflect a more realistic transfer into the liver of the animals.

For poultry no livestock feeding studies using lambda-cyhalothrin were submitted to the Meeting. A recommendation for maximum residue levels as well as for STMR and HR values is not possible.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of lambda-cyhalothrin 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 3–10% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that the long-term intake of residues of lambda-cyhalothrin 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 lambda-cyhalothrin 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 4.

The IESTI calculated on the basis of the recommendations made by the JMPR represented 0–60% of the ARfD (0.02 mg/kg bw) for children and 0–40% for the general population.

For head cabbage the prospective approach of an alternative GAP was used.

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

5.9 CYPERMETHRINS (118)

INCLUDES CYPERMETHRIN (118), ALPHA-CYPERMETHRIN AND ZETA-CYPERMETHRIN

RESIDUE AND ANALYTICAL ASPECTS

Cypermethrin was first evaluated by the 1979 JMPR and a number of times subsequently. It was reviewed for toxicology by the 2006 JMPR within the periodic review programme of the CCPR; the review included alpha-cypermethrin and zeta-cypermethrin, which had not previously been considered by the JMPR. The periodic review for residues was scheduled for 2008.

CCPR, at its 39th Session in 2007, noted that three manufacturers would submit residue data to JMPR on cypermethrins (including alpha and zeta cypermethrin) for consideration by the 2008 JMPR. Information and data were also provided by Australia, Japan, Malaysia and Thailand.

Separate monographs have been prepared for each of the three compounds, but they are considered together in a single appraisal.

The Meeting agreed that metabolism studies, environmental fate studies, methods of analysis and freezer storage stability studies of the cypermethrins were mutually supportive and should be considered together.

Comparison of composition

Isomer	cypermethrin	alpha-cypermethrin	zeta-cypermethrin
1R, cis-R	14	-	3
1S, cis-S	14	-	22
1R, cis-S	11	50	22
1S, cis-R	11	50	3
1R, trans-R	14	-	3
1S, trans-S	14	-	22
1R, trans-S	11	-	22
1S, trans-R	11	-	3

Animal metabolism

The Meeting received studies on lactating dairy cows and laying hens for both alpha-cypermethrin and cypermethrin. Studies on rats were reviewed by JMPR during the toxicology evaluation in 2006; rat studies were made available again.

After oral dosing of livestock with cypermethrins, much of the residues are readily excreted. The main component of the residue in tissues, milk and eggs is parent compound. The residue is fat soluble.

When a lactating dairy cow was orally dosed with [^{14}C]alpha-cypermethrin at the equivalent of 19 ppm in the diet over 5 days, the TRR quickly approached a plateau in milk. When milk was separated, 93% of the residue was in the cream suggesting fat solubility. TRR levels in tissue fat were approximately 20 times as high as in the muscle, also suggesting fat solubility.

Similar results were obtained from lactating dairy cow studies with cypermethrin. Levels of ^{14}C in the tissues from cypermethrin labelled in the cyclopropyl ring or the benzyl ring were much the same, suggesting that the ester bond was still intact in the residue.

When laying hens were orally dosed with [^{14}C]alpha-cypermethrin over 14 days, much of the ^{14}C was quickly excreted in the faeces. The TRR in eggs approached a plateau by days 7–9. Parent

alpha-cypermethrin was the major identified component in fat and eggs, and the distribution between tissue fat and muscle suggested fat solubility. Metabolites at low levels were produced by ester cleavage and hydroxylation of the phenoxy ring.

A study with cypermethrin dosing of laying hens produced similar results. Ester hydrolysis was the main initial metabolic pathway for cypermethrin. Parent cypermethrin was a significant part of the residue in fat and egg yolks. DCVA (3-(2,2-dichlorovinyl)2,2-dimethylcyclopropane carboxylic acid) was a major part of the residue in muscle and liver. A number of minor metabolites were identified, especially in liver, as resulting from ester cleavage and hydroxylation of the phenoxy group.

The metabolic pathways of the cypermethrins in rats, cattle and hens are qualitatively similar in the respect that the metabolic products result from ester hydrolysis and hydroxylation.

No specific information was provided on possible isomerisation during animal metabolism. However, in the abiotic hydrolysis experiments with alpha-cypermethrin, epimerization rates were more rapid than hydrolysis rates, which suggest that where hydrolysis occurs, epimerization is a possibility.

Plant metabolism

The Meeting received plant metabolism studies with cypermethrin on lettuce, sugar beet, maize, cotton and apples; alpha-cypermethrin on cabbages and wheat, and zeta-cypermethrin on maize.

When cypermethrins are applied to a crop, the highest residue occurs on parts of the plant exposed to direct application. Parent compound is the major identified residue with very little absorbed or translocated. Metabolites result from ester hydrolysis and hydroxylation processes. Exposed residues are subject to isomerisation, presumably by a photolytic process.

When [^{14}C]cypermethrin was applied to lettuce via syringe, cypermethrin was a major part of the residue in lettuce sampled 30 days later. In a second experiment with lettuce, the levels of TRR were much higher in the outer leaves than in the inner leaves.

In a later study, when [^{14}C]cypermethrin was sprayed on lettuce plants, which were harvested 18 and 21 days after the second application, the ^{14}C residue was mostly on the outer leaves and cypermethrin was the main residue component, suggesting that cypermethrin is not translocated.

In a cabbage study with [^{14}C]alpha-cypermethrin, the residue occurred mostly on the outer (exposed) leaves and alpha-cypermethrin was the major component. Very little of the alpha-cypermethrin moved elsewhere in the plant. The alpha-cypermethrin residue had undergone considerable cis-trans isomerisation, with the cis 2 component, originally constituting 100% of alpha-cypermethrin, falling to 44% and 54% of the cypermethrin residue in the old and new leaves respectively. The isomerisation was presumably a photochemical reaction.

In the wheat studies with alpha-cypermethrin, the highest residue of ^{14}C occurred in the chaff and straw, the part of the plant exposed to the application. Parent alpha-cypermethrin was a major component of the residue. Translocation to the grain was minor. Where alpha-cypermethrin was exposed to sunlight, it was subject to isomerisation. Identified metabolites, which were generally minor components of the residue, resulted from ester hydrolysis or hydroxylation of a benzene ring.

When [^{14}C]cypermethrin was foliar sprayed three times on sugar beet, parent cypermethrin was the main component of the residue in roots (TRR 0.48 and 0.68 mg/kg) and leaves (TRR 7.0 and 9.1 mg/kg) when the crop was harvested 3 weeks after the final application. Metabolite DCVA and its conjugates (glucoside, malonyl glucoside and glucoside disulfate) constituted 35% of the TRR in both foliage and roots.

When [^{14}C]cypermethrin was painted on leaves of maize plants, very little of the ^{14}C reached the ears or grain. Parent cypermethrin was the major component of the residue in parts of the plant that were directly treated constituting 64–82% of the TRR in forage, silage, fodder and husk + stalk.

DCVA and 3-phenoxybenzoic acid (and related degradation products) were identified in the residue as well as 4'-hydroxy-cypermethrin and cyperamide (-CN converted to $–CONH_2$).

The pattern of residues occurring in a maize metabolism study with foliar applied [^{14}C]zeta-cypermethrin was generally similar to that from the previous study with cypermethrin. A comparison of cis:trans ratios between the parent compound and the residue showed that the cis isomer was depleting more quickly. A parallel study with cypermethrin confirmed the similarity in residue behaviour between zeta-cypermethrin and cypermethrin. One difference was that the cis:trans ratio changed very little in the residue from cypermethrin labelled in the cyclopropyl ring.

When cotton was foliar sprayed with [^{14}C]cypermethrin and the crop harvested 74 and 88 days after treatment, parent cypermethrin was the major identified component of the residues, constituting 23–25% of TRR in the forage and 16% in the cotton seed. Numerous metabolites were identified that resulted from ester hydrolysis and hydroxylation.

In an experiment with apples where acetone solutions of [^{14}C]*cis*-cypermethrin and [^{14}C]*trans*-cypermethrin were applied to leaves or the surface of apples, residues remained mostly on the peel of apples harvested 22 days later. Part of the *cis*-cypermethrin had been converted to *trans*-cypermethrin (30% in leaf and 15% in apple peel), but not the reverse. Cypermethrin was the main component of the residue in apples. Metabolites resulting from ester hydrolysis were identified.

Environmental fate in soil

The Meeting received information on soil aerobic metabolism, soil photolysis and crop rotation.

The cypermethrins are generally not persistent in soils. Their residues in soils resulting from recommended uses should not contribute to the residues in root vegetables or to residues in succeeding crops. Identified soil metabolites result from ester hydrolysis. Cyperamide is produced in soil surface photolysis.

In laboratory soil metabolism studies, the half-lives were:

- alpha-cypermethrin at 20–25 °C: 20 days to 24 weeks (n = 3);
- cypermethrin at 20–25 °C: 6 days to 61 days (n = 10).

DCVA and 3-phenoxybenzoic acid were identified as soil metabolites.

In a series of soil metabolism studies at 25 °C with *cis*- and *trans*-cypermethrin, the percentage parent remaining after 52 weeks was 4.9–11% (n = 4) for *cis*-cypermethrin and 1.4–4.1% (n = 4) for *trans*-cypermethrin. 3-Phenoxybenzoic acid was identified as a metabolite.

The measured half-lives in soil surface hydrolysis studies were: alpha-cypermethrin 30 days; cypermethrin 470–690 hours (n = 4). DCVA, 3-phenoxybenzoic acid and cyperamide were identified as transformation products.

In a confined rotational crop study with wheat, cotton, lettuce and sugar beet, soil was treated with [^{14}C-benzyl ring]cypermethrin at the equivalent of 1 kg ai/ha and the crops were sown at 30, 60, 90 and 120 days later. Low levels of ^{14}C did enter all the crops, with concentrations lower as the time interval increased. The levels were too low for component identification. A parallel experiment with [^{14}C-cyclopropyl]cypermethrin and sugar beet produced similar results.

Metabolism in water-sediment systems

The Meeting received information on the fate of zeta-cypermethrin during aerobic aquatic metabolism.

Zeta-cypermethrin is not persistent in aerobic water-sediment systems with much of the residue being mineralized in a relatively short time.

The measured half-lives of parent zeta-cypermethrin in water-sediment systems at 20 and 25 °C were 8.8–12 days (n = 6). Identified metabolites were: 3-phenoxybenzoic acid, DCVA, DCVA dicarboxylic acid. Metabolites reached their maximum concentrations before the end of the experiments (duration 30 and 99 days), so were also metabolizing further. The degree of mineralization in 30 days was 47% and 11% and in 99 days was 16%, 21%, 52% and 57%.

Methods of analysis

The Meeting received descriptions and validation data for numerous analytical methods for residues of the cypermethrins in raw agricultural commodities, processed commodities, feed commodities, animal tissues, milk and eggs.

Residue analytical methods for the cypermethrins rely on GC-ECD, GC-MS or LC-MS-MS. Typically the residues can be measured in most matrices to an LOQ of 0.01 mg/kg (0.05 mg/kg in some older studies). Multiresidue method DFG S-19 is suitable for residue analysis of cypermethrin.

Stability of residues in stored analytical samples

Information was received on the freezer storage stability of:

- alpha-cypermethrin residues in apple, cattle fat, cattle kidney, cattle liver, cattle milk, cattle muscle, lettuce, oilseed rape plant, oilseed rape pod, oilseed rape seeds, soya bean, tomato, wheat, wheat grain, wheat green plant and wheat straw.
- cypermethrin residues in apples, cabbage, cotton seed, egg, green peas, lettuce, lettuce, poultry liver, poultry muscle, rape seed, soya beans, tomatoes and wheat grain.
- zeta-cypermethrin residues in dry pea grain, molasses, sugar beet dried pulp, sugar beet roots, wheat grain and white sugar.

Residues were apparently stable at freezer temperature for the intervals tested except for a few studies where no conclusion could be reached because of experimental problems. In an oilseed rape plant, pods and seeds study with alpha-cypermethrin, no samples were analysed until 4.5–5 months after fortification when residues were 40–50% of the nominal fortification level.

In an alpha-cypermethrin study on apples, residues were apparently stable for 52 weeks (110%) but had declined to 65% by week 84.

The results of a cypermethrin study on eggs were inconclusive because of low analytical method recoveries.

Residue definition

The parent compound (whether cypermethrin, alpha-cypermethrin or zeta-cypermethrin) is the dominant component of the residue in crop commodities and in tissues, milk and eggs from oral dosing of livestock. In animal metabolism, it displays the properties of a fat-soluble compound.

Some isomerisation and differential decay rates for different isomers occur for exposed residues in the field, so the composition of the residue is not necessarily identical with that of the applied compound.

The current residue definition, cypermethrin (sum of isomers), is a suitable analyte for enforcement purposes.

The Meeting decided that the residue would continue to be defined as fat-soluble.

The Meeting recommended a residue definition for the cypermethrins.

For plants and animals. Definition of the residue (for compliance with the MRL and for estimation of dietary intake)*: cypermethrin (sum of isomers).*

The residue is fat soluble.

Use pattern

The Meeting received information on the use patterns and labels for alpha-cypermethrin, cypermethrin and zeta-cypermethrin from many countries.

Results of supervised residue trials on crops

The Meeting received supervised trials data for alpha-cypermethrin, cypermethrin and zeta-cypermethrin.

Alpha-cypermethrin: citrus, apples, pears, cherries, peaches, grapes, strawberries, olives, leek, onion, broccoli, Brussels sprouts, cabbage head, cauliflower, cucumber, melon, egg plant, sweet peppers, sweet corn, tomato, kale, leafy cabbage, lambs lettuce, lettuce, spinach, peas, beans, soya beans, potato, sugar beet, turnip, asparagus, artichoke, barley, maize, oats, rice, sorghum, wheat, almond, cotton, linseed, rapeseed, cocoa, parsley, alfalfa, pea fodder and forage, bean fodder and forage, barley fodder and forage, maize fodder and forage, oats fodder and forage, rice fodder and forage, wheat fodder and forage, sugar beet leaves or tops, cotton fodder, rape seed fodder, hops and tea.

Cypermethrin: grapes, carambola, olives, durian, litchi, longan, mango, papaya, leek, onion, broccoli, Brussels sprouts, cabbage head, cauliflower, melon, okra, peppers Chilli, tomato, lettuce, spinach, peas, beans, carrot, potato, sugar beet, artichoke, asparagus, barley, maize, wheat, wheat, cotton seed, rapeseed, alfalfa, pea fodder and forage, bean fodder and forage, barley fodder and forage, maize fodder and forage, wheat fodder and forage and sugar beet leaves or tops.

Zeta-cypermethrin: pome fruits, stone fruits, onion, broccoli, cucurbits, peppers, tomatoes, sweet corn, endive, lettuce, lettuce, spinach, mustard greens, peas, field beans, soya bean seed, sugar beet, sugar beet, maize, barley, wheat, oats and triticale, rice, sugar cane, peanuts, oilseed rape, cotton seed, coffee, alfalfa, pea fodder and forage, bean fodder and forage, barley fodder and forage, sweet corn fodder and forage, maize fodder and forage, oats and triticale straw, wheat fodder and forage, rice straw and sugar beet tops.

Where multiple sets of sufficient residue data were available on a commodity for more than one compound or with different uses (e.g., field and glasshouse), the set of data first chosen to support an MRL for that commodity was the one producing the highest estimated maximum residue level.

Where multiple sets of sufficient residue data were available for commodities in a Codex Commodity Food Group and where the Meeting decided to recommend a Commodity Group MRL, the set of data first chosen to support the MRL for that commodity group was the one producing the highest estimated maximum residue level.

The cypermethrins are used at quite low application rates, often around the 10–50 g ai/ha. For some commodities, residue levels arising from such low application rates may not produce detectable residues even on the day of application. For example, the median residue produced on the day of treatment by a 10 g ai/ha application would be expected to be at 0.01 mg/kg or lower for apples, Brussels sprouts, cucumber, melons, oranges, peppers, plums, summer squash and tomatoes.

Questions would usually be raised about the validity of a supervised trial where residues were not detected on the day of application to an exposed commodity, but allowance must be made for the low application rate.

No residue data were received for mushrooms. The Meeting withdrew the previous recommendation of 0.05* mg/kg for mushrooms.

Citrus fruits

No suitable GAP was available to evaluate the alpha-cypermethrin trials on citrus. The Meeting withdrew the previous recommendation of 2 mg/kg for citrus fruits.

Pome fruits

Polish GAP allows the use of alpha-cypermethrin on apple trees at 0.018 kg ai/ha with a PHI of 7 days. In two French trials matching Polish GAP (± 30% application rate), alpha-cypermethrin residues on apples were 0.01 and 0.05 mg/kg. In 6 German trials on apples matching Polish GAP (± 30% application rate), alpha-cypermethrin residues were: 0.05, 0.05, 0.05, 0.07, 0.08 and 0.17 mg/kg.

No suitable GAP was available to evaluate the remaining alpha-cypermethrin apple trials or the pear trials.

US GAP for pome fruit allows the use of zeta-cypermethrin at 0.056 kg ai/ha with a 14 days PHI. In 23 US trials matching GAP, zeta-cypermethrin residues on apples were: 0.11, 0.11, 0.11, 0.12, 0.12, 0.13, 0.13, 0.13, 0.13, 0.13, 0.14, 0.15, 0.20, 0.21, 0.21, 0.22, 0.23, 0.24, 0.25, 0.25, 0.28 and 0.31 mg/kg.

US GAP for pome fruit allows the use of zeta-cypermethrin at 0.056 kg ai/ha with a 14 days PHI. In 12 US trials matching GAP, zeta-cypermethrin residues on pears were: 0.05, 0.05, 0.06, 0.07, 0.24, 0.29, 0.31, 0.33, 0.39, 0.43, 0.49and 0.56 mg/kg.

The Meeting decided to use the combined apple and pear zeta-cypermethrin data, 34 trials, for a pome fruit recommendation, rank order, median underlined: 0.05, 0.05, 0.06, 0.07, 0.11, 0.11, 0.11, 0.12, 0.12, 0.13, 0.13, 0.13, 0.13, 0.13, 0.14, 0.15, <u>0.20</u>, <u>0.21</u>, 0.21, 0.22, 0.23, 0.24, 0.24, 0.25, 0.25, 0.28, 0.29, 0.31, 0.31, 0.33, 0.39, 0.43, 0.49 and 0.56 mg/kg.

On the basis of the zeta-cypermethrin data, the Meeting estimated a maximum residue level of 0.7 mg/kg for pome fruits to replace the previous recommendation of 2 mg/kg. The Meeting estimated STMR and HR values of 0.205 and 0.56 mg/kg respectively for pome fruits.

Stone fruits

Romanian GAP allows the use of alpha-cypermethrin on cherry and peach trees at a spray concentration of 0.0015 kg ai/hL and a PHI of 7 days.

In three French trials on cherries matching Romanian GAP, alpha-cypermethrin residues on cherries were < 0.05, 0.06 and 0.11 mg/kg.

In one French trial on peaches matching Romanian GAP, alpha-cypermethrin residues on peaches were 0.02 mg/kg.

In South Africa, alpha-cypermethrin may be used on peaches with a spray concentration of 0.0005 kg ai/hL and an interval to harvest of 14 days. In two South African trials according to GAP conditions, residues in the peaches were < 0.05 and 0.06 mg/kg.

No suitable GAP was available to evaluate the remaining alpha-cypermethrin peach trials.

US GAP for stone fruit allows the use of zeta-cypermethrin at 0.056 kg ai/ha with a 14 days PHI.

In 12 US trials matching stone fruit GAP, zeta-cypermethrin residues on cherries were: 0.52, 0.52, 0.53, 0.57, 0.58, <u>0.58</u>, <u>0.60</u>, 0.64, 0.77, 0.80, 0.86 and 0.94 mg/kg. This data set was used for maximum residue level estimation.

In 18 US trials matching stone fruit GAP, zeta-cypermethrin residues on peaches were: 0.08, 0.09, 0.09, 0.09, 0.09, 0.09, 0.10, 0.10, <u>0.10</u>, <u>0.10</u>, 0.11, 0.13, 0.13, 0.14, 0.14, 0.14, 0.15 and 0.16 mg/kg.

In 12 US trials matching stone fruit GAP, zeta-cypermethrin residues on plums were: 0.06, 0.06, 0.06, 0.06, 0.07, 0.08, 0.15, 0.18, 0.18, 0.21, 0.21 and 0.27 mg/kg.

The Meeting noted that zeta-cypermethrin cherry data were probably a different population from the peach and plum data and should not be combined. The Meeting noted that the GAP was for 'stone fruit' and decided to recommend a stone fruits MRL based on the cherry data.

On the basis of the zeta-cypermethrin cherry data, the Meeting estimated a maximum residue level of 2 mg/kg for stone fruits to replace the previous recommendations for cherries, nectarines, peaches and plums. The Meeting estimated STMR and HR values of 0.59 and 0.94 mg/kg respectively for stone fruits.

Grapes

French GAP for grapes allows the use of alpha-cypermethrin at 0.015 kg ai/ha with a 14 days PHI.

In 39 French and German trials on grapes matching French GAP (± 30% application rate), alpha-cypermethrin residues on grapes were (rank order, median underlined): < 0.01 (6), 0.01 (8), 0.02 (6), 0.03 (4), 0.04, < 0.05(10), 0.05, 0.06, 0.06 and 0.07 mg/kg.

Greek and Portuguese GAPs for grapes allow the use of alpha-cypermethrin at 0.015 kg ai/ha with a 7 days PHI.

In 18 Greek, Italian and Spanish trials on grapes matching Greek and Portuguese GAP (± 30% application rate), alpha-cypermethrin residues on grapes were: < 0.01 (4), 0.01 (4), 0.03, 0.03, 0.04, 0.05, 0.05, < 0.05 (4) and 0.05 mg/kg.

In 18 French trials on grapes matching Greek and Portuguese GAP (± 30% application rate), alpha-cypermethrin residues on grapes were: < 0.01 (10), 0.01, 0.01, 0.03, 0.04, 0.06, 0.08, 0.08 and 0.09 mg/kg. This data set was used for maximum residue level estimation.

No suitable GAP was available for evaluating the cypermethrin trials on grapes.

On the basis of the 18 alpha-cypermethrin trials in France matching Greek and Portuguese GAP, the Meeting estimated a maximum residue level of 0.2 mg/kg for grapes. The Meeting estimated STMR and HR values of 0.01 and 0.09 mg/kg respectively for grapes.

Strawberries

Alpha-cypermethrin may be used in Greece and Italy on glasshouse strawberries at 0.050 kg ai/ha with a PHI of 3 days. No glasshouse trials on strawberries were available at an application rate of 0.050 kg ai/ha.

Alpha-cypermethrin may be used on strawberries in the field in France at an application rate of 0.011 kg ai/ha with harvest 3 days later.

In 16 strawberry trials in Belgium, France, Germany, Netherlands and the UK matching French GAP (± 30% application rate), alpha-cypermethrin residues (rank order, median underlined) were: 0.005, 0.006, < 0.01 (11), 0.02, 0.02, 0.03 mg/kg.

Greek GAP allows the use of alpha-cypermethrin on strawberries in the field at 0.030 kg ai/ha with harvest 3 days later.

In eight strawberry trials in Greece, Italy and Spain matching Greek GAP (± 30% application rate), alpha-cypermethrin residues (rank order, median underlined) were: < 0.01 (5), 0.02, 0.02 and 0.05 mg/kg. This data set was used for maximum residue level estimation.

The two data populations are quite similar. The Meeting agreed to use the eight trials from Greece, Italy and Spain as the basis for the residue estimations.

On the basis of the eight alpha-cypermethrin trials in Greece, Italy and Spain matching Greek GAP, the Meeting estimated a maximum residue level of 0.07 mg/kg for strawberries. The Meeting estimated STMR and HR values of 0.01 and 0.05 mg/kg respectively for strawberries.

Olives

In Greece, alpha-cypermethrin may be used on olive trees at 0.030 kg ai/ha with a 7-days PHI. No trials were available to support the Greek GAP.

In Algeria, alpha-cypermethrin is registered for use on olive trees at a spray concentration of 0.002 kg ai/hL with harvest 14 days later.

In eight trials on olives in Greece and Spain where alpha-cypermethrin was used according to Algerian GAP (± 30% spray concentration), alpha-cypermethrin residues were: < 0.05 mg/kg (8). Residues were present in some samples from the trials, so it is not an 'essentially zero residue' situation and the STMR and HR are estimated equivalent to the LOQ.

No relevant GAP was available to evaluate the cypermethrin trials on olives.

On the basis of the eight alpha-cypermethrin trials in Greece and Spain matching Algerian GAP, the Meeting estimated a maximum residue level of 0.05* mg/kg for olives. The Meeting estimated STMR and HR values of 0.05 and 0.05 mg/kg respectively for olives.

Carambola

Cypermethrin is registered for use on carambola in Malaysia at 0.023 kg ai/ha with a PHI of 3 days.

In five carambola trials from Malaysia with cypermethrin use matching GAP, residues were (rank order, median underlined): < 0.02, < 0.02, < 0.<u>02</u>, 0.03 and 0.09 mg/kg.

The Meeting recognized that carambola is a minor crop and that five trials were sufficient for estimating a maximum residue level.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in carambola of 0.2, 0.02 and 0.09 mg/kg respectively.

Durian

In Thailand, cypermethrin is registered for use on durians at a high-volume spray concentration of 0.0125 kg ai/hL with harvest 14 days later.

In six durian trials from Thailand with cypermethrin use matching GAP, residues were (rank order, median underlined): 0.04, 0.08, <u>0.10</u>, <u>0.17</u>, 0.38 and 0.47 mg/kg. No information was available on residues in edible portion.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in durian of 1, 0.135 and 0.47 mg/kg respectively.

Litchi

In Thailand, cypermethrin is registered for use on litchis at a high-volume spray concentration of 0.0075 kg ai/hL with harvest 14 days later.

In six litchi trials from Thailand with cypermethrin use matching GAP, residues were (rank order, median underlined): 0.25, 0.41, <u>0.45</u>, <u>0.54</u>, 0.57 and 0.79 mg/kg. No information was available on residues in edible portion.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in litchis of 2, 0.495 and 0.79 mg/kg respectively.

Longan

In Thailand, cypermethrin is registered for use on longans at a high-volume spray concentration of 0.0075 kg ai/hL with harvest 14 days later.

In six longan trials from Thailand with cypermethrin use matching GAP, residues were (rank order, median underlined): 0.25, 0.27, 0.28, 0.32, 0.36 and 0.47 mg/kg. No information was available on residues in edible portion.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in longans of 1, 0.30 and 0.47 mg/kg respectively.

Mango

In Thailand, cypermethrin is registered for use on mangos at a high-volume spray concentration of 0.005 kg ai/hL with harvest 5 days later.

In six mango trials from Thailand with cypermethrin use matching GAP, residues were (rank order, median underlined): 0.09, 0.10, 0.15, 0.23, 0.25 and 0.35 mg/kg. No information was available on residues in edible portion.

The cypermethrin data on mangos from Malaysia could not be evaluated because no suitable GAP was available.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in mango of 0.7, 0.19 and 0.35 mg/kg respectively.

Papaya

In Malaysia, cypermethrin is registered for use on papaya at an application rate of 0.0275 kg ai/ha with harvest 14 days later.

In six papaya trials from Malaysia with cypermethrin use matching GAP, residues were (rank order, median underlined): 0.08, 0.10, 0.12, 0.15, 0.15 and 0.23 mg/kg. No information was available on residues in edible portion.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in papaya of 0.5, 0.135 and 0.23 mg/kg respectively.

Leek

In Germany, alpha-cypermethrin is registered for use on leeks at an application rate of 0.009 kg ai/ha with harvest 14 days later.

In eight leek trials from Germany with alpha-cypermethrin use matching GAP, residues were (rank order, median underlined): < 0.01 (4), 0.01, 0.02, 0.02 and 0.03 mg/kg.

In Spain, alpha-cypermethrin is registered for use on leeks at an application rate of 0.03 kg ai/ha with harvest 2 days later.

In two leek trials from France, one from Italy and one from Spain with alpha-cypermethrin use approximately matching GAP, residues were: 0.02, 0.03, 0.06 and 0.11 mg/kg.

No suitable GAP was available for evaluating the cypermethrin trials on leeks in France, Germany and Poland.

The number of trials on leeks matching Spanish GAP was too few to make a recommendation.

On the basis of the eight alpha-cypermethrin trials in Germany matching GAP, the Meeting estimated a maximum residue level of 0.05 mg/kg for leeks. The Meeting estimated STMR and HR values of 0.01 and 0.03 mg/kg respectively for leeks.

Onion

In Germany, alpha-cypermethrin is registered for use on onions at an application rate of 0.013 kg ai/ha with harvest 14 days later.

In 16 onion trials with alpha-cypermethrin use matching German GAP from Germany (4), France (6), Netherlands (4) and the UK (2), residues were: < 0.01 mg/kg (16). This data set was used for maximum residue level estimation.

No suitable GAP for onions was available to evaluate the cypermethrin residue trials from France, Germany, Greece, Italy, Poland, Spain and UK.

In Brazil, zeta-cypermethrin may be applied to onions at a spray concentration of 0.0036 kg ai/hL with a 5 days PHI.

In one trial in Brazil at GAP and a second trial at double application rate, zeta-cypermethrin residues in onion bulbs were < 0.05 mg/kg (2).

In USA, zeta-cypermethrin is registered for use on onions at an application rate of 0.056 kg ai/ha with harvest 7 days later.

In two US trials with zeta-cypermethrin on onions matching GAP, residues in onion bulbs were < 0.01 mg/kg (2).

Residues in the green onions were 0.19 and 0.57 mg/kg.

On the basis of the alpha-cypermethrin trials in Europe matching German GAP, the Meeting estimated a maximum residue level of 0.01* mg/kg for bulb onions. The Meeting estimated STMR and HR values of 0.01 and 0.01 mg/kg respectively for cypermethrin residues in bulb onions.

The data on green onions (2 trials) were insufficient to estimate a maximum residue level.

Broccoli

In Denmark, alpha-cypermethrin is registered for use on broccoli at an application rate of 0.015 kg ai/ha with harvest 7 days later.

In 16 broccoli trials with alpha-cypermethrin use matching Danish GAP from Denmark (2), France (4), Germany (4), Netherlands (2) and the UK (4), residues were (rank order, median underlined): < 0.01 (3), 0.01 (4), <u>0.02</u> (7), 0.03 and 0.03 mg/kg.

In Greece, alpha-cypermethrin is registered for use on broccoli at an application rate of 0.03 kg ai/ha with harvest 7 days later.

In four broccoli trials with alpha-cypermethrin use matching Greek GAP from Greece (1), France (1), Italy (1) and Spain (1), residues were: 0.01, 0.01, 0.02 and 0.03 mg/kg.

In Spain, cypermethrin is registered for use on broccoli at a spray concentration of 0.01 kg ai/hL with harvest 7 days later.

In one trial in France matching Spanish GAP for cypermethrin use, residues were 0.04 mg/kg.

In USA, zeta-cypermethrin is registered for use on broccoli at an application rate of 0.056 kg ai/ha with harvest 1 day later.

In two US trials with zeta-cypermethrin use on broccoli matching GAP, residues were < 0.05 and 0.57 mg/kg.

Brussels sprouts

In UK, alpha-cypermethrin is registered for use on Brussels sprouts at an application rate of 0.01 kg ai/ha with harvest 7 days later.

In 16 trials with alpha-cypermethrin use matching the UK GAP (± 30% application rate) from UK (4), Belgium (2), France (4), Germany (4) and Netherlands (2), residues were (rank order, median underlined): < 0.01 (6), 0.01 (4), 0.02 (4), 0.03 and 0.05 mg/kg.

In Greece, alpha-cypermethrin is registered for use on Brussels sprouts at an application rate of 0.03 kg ai/ha with harvest 7 days later.

In four Brussels sprouts trials with alpha-cypermethrin use matching Greek GAP from Greece (1), France (1), Italy (1) and Spain (1), residues were: < 0.01, < 0.01, 0.01 and 0.02 mg/kg.

In UK, cypermethrin is registered for use on Brussels sprouts at an application rate of 0.025 kg ai/ha with no PHI specified.

In nine trials with cypermethrin use on Brussels sprouts matching GAP of the UK (accepting highest residue from 0–7 days after application) from UK (3), Germany (5) and Poland (1), residues were (rank order, median underlined): < 0.01 (4), 0.01, and 0.02 (4) mg/kg.

Cabbage, head

In UK, alpha-cypermethrin is registered for use on cabbages at an application rate of 0.01 kg ai/ha and a PHI of 7 days.

In 53 trials with alpha-cypermethrin use on cabbage matching the UK GAP (± 30% application rate) from the UK (21), Belgium (2), France (10) and Germany (20), residues were (rank order, median underlined): < 0.01 (17), 0.01 (4), 0.02 (6), 0.03, < 0.05 (13), 0.05 (4), 0.06, 0.07, 0.10 (3) , 0.11, 0.12 and 0.65 mg/kg. This data set was used for maximum residue level estimation.

In Denmark, alpha-cypermethrin is registered for use on cabbages at an application rate of 0.015 kg ai/ha and with a PHI of 7 days.

In nine trials with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Denmark (2), France (4) and UK (3), residues were: 0.03 and < 0.05 (8) mg/kg.

In the UK, cypermethrin is registered for use on cabbages at an application rate of 0.025 kg ai/ha with no PHI specified.

In nine trials with cypermethrin use on cabbage matching the UK GAP (accepting highest residue from 0–7 days after application) from UK (2), France (2) and Germany (5), residues were (rank order, median underlined): < 0.01 (7), 0.05 and 0.19 mg/kg.

Cauliflower

In UK, alpha-cypermethrin is registered for use on cauliflower at an application rate of 0.01 kg ai/ha and with a PHI of 7 days.

In 41 trials with alpha-cypermethrin use on cauliflower matching the UK GAP (± 30% application rate) from the UK (17), Denmark (2), France (5), Germany (13) and Netherlands (4), residues were (rank order, median underlined): < 0.01 (24), 0.01 (5), 0.02, < 0.05 (9), 0.05 and 0.09 mg/kg.

In Italy, alpha-cypermethrin is registered for use on cauliflower at an application rate of 0.03 kg ai/ha and with a PHI of 7 days.

In eight trials with alpha-cypermethrin use matching Italian GAP (± 30% application rate) from Italy (3), France (3), Greece (1) and Spain (1), residues were: < 0.01 (7) and 0.01mg/kg.

In the UK, cypermethrin is registered for use on cauliflowers at an application rate of 0.025 kg ai/ha with no PHI specified.

In six trials with cypermethrin use on cauliflower matching the UK GAP (accepting highest residue from 0–7 days after application) from the UK (2), France (2) and Germany (5), residues were: < 0.01 (3), 0.02, 0.03 and 0.03 mg/kg.

Brassica vegetables – summary

The Meeting noted that broccoli, Brussels sprouts, cabbages and cauliflowers are the major commodities of the Brassica vegetables group and that the cabbage data produced the highest maximum residue level. Alpha-cypermethrin is registered for use on the crop group Brassica vegetables in Spain, demonstrating that residues could occur on any of the Brassica vegetables.

On the basis of the alpha-cypermethrin cabbage data from 53 trials in Europe matching the UK GAP, the Meeting estimated a maximum residue level of 1 mg/kg for Brassica vegetables confirming the previous recommendation of 1 mg/kg. The Meeting estimated STMR and HR values of 0.02 and 0.65 mg/kg respectively for cypermethrin residues in Brassica vegetables.

Cucumber

In Denmark, alpha-cypermethrin is registered for use on greenhouse cucumbers at an application rate of 0.015 kg ai/ha and with a PHI of 7 days.

In 17 trials on protected cucumbers with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Denmark (3), France (4), Germany (2), Greece (2), Italy (2), Netherlands (2) and Spain (2), residues were: < 0.01 mg/kg (17).

Italian GAP allows alpha-cypermethrin use on greenhouse cucumbers at 0.05 kg ai/ha with harvest 7 days later.

In eight trials on protected cucumbers with alpha-cypermethrin use matching Italian GAP (± 30% application rate) from Italy (1), Belgium (1), Denmark (1), France (2), Germany (1), Greece (1) and Spain (1), residues were: < 0.01 (4) and 0.01 mg/kg (4).

The Meeting combined the data from the Danish GAP and Italian GAP as essentially of one population: < 0.01 (11) and 0.01 mg/kg (3).

Zeta-cypermethrin is registered for use on cucumbers in the USA with an application rate of 0.056 kg ai/ha and a PHI of 1 day.

In six US trials with zeta-cypermethrin use on cucumbers matching GAP, residues were: < 0.05 mg/kg (6).

Melon

Alpha-cypermethrin is registered for use on greenhouse melons in Greece with an application rate of 0.05 kg ai/ha and a PHI of 7 days.

In eight trials with alpha-cypermethrin use on glasshouse melons matching Greek GAP (± 30% application rate) from Greece (1), Belgium (1), Denmark (1), France (2), Germany (1), Italy (1) and Spain (1), residues were: < 0.01 (5), 0.02, 0.03 and 0.05 mg/kg. This data set was used for maximum residue level estimation.

Alpha-cypermethrin is registered for use on field-grown melons in France with an application rate of 0.03 kg ai/ha and a PHI of 7 days.

In eight trials with alpha-cypermethrin use on field-grown melons matching French GAP (± 30% application rate) from France (3), Greece (1) Italy (2) and Spain (2), residues were: < 0.01 (7) and 0.03 mg/kg.

In Spain, cypermethrin may be used on melons with a spray concentration of 0.01 kg ai/hL and with harvest 3 days later.

In nine trials with cypermethrin use on melons matching Spanish GAP from Spain (4), France (2) and Italy (3), residues were: < 0.01 (5), 0.01, 0.01, 0.02 and 0.02 mg/kg.

Zeta-cypermethrin is registered for use on cantaloupe in the USA with an application rate of 0.056 kg ai/ha and a PHI of 1 day.

In six US trials with zeta-cypermethrin use on cantaloupe matching GAP, residues were: < 0.02 and < 0.05 mg/kg (5).

In three alpha-cypermethrin trials and five cypermethrin trials, residues exceeded the LOQ in the fruit but residues in the pulp were all < LOD. However, it is not clear evidence of a nil residue.

Cucurbit fruiting vegetables – summary

The Meeting noted that cucumber and melons are two of the important commodities of the cucurbit vegetables group and that the melon data produced the highest maximum residue level. Alpha-cypermethrin is registered for use on the cucurbits crop group in Spain, demonstrating that residues could occur on any of the cucurbits.

On the basis of the alpha-cypermethrin trials on glasshouse melons in Europe matching Greek GAP, the Meeting estimated a maximum residue level of 0.07 mg/kg for cucurbit fruiting vegetables. On the basis of the whole melon data, the Meeting estimated STMR and HR values of 0.01 and 0.05 mg/kg respectively for cypermethrin residues in cucurbit fruiting vegetables.

Because melons have inedible peel, the Meeting estimated STMR and HR values for melons of 0.01 and 0.01 mg/kg respectively, based on the melon pulp data.

Eggplant

In France, alpha-cypermethrin may be used on egg plant at 0.012 kg ai/ha with harvest 7 days later. In a plastic tunnel trial and a glasshouse trial in France in line with French GAP, residues in egg plant were < 0.01 and 0.01 mg/kg.

The Meeting decided to use tomato data from a similar greenhouse use to support an eggplant maximum residue level.

In Denmark, alpha-cypermethrin is registered for use on greenhouse tomatoes at an application rate of 0.015 kg ai/ha and with a PHI of 7 days. In 18 trials on protected tomatoes with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Denmark (3), France (5), Germany (2), Greece (2), Italy (2), Netherlands (2) and Spain (2), residues were: < 0.01 (14), 0.01, 0.01, 0.02 and 0.02 mg/kg.

On the basis of the alpha-cypermethrin trials on greenhouse tomatoes in Europe, the Meeting estimated a maximum residue level of 0.03 mg/kg for egg plant (extrapolation of tomato data to egg plant) to replace the previous recommendation of 0.2 mg/kg. The Meeting estimated STMR and HR values of 0.01 and 0.02 mg/kg respectively for cypermethrin residues in egg plant.

Sweet peppers

Alpha-cypermethrin is registered in Greece for use on greenhouse sweet peppers with an application rate of 0.05 kg ai/ha and a PHI of 7 days.

In six trials with alpha-cypermethrin use on greenhouse sweet peppers matching Greek GAP from Greece (1), Belgium (1), France (2), Italy (1) and Spain (1), residues were: 0.01, 0.02(3), 0.03 and 0.03 mg/kg.

Alpha-cypermethrin is registered in Greece for use on field-grown sweet peppers with an application rate of 0.03 kg ai/ha and a PHI of 7 days.

In eight trials with alpha-cypermethrin use on field-grown sweet peppers matching Greek GAP from Greece (2), France (2), Italy (2) and Spain (2), residues were: < 0.01 (4), 0.02 (3) and 0.03 mg/kg.

Zeta-cypermethrin is registered in the USA for use on peppers at 0.056 kg ai/ha with a 1-day PHI.

In six US trials with zeta-cypermethrin use on bell peppers matching GAP, residues were: < 0.02, < 0.02, < 0.05 (3) and 0.07 mg/kg. This data set was used for maximum residue level estimation.

On the basis of the zeta-cypermethrin trials on bell peppers in USA, the Meeting estimated a maximum residue level of 0.1 mg/kg for sweet peppers to replace the previous recommendation of 0.5 mg/kg for peppers. The Meeting estimated STMR and HR values of 0.05 and 0.07 mg/kg respectively for cypermethrin residues in sweet peppers.

Chilli peppers

In Thailand, cypermethrin is registered for use on Chilli peppers at a high-volume spray concentration of 0.025 kg ai/hL with harvest 7 days later.

In six Chilli pepper trials from Thailand with cypermethrin spray concentration 0.019 kg ai/hL (24% below GAP concentration, but within tolerance), residues 7 days after spraying were (rank order, median underlined): 0.24, 0.25, 0.45, 0.54, 0.62 and 0.69 mg/kg.

Zeta-cypermethrin is registered in the USA for use on peppers at 0.056 kg ai/ha with a 1-day PHI.

In three US trials with zeta-cypermethrin use on Chilli peppers matching GAP, residues were: < 0.02, < 0.05, and 0.19 mg/kg.

On the basis of the cypermethrin trials on Chilli peppers in Thailand, the Meeting estimated a maximum residue level of 2 mg/kg for Chilli peppers to replace the previous recommendation of 0.5 mg/kg for peppers. The Meeting estimated STMR and HR values of 0.495 and 0.69 mg/kg respectively for cypermethrin residues in Chilli peppers.

Okra

In Thailand, cypermethrin is registered for use on okra at a high-volume spray concentration of 0.011 kg ai/hL with harvest 5 days later.

In six okra trials from Thailand matching GAP conditions, residues 5 days after spraying were (rank order, median underlined): 0.01, 0.02, 0.05, 0.11, 0.18 and 0.20 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in okra of 0.5, 0.08 and 0.20 mg/kg respectively.

Sweet corn

No relevant GAP was available to evaluate the alpha-cypermethrin data on sweet corn.

Zeta-cypermethrin is registered in the USA for use on sweet corn at 0.056 kg ai/ha with a 3-days PHI.

No residues were detected (LOD = 0.01 mg/kg) in any sample in nine US trials with zeta-cypermethrin use on sweet corn matching GAP. Also, residues were not detected in a trial with application rate at 0.11 kg ai/ha. The LOQ in these trials was 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg for sweet corn, which is the same as the previous recommendation. The Meeting estimated STMR and HR values of 0 and 0 mg/kg respectively for cypermethrin residues in sweet corn.

Tomato

In Denmark, alpha-cypermethrin is registered for use on greenhouse tomatoes at an application rate of 0.015 kg ai/ha and with a PHI of 7 days.

In 18 trials on protected tomatoes with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Denmark (3), France (5), Germany (2), Greece (2), Italy (2), Netherlands (2) and Spain (2), residues were: < 0.01 (14), 0.01, 0.01, 0.02 and 0.02 mg/kg.

In France, alpha-cypermethrin is registered for use on tomatoes at an application rate of 0.011 kg ai/ha and with a PHI of 3 days.

In 26 trials on field-grown tomatoes with alpha-cypermethrin use matching French GAP (± 30% application rate) from France (12), Belgium (2), Germany (12), residues were: < 0.01 (23), 0.01, < 0.02 and < 0.02 mg/kg.

In Italy, alpha-cypermethrin is registered for use on field-grown tomatoes at an application rate of 0.03 kg ai/ha and with a PHI of 7 days.

In 13 trials on field-grown tomatoes with alpha-cypermethrin use matching Italian GAP (± 30% application rate) from Italy (2), France (6), Greece (1), and Spain (4), residues were: < 0.01 (9), 0.01 (3) and 0.02 mg/kg.

In Italy, alpha-cypermethrin is registered for use on glasshouse tomatoes at an application rate of 0.05 kg ai/ha and with a PHI of 7 days.

In seven trials on protected tomatoes with alpha-cypermethrin use matching Italian GAP (± 30% application rate) from Italy (1), Belgium (1), France (1), Germany (2), Greece (1), and Spain (1), residues were: < 0.01 (4), 0.01, 0.02 and 0.02 mg/kg.

Alpha-cypermethrin may be used on tomatoes in Brazil at 0.03 kg ai/ha with a 5-days PHI. In one trial matching GAP, residues were 0.03 mg/kg.

Alpha-cypermethrin may be used on tomatoes in South Africa at 0.01 kg ai/ha with a 4-days PHI. In 2 trials matching GAP, residues were both below LOQ (< 0.05 mg/kg).

No suitable GAP was available for evaluating the cypermethrin trials on tomatoes.

Zeta-cypermethrin may be used on tomatoes in Brazil at 0.02 kg ai/ha with a 5-days PHI.

In three zeta-cypermethrin trials on tomatoes in Brazil matching GAP conditions, residues 5 days after spraying were < 0.02, 0.02 an 0.04 mg/kg.

Zeta-cypermethrin may be used on tomatoes in USA at 0.056 kg ai/ha with a 1-day PHI.

In 12 zeta-cypermethrin trials on tomatoes in USA matching GAP conditions, residues 1 day after spraying were (rank order, median underlined): < 0.05 (6), 0.05, 0.06, 0.07, 0.08, 0.08 and 0.08 mg/kg. This data set was used for maximum residue level estimation.

On the basis of the zeta-cypermethrin trials on tomatoes in USA, the Meeting estimated a maximum residue level of 0.2 mg/kg for tomatoes to replace the previous recommendation of 0.5 mg/kg. The Meeting estimated STMR and HR values of 0.05 and 0.08 mg/kg respectively for cypermethrin residues in tomatoes.

Endive

Zeta-cypermethrin is registered for use on endives in Italy with a spray concentration of 0.0026 kg ai/hL and a PHI of 7 days.

In three zeta-cypermethrin trials on endives in Italy matching GAP conditions, residues were: 0.27, 0.36 and 0.38 mg/kg.

Lettuce

In Italy, alpha-cypermethrin is registered for use on glasshouse lettuce at an application rate of 0.05 kg ai/ha and with a PHI of 7 days.

In eight trials on protected lettuce with alpha-cypermethrin use matching Italian GAP (± 30% application rate) from Italy (1), Belgium (1), Denmark (1), France (2), Germany (1), Greece (1), and Spain (1), residues were: 0.09, 0.21, 0.27, 0.30, 0.30, 0.57, 0.68 and 0.68 mg/kg.

In Italy, alpha-cypermethrin is registered for use on field-grown lettuce at an application rate of 0.03 kg ai/ha and with a PHI of 7 days.

In 12 trials on field-grown lettuce with alpha-cypermethrin use matching Italian GAP (± 30% application rate) from Italy (4), France (2), Greece (2), and Spain (4), residues were: < 0.01, 0.04, 0.04, 0.06, 0.07 (3), 0.10, 0.11, 0.12, 0.13 and 0.52 mg/kg. This data set was used for maximum residue level estimation.

In Germany, alpha-cypermethrin is registered for use on lettuce at an application rate of 0.009 kg ai/ha and with a PHI of 3 days.

In 27 trials on lettuce with alpha-cypermethrin use matching German GAP (± 30% application rate) from Germany (17), Belgium (1), Denmark (2), France (2) and UK (5), residues were: 0.01, 0.01, 0.02, 0.02, 0.03, 0.04, < 0.05, 0.05, 0.05, 0.06, 0.06, 0.07, 0.07, 0.09, 0.10 (4), 0.11, 0.12, 0.15, 0.17, 0.17, 0.19, 0.21, 0.25 and 0.26 mg/kg.

Cypermethrin residue data on lettuce could not be evaluated because no relevant GAP was available.

Zeta-cypermethrin may be used on head lettuce in USA at 0.056 kg ai/ha with a 5-days PHI.

The US zeta-cypermethrin trials on head lettuce were sampled at days 3 and 7. From the 12 trials, the average decline rate of residues was calculated (half-life of residues = 7.2 days), equivalent to a 30% decline in residues in 3.7 days. Day 3 data are therefore an acceptable substitute for day 5 data (< 30% difference in 2 days interval).

In 12 zeta-cypermethrin trials on head lettuce in USA matching GAP conditions, except that day-3 data (or day-7, if higher) are used instead of day-5 data, residues were (rank order, median underlined): 0.16, 0.29, 0.34, 0.48, 0.75, 0.95, 1.4, 1.6, 1.9, 2.4, 2.5 and 2.8 mg/kg.

Zeta-cypermethrin is registered for use on lettuce in Italy with a spray concentration of 0.0026 kg ai/hL and a PHI of 7 days.

In three zeta-cypermethrin trials on lettuce in Italy matching GAP conditions, residues were: 0.18, 0.18 and 0.28 mg/kg.

Zeta-cypermethrin may be used on leaf lettuce in USA at 0.056 kg ai/ha with a 1-day PHI.

In eight zeta-cypermethrin trials on leaf lettuce in USA matching GAP conditions, residues were (rank order, median underlined): 1.5, 1.6, 2.3, 2.3, 2.4, 2.4, 2.7 and 3.3 mg/kg.

On the basis of the zeta-cypermethrin trials on head lettuce in USA, the Meeting estimated STMR and HR values of 1.18 and 2.8 mg/kg respectively for cypermethrin residues in head lettuce. However, the IESTI calculated from the HR (2.8 mg/kg) for head lettuce exceeded the ARfD and the Meeting examined data from an alternative GAP as suitable for establishing an MRL.

On the basis of the zeta-cypermethrin trials on leaf lettuce in USA, the Meeting estimated STMR and HR values of 2.35 and 3.3 mg/kg respectively for cypermethrin residues in leaf lettuce. However, the IESTI calculated from the HR (3.3 mg/kg) for leaf lettuce exceeded the ARfD and the Meeting examined data from an alternative GAP as suitable for establishing an MRL.

Kale

No suitable GAP was available for evaluating the alpha-cypermethrin trials on kale.

Leafy cabbage, lambs lettuce

In France, alpha-cypermethrin may be used on lettuce and similar at 0.011 kg ai/ha with harvest 7 days later. This GAP was accepted as including leafy cabbage. The same use pattern applies to lambs lettuce.

In four trials on leafy cabbage with alpha-cypermethrin use matching French GAP (± 30% application rate) from France (2) and Netherlands (2), residues were: 0.15, 0.21, 0.22 and 0.35 mg/kg.

In two trials on lambs lettuce with alpha-cypermethrin use matching French GAP, residues were 0.28 and 0.29 mg/kg.

The numbers of trials were too few to support recommendations.

Spinach

No suitable GAP was available to evaluate the alpha-cypermethrin trials on spinach in France, Germany and Netherlands.

In Spain, cypermethrin is approved for use on spinach at a spray concentration of 0.01 kg ai/hL with harvest 7 days later.

In three trials on spinach with cypermethrin use matching Spanish GAP (± 30% application rate) from France (1) and Germany (2), residues were: 0.34, 0.45 and 0.50 mg/kg.

Zeta-cypermethrin may be used on spinach in USA at 0.056 kg ai/ha with a 1-day PHI.

In eight zeta-cypermethrin trials on spinach in USA matching GAP conditions, residues were (rank order, median underlined): 2.8, 3.1, 3.4, <u>3.4</u>, <u>3.6</u>, 4.5, 5.0 and 5.7 mg/kg.

On the basis of the zeta-cypermethrin trials on spinach in USA, the Meeting estimated STMR and HR values of 3.5 and 5.7 mg/kg respectively for cypermethrin residues in spinach.

However, the IESTI calculated from the HR (5.7 mg/kg) for spinach exceeded the ARfD and the Meeting examined data from an alternative GAP.

The three cypermethrin trials on spinach were insufficient on their own to estimate a maximum residue level

Mustard greens

No suitable GAP was available to evaluate the zeta-cypermethrin trials on mustard greens in USA.

Leafy vegetables group – summary

The Meeting noted that lettuce and spinach are major commodities of the leafy vegetables group and that the spinach data produced the highest estimated maximum residue level. However, some trials data for lettuce and spinach at higher GAPs could not be used because the calculated IESTI values exceeded the ARfD. For lettuce, an assessment was possible on data from an alternative GAP. Alpha-cypermethrin is registered for use on 'vegetables' in Bulgaria, demonstrating that residues could occur on any of the leafy vegetables.

On the basis of the alpha-cypermethrin trials on protected lettuce in Europe matching Italian GAP, the Meeting estimated an HR value of 0.68 mg/kg for cypermethrin residues in leafy vegetables. However, the IESTI calculated with an HR of 0.68 mg/kg for spinach exceeded the ARfD, suggesting preference for an alternative GAP.

On the basis of the 12 alpha-cypermethrin trials on field-grown lettuce in Italy, France, Greece and Spain matching Italian GAP, the Meeting estimated a maximum residue level of 0.7 mg/kg for leafy vegetables to replace the previous recommendations for kale, lettuce and spinach. The Meeting estimated STMR and HR values of 0.07 and 0.52 mg/kg for cypermethrin residues in leafy vegetables.

Peas – legume vegetables

In Denmark, alpha-cypermethrin is registered for use on peas at an application rate of 0.015 kg ai/ha and with a PHI of 7 days.

In 16 trials on peas with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Denmark (2), France (4), Germany (4), Netherlands (2) and the UK (4) residues in peas (seeds) were all below LOQ: < 0.01 (16).

No suitable GAP was available for evaluating the alpha-cypermethrin data on pea pods.

In Spain, cypermethrin is registered for use on peas with a spray concentration of 0.01 kg ai/hL and a 7-days PHI.

In six trials on peas with cypermethrin use matching Spanish GAP (± 30% application rate) from France (4) Germany (2), residues in pea pods were: 0.02, 0.02, 0.03, 0.05, 0.06 and 0.13 mg/kg.

In Italy, cypermethrin is registered for use on peas with a spray concentration of 0.0075 kg ai/hL and a 14-days PHI.

In three trials on peas with cypermethrin use matching Italian GAP (± 30% application rate) from France (1) Germany (2), residues in peas (seeds) were all below LOQ: < 0.01 (2) and < 0.02 mg/kg. In 1 trial, residues in pea pods were measured at 0.09 mg/kg.

In France, zeta-cypermethrin is registered for use on peas at 0.018 kg ai/ha and with a 7-days PHI.

In 14 trials on peas with zeta-cypermethrin use matching French GAP (± 30% application rate) from France (7), Italy (3) and the UK (4), residues in shelled peas were all non-detects or below LOQ: < 0.01 mg/kg (14).

In 10 trials on peas with zeta-cypermethrin use matching French GAP (± 30% application rate) from France (7), Italy (1) and the UK (2), residues in pea pods were: < 0.01 (4), 0.02 (4), 0.03 and 0.03 mg/kg.

In the UK, zeta-cypermethrin is registered for use on peas at 0.015 kg ai/ha and with a 14-days PHI.

In two trials on peas with zeta-cypermethrin use matching the UK GAP (± 30% application rate) from France (2), residues in and shelled peas were below LOQ: and < 0.05 mg/kg (2).

In USA, zeta-cypermethrin is registered for use on peas at 0.056 kg ai/ha with a 1-day PHI for succulent peas.

In six zeta-cypermethrin trials on peas in USA matching GAP conditions, residues in succulent shelled peas were: < 0.03 (3), < 0.05, 0.05 and 0.06 mg/kg.

Beans – legume vegetables

In France, alpha-cypermethrin may be used on beans at 0.03 kg ai/ha with harvest 7 days later.

In 18 trials on beans with alpha-cypermethrin use matching French GAP (± 30% application rate) from France (13), Greece (1), Italy (2) and Spain (2), residues in bean pods were: < 0.01, 0.01, 0.02 (4), 0.03, < 0.05 (8), 0.07, 0.09 and 0.11 mg/kg.

In Denmark, alpha-cypermethrin may be used on beans at 0.015 kg ai/ha with harvest 7 days later.

In 18 trials on beans with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Belgium (2), France (6), Germany (2), Netherlands (4) and the UK (4), residues in bean pods were: < 0.01 (4), 0.01 (5), 0.02 (6), 0.03, 0.03 and 0.04 mg/kg.

In Spain, cypermethrin may be applied to beans with a spray concentration of 0.01 kg ai/hL with a 3-days PHI.

In eight trials on beans with cypermethrin use matching Spanish GAP (± 30% application rate) from Spain (2), France (1), Germany (2), Greece (1), Italy (1) and the UK (1), residues in bean pods were: 0.01, 0.02, 0.02, 0.02, 0.03, 0.03, 0.05 and 0.08 mg/kg.

Zeta-cypermethrin may be used on beans in the UK at 0.015 kg ai/ha with a 14-days PHI.

In 12 zeta-cypermethrin trials on beans in the UK matching GAP conditions, residues on the whole bean or bean pods were (rank order, median underlined): < 0.01 (3), 0.02, 0.02, <u>0.22</u>, <u>0.22</u>, 0.26, 0.30, 0.32, 0.41 and 0.45 mg/kg. This data set was used for maximum residue level estimation.

In USA, zeta-cypermethrin is registered for use on beans at 0.056 kg ai/ha with a 1-day PHI for succulent beans.

In six zeta-cypermethrin trials on beans in USA matching GAP conditions, residues on the whole pods were: < 0.05, 0.07, 0.09, 0.21, 0.29 and 0.30 mg/kg.

In six zeta-cypermethrin trials on beans in USA matching GAP conditions, residues on the succulent shelled beans were all non-detects: < 0.01 mg/kg (6).

Legume vegetables – summary

Because of sufficient data on peas and beans, the Meeting agreed that a legume vegetable group maximum residue level should be estimated. In Bulgaria, alpha-cypermethrin is registered for use on 'vegetables', which includes peas and beans with and without pods, suggesting that residues could occur on any of the legume vegetables.

On the basis of the zeta-cypermethrin trials on beans in the UK (residues on whole bean or bean pods), the Meeting estimated a maximum residue level of 0.7 mg/kg for legume vegetables. The Meeting estimated STMR and HR values of 0.22 and 0.45 mg/kg respectively for cypermethrin residues in legume vegetables.

Peas - pulses

In Spain, cypermethrin is registered for use on peas with a spray concentration of 0.01 kg ai/hL and a 7-days PHI.

In six trials on peas with cypermethrin use matching Spanish GAP (± 30% application rate) from France (4) Germany (2), residues in peas (seeds) were all not detected or below LOQ: < 0.01 mg/kg (6).

In UK, zeta-cypermethrin is registered for use on peas at 0.015 kg ai/ha and with a 14-days PHI.

In three trials on peas with zeta-cypermethrin use matching the UK GAP (± 30% application rate) from UK, residues in and pea seeds were below LOQ: < 0.01 mg/kg (3).

In USA, zeta-cypermethrin is registered for use on peas at 0.056 kg ai/ha with a PHI for dried peas of 21 days.

In two zeta-cypermethrin trials on peas in USA matching GAP conditions, residues in dry shelled peas were: < 0.05 mg/kg (2).

Beans – pulses

See 'beans – legumes' for GAP on beans.

Numerous data (all below LOQ) were available on bean seeds with various application rates and intervals between application of alpha-cypermethrin and harvest. The following data for bean seed arise from trials where the application rate was 0.015 kg ai/ha (the GAP rate) or higher and the PHI was between 0 and 7 days:< 0.01(15), < 0.05 mg/kg (8). The 23 trials originate from France (7), Italy (1), Netherlands (2), Spain (2) and the UK (11).

In USA, zeta-cypermethrin is registered for use on beans at 0.056 kg ai/ha with a 21-days PHI for dried beans.

In seven zeta-cypermethrin trials on beans in USA matching GAP conditions, residues on the dried beans were: < 0.01 (5) and < 0.05 mg/kg (2).

Soya bean

No relevant GAP was available to evaluate the alpha-cypermethrin trials on soya bean in Brazil.

In Brazil, zeta-cypermethrin is registered for use on soya beans at 0.015 kg ai/ha with a 15-days PHI or at 0.05 kg ai/ha with a 30-days PHI.

In three zeta-cypermethrin trials in soya bean in Brazil with conditions in line with GAP, residues in soya beans were < 0.05 mg/kg (3).

In USA, zeta-cypermethrin is registered for use on soya beans at 0.056 kg ai/ha with a 21-days PHI.

In two zeta-cypermethrin trials in soya bean in USA with conditions in line with GAP, residues in soya beans were < 0.03 mg/kg (2). Thirteen other trials were reported where the interval between final treatment and harvest was 28-30 days (longer than the specified 21 days), In each case the residue was below the limit of detection (0.03 mg/kg).

The Meeting accepted the 30-days data in support of the GAP data.

Pulses - summary

The Meeting noted that dry peas, beans and soya beans are major commodities of the pulses group and that the soya bean data produced the highest estimated maximum residue level. Residues were not present in the pulses, but the soya bean data had been produced by an analytical method with the highest LOQ. Alpha-cypermethrin is registered for use on 'pulses' in Spain, suggesting that alpha-cypermethrin could be used on any pulse crop.

On the basis of the cypermethrin soya bean data, the Meeting estimated a maximum residue level of 0.05* mg/kg for pulses to replace the previous recommendation for soya bean (dry). The Meeting estimated an STMR value of 0.05 mg/kg for cypermethrin residues in pulses.

Potato

Alpha-cypermethrin is registered for use on potato crops in France with an application rate of 0.0125 kg ai/ha and a PHI of 21 days.

Because the residues in the tubers are below LOQ (0.01 mg/kg) we can accept data also from trials with higher application rates and shorter PHIs. There are 36 potato trials that meet these criteria. Residues in the tubers in the 36 trials were all below LOQ (0.01 mg/kg).

Cypermethrin is registered for use on potato crops in Poland with an application rate of 0.02 kg ai/ha and a PHI of 30 days. As before, we can accept trials with higher application rates and

shorter PHIs. There are 12 potato trials with cypermethrin that meet the criteria. Residues in the tubers were all below LOQ (0.01 mg/kg).

The metabolism studies suggest non-translocation of cypermethrin, so it is not expected to migrate to the tubers. A number of the supervised trials on potatoes were at exaggerated rates, which suggests an "essentially zero" residue situation.

Carrot

Cypermethrin is registered for use on carrot crops in Spain with a spray concentration of 0.01 kg ai/hL and a PHI of 7 days.

In six trials on carrots with cypermethrin use matching Spanish GAP (± 30% application rate) from Germany (3) and UK (3), residues in carrots were all below the LOD (0.003 mg/kg). Note that the LOQ for the analytical method in these trials was 0.01 mg/kg. Residues were detected in carrots in trials with higher application rates.

Sugar beet

Alpha-cypermethrin is registered for use on sugar beet crops in Germany with an application rate of 0.01 kg ai/ha and no specified PHI.

In eight alpha-cypermethrin trials on sugar beet in Germany with conditions in line with GAP, the highest residues in sugar beet root on any day of the trial were: < 0.01 (3), < 0.02 (4) and 0.07 mg/kg. This data set was used for maximum residue level estimation.

Alpha-cypermethrin is registered for use on sugar beet crops in Greece with an application rate of 0.03 kg ai/ha and a 14-days PHI.

In seven alpha-cypermethrin trials on sugar beet in Greece (2), Italy (3) Spain (2), with conditions in line with Greek GAP, residues in sugar beet root were all below LOQ (0.01 mg/kg):

The cypermethrin trials on sugar beet could not be evaluated because no suitable GAP was available.

In USA, zeta-cypermethrin is registered for use on sugar beet at 0.056 kg ai/ha with a 21-days PHI.

In eight zeta-cypermethrin trials in sugar beet in USA with conditions in line with GAP, residues in sugar beet root on day 21 after the final application were all non-detects (< 0.02 mg/kg).

On the basis of the alpha-cypermethrin trials on sugar beet in Germany, the Meeting estimated a maximum residue level of 0.1 mg/kg for sugar beet. The Meeting estimated an STMR value of 0.01 mg/kg for cypermethrin residues in sugar beet.

Root and tuber vegetables - summary

The Meeting noted that potatoes, carrots and sugar beet are major commodities of the root and tuber vegetables group and that residues did not exceed LOQ except for sugar beet from one trial.

On the basis of the alpha-cypermethrin and cypermethrin data for potatoes and carrots, the Meeting estimated a maximum residue level of 0.01* mg/kg for root and tuber vegetables (except sugar beet) to replace the previous recommendation of 0.05* mg/kg. The Meeting estimated STMR and HR values of 0.01 and 0.01 mg/kg respectively for cypermethrin residues in root and tuber vegetables (except sugar beet).

Asparagus

Alpha-cypermethrin is registered for use on asparagus crops in Germany with an application rate of 0.0125 kg ai/ha and no specified PHI.

In seven alpha-cypermethrin trials on asparagus in France with conditions in line with German GAP, the residues in asparagus stalks were all below LOQ: < 0.01 (3), and < 0.02 mg/kg (4).

In Thailand, cypermethrin is registered for use on asparagus at a high-volume spray concentration of 0.025 kg ai/hL with harvest 3 days later.

In two asparagus trials from Thailand matching GAP conditions, residues 3 days after spraying were: 0.06 and 0.18 mg/kg.

The two Thai trials were insufficient for estimating a maximum residue level.

On the basis of the alpha-cypermethrin trials on asparagus in France, the Meeting estimated a maximum residue level of 0.01* mg/kg for asparagus. The Meeting estimated an STMR value and an HR value of 0.01 and 0.01 mg/kg respectively for cypermethrin residues in asparagus.

Artichoke

In Italy, alpha-cypermethrin is registered for use on artichokes at 0.03 kg ai/ha with a PHI of 7 days.

In four trials on artichokes with alpha-cypermethrin use matching Italian GAP (± 30% application rate) from Italy (1), France (1), Greece (1) and Spain (1), residues in artichokes were: 0.02, <u>0.02</u>, <u>0.03</u> and 0.04 mg/kg.

No suitable GAP was available to evaluate the cypermethrin trials on artichoke from France and Spain.

On the basis of the alpha-cypermethrin trials on artichokes matching Italian GAP, the Meeting estimated a maximum residue level of 0.1 mg/kg for artichoke. The Meeting estimated an STMR value and an HR value of 0.025 and 0.040 mg/kg respectively for cypermethrin residues in artichokes.

Barley

In Denmark, alpha-cypermethrin may be used on barley at 0.015 kg ai/ha with harvest 42 days later.

In 26 trials on barley with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Denmark (2), France (4), Germany (18) and the UK (2), residues in barley grain were (rank order, median underlined): < 0.01 (4), 0.01, 0.02 (4), <u>0.03</u> (4), <u>0.04</u> (4), 0.05, 0.05, 0.06, 0.06, 0.08, 0.09, 0.17, 0.17 and 0.22 mg/kg. This data set was used for maximum residue level estimation.

In Poland, cypermethrin may be used on cereals at 0.03 kg ai/ha and a PHI of 30 days.

In seven trials on barley with cypermethrin use matching Polish GAP (± 30% application rate) from Poland (2), France (2), Hungary (1) and the UK (2), residues in barley grain were (rank order, median underlined): 0.05, 0.05, 0.09, <u>0.10</u>, 0.11, 0.12 and 0.19 mg/kg.

In Germany, zeta-cypermethrin may be used on barley at 0.015 kg ai/ha and a PHI of 35 days.

In 10 trials on barley with zeta-cypermethrin use matching German GAP (± 30% application rate) from Germany (4), France (3) and the UK (3), residues in barley grain were (rank order, median underlined): 0.01, < 0.02, 0.02, 0.02, <u>0.02</u>, <u>0.03</u>, 0.03, 0.04, 0.17 and 0.19 mg/kg.

Maize

In France, alpha-cypermethrin may be used on maize at 0.03 kg ai/ha with a PHI of 21 days.

Because the residues in maize grain were below LOQ irrespective of application rates or interval between treatment and harvest, trials with higher application rates or shorter PHIs are acceptable in supporting the residue evaluation for the selected GAP.

In six trials on maize with alpha-cypermethrin use in France matching French GAP or at higher rates or briefer PHIs, residues in maize grain were all below LOQ (0.01 mg/kg).

In Austria, cypermethrin may be used on maize at a spray concentration of 0.0075 kg ai/hL with a PHI of 49 days. In one cypermethrin trial in France at 0.015 kg ai/hL (2× Austrian GAP), residues in maize kernels harvested 29 days after treatment were not detected (LOD = 0.003 mg/kg). The other cypermethrin-maize trials could not be evaluated because no relevant GAP was available.

In USA, zeta-cypermethrin is registered for use on maize at 0.056 kg ai/ha with a PHI of 30 days to grain harvest.

In 25 zeta-cypermethrin trials on maize in USA with conditions in line with GAP, residues in maize grain were either below LOD (23 trials < 0.01 mg/kg) or below LOQ (2 trials < 0.05 mg/kg).

In Brazil, zeta-cypermethrin is registered for use on maize at 0.020 kg ai/ha with a PHI of 20 days.

In seven zeta-cypermethrin trials on maize in Brazil with application rates equal to or higher than required by Brazilian GAP, residues in maize grain were all below LOQ (0.05 mg/kg).

The other zeta-cypermethrin trials on maize could not be evaluated because no suitable GAP was available.

Oats

In Germany, alpha-cypermethrin may be used on cereals at 0.013 kg ai/ha with a PHI of 35 days.

In seven alpha-cypermethrin trials on oats in Germany with conditions in line with GAP, residues in oat grain on days 35-39 after the final application were: < 0.01, 0.01, < 0.02 (4) and 0.05 mg/kg.

No suitable GAP was available for evaluating the zeta-cypermethrin trials on oats and triticale.

Rice

No suitable GAP was available for evaluating the alpha-cypermethrin trials on rice.

In USA, zeta-cypermethrin is registered for use on rice at 0.056 kg ai/ha with a PHI of 14 days.

In 22 zeta-cypermethrin trials on rice in USA with conditions in line with US GAP, residues in rice grain (rank order, median underlined) were: 0.15, 0.39, 0.39, 0.40, 0.41, 0.42, 0.45, 0.49, 0.54, 0.56, <u>0.57</u>, <u>0.57</u>, 0.59, 0.59, 0.61, 0.63, 0.63, 0.73, 0.74, 0.75, 0.87 and 1.1 mg/kg. This data set was used for maximum residue level estimation.

Sorghum

No suitable GAP was available for evaluating the alpha-cypermethrin trials on sorghum.

Wheat

In Denmark, alpha-cypermethrin may be used on wheat at 0.015 kg ai/ha with harvest 42 days later.

In 39 trials on wheat with alpha-cypermethrin use matching Danish GAP (± 30% application rate) from Belgium (2), France (18), Germany (17) and the UK (2), residues in wheat grain were (rank order, median underlined): < 0<u>.01</u> (21), 0.01, 0.02, < 0.02 (3), < 0.05 (12) and 0.36 mg/kg. The

0.36 mg/kg appears out-of-context with all the other data on wheat grain; it also disagrees with residue levels in the grain at days 28 and 34 from the same trial (< 0.05 and < 0.05 mg/kg). The residue value was disregarded.

No suitable GAP was available for evaluating the other alpha-cypermethrin trials on wheat.

In France, cypermethrin is registered for use on cereals at 0.025 kg ai/ha with no specified PHI.

In eight trials on wheat with cypermethrin use matching French GAP (± 30% application rate) from Germany (2), Hungary (2), Poland (2) and the UK (2), residues in wheat grain were (rank order, median underlined): < 0.01 (5), 0.01, 0.02 and 0.02 mg/kg.

No GAP information was available to support evaluation of the 4 trials with post-harvest treatment of wheat with cypermethrin.

In Germany, zeta-cypermethrin is registered for use on wheat at 0.015 kg ai/ha with a 35-days PHI.

In 16 trials on wheat with zeta-cypermethrin use matching German GAP (± 30% application rate) from Germany (8), France (3), Italy (2), Spain (1) and the UK (2), residues in wheat grain were: < 0.01 (13), 0.01, 0.01 and 0.02 mg/kg.

In USA, zeta-cypermethrin is registered for use on wheat at 0.056 kg ai/ha with a 14-days PHI for grain, forage or hay harvest.

In two zeta-cypermethrin trials on wheat in USA with conditions in line with GAP, residues in wheat grain on days 14-15 after the final application were < 0.05 and 0.05 mg/kg.

Cereal grains – summary

Alpha-cypermethrin is registered for use on 'cereals' in Belgium, Bulgaria and Spain, suggesting that residues could occur on any of the cereal grains. The Meeting agreed to estimate a rice maximum residue level and a cereal grains (except rice) group maximum residue level.

On the basis of the alpha-cypermethrin trials on barley matching Danish GAP, the Meeting estimated a maximum residue level of 0.3 mg/kg for cereal grains (except rice) to replace the previous recommendations for barley, maize and wheat. The Meeting estimated an STMR value of 0.035 mg/kg for cypermethrin residues in cereal grains (except rice).

On the basis of the zeta-cypermethrin trials on rice in USA, the Meeting estimated a maximum residue level of 2 mg/kg for rice. The Meeting estimated an STMR value of 0.57 mg/kg for cypermethrin residues in rice.

Sugar cane

In USA, zeta-cypermethrin is registered for use on sugar cane at 0.056 kg ai/ha with a 21-days PHI.

In nine zeta-cypermethrin trials on sugar cane in USA with conditions in line with GAP, residues in cane stems (foliage removed) on days 20-21 after the final application were: < 0.01 (4), < 0.05 (2), 0.05, 0.09 and 0.17 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for cypermethrin in sugar cane of 0.2, 0.05 and 0.17 mg/kg respectively.

Almond

No suitable GAP was available for evaluating the alpha-cypermethrin trials on almond.

Cotton

In Colombia, alpha-cypermethrin is registered for use on cotton at 0.035 kg ai/ha with a 15-days PHI.

In two alpha-cypermethrin trials on cotton in Colombia with conditions in line with GAP (± 30% application rate), residues in cotton seed were below LOQ (0.01 mg/kg).

In South Africa, alpha-cypermethrin is registered for use on cotton at 0.035 kg ai/ha with a 28-days PHI.

In one alpha-cypermethrin trial on cotton in South Africa with conditions approximating GAP (application rate 0.03 kg ai/ha and PHI 16 days), residues in cotton seed were below LOQ (0.01 mg/kg).

In Greece, alpha-cypermethrin is registered for use on cotton at 0.03 kg ai/ha with a 7-days PHI.

In eight alpha-cypermethrin trials on cotton in Greece (3) and Spain (5) with conditions in line with Greek GAP (± 30% application rate), residues in cotton seed were mostly below LOQ: < 0.01 (7) and 0.02 mg/kg.

In Italy, cypermethrin is registered for use on cotton at a spray concentration of 0.005 kg ai/hL with a 21-days PHI.

In eight cypermethrin trials on cotton in Greece (4) and Spain (4) with application spray concentrations 2× to 3× concentration specified by Italian GAP and with sampling 21 days after the final treatment, residues in cotton seed were all less than LOD (0.015 mg/kg).

In Brazil, zeta-cypermethrin is registered for use on cotton at an application rate of 0.05 kg ai/ha and with a PHI of 15 days.

In seven zeta-cypermethrin trials on cotton in Brazil with conditions in line with GAP (± 30% application rate), residues in cotton seed were all below LOQ: < 0.02 (4) and < 0.05 mg/kg (3). Parallel trials with 2× application rate also produced no residues above LOQ.

No suitable GAP was available to evaluate the other cotton seed data.

Peanuts

In USA, zeta-cypermethrin is registered for use on peanuts at 0.056 kg ai/ha with a 7-days PHI.

In 11 zeta-cypermethrin trials on peanuts in USA with conditions in line with GAP, residues in peanut kernels on day 7 after the final application were all non-detects (< 0.02 mg/kg). The LOQ for the analyses was 0.05 mg/kg.

Linseed

In Belgium, alpha-cypermethrin may be used on linseed at 0.013 kg ai/ha with no specified PHI.

In two alpha-cypermethrin trials on linseed in France with conditions in line with Belgian GAP (± 30% application rate), residues in linseed were both below LOQ: < 0.01 mg/kg.

The Meeting noted that the linseed data were consistent with data from the other oilseeds, where the residues do not generally penetrate the seed pods to reach the seeds.

Oilseed rape

In France, alpha-cypermethrin may be used on oilseed rape at 0.011 kg ai/ha with a PHI of 49 days.

In 21 alpha-cypermethrin trials on oilseed rape in France (10), Germany (9) and Spain (2) with conditions in line with French GAP (± 30% application rate), residues in rape seed were: < 0.01 (8), < 0.05 (11), 0.06 and 0.42 mg/kg. The Meeting noted that the 0.42 mg/kg residue was reported in

an old trial (1986) with no field or laboratory reports, so it was not possible to confirm the validity of this residue value, which seemed out-of-context. The residue value was disregarded. This data set was used for maximum residue level estimation.

In Poland, cypermethrin is registered for use on oilseed rape at 0.03 kg ai/ha with a PHI of 21 days.

In nine cypermethrin trials on oilseed rape in France (2), Greece (4) and Spain (3) with conditions in line with Polish GAP (± 30% application rate), residues in rape seed were: < 0.003 (5), < 0.01 (3) and 0.01 mg/kg.

In Germany, zeta-cypermethrin is registered for use on oilseed rape at 0.01 kg ai/ha with a PHI of 56 days.

In six zeta-cypermethrin trials on oilseed rape in Germany (4) and the UK (2) with conditions in line with German GAP (± 30% application rate), residues in rape seed were: < 0.01 mg/kg (6).

Oilseed group – summary

The Meeting noted that cotton seed, peanuts and oilseed rape are major commodities of the oilseeds group and that the oilseed rape data produced the highest estimated maximum residue level.

On the basis of the alpha-cypermethrin oilseed rape data from trials in France, Germany and Spain with conditions aligned with French GAP, the Meeting estimated a maximum residue level of 0.1 mg/kg for oilseed to replace the previous recommendations for peanut and oilseed except peanut. The Meeting estimated an STMR value of 0.05 mg/kg for cypermethrin residues in oilseed.

Cacao and coffee

In Malaysia, alpha-cypermethrin may be used on cacao at 0.01 kg ai/ha (200 l/ha spray) with a PHI of 7 days.

In an alpha-cypermethrin trial on cacao in Malaysia with conditions in line with GAP (spray concentration 0.005 kg ai/hL), residues in cocoa on day 7 after the final application were < 0.01 mg/kg.

The data were insufficient to support the estimate of a maximum residue level for cacao.

No suitable GAP was available to evaluate the alpha-cypermethrin data on coffee.

Zeta-cypermethrin may be used on coffee in Brazil at 0.015 kg ai/ha with a 14-days PHI.

In five zeta-cypermethrin trials on coffee in Brazil with conditions in line with GAP (± 30% application rate), residues in coffee beans were: < 0.05 mg/kg (5). In 2 more trials at higher application rates (0.04 kg ai/ha), residues were also below LOQ (< 0.05 mg/kg).

On the basis of the zeta-cypermethrin trials on coffee in Brazil, the Meeting estimated a maximum residue level of 0.05* mg/kg for coffee beans, confirming the previous recommendation. The Meeting estimated an STMR value of 0 mg/kg for cypermethrin residues in coffee beans.

Parsley

No suitable GAP was available to evaluate the single trial on parsley.

Dried Chilli pepper

The 2007 JMPR recommended that, where the residues on fresh Chilli peppers are available, a concentration factor of 7 should be used for the estimation of maximum residue levels in dried Chilli peppers. The concentration factor should be used to multiply the actually measured residue values in the fresh chilli peppers.

In Thailand, cypermethrin is registered for use on Chilli peppers at a high-volume spray concentration of 0.025 kg ai/hL with harvest 7 days later. In six Chilli pepper trials from Thailand with cypermethrin spray concentration 0.019 kg ai/hL (24% below GAP concentration, but within tolerance), residues 7 days after spraying were (rank order, median underlined): 0.24, 0.25, 0.45, 0.54, 0.62 and 0.69 mg/kg.

Conversion of the fresh Chilli pepper data to dried Chilli pepper data (multiply by 7) produces: 1.7, 1.8, 3.2, 3.8, 4.3 and 4.8 mg/kg.

On the basis of the cypermethrin trials on Chilli peppers in Thailand and a processing factor of 7, the Meeting estimated a maximum residue level of 10 mg/kg for dried Chilli peppers. The Meeting estimated STMR and HR values of 3.5 and 4.8 mg/kg respectively for cypermethrin residues in dried Chilli peppers.

Alfalfa

No suitable GAP was available to evaluate the alpha-cypermethrin or cypermethrin trials on alfalfa.

In USA, zeta-cypermethrin is registered for use on alfalfa at 0.056 kg ai/ha with a 3-days PHI for cutting or grazing.

In zeta-cypermethrin trials on alfalfa in USA with conditions in line with GAP, residues in alfalfa hay on day 3 after an application were: 8.2, 9.0, 9.5, 11, 14 and 18 mg/kg. After an allowance for 89% dry matter in alfalfa hay, the median and high residue become 11.5 and 20 mg/kg, respectively. This data set was used for maximum residue level estimation.

In six zeta-cypermethrin trials (each with 3 cuts, highest residue chosen) on alfalfa in USA with conditions in line with GAP, residues in alfalfa forage on day 3 after an application were: 2.3, 2.8, 3.5, 3.8, 4.5 and 11 mg/kg.

On the basis of the zeta-cypermethrin trials on alfalfa in USA, the Meeting estimated a high residue level and an STMR value of 11 and 3.65 mg/kg respectively for cypermethrin residues in alfalfa forage. The Meeting also estimated a maximum residue level, an STMR value and a high residue level of 30, 11.5 and 20 mg/kg respectively, for cypermethrin residues in alfalfa hay.

Pea fodder and forage

In Denmark, alpha-cypermethrin is registered for use on peas at an application rate of 0.015 kg ai/ha. No information was available on restrictions on cutting and grazing, so, in each trial, the high residue on the plant material was accepted as residues on pea forage.

In 29 alpha-cypermethrin trials on peas in Denmark (2), France (4), Germany (4), Netherlands (2) and the UK (17) with conditions in line with Danish GAP (± 30% application rate), residues in pea forage were (rank order, median underlined):0.06, 0.07, 0.07, 0.08, 0.16, 0.23, 0.25, 0.25, 0.28, 0.29, 0.35, 0.42, 0.42, 0.43, 0.45, 0.48, 0.51, 0.56, 0.62, 0.64, 0.64, 0.65, 0.65, 0.65, 0.71, 0.74, 0.80, 0.83 and 0.86 mg/kg.

Samples described as 'haulms' are accepted as straw.

In 10 alpha-cypermethrin trials on peas in France (4), Germany (2), and the UK (4) with conditions in line with Danish GAP (± 30% application rate), residues in pea straw were (rank order, median underlined): 0.24, 0.27, 0.27, 0.35, 0.37, 0.37, 0.39, 0.55, 0.58 and 1.0 mg/kg. After an allowance for 88% dry matter in pea hay (or straw), the median and high residue become 0.42 and 1.1 mg/kg, respectively. This data set was used for maximum residue level estimation.

In Greece, alpha-cypermethrin is registered for use on peas at an application rate of 0.03 kg ai/ha. No information was available on restrictions on cutting and grazing, so, in each trial, the highest residue on the plant material was accepted as residues on pea forage.

In three alpha-cypermethrin trials on peas in, France (1), Italy (1) and Spain (1) with conditions in line with Greek GAP (± 30% application rate), residues in pea forage were: 0.27, 0.72 and 1.0 mg/kg.

In four alpha-cypermethrin trials on peas in, France (1), Greece (1), Italy (1) and Spain (1) with conditions in line with Greek GAP (± 30% application rate), residues in pea straw were: 0.23, 1.1, 1.2 and 1.5 mg/kg.

In Spain, cypermethrin is registered for use on peas with a spray concentration of 0.01 kg ai/hL.

In three cypermethrin trials on peas in France (2) and Germany (1) with conditions in line with Spanish GAP (± 30% application rate), residues in pea straw were: 1.4, 2.6 and 4.1 mg/kg.

In France, zeta-cypermethrin is registered for use on peas at 0.018 kg ai/ha.

In 17 zeta-cypermethrin trials on peas in France (4), Italy (4) and the UK (9) with conditions in line with French GAP (± 30% application rate), residues in pea straw were: < 0.02, 0.03, < 0.05, 0.10, 0.13, 0.17, 0.19, 0.22, 0.28, 0.3, 0.33, 0.39, 0.41, 0.5, 0.66, 0.99 and 1.0 mg/kg.

On the basis of the 10 alpha-cypermethrin trials on peas in France, Germany and the UK matching Danish GAP, the Meeting estimated a maximum residue level, an STMR value and a high residue level of 2, 0.42 and 1.1 mg/kg respectively for cypermethrin residues in pea hay or pea fodder.

On the basis of the alpha-cypermethrin trials on peas matching Danish GAP, the Meeting estimated an STMR value and a high residue level of 0.45 and 0.86 mg/kg respectively for cypermethrin residues in pea forage (pea vines, green).

Bean fodder and forage

In France, alpha-cypermethrin may be used on beans at 0.03 kg ai/ha. No information was available on restrictions on cutting and grazing, so, in each trial, the highest residue on the plant material was accepted as residues on bean forage.

In 18 alpha-cypermethrin trials on beans in France (10), Greece (1), Italy (2), Spain (2) and the UK (3) with conditions in line with French GAP (± 30% application rate), residues in bean forage were (rank order, median underlined): 0.07, 0.26, 0.38, 0.50, 0.53, 0.84, 0.86, 0.89, 0.91, 0.92, 0.92, 0.98, 1.0, 1.1, 1.4, 1.4, 1.4 and 1.5 mg/kg.

In seven alpha-cypermethrin trials on beans in France (1), Italy (1), Spain (2) and the UK (3) with conditions in line with French GAP (± 30% application rate), residues in bean straw were (rank order, median underlined): 0.32, 0.32, 0.49, 0.51, 0.73, 0.76 and 1.1 mg/kg. Bean straw was assumed to have the same dry matter content as pea hay or straw. After an allowance for 88% dry matter in bean straw, the median and high residues become 0.58 and 1.3 mg/kg, respectively. This data set was used for maximum residue level estimation.

In Denmark, alpha-cypermethrin may be used on beans at 0.015 kg ai/ha.

In 18 alpha-cypermethrin trials on beans in Belgium (2), France (4), Germany (2), Netherlands (4) and the UK (6) with conditions in line with Danish GAP (± 30% application rate), residues in bean forage were (rank order, median underlined): 0.22, 0.25, 0.25, 0.28, 0.33, 0.34, 0.34, 0.36, 0.37, 0.39, 0.39, 0.39, 0.42, 0.52, 0.52, 0.54, 0.82 and 0.86 mg/kg.

In 12 alpha-cypermethrin trials on beans in France (4), Netherlands (2) and the UK (6) with conditions in line with Danish GAP (± 30% application rate), residues in bean straw were (rank order, median underlined): 0.07, 0.31, 0.36, 0.39, 0.39, 0.40, 0.44, 0.49, 0.54, 0.58, 0.59 and 0.64 mg/kg.

In Spain, cypermethrin may be applied to beans with a spray concentration of 0.01 kg ai/hL.

In seven cypermethrin trials on beans in France (1), Germany (2), Italy (1), Spain (2) and the UK (1) with conditions in line with Spanish GAP (± 30% application rate), residues in bean forage were (rank order, median underlined): 0.44, 0.49, 0.52, <u>0.71</u>, 1.5, 1.8 and 2.1 mg/kg.

Zeta-cypermethrin may be used on beans in the UK at 0.015 kg ai/ha.

In four zeta-cypermethrin trials on beans in the UK with conditions in line with GAP (± 30% application rate), residues in bean straw were: 0.13, 0.26, 0.30 and 0.47 mg/kg.

On the basis of the seven alpha-cypermethrin trials on beans (bean straw data) in France, Italy, Spain and the UK matching French GAP, the Meeting estimated a maximum residue level, an STMR value and a high residue level of 2, 0.58 and 1.3 mg/kg respectively for cypermethrin residues in bean fodder.

On the basis of the cypermethrin trials on beans matching Spanish GAP, the Meeting estimated a high residue level and an STMR value of 2.1 and 0.71 mg/kg respectively for cypermethrin residues in bean forage.

Barley straw and fodder

No information was available on restrictions on cutting and grazing, so, in each trial, the highest residue in the plant material was accepted as residues in barley forage. In some trials multiple samplings at various time intervals from 0 days up to approximately 3 weeks were available, while in other trials only one sampling, most often day zero, was available. Residue concentrations in forage were quite persistent; for example, residue concentrations in plant material 2 or 3 weeks after treatment sometimes exceeded the measured values at day 0.

In Denmark, alpha-cypermethrin may be used on barley at 0.015 kg ai/ha.

In 28 alpha-cypermethrin trials on barley in Denmark (2), France (4), Germany (14), Greece (2), Italy (2), Spain (2) and the UK (2) with conditions in line with Danish GAP (± 30% application rate), residues in barley forage (plant) were (rank order, median underlined): 0.16, 0.20, 0.23, 0.24, 0.28, 0.30, 0.32, 0.34, 0.35, 0.35, 0.35, 0.36, 0.38, <u>0.38</u>, <u>0.40</u>, 0.41, 0.44, 0.45, 0.49, 0.52, 0.52, 0.52, 0.57, 0.62, 0.66, 0.67, 0.72 and 0.80 mg/kg.

In 31 alpha-cypermethrin trials on barley in France (8), Germany (16), Greece (2), Italy (2), Spain (2) and the UK (2) with conditions in line with Danish GAP (± 30% application rate), residues in barley straw were (rank order, median underlined): < 0.01 (4), 0.05, 0.06, 0.08, 0.17, 0.22, 0.22, 0.22, 0.22, 0.24, 0.29, <u>0.30</u>, 0.32, 0.34, 0.37, 0.38, 0.46, 0.48, 0.53, 0.54, 0.66, 0.68, 0.70, 0.73, 0.83, 0.83, 0.89 and 1.1 mg/kg. After an allowance for 89% dry matter in barley straw, the median and high residues become 0.34 and 1.2 mg/kg, respectively.

In Poland, cypermethrin may be used on cereals at 0.03 kg ai/ha.

In four cypermethrin trials on barley in France (1), Hungary (1), Poland (1) and the UK (1) with conditions in line with Polish GAP (± 30% application rate), residues in barley forage (plant) were: 0.37, 0.48, 0.51 and 0.72 mg/kg.

In seven cypermethrin trials on barley in France (2), Hungary (1), Poland (2) and the UK (2) with conditions in line with Polish GAP (± 30% application rate), residues in barley straw were: 0.30, 0.33, 0.33, <u>0.33</u>, 0.37, 0.40, 0.62 mg/kg. After an allowance for 89% dry matter in barley straw, the median and high residues become 0.37 and 0.70 mg/kg, respectively.

In Germany, zeta-cypermethrin may be used on barley at 0.015 kg ai/ha.

In 10 zeta-cypermethrin trials on barley in France (1), Germany (4), Italy (2), Spain (1) and the UK (2) with conditions in line with German GAP (± 30% application rate), residues in barley forage (plant) were: 0.08, 0.11, 0.15, 0.29, <u>0.33</u>, <u>0.33</u>, 0.46, 0.75, 0.94 and 1.4 mg/kg.

In 13 zeta-cypermethrin trials on barley in France (2), Germany (4), Italy (2), Spain (1) and the UK (4) with conditions in line with German GAP (± 30% application rate), residues in barley straw were: < 0.05 (2), 0.08, 0.13, 0.14, 0.19, 0.20, 0.25, 0.32, 0.52, 0.67, 1.8 and 2.1 mg/kg. After an allowance for 89% dry matter in barley straw, the median and high residues become 0.22 and 2.4 mg/kg, respectively.

The Meeting noted that the highest STMR and highest 'high residue' did not necessarily originate from the same compound for barley straw and forage. The highest values were chosen for the final estimates.

On the basis of the zeta-cypermethrin trials on barley matching German GAP, the Meeting estimated a high residue level of 1.4 mg/kg for cypermethrin residues in barley forage. On the basis of alpha-cypermethrin trials on barley matching Danish GAP, the Meeting estimated an STMR value of 0.39 mg/kg for barley forage.

Maize fodder and forage

In France, alpha-cypermethrin may be used on maize at 0.03 kg ai/ha.

In four alpha-cypermethrin trials on maize in France with conditions in line with GAP, residues in maize plants and silage were: < 0.01 (2), 0.19 and 0.32 mg/kg.

No suitable GAP was available to evaluate the cypermethrin trials on maize fodder and forage.

In USA, zeta-cypermethrin is registered for use on maize at 0.056 kg ai/ha, with PHIs of 30 days for stover (fodder) and 60 days for forage (silage). Zeta-cypermethrin is also registered for use on sweet corn at 0.056 kg ai/ha.

In 19 zeta-cypermethrin trials on maize in USA with conditions in line with GAP, residues in maize forage were all below LOQ and most below LOD: < 0.01 (12), < 0.05 (6) and < 0.1 mg/kg.

In 24 zeta-cypermethrin trials on maize and sweet corn in USA with conditions in line with GAP, residues in maize stover (fodder) were: < 0.05, < 0.5, 0.55, 0.64, 0.73, 0.77, 0.91, 0.95, 1.0, 1.1, 1.2, 1.3, 1.4, 1.5, 1.5, 1.5, 1.7, 1.7, 1.7, 2.4, 2.4, 2.4, 3.0 and 4.7 mg/kg. After an allowance for 83% dry matter in maize stover, the median and high residue become 1.6 and 5.7 mg/kg, respectively.

In France, zeta-cypermethrin may be used on maize at 0.0375 kg ai/ha.

In 14 zeta-cypermethrin trials on maize in France with conditions in line with GAP, residues in maize silage were: < 0.05 (13) and 0.10 mg/kg.

On the basis of the zeta-cypermethrin trials on maize (data on maize silage) matching French GAP, the Meeting estimated a high residue value and an STMR value of 0.1 and 0.05 mg/kg respectively for cypermethrin residues in maize forage.

Oats straw and fodder

In Germany, alpha-cypermethrin may be used on cereals at 0.013 kg ai/ha, with a PHI of 35 days.

In seven alpha-cypermethrin trials on oats in Germany with conditions in line with GAP, residues in oats straw were: 0.08, 0.31, 0.43, 0.44, 0.45, 0.56 and 0.75 mg/kg. After an allowance for 90% dry matter in oats straw, the median and high residues become 0.49 and 0.83 mg/kg, respectively.

No suitable GAP was available to evaluate the zeta-cypermethrin trials on oats straw.

Rice straw and fodder

No suitable GAP was available to evaluate the alpha-cypermethrin trials on rice straw and fodder.

In USA, zeta-cypermethrin is registered for use on rice at 0.056 kg ai/ha with a PHI of 14 days.

In 22 zeta-cypermethrin trials on rice in USA with conditions in line with US GAP, residues in rice straw (rank order, median underlined) were: 0.11, 0.15, 0.16, 0.27, 0.29, 0.32, 0.34, 0.35, 0.35, 0.37, 0.39, 0.49, 0.49, 0.57, 0.60, 0.61, 0.64, 0.65, 0.79, 1.4, 1.5 and 1.8 mg/kg. After an allowance for 90% dry matter in rice straw, the median and high residue become 0.49 and 2.0 mg/kg, respectively.

Wheat straw and fodder

No information was available on restrictions on cutting and grazing, so, in each trial, the highest residue in the plant material was accepted as residues in wheat forage. In some trials multiple samplings at various time intervals from 0 days up to approximately 4-5 weeks were available, while in other trials only one sampling, most often day zero, was available. Residues in the plant material were quite persistent; for example residues 3-4 weeks after treatment sometimes exceeded the day 0 residues. In some trials, multiple sampling times for wheat straw were also available.

In Denmark, alpha-cypermethrin may be used on wheat at 0.015 kg ai/ha.

In 28 alpha-cypermethrin trials on wheat in Belgium (2), France (6), Germany (12), Greece (2), Italy (2), Spain (2) and the UK (2), with conditions in line with Danish GAP (± 30% application rate), residues in wheat plants were: 0.04, 0.06, 0.16, 0.18, 0.19, 0.21, 0.23, 0.23, 0.23, 0.25, 0.28, 0.32, 0.36, 0.38, 0.38, 0.41, 0.43, 0.47, 0.47, 0.48, 0.53, 0.54, 0.54, 0.55, 0.58, 0.62, 0.62 and 1.4 mg/kg.

In 60 alpha-cypermethrin trials on wheat in Belgium (2), France (23), Germany (27), Greece (2), Italy (2), Spain (2) and the UK (2), with conditions in line with Danish GAP (± 30% application rate), alpha-cypermethrin residues in wheat straw were: 0.01, 0.01, 0.02, 0.03, 0.03, 0.05, 0.06, 0.08, 0.09, 0.15, 0.15, 0.16, 0.16, 0.16, 0.17, 0.17, 0.19, 0.20, 0.21, 0.25, 0.27, 0.29, 0.30, 0.32, 0.34, 0.34, 0.37, 0.37, 0.37, 0.37, 0.38, 0.44, 0.44, 0.47, 0.48, 0.48, 0.50, 0.52, 0.54, 0.54, 0.58, 0.58, 0.60, 0.62, 0.66, 0.68, 0.73, 0.75, 0.75, 0.81, 0.91, 0.92, 0.94, 0.95, 1.1, 1.2, 1.3, 1.5, 1.7 and 2.2 mg/kg.

In France, cypermethrin is registered for use on cereals at 0.025 kg ai/ha.

In four cypermethrin trials on wheat in Germany (1), Hungary (1), Poland (1) and the UK (1), with conditions in line with French GAP (± 30% application rate), residues in wheat plants were: 0.15, 0.36, 0.43 and 1.1 mg/kg.

In nine cypermethrin trials on wheat in France (1), Germany (2), Hungary (2), Poland (2) and UK (2), with conditions in line with French GAP (± 30% application rate), residues in wheat straw were: < 0.01, 0.21, 0.25, 0.26, 0.35, 0.43, 0.44, 0.48 and 0.57 mg/kg.

In Germany, zeta-cypermethrin is registered for use on wheat at 0.015 kg ai/ha.

In 11 zeta-cypermethrin trials on wheat in France (1), Germany (5), Italy (2), Spain (1) and the UK (2), with conditions in line with German GAP (± 30% application rate), residues in wheat plant were: 0.09, 0.13, 0.17, 0.22, 0.26, 0.38, 0.38, 0.57, 0.58, 0.74 and 0.86 mg/kg.

In 15 zeta-cypermethrin trials on wheat in France (3), Germany (5), Italy (2), Spain (1) and the UK (4), with conditions in line with German GAP (± 30% application rate), residues in wheat straw were: < 0.05, < 0.05, 0.08, 0.12, 0.12, 0.14, 0.18, 0.19, 0.19, 0.21, 0.27, 0.38, 0.5, 1.0 and 1.4 mg/kg.

In USA, zeta-cypermethrin is registered for use on wheat at 0.056 kg ai/ha with a 14-days PHI for grain, forage or hay harvest.

In 16 zeta-cypermethrin trials on wheat in USA in line with GAP, residues in wheat hay were: 0.61, 1.2, 1.5, 1.7, 1.7, 1.9, 2.1, 2.2, 2.5, 2.7, 3.2, 3.4, 3.8, 4.9, 5.3 and 5.5 mg/kg.

In 16 zeta-cypermethrin trials on wheat in USA in line with GAP, residues in wheat straw were: 0.70, 0.93, 0.98, 1.2, 1.8, 1.9, 2.2, 3.2, 3.2, 3.7, 3.8, 3.8, 3.9, 5.2, 6.0 and 6.1 mg/kg. After an allowance for 88% dry matter in wheat straw, the median and high residues become 3.6 and 6.9 mg/kg, respectively. This data set was used for maximum residue level estimation.

On the basis of the alpha-cypermethrin trials on wheat matching Danish GAP, the Meeting estimated a high residue level and an STMR value of 1.4 and 0.38 mg/kg respectively for cypermethrin residues in wheat forage.

Straw and fodder of cereal grains – summary

The Meeting noted that barley, maize, oats, rice and wheat are major commodities of the cereal grains group and that the wheat straw data produced the highest estimated maximum residue level.

On the basis of the 16 zeta-cypermethrin trials on wheat (data on wheat straw) matching US GAP, the Meeting estimated a maximum residue level of 10 mg/kg for straw and fodder (dry) of cereal grains to replace the previous recommendation of 5 mg/kg. The Meeting estimated an STMR value and a high residue value of 3.6 and 6.9 mg/kg respectively, for cypermethrin residues in straw and fodder (dry) of cereal grains.

Sugar beet leaves or tops

Alpha-cypermethrin is registered for use on sugar beet crops in Germany with an application rate of 0.01 kg ai/ha and no specified PHI.

In 16 alpha-cypermethrin trials on sugar beet in Germany with conditions in line with GAP, the highest residues in sugar beet leaf on any day of the trial were: 0.10, 0.21, 0.24, 0.27, 0.29, 0.31, 0.34, 0.34, 0.37, 0.45, 0.50, 0.56, 0.75, 0.86, 1.1 and 1.9 mg/kg.

Alpha-cypermethrin is registered for use on sugar beet crops in Greece with an application rate of 0.03 kg ai/ha and a 14-days PHI.

In eight alpha-cypermethrin trials on sugar beet in France (1), Greece (2), Italy (3) and Spain (2) with conditions in line with Greek GAP, residues in sugar beet leaf were: 0.03, 0.05, 0.06, 0.06, 0.07, 0.07, 0.09 and 0.16 mg/kg.

The cypermethrin trials on sugar beet could not be evaluated because no suitable GAP was available.

In USA, zeta-cypermethrin is registered for use on sugar beet at 0.056 kg ai/ha with a 21-days PHI.

In eight zeta-cypermethrin trials in sugar beet in USA with conditions in line with GAP, residues in sugar beet tops on day 21 after the final application were: 0.25, 0.30, 0.34, 0.34, 0.36, 0.39, 0.40 and 0.55 mg/kg.

On the basis of the alpha-cypermethrin trials on sugar beet in Germany, the Meeting estimated an STMR value and a high residue value of 1.5 and 8.3 mg/kg for cypermethrin residues in sugar beet leaves or tops.

Cotton fodder

In Greece, alpha-cypermethrin is registered for use on cotton at 0.03 kg ai/ha with a 7-days PHI.

In six alpha-cypermethrin trials on cotton in Greece (3) and Spain (3) with conditions in line with Greek GAP (± 30% application rate), residues in cotton plants were: 0.20, 0.21, 0.34, 0.38, 0.46 and 0.55 mg/kg.

On the basis of the alpha-cypermethrin trials on cotton matching Greek GAP and the data on cotton plants, the Meeting estimated an STMR value and a high residue value of 0.36 and 0.55 mg/kg respectively for cypermethrin residues in cotton fodder.

Rapeseed forage

In France, alpha-cypermethrin may be used on oilseed rape at 0.011 kg ai/ha with a PHI of 49 days.

In 10 alpha-cypermethrin trials on oilseed rape in France (6), Germany (2) and Spain (2) with conditions in line with French GAP application rate (accept data from PHIs 29–35 days), residues in plant without pods were: .< 0.05 (8), 0.11 and 0.24 mg/kg.

On the basis of the alpha-cypermethrin trials on oilseed rape matching French GAP, the Meeting estimated an STMR value and a high residue value of 0.05 and 0.24 mg/kg for cypermethrin residues in rapeseed forage.

Hops

No suitable GAP was available to evaluate the alpha-cypermethrin trials on hops.

Tea

No suitable GAP was available to evaluate the alpha-cypermethrin trials on tea. The Meeting withdrew the previous recommendation of 20 mg/kg for green and black tea.

Fate of residues during processing

The Meeting received information on the fate of alpha-cypermethrin residues during the processing of barley, grapes, olives, cabbage, gherkins, tomatoes, oilseed rape and oil palm; the fate of cypermethrin residues during the processing of wheat; and the fate of zeta-cypermethrin residues during the processing of apples, beans, maize, peach, peanuts, peas, plum, soya bean, spinach, sugar beet, sugar cane, sunflower seed, tomato and wheat.

Also information was provided on hydrolysis studies of alpha-cypermethrin and cypermethrin to assist with identification of the nature of the residue during processing.

Alpha-cypermethrin and cypermethrin were stable during hydrolysis conditions simulating pasteurisation, baking, brewing and boiling. Approximately 10–15% of alpha-cypermethrin was hydrolysed during sterilisation (pH 6, 120 ˚C for 20 minutes). DCVA and 3-phenoxybenzaldehyde were identified as the hydrolysis products. Cypermethrin was not tested under sterilisation conditions.

Processing factors have been calculated for residues of the cypermethrins in a number of food processes (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 in the RAC. The median of observed values or the best estimate of the processing factors are summarized in the final column of the table.

The Meeting agreed that, because the common composition of the three compounds, a food processing factor obtained for residues of one compound would apply to the residues of the others in the current residue evaluation.

Calculated processing factors and the median or best estimate are summarized in the following table. Only those processes are included in the table that lead to STMR-P or HR-P values useful for dietary intake estimations or for livestock dietary burden calculations. Other processes and processing factors are provided in the monographs.

Compound	raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors.	Median or best estimate
Alpha-cypermethrin	barley	beer	< 0.17, < 0.5, < 0.03, < 0.04, < 0.04, < 0.09	< 0.03
Alpha-cypermethrin	grapes	pomace	1.8, 2.4, 2.8, 3.2, 3.2, 3.3, 4.6, 5.7	3.2
Alpha-cypermethrin	grapes	raisins	3.2, 3.4, 3.2, 3.4	3.3
Alpha-cypermethrin	grapes	wine	< 0.17, < 0.17, < 0.2, < 0.2, < 0.08, < 0.08, < 0.2, < 0.2	< 0.08
Alpha-cypermethrin	olives	oil meal	0.08, 0.09, 0.12, 0.25	0.11
Alpha-cypermethrin	olives	olive oil, crude	3.3, 4.6, 6.6, 8.5, 17.4, 13.9,	7.5
Alpha-cypermethrin	olives	olive oil, refined	6.1, 7.2, 9.3, 12.7	8.2
Alpha-cypermethrin	olives	olives, fermented	1.1, 1.1, 1.6, 2.0	1.3
Zeta-cypermethrin	plum	dried prune	3.6, 2.8	3.2
Alpha-cypermethrin	rape seed	crude rape seed oil	0.81, 1.6	1.6
Alpha-cypermethrin	rape seed	refined rape seed oil	1.0, 1.3	1.2
Alpha-cypermethrin	tomato	canned tomatoes	< 0.11, < 0.16, < 0.16, < 0.25	< 0.11
Alpha-cypermethrin	tomato	tomato juice	0.22, 0.25, 0.33, 0.33	0.29
Alpha-cypermethrin	tomato	tomato paste	1.0, 1.0, 1.1, 1.8	
Zeta-cypermethrin	tomato	tomato paste	< 0.56	
Summary	tomato	tomato paste	< 0.56, 1.0, 1.0, 1.1, 1.8	1.0
Zeta-cypermethrin	tomato	tomato puree	< 0.56	
Alpha-cypermethrin	tomato	tomato purée	0.33, 0.5, 0.5, 0.7	
Summary	tomato	tomato purée	0.33, 0.5, 0.5, < 0.56, 0.7	0.5
Cypermethrin	wheat grain	bran	2.6, 2.4	
Zeta-cypermethrin	wheat	bran	1.4	
Summary	wheat	bran	1.4, 2.4, 2.6	2.4
Cypermethrin	wheat grain	flour	0.27, 0.43	
Zeta-cypermethrin	wheat	flour	< 0.56	
Summary	wheat	flour	0.27, 0.43, < 0.56	0.43
Zeta-cypermethrin	wheat	germ	< 0.56	< 0.56

The processing factor for dried prunes (3.2) was applied to the estimated STMR and HR for plums (stone fruits 0.59 and 0.94 mg/kg) to produce STMR-P and HR-P values for dried prunes of 1.9 and 3.0 mg/kg respectively. The estimated HR-P falls below the estimated maximum residue level for stone fruits, so a separate maximum residue level for dried prunes is not needed.

The processing factors for grape pomace (3.2), and wine (< 0.08) were applied to the estimated STMR for grapes (0.01 mg/kg) to produce STMR-P values for grape pomace (0.032 mg/kg) and wine (< 0.001 mg/kg).

The processing factor for dried grapes (3.3) was applied to the estimated STMR and HR for grapes (0.01 and 0.09 mg/kg) to produce STMR-P and HR-P values for dried grapes (raisins) of 0.033 and 0.30 mg/kg, respectively.

The Meeting estimated a maximum residue level for cypermethrin in dried grapes (= currants, raisins, sultanas) of 0.5 mg/kg.

The processing factors for tomato puree (0.5), tomato juice (0.29) and canned tomato (< 0.11) were applied to the estimated STMR for tomatoes (0.05 mg/kg) to produce STMR-P values for tomato puree (0.025 mg/kg), tomato juice (0.015 mg/kg) and canned tomato (0.006 mg/kg).

The processing factors for crude olive oil (7.5) and refined olive oil (8.2) were applied to the estimated STMR for olives (0.05 mg/kg) to produce STMR-P values for crude olive oil (0.38 mg/kg) and refined olive oil (0.41 mg/kg)

The Meeting estimated a maximum residue level of 0.5 mg/kg for cypermethrin in both virgin olive oil and refined olive oil.

The processing factors for crude rape seed oil (1.6) and refined rape seed oil (1.2) were applied to the estimated STMR for rape seed (0.05 mg/kg) to produce STMR-P values for crude rape seed oil (0.08 mg/kg) and refined rape seed oil (0.06 mg/kg). These concentrations fall below the estimated maximum residue level for oilseeds, so maximum residue levels for the oils are not needed.

The processing factors for wheat bran (2.4), flour (0.43) and wheat germ (0.56) were applied to the estimated STMR for cereal grains (0.035 mg/kg) to produce STMR-P values for wheat bran (0.084 mg/kg), flour (0.015 mg/kg) and wheat germ (0.02 mg/kg).

The processing factor for beer from barley (< 0.03) was applied to the estimated STMR for barley grain (0.035 mg/kg) to produce an STMR-P value for beer of < 0.0011 mg/kg.

Residues in animal commodities

Livestock feeding

The meeting received lactating dairy cow feeding studies for alpha-cypermethrin and cypermethrin. The meeting also received laying hen feeding studies for alpha-cypermethrin and cypermethrin. The studies provided information on likely residues resulting in animal commodities, milk and eggs from residues of the cypermethrins in the animal diet.

Lactating dairy cows

Groups of 3 lactating Holstein dairy cows were dosed once daily via gelatin capsule with alpha-cypermethrin at nominal 4 ppm (1×), 12 ppm (3×) and 40 ppm (10×) in the dry-weight diet for 28 consecutive days. Milk was collected on 14 occasions for analysis. On day 29, within 24 h of the final dose, the animals were slaughtered for tissue collection.

Residues appeared in the fat but not in the other tissues, where residues were below LOQ (0.05 mg/kg) at the highest dose. The transfer factor between residue level in the fat and the dose (expressed as feed concentration) was similar for the three dosing levels. Residues in omental fat were: 4 ppm diet – < 0.05, 0.06 and 0.06 mg/kg; 12 ppm diet – 0.16, 0.14, 0.18 mg/kg; 40 ppm diet – 0.89, 0.42, 1.01 mg/kg.

Residue levels in milk quickly reached a plateau level, within 2 or 3 days. Again, the transfer factor between residue level in the milk and the dose (expressed as feed concentration) was similar for the two dosing levels where residues were measurable. No information was available on the residue level in milk fat.

Groups of 3 lactating Friesian-Holstein dairy cows were dosed orally once daily via gelatin capsule with cypermethrin at 0.028 mg/kg bw (1×), 0.085 mg/kg bw (3×) and 0.284 mg/kg bw (10×), for 28 consecutive days. Milk was collected throughout for analysis. Approximately 23 h after the final dose, the animals were slaughtered for tissue collection.

Cypermethrin residues were below LOQ (0.05 mg/kg) in muscle, kidney and liver at all dose levels. Cypermethrin residues were also below LOQ (0.005 mg/kg milk, 0.05 mg/kg tissue fat) in milk and tissue fat at the low dose. The residue levels in tissue fat at the 3× and 10× showed good proportionality.

Residue levels in milk reached a plateau within 3 days of the first dose and the composition of the cypermethrin (cis-trans ratio) also very soon reached a ratio of approximately 52:48 from the

original 40:60. No information was available on the distribution of the residue between the fat and non-fat milk fractions.

In another study, groups of lactating Holstein dairy cows fitted with ear tags containing cypermethrin were dosed once daily via gelatin capsule with cypermethrin at 0 ppm, 5 ppm (1×), 15 ppm (3×) and 50 ppm (10×) in the diet, for 28 consecutive days. Milk was collected on 12 occasions for analysis. Animals from each group were slaughtered within 24 hours of the final dose for tissue collection.

Residue levels of cypermethrin reached a plateau in milk at some time between 5 and 15 days after dosing was initiated. Residues of cypermethrin were just detectable in fat and cream from the ear-tag use only (LOQ 0.01 mg/kg). Residues of cypermethrin did not appear in the liver even at the highest dose, but were present in kidney and muscle (LOQ 0.01 mg/kg). Residue levels were much higher in fat than in other tissues and were approximately proportional to the dosing levels.

Residue data were available on milk and cream from day 7 where the residue concentrations in cream were on average 7 times the concentration in milk. No information was available on the lipid or water content of the cream.

Laying hens

Three groups of laying hens were dosed once daily via gelatin capsule with alpha-cypermethrin at the intended equivalent of 1.2 ppm, (1×), 6.1 ppm (5×) and 12 ppm (10×) in the diet for 28 consecutive days. Actual equivalent dietary concentrations were: 1.6 ppm, 7.2 ppm and 15 ppm. Eggs were collected approximately 3 times per week. Most of the birds were slaughtered within 24 h of the final dose for tissue collection and analysis.

Residues in liver and muscle from the highest dose group did not exceed LOQ (0.05 mg/kg). Residues in abdominal fat were: 1.6 ppm diet – < 0.05 (3) mg/kg; 7.2 ppm diet – 0.086, 0.088, 0.082 mg/kg; 15 ppm diet – 0.21 0.26 0.24 mg/kg. Residues in eggs and fat did not exceed the LOQ (0.01 and 0.05 mg/kg, respectively) for the low dose group. Residues in eggs from the highest dose group reached levels of 0.02-0.035 mg/kg. Residues in eggs from the middle dose group were in the range < 0.01–0.013 mg/kg

In another study, three groups of laying White Leghorn hens were dosed via gelatin capsule with cypermethrin at the equivalent of 2 ppm (1×), 6 ppm (3×) and 20 ppm (10×) in the diet for 28 consecutive days. Eggs were collected daily. Birds were slaughtered within 24 hours of the final dose for tissue collection.

Residues did not appear in the liver or muscle from the high dose group (LOQ 0.05 mg/kg) or in the fat or eggs from the low dose group. Residues in the fat were: 6 ppm diet – 0.066, 0.086, < 0.05 mg/kg; 20 ppm diet – 0.13, 0.19, 0.17 mg/kg. Cypermethrin appears in the yolk and not the albumen in eggs, as expected of a fat-soluble compound.

Direct animal treatment

The Meeting received studies on the residues arising in livestock from external treatment with alpha-cypermethrin as an ectoparasiticide.

In a South African study, cattle were plunge dipped in a 12000 litre dip prepared from an alpha-cypermethrin SC formulation at a nominal concentration of 70 mg/l and one animal was slaughtered on each of 4 intervals after dipping, i.e.,7, 14, 21 and 28 days later.

Alpha-cypermethrin residues were not detected (limit of detection 0.02 mg/kg) in any of the tissues from dipped animals slaughtered 1, 7, 14 and 21 days after treatment. In the 28-day animal, residues were present in perirenal fat at 0.02 mg/kg, but were below the detection limit in omental fat, muscle, kidney and liver.

In a UK study, four lactating dairy cows were topically dosed along the mid-dorsal line from upper neck to top of tail with 10 ml of a radiolabelled alpha-cypermethrin formulation at a dose equivalent to 150 mg ai/ animal. Samples of milk were collected and one animal was slaughtered at each of 7, 14, 28 and 35 days after dosing.

Concentrations of ^{14}C expressed as alpha-cypermethrin were below the limit of reliable measurement (0.01–0.03 mg/kg) in all tissue samples. A peak of radioactivity in the milk was observed at 1–2 days after treatment (highest values 0.012 and 0.014 mg/kg), but the ^{14}C concentrations expressed as alpha-cypermethrin were generally below 0.01 mg/kg.

In a second UK study, 20 cattle were topically dosed along the mid-dorsal line from shoulder to tail with 10 mL of a Pour On alpha-cypermethrin formulation at a dose equivalent to 150 mg ai/ animal. Animals were slaughtered 3, 7, 14, 21 and 28 days after treatment. Residues in fat decreased from 0.02–0.14 mg/kg 3 days after topical treatment to < 0.01–0.04 mg/kg 28 days after treatment.

No suitable registered direct uses of alpha-cypermethrin on livestock were available to permit evaluation of the supervised trials data on direct animal treatments.

Farm animal dietary burden

The Meeting estimated the dietary burden of cypermethrin in livestock on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, cypermethrin, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	20.7	7.9	24.4	8.3	31.4 [a]	11.3 [b]
Dairy cattle	13.8	5.3	17.1	7.6	21.6 [c]	8.3 [d]
Poultry - broiler	0.16	0.16	0.05	0.05	0.35	0.35
Poultry - layer	0.16	0.16	2.2 [e]	0.66 [f]	0.35	0.35

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 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 commodity maximum residue levels

Cattle

For MRL estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden (31.4 ppm) between the relevant feeding levels (12 and 40 ppm) from the alpha-cypermethrin dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups.

The STMR values for the tissues were calculated by interpolating the STMR dietary burden (11.3 ppm) between the relevant feeding levels (4 and 12 ppm) from the alpha-cypermethrin dairy cow feeding study and using the mean tissue concentrations from those feeding groups.

For milk MRL estimation, the high residues in the milk were calculated by interpolating the maximum dietary burden (21.6 ppm) between the relevant feeding levels (12 and 40 ppm) from the alpha-cypermethrin dairy cow feeding study and using the mean milk concentrations from those feeding groups.

The STMR value for milk was calculated by interpolating the STMR dietary burden (8.3 ppm) between the relevant feeding levels (0 and 12 ppm, because residues at 4 ppm feeding were below LOQ) from the alpha-cypermethrin dairy cow feeding study and using the mean milk concentrations from those feeding groups.

In the table, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding study are shown in square brackets [] and estimated concentrations related to the dietary burdens are shown without brackets.

Dietary burden (ppm)					
Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
MRL					
	mean	highest	highest	highest	highest
MRL beef cattle (31.4) [12, 40]		0.04 [< 0.05, < 0.05]	0.04 [< 0.05, < 0.05]	0.04 [< 0.05, < 0.05]	0.76 [0.16, 1.01]
MRL dairy cattle (21.6) [12, 40]	0.031 0.016, 0.059]				
STMR					
	mean	mean	mean	mean	mean
STMR beef cattle (11.5) [4, 12, 40]		0.014 [< 0.05, < 0.05, < 0.05]	0.014 [< 0.05, < 0.05, < 0.05]	0.014 [< 0.05, < 0.05, < 0.05]	0.15 [0.057, 0.16, 0.77]
STMR dairy cattle (8.3) [0, 4, 12]	0.011 [0, < 0.01, 0.016]				

The data from the cattle feeding studies were used to support the estimation of maximum residue levels for mammalian meat and milk.

Residues in milk were estimated as 0.031 and 0.011 mg/kg resulting from the maximum (21.6 ppm) and STMR (8.3 ppm) dietary burdens respectively. A feeding study with cypermethrin in dairy cows showed that cypermethrin residue concentrations in the cream were, on average, 7 times the concentration in milk. With allowance of 50% fat in the cream, the estimated cypermethrin residues in milk fat were 0.43 and 0.15 mg/kg respectively from the two dietary burdens (0.031×7×2=0.43; 0.011×7×2=0.154).

The Meeting estimated a maximum residue level for cypermethrin in milks of 0.05 to replace the previous recommendation of 0.05 F mg/kg. The Meeting also estimated an STMR for milk of 0.011 mg/kg. The Meeting estimated a maximum residue level and an STMR value for milk fats of 0.5 and 0.15 mg/kg respectively.

The Meeting estimated a maximum residue level for cypermethrin in edible offal of 0.05* mg/kg, confirming the previous recommendation. The estimation is based on the liver and kidney data. The Meeting estimated an STMR value and an HR value of 0.014 and 0.04 mg/kg respectively for edible offal.

For muscle, the residue arising from a dietary burden of 31.4 ppm was below LOQ, 0.05 mg/kg. For fat, the residue arising from a dietary burden of 31.4 ppm was 0.76 mg/kg, while the residue resulting from a dietary burden of 11. 5 ppm was 0.15 mg/kg.

Because the available feeding study was on dairy cows and cypermethrin is fat-soluble with secretion in the milk, higher residues would be expected in the fat of beef cattle than in dairy cattle. The Meeting, allowing for the possible higher residues in beef cattle, estimated a maximum residue level for cypermethrin in mammalian meat (fat) of 2 mg/kg (an estimate for fat of dairy cows only would be 1 mg/kg). The Meeting estimated STMR and HR values for meat (fat) of 0.15 and 0.76 mg/kg respectively. The Meeting estimated STMR and HR values for meat (muscle) of 0.014 and 0.04 mg/kg respectively.

The Meeting was aware that CCRVDF had established veterinary drug MRLs for cypermethrin and alpha-cypermethrin in cattle muscle (50 µg/kg), cattle liver (50µg/kg), cattle kidney (50 µg/kg) and cattle fat (1000 µg/kg) and the same for sheep muscle (50 µg/kg), sheep liver (50µg/kg), sheep kidney (50 µg/kg) and sheep fat (1000 µg/kg).

The CCRVDF MRLs and the estimated maximum residue levels are apparently in agreement, except for the JMPR estimate of 2 mg/kg for mammalian meat (fat) and the CCRVDF value of 1000 µg/kg for cattle fat.

Poultry

In the table, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding study are shown in square brackets [] and estimated concentrations related to the dietary burdens are shown without brackets.

Dietary burden (ppm)				
Feeding level [ppm]	Eggs	Muscle	Liver	Fat
MRL				
	highest	highest	highest	highest
MRL laying hens (2.2) [0, 1.6, 7.2]	0.0033 [0, < 0.01, 0.011]	0.007 [0, < 0.05, < 0.05]	0.007 [0, < 0.05, < 0.05]	0.027 [0, < 0.05, 0.088]
STMR				
	mean	mean	mean	mean
STMR laying hens (0.66) [0, 1.6, 7.2]	0.001 [0, < 0.01, 0.011]	0.002 [0, < 0.05, < 0.05]	0.002 [0, < 0.05, < 0.05]	0.0.008 [0, < 0.05, 0.088]

The data from the laying hen feeding studies were used to support poultry meat and egg MRLs.

For poultry liver and muscle, residues were below LOQ (0.05 mg/kg) even at the 15 ppm feeding level, so an estimate of the STMRs was made by dividing the dietary burden (0.66 ppm) by 15 ppm and multiplying by the LOQ (0.05 mg/kg) to produce a value of 0.002 mg/kg. An estimate of the HRs was made by dividing the dietary burden (2.2 ppm) by 15 ppm and multiplying by the LOQ (0.05 mg/kg) to produce a value of 0.0007 mg/kg.

For eggs, residues were below LOQ (0.01 mg/kg) at the 1.6 ppm feeding level, so an estimate of the STMR was made by dividing the dietary burden (0.66 ppm) by 7.2 ppm and multiplying by the residue at that dosing level (0.011 mg/kg) to produce a value of 0.001 mg/kg. Similarly, a calculation for the HR for eggs produced a value of 0.0033 mg/kg.

The Meeting estimated a maximum residue level of 0.01* mg/kg for eggs to replace the previous recommendation. It also estimated an STMR value and an HR value of 0.001 and 0.0033 mg/kg respectively for poultry eggs.

The Meeting estimated a maximum residue level, an STMR value and an HR value of 0.05*, 0.002 and 0.007 mg/kg respectively for poultry edible offal.

The Meeting estimated a maximum residue level of 0.05*mg/kg for poultry meat (fat). The Meeting also estimated an STMR value of 0.002 (muscle) 0.008 (fat) and an HR value of 0.007 (muscle) 0.027 (fat) mg/kg, respectively.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of cypermethrin, alpha-cypermethrin and zeta-cypermethrin 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 estimated STMRs were 5–20% of the maximum ADI (0.02 mg/kg bw). The Meeting concluded that the long-term intake of residues of the cypermethrins 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 cypermethrin, alpha-cypermethrin and zeta-cypermethrin was calculated for the food commodities (and their processing fractions) for which maximum residue levels and HRs and STMRs were estimated and for which consumption data were available. The results are shown in Annex 4.

Initially, calculated IESTI values on residues in spinach, head lettuce and leaf lettuce, which are all leafy vegetables, exceeded the ARfD. Sufficient residue data related to an alternative GAP for head lettuce were available where a calculated IESTI did not exceed the ARfD, which allowed the estimation of a maximum residue levels for leafy vegetables that could be recommended as an MRL.

The IESTI varied from 0–40% of the ARfD (0.04 mg/kg bw) for the general population and from 0–90% of the ARfD for children 6 years and below. The Meeting concluded that the short-term intake of residues of the cypermethrins from used considered by the Meeting was unlikely to present a public health concern.

5.10 DIMETHOATE (027)

Dimethoate (027) – Alternative GAP

Dimethoate was evaluated by the JMPR in several years from 1965–1994 and under the CCPR periodic review programme in 1998. The compound was re-evaluated in 2003 for residues and toxicology. The 2003 Meeting recommended a number of MRLs and established an acute reference dose (ARfD) of 0.02 mg/kg bw. In 2006 the JMPR evaluated a pending request from CCPR about residues in barley and decided that the MRL for barley was acceptable. The 39th session of the CCPR in 2007 decided to retain draft MRLs for head lettuce (3 mg/kg) and sweet peppers (5 mg/kg) at Step 7 because of short-term dietary intake concerns and requested that an evaluation of alternative GAP for these commodities be undertaken by the JMPR at its 2008 Meeting (ALINORM 07/30/24). The draft MRL for cabbage, head (2 mg/kg) was deleted.

New GAP data were submitted by the manufacturer for the consideration of alternative GAP for lettuce, utilising supervised residue trial data, previously submitted to the 2003 JMPR. On sweet peppers, new residue and GAP data for dimethoate following foliar treatment were submitted by Australia and information on GAP by Japan.

Results of supervised residue trials on crops

The toxicological evaluation of omethoate, the major plant metabolite of dimethoate, indicated a greater level of toxicity than dimethoate, i.e., by a factor of 10. Since consumers are exposed to both dimethoate and omethoate residues at the time of consumption, the difference in toxicity was taken into account (1998 JMPR residue evaluations, p. 510) by multiplying the omethoate residues by a factor of 10 for calculation of the sum of the residues. The total toxicologically significant residues, calculated in this way, were used for the estimation of dietary exposure. The present Meeting followed the same practice. The sum (C_T) of dimethoate (C_D) and omethoate (C_O) residue concentrations reported for the specific commodities was calculated as $C_T = C_D + (10 \times C_O \times 1.075$[37]$)$. The HRs and STMRs were estimated on the basis of the calculated C_T values.

In the case of undetectable residues, the concentration of omethoate residues was calculated by taking into account the average ratio of dimethoate to omethoate in the edible portions of the crop at the specified pre-harvest interval.

Peppers, sweet

Dimethoate is approved in Australia for use in vegetables, and capsicums (Sweet peppers) for the control of aphids, thrips, leafhoppers, mites, bugs, wingless grasshoppers and fruit fly with a foliar spray concentration of 0.03 kg ai/hL. The pre-harvest interval is either 7 days (all States) or 3 days (against fruit fly in Queensland, Western Australia and New South Wales only). The labels were submitted for consideration as alternative GAPs.

Data from two new Australian supervised residue trials and the residue data reported by JMPR 2003 were evaluated according to Australian GAP for pre-harvest foliar spray applications at 0.03 kg ai/hL and a PHI of 3 days or of 7 days. The residues found 3 days after the last treatment of 3× 0.03 kg ai/hL were 0.04, 0.08, 0.14, 0.19 and 0.42 mg/kg for dimethoate and < 0.02, 0.02, < 0.04, 0.06 and 0.15 mg/kg for omethoate. After 7 days, the residues found were 0.03, 0.03, 0.06, 0.14 and 0.26 mg/kg for dimethoate and < 0.02, 0.02, 0.02, < 0.04 and 0.1 mg/kg for omethoate.

Based on the ratio of omethoate to dimethoate residues at 3 or 7 days after application, factors of 0.32, 0.33, 0.36, 0.38, 0.5, 0.67 were estimated. In the case of the two Australian trials with

[37] The molecular mass of dimethoate is 229.28 and for omethoate 213.19, resulting in a factor of 1.075

omethoate residues at LOQ (< 0.02, < 0.04 mg/kg) an average factor of 0.4 was included: $C_T = C_D + (LOQ \times 10 \times 1.075 \times 0.4)$.

The dimethoate equivalents of the sum of dimethoate and omethoate residues in sweet peppers 3 days after the final application were 0.17, 0.26, 0.31, 0.84 and 2.03 mg/kg. Using the value of 2.03 mg/kg as HR for the short-term dietary intake calculation, the ARfD was exceeded for children (130%). Therefore, the JMPR could not estimate a maximum residue level based on the GAP with a PHI of 3 days following a final foliar spray of 0.03 kg ai/hL.

The dimethoate equivalents of the sum of dimethoate and omethoate residues in sweet peppers 7 days after the final application were 0.03 kg ai/hl 0.12, 0.25, 0.28, 0.31 and 1.3 mg/kg. The trials match the second alternative GAP submitted by Australia. Based on the dimethoate residue data for a 7 day PHI, the Meeting estimated a maximum residue level of 0.5 mg/kg for sweet peppers and proposed to withdraw the previous recommendation of 5 mg/kg. According to the residue definition for risk assessment of dimethoate and 10 times omethoate, an STMR value of 0.28 mg/kg and HR value of 1.3 mg/kg were estimated.

Dried chilli peppers

Based on the residues in sweet peppers and a default concentration factor of 10, the Meeting estimated a maximum residue level of 3 mg/kg for dried chilli peppers and withdrew its previous recommendation of 50 mg/kg. According to the residue definition for risk assessment of dimethoate and 10 times omethoate, an STMR value of 2.8 mg/kg and HR value of 13 mg/kg were estimated.

Lettuce, head

The residue data on lettuce reported by JMPR 2003 were evaluated according to new information on GAP.

As described above, the dimethoate equivalents of dimethoate and omethoate residues were calculated as follows: $C_T = C_D + (C_O \times 10 \times 1.075)$. Based on the ratio of omethoate to dimethoate residues 14 or 28 days after application, factors of 0.18, 0.27, 0.25, 0.29, 0.5, 0.5, 0.55, 1.3, 1.5 were estimated. Because of the wide range, the LOQ values for omethoate were not corrected by a factor.

The 2003 JMPR evaluated outdoor residue trials data on head lettuce from Greece (1), Spain (4) and Italy (4) with application of 0.04 kg ai/hL and 14 days PHI against Italian GAP. The residues at 14 days, in ranked order, were: < 0.01 (6), 0.03, 0.07 and 0.11 mg/kg for dimethoate, and < 0.01 (5), 0.01, 0.02, 0.04 and 0.06 for omethoate. For dietary risk assessment purposes, the dimethoate equivalents of the sum of dimethoate and omethoate residues were estimated as follows: < 0.12 (4), 0.12, 0.18, 0.23, 0.46 and 0.76 mg/kg.

Eight outdoor trials on head lettuce from the UK submitted to the 2003 JMPR were evaluated against Irish GAP (6 × 0.34 kg ai/ha, PHI 14 days). The residues at 14 days, in ranked order were: 0.01, 0.02, 0.02, 0.02, 0.04, 0.07, 0.07 and 0.11 mg/kg for dimethoate and < 0.01 (5), 0.02, 0.03 and 0.03 mg/kg for omethoate. For dietary risk assessment purposes, the dimethoate equivalents of the sum of dimethoate and omethoate residues were estimated as follows: 0.12, 0.13, 0.13, 0.15, 0.18, 0.29, 0.34 and 0.43 mg/kg.

The 2003 JMPR evaluated eleven residue trials conducted in glasshouses in the UK completed in 1996 and 1998. Dimethoate EC 400 g/L was applied once at 0.34 kg ai/ha (0.17 kg ai/hL) with a PHI of 28 days. GAP for glasshouse use was reported from Ireland (0.34 kg ai/ha, repeated as necessary with a 28-day PHI). The 2008 JMPR was informed that the Irish GAP had been modified as follows: spraying, up to and including 9th leaf unfolded stage or before the head starts to form (up to and including BBCH 19). Eight from eleven supervised trials complied with new Irish glasshouse GAP. The residues in ranked order were < 0.01, 0.01, 0.01, 0.02, 0.02, 0.06, 0.16 and 0.17 mg/kg for dimethoate and < 0.01 (4), 0.01, 0.03, 0.03 and 0.04 mg/kg for

omethoate. For dietary risk assessment purposes, the dimethoate equivalents of the sum of dimethoate and omethoate residues were estimated as follows: 0.12 (3), 0.13, 0.13, 0.38, 0.49 and 0.59 mg/kg.

The Meeting was aware that the three data sets (outdoor Southern Europe, outdoor UK and indoor UK) are based on different GAPs but recognized no observable difference in the estimation of a maximum residue level between the data sets. The maximum dimethoate value of 0.17 mg/kg results from the UK indoor data set and the highest omethoate residue of 0.06 mg/kg (which leads to an HR of 0.76 mg/kg dimethoate equivalents) from the outdoor European data set. The Meeting concluded that the data can be combined. Residues in rank order (n = 25) were: < 0.01 (7), 0.01 (3), 0.02 (5), 0.03, 0.04, 0.06, 0.07 (3), 0.11 (2), 0.16 and 0.17 mg/kg for dimethoate and < 0.01 (14), 0.01, 0.01, 0.02, 0.02, 0.03 (4), 0.04, 0.04 and 0.06 mg/kg for omethoate.

The dimethoate equivalents, of the sum of dimethoate and omethoate residues, in head lettuce were: < 0.12 (4), 0.12 (5), 0.13 (4), 0.15, 0.18 (2), 0.23, 0.29, 0.34, 0.38, 0.43, 0.46, 0.49, 0.59 and 0.76 mg/kg. Based on the dimethoate residue data, the Meeting estimated a maximum residue level of 0.3 mg/kg for head lettuce and withdrew its previous recommendation of 3 mg/kg. According to the residue definition for risk assessment of dimethoate and 10 times omethoate, an STMR value of 0.13 mg/kg and an HR value of 0.76 mg/kg were estimated.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of dimethoate including its metabolite omethoate were estimated for the 13 GEMS/Food cluster diets based on 22 commodities. The results are shown in Annex 3.

The IEDI of dimethoate including its metabolite omethoate was calculated on the basis of the STMRs and STMR-Ps estimated by the JMPR in 2003/2008 for globe artichoke, Brussels sprouts, cauliflower, celery, citrus fruits, head lettuce, mango, olives, olive oil, sweet peppers, wheat (except flour and wholemeal), wheat flour and wheat wholemeal as sum of dimethoate and omethoate residues, considering the ten times higher toxicity of omethoate. The 1998 JMPR estimated separate STMRs for dimethoate and omethoate, arising from the use of dimethoate, for asparagus, barley, Savoy cabbage, cherries, peas (pods and succulent, immature seeds), potato, sugar beet, and garden turnip. Because no sum STMR was calculated by the 1998 JMPR, the sum of the separate STMRs of omethoate (multiplied by 10) and dimethoate was used in the IEDI calculation by the current Meeting.

The IEDI for the 13 GEMS/Food cluster diets was 20–100% of the maximum ADI of 0.002 mg/kg bw. The Meeting concluded that the long-term intake of residues of dimethoate from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) of dimethoate and its metabolite omethoate 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: i.e., sweet peppers and head lettuce. The results are shown in Annex 4.

For head lettuce, an IESTI of 40% of the ARfD (0.02 mg/kg bw) was calculated for the general population and 80% for children 6 years and below. For sweet peppers, an IESTI of 30% of the ARfD was calculated for the general population and 80% for children 6 years and below.

The Meeting concluded that the short-term intake of residues of dimethoate (including its metabolite omethoate) from uses considered by the current Meeting is unlikely to present a public health concern.

5.12 DIPHENYLAMINE (030)

RESIDUE AND ANALYTICAL ASPECTS

The CCPR at its 36th Session advanced the MRL for cattle milk, 0.0004 (*) F mg/kg, to Step 8. Subsequently the 38th Session requested JMPR to review the basis for setting the cattle milk MRL. The issue was referred to the JMPR Secretariat with a direction to separate the MRLs for milk and cream.

The CCPR at its 40th Session decided that where separate MRLs are established for whole milk and milk fat, regulation and monitoring of fat-soluble pesticides in milk should be in reference to whole milk. That is, whole milk should be analysed and the result compared to the MRL of whole milk.

Relevant studies on analytical method, livestock metabolism, and livestock feeding were supplied by the Northwest Horticultural Council (USA). All were studies considered during the periodic re-evaluation of diphenylamine (2001 Report). No new data were made available.

The residue definition is diphenylamine. The residue is fat soluble (JMPR Report 2001).

In the Holstein cow feeding study, diphenylamine was detectable at the 0.005 mg/kg LOD only occasionally at the 30 and 90 ppm dosing levels. At the 300 ppm dosing level, the diphenylamine was equal to or above the level of detection in all three cows (day 24): 0.005, 0.012, and 0.008 mg/kg, but below the demonstrated level of quantitation (LOQ), 0.01 mg/kg. The dietary burdens for the estimated MRL and STMR values are the same, 11.5 ppm (as determined in 2001).

Cream samples were also analysed from day 14, but the method of separation (mechanical, chemical) of the cream (milk fat) is not described. The maximum residue level at the 30 ppm feeding level was 0.011 mg/kg and the average was 0.0098 mg/kg, range 0.008 to 0.011 mg/kg for three cows at two milking sessions on day 14. The separation technique is questionable given that one sample of skim milk contained 0.011 mg/kg diphenylamine (whole milk < 0.005 mg/kg). This is an unexpected result for a fat-soluble pesticide, or at least indicates factors other than fat solubility entering into the distribution of the pesticide. The maximum residue level estimate for milk fat would be 0.01* mg/kg, based on the limit of quantitation of the analytical method, which would be the recommended maximum residue level estimate of 0.0004* mg/kg for whole milk at 4% fat (0.04× 0.01).

Based on the dietary burden of 11.2 ppm for dairy cattle (JMPR 2001) and average residues at a 30 ppm feeding level < 0.005 mg/kg (0.005 mg/kg maximum), the current Meeting estimated a maximum residue level of 0.01 (*) mg/kg and an STMR of 0.0019 mg/kg (0.005 mg/kg × 11.2 / 30) for whole milk (ML 106). This replaces a previous maximum residue recommendation for 0.0004 (*) mg/kg for cattle milk. The Meeting further recommended a maximum residue level of 0.01 mg/kg for milk fats (0.011 mg/kg × 11.5 / 30 × 2 = 0.0084, detectable but < LOQ) and an STMR of 0.0075 mg/kg (0.0098 × 11.5 / 30 × 2 = 0.0075). This assumes that cream is 50% milk fat.

5.13 ETHOXYQUIN (035)

RESIDUE AND ANALYTICAL ASPECTS

Ethoxyquin was reviewed by JMPR in 1999 under the periodic review programme. At the time the Meeting made no maximum residue level recommendation for pears due to uncertainty on the toxicity of the degradation products. The 2005 JMPR established an ARfD for ethoxyquin and noted that both the ARfD and the ADI were defined in terms of the parent and metabolites/degradates methylethoxyquin (MEQ), dihydroethoxyquin (DHEQ) and dehydromethylethoxyquin (DHMEQ).

Methods of Analysis

Available analytical methods determine only parent ethoxyquin. There are no methods for the routine determination of MEQ, DHEQ and DHMEQ as needed for dietary risk assessment.

Previously reviewed studies (JMPR 1999) indicated there was up to a 60% conversion of radiolabelled ethoxyquin to the metabolites/degradates, including MEQ, DHEQ and DHMEQ. This occurred over a 33 week storage interval at –2 °C.

The Meeting concluded that total residues, for dietary intake assessment, may be estimated by multiplying the measured ethoxyquin residue by a factor of 2.5. This reflects the result of the radiolabelled degradation study and typical cold storage conditions for treated pears.

Stability of pesticide residues in stored analytical samples

Ethoxyquin on pears is unstable under conditions of frozen storage at –20 °C in plastic. The apparent concentration of ethoxyquin drops to 33% of the applied dose within one day, but returns to or exceeds 100% over the next 40 days. This may have been due to an interaction between the plastic container and ethoxyquin.

Ethoxyquin on pear is somewhat more stable when stored wrapped in foil in evacuated bags at –20 °C.

The Meeting concluded that pear samples being tested for ethoxyquin should be stored frozen and protected from oxygen to the extent possible. Pears should be prepared for analysis in as short a time as possible following collection.

Results of supervised residue trials on crops

Pear

The Meeting received studies of the post-harvest treatment of pears by spraying, a combination of spraying and wrapping in treated paper, and by thermofogging.

Twelve trials were conducted at the maximum USA GAP (Ethoxyquin EC, 2700 mg ai/L, brush or spray application). Residues in ranked order were: 1.6, 1.7 (2), 1.8 (2), 1.9, 2.0 (2), 2.2, 2.3 (2), 2.4 mg/kg.

Four trials were conducted at the maximum USA GAP (18% ethoxyquin, thermofog application, 16.2 g ai/1000 kg). Residues in ranked order were: < 0.3 (4) mg/kg.

Three trials were conducted at a rate slightly in excess of the maximum USA GAP (EC 460 g/kg, 1000–1500 ppm drench + impregnated paper wraps). The trials involved a spray at a concentration of 1700 ppm followed by wrapping with impregnated paper. The Meeting considered the trials to be within 120% of the maximum GAP and therefore acceptable. The residues in ranked order were: 1.2, 1.5, 1.6 mg/kg.

Based on the 12 post-harvest spray trials of pears, the Meeting estimated an STMR of 5 mg/kg (2.0× 2.5) and an HR of 6.0 (2.4× 2.5) and a maximum residue level of 3 mg/kg.

Residue definition

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

Definition of the residue (for estimation of dietary intake) for plant commodities: *ethoxyquin plus degradates methylethoxyquin (MEQ), dihydroethoxyquin (DHEQ) and dehydromethylethoxyquin (DHMEQ).*

DIETARY RISK ASSESSMENT

Long-term intake

The current maximum ADI for ethoxyquin is 0.005 mg/kg bw. The International Estimated Daily Intakes (IEDIs) of ethoxyquin based on the STMRs estimated for one commodity for the thirteen GEMS/Food cluster diets were in the range of 0% to 40% of the maximum ADI. The Meeting concluded that the long-term intake of residues of ethoxyquin resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

An ARfD for ethoxyquin of 0.5 mg/kg bw was established by the 2005 JMPR. The IESTIs of ethoxyquin by the general population and by children were calculated for commodities for which HRs were estimated. The IESTI was 20% of the ARfD for the general population and 50% of the ARfD for children.

The Meeting concluded that short-term intake of residues of ethoxyquin from its use on pears is unlikely to present a public health concern.

5.14 IMIDACLOPRID (206)

RESIDUE AND ANALYTICAL ASPECTS

Imidacloprid was evaluated by the JMPR in 2001 for toxicology and in 2002 and 2006 for residues. An ADI of 0–0.06 mg/kg bw/day and an ARfD of 0.4 mg/kg bw/day were established, and numerous maximum residue levels were estimated. The residues were defined by the 2002 JMPR as the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety for both regulatory and dietary intake assessment purposes.

Imidacloprid was scheduled by the 39th session of the CCPR for residue evaluation of additional crops. The Interregional Research Project No. 4 (IR-4) in the USA provided residue data for avocado, banana, blueberry, caneberry, carrot, coffee, pea, peanut, pomegranate, radish, strawberry, sugar apple, sunflower and tree nuts. Japan supplied information on use patterns of imidacloprid on agricultural and horticultural crops and the manufacturer provided labels of products registered in the USA.

Results of supervised residue trials on crops

Berries and other small fruits (except cranberries, grapes and strawberries)

The registered GAP in the USA for blueberries is soil application at a maximal rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of five foliar applications at a maximum rate of 0.112 kg ai/ha with an interval of 7 days and a PHI of 3 days.

Eleven field trials were conducted, two on low bush blueberry and nine on high bush blueberry. Each of the field trial sites consisted of one untreated control plot and one treated plot, but the three Michigan trials on high bush blueberry used two treated plots each, one for a soil-directed application and the other for foliar applications. Eight of the nine trials on high bush blueberry matched the registered use in the USA. After soil application, the residues were < 0.05 (4), 0.09 mg/kg. After foliar spray, the residues were: 0.38, 0.49, 0.52, 0.89, 1.1, 2.2 and 2.8 mg/kg.

The registered GAP on caneberries (raspberries, blackberries, boysenberries, marionberries) in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of three foliar applications at a maximum rate of 0.112 kg ai/ha with an interval of 7 days and a PHI of 3 days. Four field trials were conducted on raspberries which matched the registered use in the USA; the residues were 0.48, 0.49, 0.59, 0.96 mg/kg.

Three field trials with foliar treatment were conducted on blackberries and matched the registered use in the USA; the residues were 0.38, 0.69, 0.70 mg/kg.

One field trial each with foliar treatment was conducted on boysenberries and marionberries and matched the registered use in the USA; the residues were 1.5 and 1.7 mg/kg, respectively.

Based on the blueberry foliar spray residue data, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 0.89 mg/kg and an HR of 2.8 mg/kg for the group of berries and other small fruits except cranberries, grapes and strawberries.

Strawberry

The registered GAP on strawberry in the USA is soil application at a maximal rate of 0.56 kg ai/ha with a PHI of 14 days, and/or a maximum of three foliar applications at a maximal rate of 0.053 kg ai/ha with an interval of 5 days and a PHI of 7 days. Nine field trials were conducted; a combination of one soil application matching the registered soil application GAP and three foliar

applications matching the registered foliar application GAP was used. Residues were 0.12, 0.14, 0.15 (2), 0.17 (2), 0.21, 0.32, 0.35 mg/kg.

The Meeting estimated an STMR of 0.17 mg/kg and an HR of 0.35 mg/kg, and recommended a maximum residue level of 0.5 mg/kg in strawberry for imidacloprid.

Avocado

The registered GAP on avocado in the USA is soil application at a maximal 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 0.112 kg ai/ha with an interval of 10 days and a PHI of 7 days. Five field trials were conducted with soil application at 98–104% GAP rate, but with a PHI of 50–69 days, no trials matched the registered GAP in the USA.

The Meeting decided that the trials submitted were inadequate for the purpose of estimating a maximum residue level for avocado.

Banana

The 2002 JMPR evaluated trials from Africa and Central America with an application rate 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.

New GAP and residue data for banana were submitted in 2008. The GAP in the USA is for a 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 0.112 kg ai/ha with a treatment interval of 14 days and a 0 day PHI. Five field trials 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 0.44 (2), 0.50, 0.53 mg/kg for unbagged bananas and 0.13 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 and that the previous recommendation of 0.05 mg/kg should be maintained.

Pomegranate

The registered GAP on pomegranate in the USA is for a soil application at a maximum rate of 0.56 kg ai/ha with a 0 day PHI, and/or a maximum of three foliar applications at a maximum rate of 0.112 kg ai/ha with an interval of 7 days and a PHI of 7 days. Three field trials were conducted, a combination of one soil application at 57–63% of the GAP rate and three foliar applications matching the registered foliar application GAP. Residues in whole fruit were 0.42, 0.43, 0.55 mg/kg. The Meeting considered three trials adequate for estimation of a maximum residue level for this minor crop.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in pomegranate of 1, 0.43 and 0.55 mg/kg, respectively.

Sugar apple

The registered GAP on sugar apple in the USA is a maximum of five foliar applications at a maximum rate of 0.112 kg ai/ha with a treatment interval of 10 days and a PHI of 7 days. Three field trials were conducted with a PHI of 14/15 days and did not match the registered GAP in the USA

The Meeting decided that the trials submitted were inadequate for the purpose of estimating a maximum residue level for pomegranate.

Radish leaves (including tops)

The registered GAP on radish in the USA is one soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 21 days, and/or one foliar application at a maximal rate of 0.049 kg ai/ha with a PHI of 7 days. Five field trials were conducted, a combination of one soil application matching the registered soil application GAP and one foliar application matching the registered foliar application GAP. Residues in radish leaves (including tops) were 0.53, 0.67, 0.70, 1.8 and 2.7 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in radish leaves of 5, 0.7 and 2.7 mg/kg, respectively.

Peas (pods and succulent, immature seeds)

The registered GAP on pea in the USA is seed treatment at a maximal rate of 1.116 g ai/kg seeds, and/or soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg ai/ha with an interval of 7 days and a PHI of 7 days. Four field trials were conducted, a combination of one seed treatment with 200% GAP rate, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. Residues were 0.20, 0.27, 0.92, 3.8 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in peas (pods and succulent, immature seeds) of 5, 0.60 and 3.8 mg/kg, respectively.

Peas, shelled (succulent seeds)

The registered GAP on pea in the USA is seed treatment at a maximal rate of 1.116 g ai/kg seeds, and/or soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg ai/ha with an interval of 7 days and a PHI of 7 days. Six field trials were conducted, a combination of one seed treatment with 200% GAP rate, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. Residues were 0.31, 0.42, 0.54, 0.62, 0.88 and 1.1 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in peas (succulent, shelled) of 2, 0.58 and 1.1 mg/kg, respectively.

Peas (dry)

The registered GAP on pea in the USA is seed treatment at a maximal rate of 1.116 g ai/kg seeds, and /or soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximum rate of 0.049 kg ai/ha with an interval of 7 days and a PHI of 7 days. Six field trials were conducted, a combination of one seed treatment at 2× GAP rate, one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. Residues were 0.14, 0.2, 0.32, 0.91, 0.94, and 1.0 mg/kg in dry shelled peas.

The Meeting estimated a maximum residue level for imidacloprid in peas (dry) of 2 mg/kg and an STMR of 0.62 mg/kg, respectively.

Root and tuber vegetables

The 2002 JMPR evaluated residue supervised trials data for imidacloprid on potatoes and sugar beet. New residue data were submitted to the current Meeting for carrots and radish.

Carrot

The registered GAP on carrot in the USA is for soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 21 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg

ai/ha with an interval of 5 days and a PHI of 7 days. Six field trials were conducted involving a combination of one soil application, matching the registered soil application GAP (with trial 96-TX*27 an exception at 168% GAP rate), and one foliar application matching the registered foliar application GAP (with trial 96-OH*20 an exception at 135% GAP rate). The data from these trials were used for the evaluation and the residues were < 0.05 (5), 0.09 mg/kg.

Radish

The registered GAP on radish in the USA is one soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 21 days, and/or one foliar application at a maximal rate of 0.049 kg ai/ha with a PHI of 7 days. Five field trials were conducted, a combination of one soil application matching the registered soil application GAP and one foliar application matching the registered foliar application GAP. Residues were < 0.05 (4), 0.13 mg/kg in roots.

Potato

The 2002 JMPR estimated a maximum residue level, an STMR and an HR for imidacloprid in potatoes of 0.5, 0.05 and 0.28 mg/kg, respectively.

Sugar beet

The 2002 JMPR estimated a maximum residue level and an STMR for imidacloprid in sugar beet of 0.05* mg/kg and 0.05 mg/kg.

The Meeting estimated a maximum residue level, an STMR and an HR for imidacloprid in root and tuber vegetables of 0.5, 0.05 and 0.28 mg/kg, respectively, based on the potato residue data, i.e., commodity with the highest residues in the crop group. The Meeting agreed to withdraw it previous recommendations for potatoes of 0.5 mg/kg and for sugar beet of 0.05* mg/kg.

Tree nuts

The registered GAP on tree nuts in the USA is for a soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of four foliar applications at a maximal application (per season) of 0.403 kg ai/ha with an interval of 6 days and a PHI of 7 days. Ten field trials each were conducted on almonds and pecans. These trials matched the registered GAP in the USA. Residues were < 0.01 (19) and 0.01 mg/kg in the almond and pecan nutmeat (kernels).

The 2002 JMPR recommended a maximum residue level of 0.05 mg/kg for pecan based on supervised residue trials from the USA carried out in 1993 and 1998. The residue data of the trials carried out in1998 were submitted to the 2008 JMPR. The Meeting noted that the LOQ for the determination of imidacloprid in pecan nutmeat from the 1993 trials was 0.05 mg/kg whereas it was 0.01 mg/kg for the 1998 trials and decided to estimate the maximum residue level on the basis of the 1998 residue data only.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in tree nuts of 0.01*, 0.01 and 0.01 mg/kg, respectively. The Meeting agreed the previous recommendation of a maximum residue level of 0.05 mg/kg for pecan should be withdrawn.

Sunflower seed

The registered GAP on sunflower in the USA is as a seed treatment at a maximum rate of 0.5 mg ai/seed equivalent or 9.7 g ai/kg seeds. Five field trials were conducted according to GAP with a treatment of 9.38 g ai/kg seeds. In two further trials the application rate was 46.9 g ai/kg seeds. The residues found in the seeds, following a harvest interval of 119–143 days, were: < 0.05 (7) mg/kg.

The Meeting estimated a maximum residue level and an STMR value for imidacloprid in sunflower seed of 0.05* mg/kg and 0.05 mg/kg.

Peanuts

The registered GAP on peanut in the USA is for a soil application at a maximum rate of 0.42 kg ai/ha with a PHI of 14 days, and/or a maximum of three foliar applications at a maximum rate of 0.049 kg ai/ha with an application interval of 5 days and a PHI of 14 days. Twelve field trials were conducted consisting of a combination of one soil application, matching the registered soil application GAP, and three foliar applications, matching the registered foliar application GAP. Residues in the peanut kernels were < 0.05 (4), 0.10, 0.11, 0.12, 0.15, 0.17, 0.23, 0.26, 0.40 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and an HR value for imidacloprid in peanuts of 1, 0.12 and 0.4 mg/kg, respectively.

Coffee

The registered GAP on coffee in the USA is soil application at a maximum rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of five foliar applications at a maximum rate of 0.112 kg ai/ha with an application interval of 7 days and a PHI of 7 days. Five trials were conducted complying with the GAP of the USA. Residues were: 0.19, 0.30, 0.35, 0.37 and 0.48 mg/kg in green coffee beans.

The Meeting recommended a maximum residue level of 1 mg/kg for imidacloprid in green coffee beans. The Meeting also estimated an STMR of 0.35 mg/kg.

Primary animal feed commodities

Almond hulls

The registered GAP on tree nuts (almond) in the USA is soil application at a maximal rate of 0.56 kg ai/ha with a PHI of 7 days, and/or a maximum of four foliar applications at a maximal application (per season) of 0.403 kg ai/ha with an interval of 6 days and a PHI of 7 days. Ten field trials were conducted on almonds. These trials matched the registered GAP in the USA. The residues were in rank order 0.23, 1.0, 1.1, 1.4 (2), 1.5, 1.9, 2.4, 2.5 and 2.6 mg/kg in almond hulls (fresh weight basis).

Allowing for the standard 90% dry matter, the Meeting estimated a maximum residue level and an STMR value for imidacloprid in almond hulls of 5 mg/kg and 1.7 mg/kg, respectively.

Peanut fodder

The registered GAP on peanut in the USA is soil application at a maximal rate of 0.42 kg ai/ha with a PHI of 14 days, and/or a maximum of three foliar applications at a maximal rate of 0.049 kg ai/ha with an interval of 5 days and a PHI of 14 days. Twelve field trials were conducted, consisting of a combination of one soil application matching the registered soil application GAP and three foliar applications matching the registered foliar application GAP. The residues were in rank order 0.95, 1.1, 4.0, 4.1, 7.0, 7.9, 9.5, 12 (2), 21, 23 and 24 mg/kg in peanut fodder (fresh weight basis).

Allowing for the standard 85% dry matter, the Meeting estimated a maximum residue level, an STMR value and highest residue for imidacloprid in peanut fodder of 30 mg/kg, 10.2 mg/kg and 28 mg/kg, respectively.

Residues in animal commodities

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations based on the feed items evaluated by the JMPR in 2002 and 2008 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 and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, imidacloprid, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	8.29	2.64	2.29	0.78	18.01	6.07
Dairy cattle	7.16	2.30	2.38	0.93	18.01[a]	6.14[b]
Poultry - broiler	0.18	0.28	0.46	0.26	0.12	0.12
Poultry - layer	0.19	0.28	1.02[c]	0.37[d]	0.09	0.12

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

[b] Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat and milk

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

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

Animal commodity maximum residue levels

Because of the changes in the animal dietary burden, the residue concentrations in animal products were re-calculated by the 2008 JMPR.

Cattle

A feeding study on dairy cows dosed with imidacloprid in capsules at the equivalent of 5, 15 or 50 ppm in the diet for 28 days was submitted to the 2002 JMPR. The 2002 Meeting estimated mean transfer factors (concentration of residue ÷ concentration in feed) for cattle tissues and milk as follows: liver 0.01, kidney 0.006, muscle 0.002, fat 0.0012 and milk 0.0029.The Meeting agreed to apply the transfer factors to maximum and mean dietary burdens calculated by the 2008 JMPR (transfer factor × dietary burden in mg/kg feed).

The maximum concentrations of residues expected in tissues and milk based on a dietary burden of 18.01 ppm are: 0.18 mg/kg in liver, 0.11 mg/kg in kidney, 0.04 mg/kg in muscle, 0.02 mg/kg in fat and 0.05 mg/kg in milk.

The mean concentrations of residues expected in tissues and milk based on a dietary burden of 6.14 ppm are: 0.06 mg/kg in liver, 0.04 mg/kg in kidney, 0.012 mg/kg in muscle, 0.007 mg/kg in fat and 0.018 mg/kg in milk.

The Meeting estimated maximum residue levels of 0.1 mg/kg for meat (mammalian), 0.3 mg/kg in edible offal (mammalian) and 0.1 mg/kg in milks. The previous recommendation for 0.02* mg/kg for meat (mammalian) and milks, as well as 0.05 mg/kg for edible offal, should be withdrawn.

The Meeting recommended that the HR values should be 0.04 mg/kg in meat (mammalian), 0.18 mg/kg in edible offal (mammalian), and 0.02 mg/kg in fat (mammalian). The estimated STMR

values are 0.012 mg/kg for meat (mammalian), 0.06 mg/kg for edible offal (mammalian), 0.007 mg/kg for fat (mammalian) and 0.018 mg/kg for milks.

Poultry

A feeding study on laying hens dosed with imidacloprid at the equivalent of 2, 6 or 20 ppm in the diet for 30 days was submitted to the 2002 JMPR. The 2002 Meeting estimated mean transfer factors (concentration of residue ÷ concentration in feed) for poultry tissues and eggs as follows: liver 0.02, muscle 0.0027, fat 0.001 and eggs 0.007.The Meeting agreed to apply the transfer factors to maximum and mean dietary burdens calculated by the 2008 JMPR (transfer factor • dietary burden in mg/kg feed).

The maximum concentrations of residues expected in poultry tissues and eggs based on a maximum dietary burden of 1.02 ppm are: 0.02 mg/kg in liver, 0.003 mg/kg in muscle, 0.001 mg/kg in fat and 0.007 mg/kg in eggs.

The mean concentrations of residues expected in poultry tissues and eggs based on a mean dietary burden of 0.37 ppm are: 0.007 mg/kg in liver, 0.001 mg/kg in muscle, 0.0004 mg/kg in fat and 0.003 mg/kg in eggs.

The Meeting estimated maximum residue levels of 0.02 mg/kg for eggs and poultry meat and confirmed its previous recommendation. For poultry edible offal a maximum residue level of 0.05 mg/kg was estimated. The previous recommendation of 0.02* mg/kg for poultry edible offal should be withdrawn.

The Meeting recommended that the HR values should be 0.003 mg/kg in poultry meat, 0.02 mg/kg in poultry edible offal, 0.001 mg/kg in poultry fat and 0.007 mg/kg in eggs. The estimated STMR values are 0.001 mg/kg for poultry meat, 0.007 mg/kg for edible offal, 0.0004 mg/kg for poultry fat and 0.003 mg/kg for eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of imidacloprid were estimated for the 13 GEMS/Food cluster diets based on 65 commodities. The results are shown in Annex 3.

The IEDI for the 13 GEMS/Food cluster diets was 1–5% of the maximum ADI of 0.06 mg/kg bw. The Meeting concluded that the long-term intake of residues of imidacloprid from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) of 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 Meeting noticed the very high consumption for black currants of 1054 g for children in the UK with a body weight of 14.5 kg in the large portion and recommended confirmation of this figure.

The IESTI represented for the general population 0–10% and for children 0–50% 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.

5.15 HEXYTHIAZOX (176)

TOXICOLOGY

Hexythiazox is the ISO approved name for (*trans*-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxo-3-thiazolidine-carboxamide (CAS No. 78587-05-0). Hexythiazox is an acaricide that acts against egg, larval and nymph stages. The precise mechanism of acaricidal action is unknown.

Hexythiazox was evaluated previously by the JMPR in 1991 when an ADI of 0–0.03 mg/kg bw was established based on a NOAEL of 3.2 mg/kg bw per day identified in a 2-year study in rats and with a safety factor of 100. Hexythiazox was reviewed by the present Meeting as part of the CCPR periodic review programme. Two additional studies of genotoxicity and some revised study reports were available to the present Meeting.

Most of the pivotal studies met the basic requirements of the relevant OECD or national test guidelines. Only a small number of study reports contained certificates of compliance with good laboratory practice (GLP).

Biochemical aspects

The absorption, distribution and excretion of [^{14}C]hexythiazox was rapid in rats at 10 mg/kg bw, but much slower at 880 mg/kg bw. The extent of absorption at 10 mg/kg bw was approximately 30% on the basis of the level of urinary excretion, but significantly lower at 880 mg/kg bw. The maximum plasma concentrations of radiolabel were observed about 3–4 h after administration of the lower dose. The elimination half-life was about 10 h at 10 mg/kg bw, and was prolonged to about 20 h at 880 mg/kg bw, presumably reflecting saturation. This was confirmed by data on excretion. Most (about 60–90%, depending on the administered dose) of the radiolabel was excreted in the faeces within 3 days. About 10–20% of the administered dose was excreted as intact hexythiazox at the lower dose and 65–70% at the higher dose. The highest concentrations of tissue residues were found in fat, adrenals, liver and ovaries; the main component in fat was hexythiazox. Metabolism was extensive, but most of the radioactive material was not attributed to specific metabolites. The main metabolic reactions identified were hydroxylation of the cyclohexane ring and cleavage of the amide bond to the cyclohexane ring.

Toxicological data

Hexythiazox was of low acute toxicity when administered orally (LD_{50} > 5000 mg/kg bw), dermally (LD_{50} > 5000 mg/kg bw) or by inhalation (LC_{50} >2.0 mg/L) routes. No deaths were reported in any of the submitted studies. Hexythiazox was not irritating to the skin of rabbits; was a slight, transient eye irritant and produced no evidence for skin sensitizing potential in a Magnussen and Kligman maximization study in guinea-pigs.

The toxicity of hexythiazox given as repeated doses has been investigated in mice, rats and dogs. Effects on body weight and the liver (which showed hypertrophy and, in some studies, necrosis) were seen relatively consistently. However, a number of other effects were seen at lower doses in dogs.

In a 28-day study in mice, body-weight gain was reduced, total cholesterol concentration in plasma was decreased, liver weights were increased and there were alterations in liver pathology at 1800 ppm and above. The NOAEL was 300 ppm, equal to 55 mg/kg bw per day.

In a 90-day study in rats, there were reductions in body-weight gain, alterations in erythrocyte parameters and increases in liver, kidney and adrenal weights and fatty degeneration of the adrenals at 500 ppm, equal to 36 mg/kg bw per day, and above. At 3500 ppm, the incidence of hepatocellular

hypertrophy was increased in males and females and the incidence of glomerulonephrosis was increased in males. The NOAEL was 70 ppm, equal to 4.9 mg/kg bw per day.

In a preliminary 4-week study in groups of two male and two female dogs, the NOAEL was 125 ppm, equal to 5.5 mg/kg bw per day, on the basis of increased adrenal weights at 500 ppm and above. In a 1-year study in dogs, adrenal weights were increased and there was an increased incidence of adrenocortical hypertrophy at 500 ppm, equal to 13 mg/kg bw per day, and above. Also at 500 ppm, erythrocyte parameters and serum concentrations of inorganic phosphorus were reduced. At 5000 ppm, increased liver weights were associated with hepatocellular hypertrophy. The NOAEL in the 1-year study in dogs was 100 ppm, equal to 2.9 mg/kg bw per day.

The toxicity and carcinogenicity of hexythiazox has been investigated in long-term dietary studies in $B6C3F_1$ mice and F344 rats. In both studies, survival was > 70% in all groups at 2 years. Hexythiazox had no effect on survival in either study.

In mice, non-neoplastic findings included reduced body-weight gain, decreases in erythrocyte parameters, and increases in liver weight, hepatic necrosis, hepatic nodules and adrenal weights at 1500 ppm. At 250 ppm and above, there were reductions in leukocyte counts throughout the study and increases in the frequency of proteinaceous casts in the kidneys. Reductions in body-weight gain at 40 and 250 ppm were not considered to be biologically significant as the absolute body-weight values were similar to those of the historical controls. The incidences of hepatocellular adenoma and carcinoma were increased in males at 1500 ppm, but not statistically significantly ($p > 0.05$). In females the incidence of hepatocellular adenoma was increased significantly ($p = 0.033$) at 1500 ppm, but there was no change in the incidence of hepatocellular carcinoma in females. Low incidences of hepatoblastoma were seen in 3 out of 70 males at 1500 ppm**,** compared with a mean incidence in historical controls of 0.2% (range, 0 out of 50 to 1 out of 50). Two of the three mice with hepatoblastoma also had hepatocellular adenoma and carcinoma, and the hepatoblastomas were considered to be part of the general pattern of liver tumours in these aged mice. The incidences of adenomas and carcinomas were related to age or duration of treatment as they were not increased in mice terminated or dying before week 78, the normal duration of a study of carcinogenicity in mice. The NOAEL for non-neoplastic effects was 40 ppm, equal to 6.7 mg/kg bw per day, and the NOAEL for carcinogenicity was 250 ppm, equal to 42 mg/kg bw per day.

In rats, non-neoplastic findings included increased adrenal weights and severity of vacuolation; withdrawn/swollen testes and the severity of chronic nephritis at 430 ppm and above, although the latter was statistically significant only in males at the highest dose at 12 months. At 3000 ppm, there were increases in liver weight and the incidence of hepatocellular cytoplasmic alterations, and increased ovary and spleen weights. The incidence of mammary-gland fibroadenoma was increased in males at 3000 ppm compared with values for historical controls, but not statistically significantly according to a pair-wise comparison with concurrent controls. The incidence of testicular interstitial-cell adenoma was increased at 3000 ppm at the interim 12-month kill relative to values for historical controls; the incidence in rats in the control group at study termination was > 90%, as is typical for the F344 strain. The size of interstitial-cell tumours and the occurrence of withdrawn/swollen testes might be related, but no specific measurements of tumour size were reported. The NOAEL for non-neoplastic effects was 60 ppm, equal to 3.2 mg/kg bw per day, and the NOAEL for carcinogenicity was 430 ppm, equal to 23 mg/kg bw per day.

Hexythiazox produced negative results in an adequate and extensive range of assays for genotoxicity in vitro and in vivo. An equivocal result in a non-standard study in yeast was not considered to be of significance when compared with the overall database.

The Meeting concluded that hexythiazox was unlikely to be genotoxic.

No investigations had been performed into potential mechanisms behind the increases in incidence of tumours.

On the basis of the negative results of tests for genotoxicity, the relatively high doses producing tumours and the NOAELs for non-neoplastic effects, the Meeting concluded that the

increased incidences of tumours in rodents exposed to hexythiazox were likely to be threshold phenomena and that hexythiazox was unlikely to present a carcinogenic risk to humans at exposure levels associated with residues in food.

In a two-generation study of reproductive toxicity, parental rats showed toxicity consistent with other studies in rats; effects included: reduced body-weight gain, increased liver, kidney and adrenal weights. The NOAEL for adults was 400 ppm, equal to 24 mg/kg per day. The NOAEL for offspring was also 400 ppm, equal to 24 mg/kg bw per day, on the basis of reduced pup weights and associated changes in developmental landmarks at 2400 ppm. There were no effects on mating performance, gestation, litter size or pup survival at the highest dose tested, 2400 ppm, equal to 136 mg/kg bw per day.

In studies of developmental toxicity, hexythiazox did not induce specific malformations in either rats or rabbits. In the study of developmental toxicity in rats, the NOAEL for maternal toxicity (reduced body-weight gain) was 240 mg/kg bw per day; the NOAEL for developmental effects (reduced metatarsal ossification) was also 240 mg/kg bw per day. In the study of developmental toxicity in rabbits, there was no evidence of maternal toxicity at the highest dose tested, 1080 mg/kg bw per day, a dose that produced a slight increase in the number of fetuses with overlapping of the vertebral arches. The NOAEL for foetotoxicity in rabbits was 360 mg/kg bw per day.

The Meeting concluded that hexythiazox was not teratogenic and was not selectively toxic to the developing fetus.

No specific studies on neurotoxicity were submitted. Hexythiazox did not produce any neurotoxic effects in routine studies.

The effects of hexythiazox on the central nervous system, cardiovascular and respiratory system, skeletal muscle, isolated smooth muscle, intestinal motility, gastric secretion and on blood coagulation were studied in a general pharmacology study in a range of species. In these assays, hexythiazox did not demonstrate any pharmacological activity that would be of concern at dietary exposure levels.

A number of rat metabolites were investigated, all of which gave negative results in Ames tests. PT-1-2 (5-(4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine-carboxamide) and PT-1-3 (5-(4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine) were of moderate acute oral toxicity (LD_{50}s of about 1500 and 420 mg/kg bw, respectively). Other metabolites were of low acute oral toxicity (LD_{50}s of > 5000 mg/kg bw) in rats.

No reports of adverse effects or any unusual patterns in the data were evident in medical assessments of personnel from manufacturing plants spanning 20 years. Hexythiazox had not been linked to any epidemiological reports of adverse effects. A single poisoning incident was been reported in the Philippines, but no details were available.

The Meeting concluded that the existing database on hexythiazox was adequate to characteriz e the potential hazards to fetuses, infants and children

Toxicological evaluation

An ADI of 0–0.03 mg/kg bw was established for hexythiazox based on the NOAEL of 3.2 mg/kg bw per day, identified in the 2-year study in rats on the basis of increases in fatty vacuolation of the adrenals in both sexes, the severity of chronic nephritis and the incidence of swollen/withdrawn testes in males at 23 mg/kg bw per day and with a safety factor of 100. This was supported by the NOAEL of 2.9 mg/kg bw per day in the 1-year study in dogs.

The Meeting concluded that the establishment of an ARfD for hexythiazox was unnecessary on the basis of its low acute toxicity, the absence of developmental toxicity in rats and rabbits, the lack of evidence for any acute neurobehavioral effects, and the absence of any other toxicologically relevant effect that would be elicited by 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	40 ppm, equal to 6.7 mg/kg bw per day	250 ppm, equal to 42 mg/kg bw per day
		Carcinogenicity	250 ppm, equal to 42 mg/kg bw per day	1500 ppm, equal to 267 mg/kg bw per day
Rat	Two-year studies of toxicity and carcinogenicity [a]	Toxicity	60 ppm, equal to 3.2 mg/kg bw per day	430 ppm, equal to 23 mg/kg bw per day
		Carcinogenicity	430 ppm, equal to 23 mg/kg bw per day	3000 ppm, equal to 163 mg/kg bw per day
	Multigeneration study of reproductive toxicity[a]	Reproductive toxicity	2400 ppm, equal to 136 mg/kg bw per day[c]	—
		Parental toxicity	400 ppm, equal to 24 mg/kg bw per day	2400 ppm, equal to 136 mg/kg bw per day
		Offspring toxicity	400 ppm, equal to 24 mg/kg bw per day	2400 ppm, equal to 136 mg/kg bw per day
	Developmental toxicity[b]	Maternal toxicity	240 mg/kg bw per day	2160 mg/kg bw per day
		Embryo and fetal toxicity	240 mg/kg bw per day	2160 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	1080 mg/kg bw per day[c]	—
		Embryo and fetal toxicity	360 mg/kg bw per day	1080 mg/kg bw per day
Dog	One-year study of toxicity[a]	Increased adrenal weight and adrenal hypertrophy	100 ppm, equal to 2.9 mg/kg bw per day	500 ppm, equal to 13 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.03 mg/kg bw

Estimate of acute reference dose

Unnecessary

Information that would be useful for 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 hexythiazox

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid: $Cm_{ax,}$ 3–4 h; limited, about 30%, based on concentrations in urine.
Distribution	Extensive; highest concentrations in fat, liver, adrenals and ovaries.
Potential for accumulation	Slight, some persistence of low concentrations of hexythiazox in fat
Rate and extent of excretion	Rapid, > 70% in 24 h and relatively extensive, > 90% in 3 days
Metabolism in animals	Extensive but not fully identified. Major reactions are hydroxylation and cleavage of the amide bond to the cyclohexane ring
Toxicologically significant compounds (animals, plants and environment)	Hexythiazox and metabolites PT-1-2 and PT-1-3
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 2 mg/L (highest technically achievable), 4 h, whole body
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Slight transient irritation
Guinea-pig, skin sensitization	Not a sensitizer (Magnussen & Kligman)
Short-term studies of toxicity	
Target/critical effect	Reduced body-weight gain; increased liver and adrenal weight and associated pathology changes.
Lowest relevant oral NOAEL	2.9 mg/kg bw per day (1-year study in dogs; 100 ppm)
Lowest relevant dermal NOAEL	No data

Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	No genotoxic potential in vitro or in vivo
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body-weight gain, hepatotoxicity, adrenal fatty vacuolation, nephritis; testes (rat); haematology (mice).
Lowest relevant NOAEL	3.2 mg/kg bw per day (2-year study in rats, 60 ppm)
Carcinogenicity	None relevant at levels of human dietary exposure
Reproductive toxicity	
Reproduction target/critical effect	No adverse effect on reproduction
Lowest relevant reproductive NOAEL	136 mg/kg bw per day (rats, 2400 ppm, highest dose tested)
Developmental target/critical effect	Reduced ossification of metatarsals (rats)
	Increase in overlapping of the vertebral arches (rabbits)
Lowest relevant developmental NOAEL	240 mg/kg bw per day (rats)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity	No specific studies; no indications from routine studies
Other toxicological studies	
	Screen for pharmacological activity did not identify any potent activity.
	All rat metabolites tested were negative in Ames tests. Two, PT-1-2 & PT-1-3, were of moderate acute oral toxicity; other metabolites were of low acute oral toxicity in rats
Medical data	
	No adverse reports from health surveillance of production plant workers. No reports of adverse findings in the published literature. One report of a poisoning case in the Philippines.

Summary

	Value	*Study*	*Safety factor*
ADI	0–0.03 mg/kg bw	Rat, 2-year study	100
ARfD	Unnecessary	—	—

5.16 MALATHION (049)

Malathion was considered as a periodic review chemical by the 1999 JMPR and re-evaluated in 2004 and 2005. The manufacturer has supplied a new study on the post-harvest treatment of wheat and processing into flour and bread.

Methods of analysis

The analytical method involved extraction with acetonitrile and analysis by HPLC/MS-MS with external standard calibration. The method determined malathion, malaoxon, and desmethyl malathion in wheat grain and various processed commodities.

A limit of quantitation of 0.01 mg/kg for each analyte was demonstrated for wheat and the processed commodities, and the concurrent recoveries were acceptable.

The Meeting concluded that the method is acceptable for data collection.

Wheat field trials

Three post-harvest experiments were conducted in the USA. The trials were conducted at the maximum GAP: 0.6 kg/L EC applied as a 2.4 kg ai/hL spray (1 application) to empty storage bin surfaces, 60 g/kg DP applied at 0.010 kg ai/metric ton (1 application) to grain in transport wagons prior to entry into storage bins, and 60 g/kg DP applied to the surface of grain in the storage bin at a rate of 0.15 kg ai/100 m^2 (multiple). The subject trials used two applications for the last treatment.

The three experiments were independent, in that three transfer wagons with corresponding bins were utilized. Equipment calibrations and application preparations were conducted independently for each experiment. The experiments were conducted simultaneously at the same geographic location and under identical environmental conditions.

The bins were smaller than those typically used for commercial storage. Each bin was 1.2×1.1×1.2 m (ht), or 1.6 m^3 and was filled with 910 kg wheat. Commercial cylindrical bins may be as large as 32 m diameter × 25 m height and hold 18000 metric tons.

The surface area to volume ratio in the trial bins is 0.82. The surface area to volume ratio in the commercial bin is 0.040. As the malathion DP is applied only to the grain surface (at a fixed m^2 rate), the experimental bin with the lower surface to volume ratio would be anticipated to yield higher grain residues. For commercial size storage units, the major contribution to the wheat residue arises from treatment of the grain on the transport vehicle, i.e., 10 mg/kg. In the trials, the total wheat surface treatment was 4 mg/kg (2×151 g ai/100 m^2 × 1.3 m^2 × 1 / 910 kg). In a typical commercial storage tower, the equivalent total surface treatment would be about 0.014 mg/kg (2×151 g ai/100 m^2 ×3.1416×162 m^2 × 1/18,000,000 kg).

Thus, extrapolation from the small size of the storage containers in the current trials to a typical commercial scale unit would make the treatment of grain in transport the only significant contributor to the overall residue. The theoretical maximum level from malathion application to wheat in the transport vehicle at the maximum rate per GAP would be 10 mg/kg.

The Meeting also noted that the grain moisture was relatively low at 12% and the ambient temperature was cold, at –2.6 to 6.5 °C. Both factors would tend to increase the stability of the malathion, i.e., yield higher residue concentrations on the grain. Literature indicates that increasing temperature and increasing humidity contribute to the decay of malathion on grains.

Residues from the three independently treated bins of wheat are in ranked order: 13, 15, 15 mg/kg, at 29 days after the last of four treatments. The maximum theoretical concentration of malathion on wheat is 36 mg/kg, or 14 mg/kg if the malathion sprayed on the container walls is

considered unavailable. The calculated value of 14 mg/kg is in excellent agreement with the measured residue of 13–15 mg/kg. The combination of freezing storage conditions and the high area to volume ratio means that the residue concentrations found are a significant exaggeration of concentrations in typical commercial practice. The findings are in agreement with previous studies, reported in the literature, which have shown that the initial malathion content on wheat is about 80% of the theoretical value from postharvest treatment.

The relatively short storage interval (29 days after the final treatment) and the freezing ambient temperature would contribute to elevated residues of malathion, relative to extended storage (6 months or more) and a range of ambient temperature. The trials were not conducted so as to mimic typical commercial practice, but do represent a probable worst case scenario.

The Meeting estimated an STMR of 10 mg/kg, and an HR of 10 mg/kg. The Meeting decided to withdraw it previous maximum residue level recommendation of 0.5 mg/kg for wheat grain and to estimate a new maximum residue level of 10 mg/kg.

Wheat processing

Wheat was processed into flour, gluten, and the various by-products by a simulation of commercial milling. Whole wheat and white breads were also prepared. The processing factors and resulting HR-P/STMR-P values are summarized as follows:

Commodity	Processing (Transfer) Factor	HR/HR-P / STMR/STMR-P (mg/kg)
Wheat grain	1	10
Wheat aspirated grain fraction	180	1800
Wheat cleaned	0.8	8
Wheat bran	0.54[a] [2.5]	25[a]
Wheat germ	0.93[b]	-
Wheat flour	0.087	0.87
Whole meal flour	0.75	7.5
Gluten	0.0012	0.012
Whole meal bread	0.12	1.2
Wheat white bread	0.020	0.20

a The 0.54 value determined for wheat bran in the processing study was regarded as very unlikely, given numerous studies in the literature and past experiences with post harvest treatments of grains. The value of 2.5 was selected as appropriate.

b The value of 0.93 measured for wheat germ was considered suspect and not used.

The processing factors for wheat flour, whole meal flour, whole meal bread, and wheat white bread are in reasonable agreement with previous results reported in the literature for flour, whole meal flour, wholemeal bread, and wheat white bread. However, literature values do not agree with the current processing findings for bran. Former studies indicate an increase in residue in the bran (2–3×) relative to the grain for grain stored for a comparable interval after treatment at a similar level. This is expected for a surface residue such as malathion. The present study indicates a decrease in malathion concentration in bran (0.5×) relative to grain. The Meeting concluded that the mechanical separation of grain into bran, and middlings and germ had most likely not been conducted properly.

Based on the wheat grain processing study and an HR of 10 mg/kg for the postharvest treated wheat grain, the Meeting estimated the following HR-P/STMR-P values suitable for use in dietary intake calculations: wheat flour, 0.87 mg/kg; whole meal flour, 7.5 mg/kg; wheat gluten, 0.012 mg/kg; whole meal bread, 1.2 mg/kg; wheat white bread, 0.20 mg/kg.

Given the apparent error in the wheat to wheat bran and germ processing's, the Meeting decided to utilize a processing factor of 2.5 for the conversion of wheat to unprocessed wheat bran,

based on literature values and previous recommendations of JMPR for postharvest treatments of grains with various pesticides, and estimated a maximum residue level of 25 mg/kg for wheat bran and an STMR of 25 mg/kg.

The Meeting recommended withdrawing it previous maximum residue level recommendation of 0.2 mg/kg for wheat flour, as the maximum residue level recommendation of 10 mg/kg for wheat grain will suffice for wheat flour, i.e., the residue declines upon processing.

DIETARY RISK ASSESSMENT

Long-term intake

The current ADI for malathion is 0–0.3 mg/kg bw. The International Estimated Daily Intakes (IEDIs) were calculated for commodities for human consumption for which STMRs were previously estimated by the 1999 JMPR and by the 2004 JMPR. The present Meeting found that IEDI of malathion based on the STMRs estimated for 25 commodities for the thirteen GEMS/Food cluster diets were in the range of 0% to 3% of the maximum ADI (0.3 mg /kg bw). The Meeting concluded that the long-term intake of residues of malathion, resulting from its uses that have been considered by JMPR, is unlikely to present a public health concern.

Short-term intake

An ARfD for malathion of 2 mg/kg bw was established by the 2003 JMPR. The IESTIs of malathion by the general population and by children were calculated for commodities for which STMR and highest residue values were estimated by the 2004 JMPR. The IESTI was 0–4% of the ARfD for the general population and 0–10% of the ARfD for children (2004 JMPR). The IESTIs of malathion by the general population and by children were calculated for wheat grain and processed wheat commodities for which STMR and highest residue values were estimated by the current Meeting. The IESTI for wheat was 7% of the ARfD for the general population and 10% of the ARfD for children for wheat grain and a maximum of 2% of the ARfD for the general population and 2% of the ARfD for children for processed wheat commodities.

The Meeting concluded that short-term intake of residues of malathion from its use in wheat grain and processed wheat commodities arising from use on wheat is unlikely to present a public health concern.

5.17 MANDIPROPAMID (231)

TOXICOLOGY

Mandipropamid is the ISO approved name for 4-chloro-*N*-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-α-(2-propynyloxy)-benzeneacetamide (CAS No. 374726-62-2). It is a new fungicide that belongs to the subset mandelamides in the class carboxylic acid amides. The proposed fungicidal mode of action is by inhibition of phospholipid biosynthesis. Mandipropamid has not been evaluated previously by the JMPR and was reviewed by the present Meeting at the request of CCPR. All the pivotal studies contained certificates of compliance with GLP.

Biochemical aspects

The extent of absorption of radiolabelled mandipropamid was similar in male and female rats dosed by gavage. Absorption was incomplete, with 67–74% of the administered dose being absorbed at the lower dose (3 mg/kg bw) and only 30–45% absorbed at the higher dose (300 mg/kg bw). Absorption was more rapid in females, with peak blood concentrations occurring at 4.5 h for the lower dose and 10 h at the higher dose, while for males the values were 8.5 h and 24 h, respectively. Little or no radioactivity was recovered in the expired air (less than 0.16% of the administered dose). Excretion was predominantly via the bile (lower dose) and faeces and > 90% of the administered dose was eliminated within 168 h. In males, a greater proportion of the administered dose was excreted in the faeces, while in females a significantly greater proportion was excreted via the urine. The greater extent of biliary elimination in males than in females was consistent with faecal excretion being the major route of elimination in males (73%) and of lesser importance in females (55%) at the lower dose. Some reabsorption of biliary metabolites was apparent at both doses. Tissue retention of the radiolabelled material was low, even after multiple doses. The total concentration of tissue residues including the carcass was < 0.3%, therefore demonstrating no evidence of bioaccumulation. The highest concentration of residues was found in the liver.

The biotransformation of mandipropamid was relatively simple since no cleavage of the molecule was observed. The major metabolic transformations involved loss of one or both of the propargyl groups of the molecule, followed by glucuronidation and *O*-demethylation, to produce six major metabolites. While the qualitative metabolite profile was largely independent of sex and dose, quantitative differences were found. Increasing the dose resulted in increasing amounts of radioactivity isolated as parent, indicating saturation of metabolic processes.

Toxicological data

Mandipropamid was of low acute toxicity in rats given a single dose orally (LD_{50} > 5000 mg/kg bw), dermally (LD_{50} > 5000 mg/kg bw) or by inhalation (LC_{50} > 5.19 mg/L). Mandipropamid was minimally irritating to the skin and eyes and was not found to be a dermal sensitizer (local lymph node assay in mice).

In short-term studies of toxicity with mandipropamid, the target organ was the liver, at doses that also resulted in decreased body weight and body-weight gain.

In a 90-day dietary study in rats, decreased body weight, body-weight gain and food consumption were observed at doses of 3000 ppm (260 mg/kg bw per day) and above. Various erythrocyte parameters (haemoglobin, erythrocyte volume fraction, mean cell volume, mean cell haemoglobin and mean cell haemoglobin concentration) were decreased in both sexes at doses of 3000 ppm (260 mg/kg bw per day) and above. Increases in liver weight (both sexes), plasma gamma-glutamyl transferase (58–105% in females only) at doses of 3000 ppm (260 mg/kg bw per day) and above were not considered to be adverse in the absence of findings of liver toxicity. The periportal hypertrophy/eosinophilia observed in the liver was considered to be treatment-related, but of

questionable toxicological significance given the minimal to slight severity and the lack of any evidence of progression in the long-term study. The NOAEL for short-term toxicity in rats was 500 ppm (41 mg/kg bw per day).

In dogs given capsules containing mandipropamid, increases in liver weights, cholesterol concentration, ALP and ALT activity were seen after 13 weeks at 100 mg/kg bw per day. The NOAEL in the 90-day study in dogs was 25 mg/kg bw per day. In the 1-year study in dogs, body-weight gain and food consumption were decreased at 400 mg/kg bw per day, together with increased liver weight. At 40 mg/kg bw per day or above, there was also increased ALP and ALT activity and minimal to moderate pigmentation of the liver by porphyrin. The NOAEL in the 1-year study in dogs was 5 mg/kg bw per day. Considering the spacing of doses used and on the basis of the similarity of effects observed in the 90-day and 1-year studies in dogs, the overall NOAEL for dogs was 25 mg/kg bw per day.

In a 78-week study, mice were given diets containing mandipropamid at a concentration of 0, 100, 500 or 2000 ppm, equal to 0, 11, 55 or 223 mg/kg bw per day. There were no treatment-related changes in survival, or the incidence of tumours or non-neoplastic lesions. The only significant findings were observed at the highest dose: reductions in body weight and food conversion efficiency. There was no evidence of carcinogenicity with mandipropamid in this study. The NOAEL was 55 mg/kg bw per day.

In a 104-week study, rats were given diets containing mandipropamid at a concentration of 0, 50, 250 or 1000 ppm, equal to 0, 3, 15 or 61 mg/kg bw per day. There were no treatment-related changes in survival or the incidence of tumours. The only significant findings were in males at the highest dose: reductions in body weight, body-weight gain and food conversion efficiency, gross and histopathological changes in the kidneys (roughened surface, and increased severity of chronic progressive nephropathy), and associated osteodystrophia fibrosa and histopathological changes in the parathyroid (increased severity of hyperplasia). Mandipropamid was not carcinogenic in this study. The NOAEL was 15 mg/kg bw per day.

Mandipropamid gave negative results in an adequate range of studies of genotoxicity in vitro and in vivo. The Meeting concluded that mandipropamid was unlikely to be genotoxic.

On the basis of the absence of carcinogenicity in rodents and the absence of genotoxicity, the Meeting concluded that mandipropamid is unlikely to pose a carcinogenic risk to humans.

In a multigeneration study of reproductive toxicity in rats, the target organ was also the liver. No reproductive effects were observed. The NOAEL for parental systemic toxicity was 250 ppm, equal to 22.9 mg/kg bw per day, on the basis of slightly lower body weight and body-weight gain in F_1 males during premating and increased absolute and relative liver weights in male and female parental animals sexes and in F_1 females. The NOAEL for reproductive toxicity was 1500 ppm, equal to 146.3 mg/kg bw per day, the highest dose tested. Toxicity observed in offspring at 1500 ppm included decreased pup weight from day 15 of lactation, increased liver weights in both generations and an increased time to preputial separation in male F_1 pups. The NOAEL for offspring toxicity was 250 ppm, equal to 22.9 mg/kg bw per day.

In a study of developmental toxicity in rats, the NOAEL for maternal and developmental toxicity was 1000 mg/kg bw per day, the highest dose tested. No developmental toxicity or teratogenicity was observed. In rabbits, no effects were observed in dams or fetuses at up to the limit dose of 1000 mg/kg bw per day.

In a study of acute neurotoxicity in rats, mandipropamid exhibited no systemic toxicity or evidence of neurotoxicity at 2000 mg/kg bw. In a 13-week study of neurotoxicity in rats, systemic toxicity was observed at 2500 ppm, equal to 192 mg/kg bw per day, as reductions in body weight, body-weight gain and food efficiency. No evidence of neurotoxicity was observed. The NOAEL was 37 mg/kg bw per day.

There were no reports of adverse health effects in manufacturing-plant personnel or in operators and workers exposed to mandipropamid formulations.

The Meeting concluded that the existing database on mandipropamid was adequate to charact erize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.2 mg/kg bw based on the NOAEL of 15.2 mg/kg bw per day, identified on the basis of decreased body weight and kidney effects (increased severity of chronic progressive nephropathy and associated osteodystrophia fibrosa) at 61.3 mg/kg bw per day in the long-term dietary study in rats and using a safety factor of 100.

The Meeting noted that mandipropamid was not acutely toxic after short-term dosing, that there were no adverse findings in a study of acute neurotoxicity and that mandipropamid did not exhibit developmental toxicity. The Meeting concluded that the establishment of an ARfD was unnecessary.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year studies of toxicity and carcinogenicity [a]	Toxicity	500 ppm, equal to 55 mg/kg bw per day	2000 ppm, equal to 223 mg/kg bw per day
		Carcinogenicity[d]	2000 ppm, equal to 223 mg/kg bw per day	—
Rat	Two-year studies of toxicity and carcinogenicity[a]	Toxicity	250 ppm, equal to 15 mg/kg bw per day	1000 ppm, equal to 61 mg/kg bw per day
		Carcinogenicity[d]	1000 ppm, equal to 61 mg/kg bw per day	—
	Multigeneration study of reproductive toxicity[a]	Parental toxicity	250 ppm, equal to 23 mg/kg bw per day	1500 ppm, equal to 146 mg/kg bw per day
		Offspring toxicity	250 ppm, equal to 23 mg/kg bw per day	1500 ppm, equal to 146 mg/kg bw per day
		Reproduction[d]	1500 ppm, equal to 146 mg/kg bw per day	—
	Developmental toxicity[a,b]	Maternal toxicity[d]	1000 mg/kg bw per day	—
		Embryo and fetal toxicity[d]	1000 mg/kg bw per day	—
Rabbit	Developmental toxicity [,b]	Maternal toxicity[d]	1000 mg/kg bw per day	—

		Embryo and fetal toxicity[d]	1000 mg/kg bw per day	—
Dog	90-day and one-year study of toxicity [c]	Toxicity	25 mg/kg bw per day [e]	40 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Capsule administration.

[d] Highest dose tested.

[e] Based on an overall NOAEL from the two studies.

Estimate of acceptable daily intake for humans

0–0.2 mg/kg bw

Estimate of acute reference dose

Unnecessary

Information that would be useful for 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 mandipropamid

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid, extent dependent on dose, 67–74% at the lower dose, 30–45% at the higher dose
Distribution	Highest concentrations in the liver and kidney
Potential for accumulation	No evidence
Rate and extent of excretion	High, virtually complete by 168 h
Metabolism in animals	Mainly glucuronidation (> 50% of excreted dose mandipropamid glucuronide)
Toxicologically significant compounds (animals, plants and environment)	Parent
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 5050 mg/kg bw
Rat, LC_{50}, inhalation	> 5.19 mg/L
Rabbit, dermal irritation	Minimal irritation
Rabbit, ocular irritation	Minimal irritation
Mouse, dermal sensitization	Not sensitizing (local lymph node assay)

Short-term studies of toxicity

Target/critical effect	Liver, body weight
Lowest relevant oral NOAEL	25 mg/kg bw per day (90-day and 1-year study in dogs)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (28-day study in rats, highest dose tested)
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	Not genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight, kidney, parathyroid
Lowest relevant NOAEL	15 mg/kg bw per day (rats)
Carcinogenicity	Not carcinogenic in rats and mice
Reproductive toxicity	
Reproduction target/critical effect	None
Lowest relevant reproductive NOAEL	146 mg/kg bw per day (rats, highest dose tested)
Developmental target/critical effect	None
Lowest relevant developmental NOAEL	1000 mg/kg bw per day (rats, rabbits, highest dose tested)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity and studies of short-term neurotoxicity	No indications of neurotoxicity in studies of acute toxicity or repeat-dose studies
Medical data	
	No occupational or accidental poisoning reported

Summary			
	Value	*Study*	*Safety factor*
ADI	0–0.2	Rat, 2-year study	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

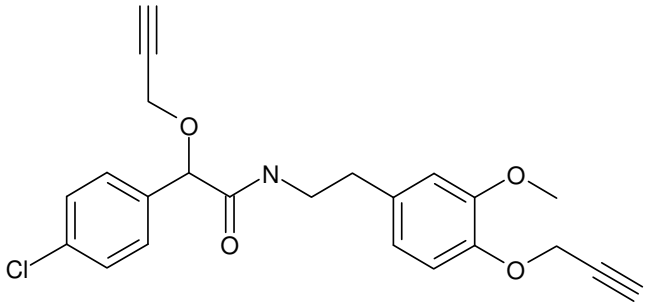
Mandipropamid was considered for the first time by the present Meeting. It belongs to the mandelamide chemical class of fungicides and is a synthetic fungicide intended for the control of Oomycete fungal pathogens in a range of crops.

At the 39th session of the CCPR (ALINORM 07/30/24), it was scheduled for evaluation as a new compound by 2008 JMPR. The Meeting received information on physical and chemical properties, animal and plant metabolism, environmental fate, analytical methods, storage stability, national registered use patterns, supervised residue trials and processing.

The 2008 JMPR established an ADI for mandipropamid of 0–0.2 mg/kg bw/day and concluded that an ARfD was unnecessary.

Mandipropamid is

2-(4-chlorophenyl)-*N*-[3-methoxy-4-(prop-2-ynyloxy)phenethyl]-2-(prop-2-ynyloxy)acetamide



The following abbreviations are used for the metabolites discussed below:

NOA458422	2-(4-Chlorophenyl)-*N*-[2-(4-hydroxy-3-methoxyphenyl)-ethyl]-2-prop-2-ynyl- oxy-acetamide
CGA380778	2-(4-Chlorophenyl)-2-hydroxy-N-[2-(3-methoxy-4-prop-2-ynyloxyphenyl)-ethyl] -acetamide
SYN521195	2-(4-Chlorophenyl)-*N*-[2-(3-hydroxy-4-prop-2-ynyloxyphenyl)-ethyl]-2-prop- 2-ynyl-oxy-acetamide
CGA380775	2-(4-Chlorophenyl)-2-hydroxy-*N*-[2-(4-hydroxy-3-methoxyphenyl)-ethyl]-acetamide
SYN500003	(4-Chlorophenyl)-prop-2-ynyloxy-acetic acid
SYN524199	(4-chloro-phenyl)-(3,4,5-trihydroxy-6-hydroxymethyl-tetrahydro-pyran-2- yloxy)-acetic acid
CGA155705	4-chloro-benzoic acid
SYN 508792	2-(4-chloro-phenyl)-*N*-{2-[3-methoxy-4-(3,4,5-trihydroxy-6-hydroxymethyl-tetrahydro-pyran-2-yloxy)-phenyl]-ethyl}-2-prop-2-ynyloxy-acetamide
SYN 508793	malonyl-O-glycoside of NOA 458422
SYN536638	N-[2-(4-Allyloxy-3-methoxyphenyl)-ethyl]-2-(4-chlorophenyl)-2-prop-2- ynyloxy-acetamide

Animal metabolism

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

The principal route of metabolism in goats includes demethylation of the methoxy phenyl functionality to generate the phenol moiety and the removal of either or both of the propargyl side chains to generate the corresponding alcohol or phenol functionalities. The metabolite patterns in the lactating goat and in rats presented qualitatively similar (See the toxicology review in this Report for more details on laboratory animal metabolism).

[^{14}C]mandipropamid, radiolabelled uniformly in either the chlorophenyl or methoxyphenyl ring, was administered orally at doses equivalent to 27–49 mg/kg in the total diet to lactating goats once daily for seven consecutive days. The majority of the radioactivity was excreted in the faeces and urine. For the [^{14}C]chlorophenyl treated goats, 46% of the administered dose was excreted in the faeces and 30% and 33% in the urine. For the remaining goat treated with [^{14}C]methoxyphenyl mandipropamid, 49% of the administered radioactivity was excreted in the faeces and 33% in the urine.

The study results show no significant differences between the metabolic profiles of the two radiolabelled treatments. All metabolites identified contained both the chlorophenyl and

methoxyphenyl moieties, indicating no cleavage of the amide bond between the two aromatic rings. TRRs were low in milk (≤ 0.01 mg/kg), muscle (0.03% TRR, 0.005 mg/kg), and fat (0.01% TRR, ≤ 0.021 mg/kg), and highest in liver (0.11% TRR, 0.48 mg/kg) and kidney (0.01% TRR, 0.13 mg/kg). Unchanged parent mandipropamid comprised the majority of the residue in goat fat (75–77% TRR), and only a small proportion of the residue in goat milk (7.9% TRR) and liver (0.8–1.4% TRR), and was not detected in kidney.

The metabolite NOA 458422 was a significant residue in kidney at 15–18% TRR (0.018–0.024 mg/kg) but was a minor residue in liver at 5.3–5.8% TRR (0.025–0.028 mg/kg). Metabolites CGA 380775, CGA 380778, SYN 505503, SYN 521195, and SYN 518495 were identified as minor residues in kidney (each ≤ 9.3% TRR, < 0.02 mg/kg) and liver (each ≤ 7.3% TRR, ≤ 0.04 mg/kg).

Plant metabolism

The Meeting received plant metabolism studies with mandipropamid on grapes, lettuce, potatoes and tomatoes.

Metabolism studies of mandipropamid in four different crop types (fruit–grapes, leafy vegetables–lettuce, root and tuber vegetables–potato and fruiting vegetables–tomato) demonstrated that metabolism of mandipropamid was similar in the foliar parts, and that the compound undergoes extensive metabolism to form a range of metabolites which are more polar than the parent. Unchanged mandipropamid remained as the major component in all aerial crop parts (ranging from approximately 40% to 94% TRR). A consistent degradation pathway was demonstrated by the four different crop studies though fewer metabolites were identified in lettuce due to a shorter period of exposure to the chemical prior to harvest. In lettuce, grapes, tomatoes and potato leaves, no individual metabolite released by room temperature extraction accounted for > 4.5% TRR mandipropamid equivalents. In peel and flesh of potato tubers, the major metabolite (SYN 500003) accounted for 13% and 11% TRR respectively, but was at very low concentrations (≤ 0.006 mg/kg mandipropamid equivalents).

When grape vines were treated six times with [^{14}C]mandipropamid (chlorophenyl- and methoxyphenyl-label) at a nominal application rate of 150 g ai/ha (1× rate) and 450 g ai/ha (3× rate), parent compound was found as the major component at all time points accounting for 54–80% of TRR. Several additional components (such as NOA 4584422, CGA380778) were detected in the room temperature extracts of the fruit samples of which the largest fraction accounted for a maximum of only 3.8% TRR or 0.040 mg/kg. The metabolite patterns in the overdose studies were very comparable to those found in the 1× rate experiments. The majority of the radioactivity in the fruit was present on the surface, accounting for 79–89% TRR. Of the remaining radioactivity 8–13% TRR was extractable using acetonitrile:water (80:20 v/v) leaving a maximum of 9% TRR unextracted. The majority of the radioactivity (83–91% TRR) in the leaves was extractable using acetonitrile:water (80:20 v/v) leaving a maximum of 17% unextracted. Parent mandipropamid was identified as the major component of the residue in all fruit samples from both labels, ranging from 79 to 80% TRR in the 0 day PHI samples and reducing to 54–59% TRR in the 28 day PHI samples.

When lettuce plants were treated twice with [^{14}C]mandipropamid (chlorophenyl- and methoxyphenyl-label) at a nominal recommended application rate of 150 g ai/ha, parent mandipropamid was the largest component of the residue accounting for 82–94% TRR. Four metabolites were identified, all of which contained both the chlorophenyl and methoxyphenyl rings. NOA458422 and CGA380778 were present both as free metabolites at maximum levels of 1.1% TRR (0.018 mg/kg) and also as conjugated metabolites at maximum levels of 0.4% TRR (0.005 mg/kg). SYN521195 and CGA380775 were only present as conjugated metabolites at maximum levels of 0.2% TRR (0.003 mg/kg). No significant difference was found between the profiles of lettuce samples derived from the two radiolabelled experiments.

Six foliar applications of [chlorophenyl-(U)-^{14}C]mandipropamid or [methoxyphenyl- (U)-^{14}C]mandipropamid were made to potato plants at a rate of 150 g ai/ha. TRRs in peel and flesh

samples were 0.040–0.59 mg/kg and were comparable with both labels and at both PHIs (7 and 21 days). TRRs in potato leaves were much higher, ranging from 2.7–6.3 mg/kg. No significant difference was found between the profiles of the leaf samples derived from the two radiolabelled experiments. Parent mandipropamid was identified as the largest component of the residue in the leaves accounting for 40–61% TRR. Three other metabolites all containing both the chlorophenyl and methoxyphenyl rings (NOA458422, CGA380775 and CGA380778) were identified at much lower levels than parent ranging from 0.4–1.8% TRR. A significant difference was found between the profiles of the peel and flesh samples derived from the two radiolabel experiments; however within each experiment the peel and flesh profiles were similar. Parent mandipropamid was identified in the peel samples at a maximum level of 4.2% TRR (0.002 mg/kg) but was not detected in the flesh. Three small acidic molecules, containing only the chlorophenyl ring, were identified in both the peel and flesh samples. These were SYN500003, SYN524199 and CGA155705 and were detected at maximum levels of 13% TRR, 7.2% TRR and 2.1% TRR respectively (maximum individual residue level of only 0.006 mg/kg). No metabolites containing only the methoxyphenyl ring were identified. Radioactivity remaining in the debris after initial extraction was further investigated using an acidic microwave extraction. A significant proportion of the radioactivity was solubilized and was shown to be mainly comprised of glucose (10–30% TRR) and a second component (7–16% TRR) proposed to be an intermediate breakdown product formed during the acid hydrolysis of starch.

Tomato plants were treated with four foliar applications of [^{14}C]mandipropamid (chlorophenyl- and methoxyphenyl-label) at a rate of 276 g ai/ha and 295 g ai/ha at 2 week intervals, followed by two further treatments at a rate of 147 g ai/ha and 149 g ai/ha in weekly intervals, resulting in a total use rate of 867 g ai/ha. Tomato fruits and leaves/foliage were harvested at 5 intervals: 0, 3, 7, 14 and 28 days after the last application (DALA). Parent compound was the major residue in fruits (61–80% TRR) and leaves (66–76% TRR). Most of the applied radioactivity remained on the surface of the fruits (69–87% TRR). Five metabolites were identified by co-chromatography with reference standards or by LC-NMR and LC-MS as CGA 380775, CGA 380778, NOA 458422, SYN 508792 and SYN 508793 and were present in a range of 0.003 mg/kg and 0.013 mg/kg.

Environmental fate in soil

The Meeting received information on the environmental fate of mandipropamid in soil, including studies on aerobic soil metabolism and crop rotational studies.

Aerobic soil metabolism

Numerous soil studies were performed, under laboratory conditions, to evaluate the route and rate of [^{14}C]mandipropamid labelled in the chlorophenyl ring or the methoxyphenyl ring. Degradation in a wide range of soil types (pH, organic matter, texture, origin) under varying test (temperature, concentration of active ingredient, soil humidity) and incubation conditions (aerobic, anaerobic, microbially active, sterile) were evaluated. The formation and degradation of non-extractable (bound) residues and mineralisation to carbon dioxide represent the main overall pathway for the metabolism of parent compound in soil. In active soils, mandipropamid residues were readily mineralized to [^{14}C]carbon dioxide and accounted for up to 9–45% of applied radioactivity after 120 days (average from 21 studies = 23%), and resulted in non-extractable soil residue levels that reached maximum levels at up to 19–44% of applied radioactivity after 120 days (average from 21 studies = 33%). In less active soils, the mineralization rate to carbon dioxide was lower. A number of metabolites were observed in aerobic degradation studies following the degradation of mandipropamid, namely CGA380778 (≤ 6.0%), NOA458422 (≤ 1.7%) and CGA380775 (< 1%), SYN536638 (≤ 3.2%) and SYN500003 (< 1%).

Aqueous photolysis

The photolysis study conducted with [methoxyphenyl-(U)-^{14}C]mandipropamid at a concentration of l mg/L in sterile buffer solution at pH 7 and 25 °C. The samples were irradiated for periods up to the equivalent of 17 days summer sunlight. The estimated half-life DT_{50} was 34 h of continuous irradiation. At least 16 degradates were formed, none of which represented > 5% of the applied radioactivity.

Aqueous hydrolysis

The hydrolysis study conducted with [ethyl-1-^{14}C]mandipropamid at a concentration of l mg/L in sterile buffer solution at pH 4, 5, 7 and 9 at 50 °C for seven days and at pH 5, 7 and 9 at 25 °C for 32 days. The recovery for all samples was between 92.7 and 105.7% of the applied radioactivity. No degradation of the test substance was observed under all conditions.

Confined rotational crop

In two outdoor confined rotational crop studies in Switzerland, soil was treated directly with [^{14}C]mandipropamid labelled in the chlorophenyl ring or methoxyphenyl ring. Crops of lettuce, radish and wheat were sown into the treated soil at intervals of 29, 58, 120 and 365 days after treatment and were grown to maturity and harvested. Wheat forage was harvested at 50% maturity. Uptake of residues was quite limited with the only identified components being mandipropamid (≤ 0.023 mg/kg), CGA380778 (≤ 0.009 mg/kg) and NOA458422 (≤ 0.016 mg/kg) all of which were identified in the primary crop metabolism studies. Levels of mandipropamid or any other metabolite in succeeding crops would not be expected to exceed 0.03 mg/kg. Since such low radioactive residues were found in analysed fractions of these rotational crop samples, mandipropamid is not readily taken up by succeeding crops.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of mandipropamid in raw agricultural commodities.

Crop samples were extracted with acetonitrile:water (80:20 v/v), extracts were centrifuged and aliquots diluted with water prior to being cleaned-up using polymeric solid-phase extraction cartridges. Residues of mandipropamid were quantified with HPLC-MS-MS. Method DFG S19 with HPLC-MS/MS was suitable for enforcement for agricultural commodities. LOQ values are at 0.01 mg/kg for various plant matrices.

Numerous recovery data on a wide range of substrates were provided from validation testing of the methods, which showed that the methods were valid over the relevant concentration ranges.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the freezer storage stability of residues of mandipropamid in plant commodities.

Residues were stable (less than 30% disappearance) in various plant matrices (tomatoes, grapes, potatoes, lettuce, cucumbers, wheat and soya bean and processed commodities) for at least up to 1 year when stored frozen at –20 °C.

Residue definition

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.

As indicated the metabolism of mandipropamid was investigated in grapes, lettuce, potatoes and tomatoes. Except for potato tubers unchanged parent compound formed the major part of the residue in these studies. The cleavage products NOA458422, CGA380778 and CGA380775 were identified or observed in all four crops. All metabolites were of minor importance. The major metabolite (SYN 500003) in potato tubers accounted for up to 13% TRR and was present at very low levels (≤ 0.006 mg/kg). Parent mandipropamid was identified in the peel samples at a maximum level of 4.2% TRR (0.002 mg/kg) but was not detected in the flesh.

A metabolism study on lactating goats showed unchanged parent mandipropamid comprised the majority of the residue in goat fat, and only a small proportion of the residue in goat milk and liver, and was not detected in kidney. The metabolite NOA 458422 was a significant residue in kidney but was a minor residue in liver.

The octanol-water partition coefficient of mandipropamid (log K_{OW} = 3.2) implied that mandipropamid may be fat-soluble. However, in the goat metabolism study, TRR in fat was about four times as high as that in liver and in the rat metabolism study, TRRs in fat and muscle were at similar levels. Based on the above information, the Meeting agreed that mandipropamid is not fat-soluble.

Based on the available comparative plant metabolism studies and lactating goat metabolism studies, the Meeting recommended the following residue definition for mandipropamid:

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

Results of supervised residue trials on crops

The Meeting received supervised trials data for mandipropamid on grapes, onion, broccoli, cabbages, cucumbers, cantaloupe, summer squash, tomatoes, peppers, mustard greens, lettuce and potatoes.

Grapes

Twelve trials were conducted on grape vines in the USA (maximum GAP: 0.15 kg ai/ha, four applications, 14-day PHI) in 2003. In all trials conducted at the maximum USA GAP, the ranked order of residues, median underlined, were: 0.20, 0.21, 0.22, 0.28, 0.38, 0.43, 0.59, 0.62, 0.63, 0.69, 0.76 and 0.85 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in grapes of 2 and 0.43 mg/kg, respectively.

Spring onions

Three trials were conducted on green onions in the USA (maximum GAP: 0.15 kg ai/ha, three applications, 7-day PHI) in 2004. The ranked order of residues, median underlined, was: 0.25, 0.48 and 1.74 mg/kg.

As there were only three trials in accordance with GAP, it was decided that a maximum residue level should be proposed that was higher than highest residue to allow for possible large uncertainty. The Meeting estimated a maximum residue level and an STMR value for mandipropamid in spring onions of 7 and 0.48 mg/kg, respectively.

Bulb onions, dry

In 2004 eight trials were conducted on bulb onions in the USA at the maximum US GAP (0.15 kg ai/ha, four applications, 7-day PHI). The ranked order of residues, median underlined, were: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.02 and 0.04 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in bulb onions (dry) of 0.1 and 0.01 mg/kg, respectively.

Broccoli

In 2004 six supervised trials were conducted on broccoli in the USA at the maximum GAP (0.15 kg ai/ha, four applications, 1-day PHI). The ranked order of residues on broccoli, median underlined, were: 0.29, 0.35, 0.43, 0.44, 0.57 and 0.70 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in broccoli of 2 and 0.435 mg/kg, respectively.

Cabbage, head

In 2004 six supervised trials were conducted on cabbages in the USA (maximum GAP: 0.15 kg ai/ha, four applications, 1-day PHI). The ranked order of residues on cabbage with wrapper leaves, median underlined, was: 0.90, 1.10, 1.11, 1.30, 1.60 and 1.80 mg/kg. The ranked order of residues on wrapper leaves of cabbages and cabbages without wrapper leaves, median underlined, was: 1.90, 2.30, 2.90, 4.20, 5.50 and 5.80 mg/kg and < 0.01, < 0.01, < 0.01, < 0.01, 0.05, 0.31 mg/kg, respectively.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in cabbages of 3 and 0.01 mg/kg respectively.

Cucumbers

In 2004 seven trials were conducted on cucumbers in the USA (maximum GAP: 0.15 kg ai/ha, four applications, 0-day PHI). The ranked order of residues on cucumbers, median underlined, was: 0.01, 0.02, 0.02, 0.02, 0.05, 0.05 and 0.07 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in cucumbers of 0.2 and 0.02 mg/kg, respectively.

Melons

Six trials were conducted on cantaloupe in the USA in 2004 (maximum GAP: 0.15 kg ai/ha, four applications, 0-day PHI). The ranked order of residues, median underlined, was: 0.06, 0.07, 0.11, 0.12, 0.19 and 0.26 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in melons, except watermelon, of 0.5 and 0.115 mg/kg, respectively.

Summer squash

Five trials were conducted on summer squash in the USA 2004 (maximum GAP: 0.15 kg ai/ha, four applications, 0-day PHI). The ranked order of residues, median underlined, was: 0.02, 0.03, 0.04, 0.07 and 0.08 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in squash of 0.2 and 0.04 mg/kg, respectively.

Tomatoes

Eleven trials were conducted on tomatoes in the USA in 2003 and 2004 (maximum GAP: 0.15 kg ai/ha, four applications, 1-day PHI). The ranked order of residues on tomato, median underlined, was: 0.02, 0.03, 0.03, 0.06, 0.06, 0.06, 0.06, 0.08, 0.09, 0.12 and 0.20 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in tomato of 0.3 and 0.06 mg/kg, respectively.

Peppers

Nine trials were conducted on sweet and chilli peppers in the USA in 2003 and 2004 (maximum GAP: 0.15 kg ai/ha, four applications, 1-day PHI). The residues on sweet peppers were 0.04, 0.07, 0.09, 0.12, 0.17 and 0.34 mg/kg, while the residues on chilli peppers were 0.11, 0.22 and 0.38 mg/kg.

As the residues were in the same range, the Meeting agreed to combine all data sets to support a MRL for peppers. The combined residues, in ranked order, median underlined, were: 0.04, 0.07, 0.09, 0.11, 0.12, 0.17, 0.22, 0.34 and 0.38 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in peppers of 1 and 0.12 mg/kg, respectively.

Under consideration of the default concentration factor of 7 for dried chilli pepper, the Meeting estimated a maximum residue level and an STMR value for mandipropamid in dried chilli peppers of 10 mg/kg and 0.84 mg/kg.

Leafy vegetables

Eleven trials were conducted on head and leaf lettuce in the USA in 2005 (maximum GAP on leafy vegetables: 0.15 kg ai/ha, four applications, 1-day PHI). The residues on leaf lettuce, median underlined, were 1.90, 4.50, 5.30, 5.70, 7.80 and 7.90 mg/kg, while the residues on head lettuce without wrapper leaves, median underlined, were: 1.60, 2.70, 3.50, 6.10 and 9.60 mg/kg.

Five trials were conducted on mustard greens in the USA in 2004 (maximum GAP on leafy vegetables: 0.15 kg ai/ha, four applications, 1-day PHI). The ranked order of residues on mustard greens, median underlined, were: 1.20, 4.00, 4.50, 4.50 and 11.5 mg/kg.

Six trials were conducted on spinach in the USA in 2005 (maximum GAP on leafy vegetables: 0.15 kg ai/ha, four applications, 1-day PHI). The residues on spinach, median underlined, were: 5.60, 8.20, 9.90, 10.2, 10.9 and 11.0 mg/kg.

The Meeting noted that the residue data populations, following treatment according to US GAP for leafy vegetables were similar, on head and leaf lettuce, mustard greens and spinach, and could be combined. The combined residues, in ranked order, median underlined, were: 1.20, 1.60, 1.90, 2.70, 3.50, 4.00, 4.50 (3), 5.30, 5.60, 5.70, 6.10, 7.80, 7.90, 8.20, 9.60, 9.90, 10.2, 10.9, 11.0 and 11.5 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in leafy vegetables of 25 and 5.65 mg/kg respectively.

Celery

Six trials were conducted on celery in the USA in 2005 (maximum GAP: 0.15 kg ai/ha, four applications, 1-day PHI). The residues on celery, median underlined, were: 0.74, 1.60, 1.80, 3.60, 6.40 and 7.80 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for mandipropamid in celery of 20 and 2.70 mg/kg, respectively.

Potato

The Meeting received information on supervised residue trials on potatoes in France, Germany, Italy, the Netherlands, Spain, Switzerland and the UK.

Supervised trials were conducted on potato, in Germany (maximum GAP, 0.15 kg ai/ha, four applications, 7-day PHI), in France (no GAP provided), in Italy (no GAP provided), in the Netherlands (maximum GAP: 0.15 kg ai/ha, six applications, no PHI) and in Spain (no GAP provided), in Switzerland (no GAP provided), in the UK (maximum GAP: 0.15 kg ai/ha, four applications, 3-day PHI) in 2002, 2003 and 2004.

The Meeting noted that residues in the tuber were below the LOQ (< 0.01 mg/kg) in all trials conducted in France (six trials), Germany (one trial), Italy (one trial), the Netherlands (one trial), Spain (three trials), Switzerland (three trials), the UK (two trials), and agreed to combine all data from the 17 trials utilizing the British GAP. The Meeting estimated a maximum residue level and an STMR value for mandipropamid in potato of 0.01* and 0.01 mg/kg, respectively.

Animal feedstuffs

Wrapper leaves of head cabbage

Six supervised trials were conducted on cabbage in the USA in 2004 (described above). The ranked order of residues on cabbage wrapper leaves, median underlined, were: 1.90, 2.30, 2.90, 4.20, 5.50 and 5.80 mg/kg.

The Meeting estimated an STMR and a high residue values for mandipropamid in wrapper leaves of cabbage of 3.55 and 5.80 mg/kg, respectively.

Fate of residues during processing

The Meeting received information on the fate of mandipropamid residues during aqueous hydrolysis under conditions of pasteurization and baking, brewing, boiling and sterilisation. Information was also provided on the fate of mandipropamid residues during the processing of grapes and tomatoes.

Mandipropamid was stable during the simulation of pasteurization (pH 4, 90 °C), baking, boiling, brewing (pH 5, 100 °C) or sterilisation (pH 6, 120 °C).

The processing factors for raisins (3.91), wet pomace (2.51), dry pomace (6.82), wine (0.85) and juice (0.33) were applied to the estimated STMR for grapes (0.43 mg/kg) to produce STMR-P values for raisins (1.68 mg/kg), wet pomace (1.16 mg/kg), dry pomace (2.93 mg/kg), wine (0.366 mg/kg) and grape juice (0.14 mg/kg). The processing factor for raisins (3.91) was applied to the grape residue data (highest value 0.85 mg/kg) to produce an estimated highest value for dried grapes (3.32 mg/kg).

The Meeting estimated a maximum residue level for mandipropamid in dried grapes (currants, raisins, sultanas) of 5 mg/kg.

The processing factors for wet pomace (0.95), dry pomace (4.45), juice (0.98), puree (1.14) and canned tomatoes (0.36) were applied to the estimated STMR for tomatoes (0.06 mg/kg) to produce STMR-P values for wet pomace (0.057 mg/kg), dry pomace (0.27 mg/kg), juice (0.059 mg/kg), puree (0.068) and canned tomatoes (0.022).

Farm animal dietary burden

The Meeting estimated the dietary burden of mandipropamid in farm animals on the basis of the diets listed in the Annex 6 of the 2006 JMPR Report. Calculation from highest residue and STMR-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. The percentage dry

matter is taken as 100% when the highest residue levels and STMRs are already expressed as dry weight.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, poultry (layer and broiler) are provided in Annex 6. The calculations were made according to the animal diets from the US–Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

The calculations are then summarized and the highest dietary burdens (underlined) are selected for MRL and STMR estimates on animal commodities.

		Animal dietary burden, mandipropamid, ppm of dry matter diet		
		US–Canada	EU	Australia
Beef cattle	Max	0.02	7.75	1.56
	Mean	0.02	4.75	0.73
Dairy cattle	Max	0.01	7.75[a]	1.56
	Mean	0.13	4.75[b]	0.73
Poultry - broiler	Max	0	1.94[c]	0
	Mean	0	0.01	0
Poultry - layer	Max	0	1.94	0
	Mean	0	1.19[d]	0

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat and milk.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat and milk.

[c] Highest maximum poultry broiler and layer dietary burden suitable for MRL estimates for poultry meat and eggs.

[d] Highest mean poultry broiler and layer dietary burden suitable for STMR estimates for milk.

Farm animal feeding studies

No animal feeding studies on ruminants are available. The lactating goat metabolism study was used to evaluate the dietary burden for ruminants. In the metabolism study, in which [^{14}C]mandipropamid equivalent to 27 – 49 ppm in the diet was orally administered to lactating goats for 7 consecutive days, highest residue parent compound (0.019 mg/kg) was found in fat. Given the low estimated animal burden (about one fourth of the administered level), no parent compound is expected to be present more than 0.005 mg/kg in tissues or milk.

For poultry, no feeding and metabolism studies are available. In addition, no analytical method for animal commodities was submitted for mandipropamid in animal commodities. The Meeting agreed that no maximum residue level could be estimated for animal commodities.

DIETARY RISK ASSESSMENT

Long-term intake

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

The International Estimated Daily Intakes (IEDIs) of mandipropamid, based on the STMRs estimated for 17 commodities, were 0–3% of the maximum ADI of 0.2 mg/kg bw for the thirteen GEMS/Food regional diets. The Meeting concluded that the long-term intake of residues of mandipropamid resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

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

5.17 METHOMYL (094) – ALTERNATIVE GAP

Methomyl was evaluated for residues and toxicology by the JMPR in 2001 under the periodic review programme, where MRLs for methomyl, arising from the use of either methomyl or thiodicarb on a number of commodities, were recommended.

The 2001 JMPR estimated short-term intakes that exceeded the ARfD of 0.02 mg/kg bw for apples, broccoli, Brussels sprouts, head cabbage, cauliflower, celery, water melon, grapes, kale, head lettuce, leaf lettuce, spinach, sweet corn and tomato.

At the 38th Session of the CCPR in 2006[38], the Committee requested JMPR to consider using alternative GAPs to recommend lower MRLs for apples, brassica vegetables, celery, fruiting vegetables, cucurbits, grapes, leafy vegetables and pears.

Information on current GAPs and new supervised trials data were submitted to the 2008 JMPR for cucurbits (cucumbers, courgettes and melons), grapes, lettuce and pears, and additional residue trials information was also provided for tomatoes. The Meeting also noted that the future of methomyl uses in EC Member States was uncertain.

No new residue data or information was available for brassica vegetables and celery and the Meeting agreed that the information evaluated by the 2001 JMPR was not sufficient to support the evaluation of an alternative GAP for these commodities.

Results of supervised residue trials on crops

Apples

Based on US GAP and residue data for thiodicarb and methomyl, the 2001 JMPR estimated a maximum residue level of 2 mg/kg, an STMR of 0.41 mg/kg and an HR (from the use of thiodicarb) of 1.6 mg/kg for methomyl in apples but indicated that the estimated short-term intakes for apples were 770% (children) and 260% (general population) of the ARfD (0.02 mg/kg bw).

The Meeting noted that the US GAP for thiodicarb, on which the 2001 JMPR had based its recommendations was no longer supported and that thiodicarb authorisations in EC Member States were also no longer supported.

Residue trials with methomyl, evaluated by the 2001 JMPR from trials in Europe matching the current GAP of Spain (0.05 kg ai/hL, PHI 7 days) and France (0.05–0.75 kg ai/hL) reported residues of 0.03, 0.05, 0.06, 0.06, 0.08, 0.08, 0.09, 0.09, 0.09, 0.1, 0.11, 0.13, 0.15, 0.16, and 0.17 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for methomyl in apples and estimated an STMR of 0.09 mg/kg and an HR of 0.17 mg/kg. The Meeting withdrew its previous recommendation of 2 mg/kg.

Pears

Based on GAP for methomyl in France and Spain and using methomyl residue data on pears and apples from Europe, the 2001 JMPR estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.09 mg/kg and an HR of 0.18 mg/kg for methomyl in pears and indicated that the estimated short-

[38] Codex Alimentarius Commission. *Report of the 38th Session of the Codex Committee on Pesticides Residues, 3–8 April 2006, Fortaleza, Brazil,* (ALINORM 06/29/24)

term intakes for pears were 50% (children) and 30% (general population) of the ARfD (0.02 mg/kg bw).

The Meeting noted that a revised variability factor used in the IESTI calculations had been adopted since 2001 and based on a re-calculation of the short-term intake estimation, the Meeting estimated revised short-term intakes of 40% (children) and 20% (general population) of the ARfD.

The Meeting agreed that an alternate GAP evaluation was therefore not required for methomyl on pears and confirmed the maximum residue level of 0.3 mg/kg for pears, as recommended by the 2001 JMPR.

Grapes

Based on GAPs and residue data for methomyl and thiodicarb on grapes in USA and France, the 2001 JMPR estimated a maximum residue level of 7 mg/kg, an STMR of 0.86 mg/kg and an HR (from the use of methomyl) of 5.2 mg/kg for methomyl in grapes but indicated that the estimated short-term intakes for grapes were 1600% (children) and 470% (general population) of the ARfD (0.02 mg/kg bw).

The results of new methomyl residue trials in France, Greece, Italy and Spain were made available to the Meeting. The Meeting noted that thiodicarb authorisations in the EC were also no longer supported and that the use of thiodicarb on grapes was also no longer supported in USA.

GAP for methomyl in France is 0.5 kg ai/ha (max), PHI 7 days for wine grapes and 28 days for table grapes. Residues in trials matching the GAP for wine grapes in France (at a PHI of 7 days) in trials evaluated by the 2001 JMPR and in the more recent trials were: 0.01, 0.04, 0.05, 0.07, 0.08, 0.09, 0.09, 0.09, 0.1, 0.14 and 0.2 mg/kg (n = 11).

In trials matching the GAP for table grapes in France (at a PHI of 28 days), residues were: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.02, 0.02, 0.03, 0.05 and 0.08 mg/kg (n = 11).

The Meeting agreed it was appropriate to use the data supporting the GAP for table grapes to determine an STMR and HR for dietary intake estimation and the data supporting the GAP for wine grapes to determine an STMR-P for wine and to estimate a maximum residue level.

The Meeting estimated a maximum residue level of 0.3 mg/kg for methomyl in grapes based on the results matching the wine grape GAP and estimated an STMR of 0.01 mg/kg and an HR of 0.08 mg/kg based on the results matching the table grape GAP.

Fruiting vegetables, Cucurbits

Based on GAPs in France and Netherlands and using residue data for methomyl on cucumbers, summer squash and melons in Europe and based on US GAP and residue data on watermelons, the 2001 JMPR estimated a maximum residue level of 0.1 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.07 mg/kg for methomyl in cucurbit vegetables but indicated that the estimated short-term intake for watermelon was 140% of the ARfD (0.02 mg/kg bw) for children.

The Meeting noted that a revised variability factor used in the IESTI calculations had been adopted since 2001 and based on a re-calculation of the short-term intake estimation, the Meeting decided that the recommendations from the 2001 JMPR did not result in any dietary intake concern with the highest short-term intake being for watermelons, at 80% of the ARfD for children.

The Meeting agreed that an alternate GAP evaluation was therefore not required for methomyl on cucurbit vegetables and confirmed the maximum residue level of 0.1 mg/kg for cucurbit vegetables, as recommended by the 2001 JMPR.

Tomato

Based on GAPs and residue data for thiodicarb on protected tomatoes in Australia and Spain, the 2001 JMPR estimated a maximum residue level of 1 mg/kg, an STMR of 0.16 mg/kg and an HR (from the use of thiodicarb) of 0.73 mg/kg for methomyl in tomatoes but estimated that the short-term intake for tomatoes was 190% of the ARfD (0.02 mg/kg bw) for children.

The Meeting noted that a revised variability factor used in the IESTI calculations had been adopted since 2001 and based on a re-calculation of the short-term intake estimation; the Meeting decided that the recommendations from the 2001 JMPR did not result in any dietary intake concern, with the highest short-term intake being 100% of the ARfD for children.

The Meeting agreed that an alternate GAP evaluation was therefore not required for methomyl on tomato and confirmed the maximum residue level of 1 mg/kg for tomato, as recommended by the 2001 JMPR.

Leafy vegetables

Based on GAPs for methomyl and/or thiodicarb on lettuce, spinach and collards in USA and on residue data from USA on head lettuce (thiodicarb), leaf lettuce (thiodicarb), collards (thiodicarb) and spinach (methomyl and thiodicarb), the 2001 JMPR estimated a maximum residue level of 30 mg/kg, an STMR of 1.4 mg/kg and an HR (from the use of thiodicarb) of 25 mg/kg for methomyl in leafy vegetables but estimated that the respective short-term intakes for head lettuce, leaf lettuce and spinach were 3000%, 3800% and 7200% of the ARfD (0.02 mg/kg bw) for children and 2000%, 1500% and 2800% of the ARfD for the general population.

The Meeting noted that no additional information had been received to support consideration of an alternative GAP for thiodicarb on leafy vegetables and agreed to evaluate an alternative GAP for methomyl alone.

Lettuce

The Meeting received results of new residue trials with methomyl on lettuce in France, Italy. In Spain, GAP for lettuce is 0. 5 kg ai/ha, maximum 2 applications/season (at least 14 days apart), PHI 14 days and in trials in France and Spain matching this GAP, residues were: < 0.01, < 0.01, < 0.01 < 0.01, 0.03, 0.03, 0.04 and 0.07 mg/kg.

Residues following treatments matching the GAP of Spain but involving a single application were: < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.02, 0.02 and 0.02 mg/kg.

The Meeting agreed that the residues from these two data sets could be combined because the residues from the initial application, at least 28 days before harvest would not contribute significant to the final residue. The combined data set was: < 0.01 (8), 0.01, 0.02, 0.02, 0.02, 0.025, 0.03, 0.04 and 0.07 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for methomyl in lettuce, head and lettuce, leaf and estimated an STMR of 0.01 mg/kg and an HR of 0.07 mg/kg for lettuce.

The Meeting also agreed to withdraw the previous recommendation for a maximum residue level of 30 mg/kg for methomyl on leafy vegetables.

Fate of residues during processing

The Meeting estimated STMR-Ps for apples juice and tomato paste using the methomyl processing factors reported for these commodities by the 2001 JMPR.

Using the processing factor of 0.29 for apple juice and the STMR of 0.09 mg/kg proposed for apples, the Meeting estimated an STMR-P of 0.026 mg/kg for apple juice.

Using the processing factor of 0.053 for tomato paste and the STMR of 0.16 mg/kg confirmed for tomatoes, the Meeting estimated an STMR-P of 0.0085 mg/kg for tomato paste.

The Meeting received information on the fate of incurred residues of methomyl during the processing of grapes. Based on the results of four processing studies conducted in France, processing factors were calculated for a range of processing fractions including red wine (0.96), white wine (0.22), grape juice (0.19), raisins (< 0.2) and grape pomace (1).

Based on the STMR value of 0.09 mg/kg for wine grapes (estimated from the results matching the GAP for wine grapes) and the median processing factors of 0.59 (red and white wine combined), 0.22 for grape juice, < 0.2 for raisins and 1 for wet pomace, the STMR-Ps for methomyl residues were 0.053 mg/kg in wine, 0.0198 mg/kg in grape juice, 0.018 mg/kg in dried grapes and 0.09 mg/kg in grape pomace, wet.

Based on the HR of 0.2 mg/kg estimated for table grapes (estimated from the results that matched the table grape GAP) and the processing factor of 0.2 for raisins, the Meeting estimated an HR-P of 0.04 mg/kg for methomyl in dried grapes.

DIETARY RISK ASSESSMENT

Long-term intake

This evaluation of methomyl has resulted in revised recommendations for MRLs and STMRs for raw and processed commodities based on the evaluation of alternative GAPs leading to lower maximum residue levels. Consumption data were available for 40 food commodities and were used in the dietary intake calculation. The results are shown in Annex 3.

The International Estimated Daily Intakes in the 13 GEMS/Food cluster diets, based on the estimated STMRs were in the range 0–3% of the maximum ADI of 0.02 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of thiodicarb and methomyl 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 methomyl 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 varied from 0–50% of the ARfD (0.02 mg/kg bw) for the general population. The IESTI varied from 0–100% of the ARfD for children 6 years and below. The Meeting concluded that the short-term intake of residues of methomyl from used considered by the Meeting was unlikely to present a public health concern.

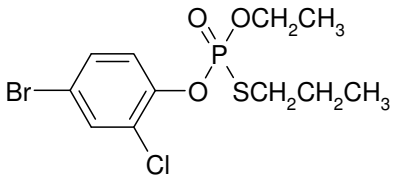
5.18 PROFENOFOS (171)

RESIDUE AND ANALYTICAL ASPECTS

Profenofos, an organophosphorus insecticide, was first evaluated by the JMPR in 1990 and has been reviewed for residue in 1992, 1994 and 1995. It was listed for periodic re-evaluation for residue evaluation at the 39th Session of the CCPR by the 2008 JMPR. The toxicology of profenofos was re-evaluated by the 2007 JMPR which estimated an ADI of 0–0.03 mg/kg bw and an ARfD of 1 mg/kg bw.

The Meeting received information on physical and chemical properties, animal and plant metabolism, environmental fate, analytical methods, storage stability, use pattern, supervised trials, processing and animal feeding studies.

O-(4-bromo-2-chlorophenyl) *O*-ethyl S-propyl phosphorothioate



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

CGA 55960	4-bromo-2-chlorophenol
BCPEE	4-bromo-2-chlorophenyl ethyl ether
BCPME	4-bromo-2-chlorophenyl methyl ether
THPME	2-thioethylenecarboxy-4-hydroxyphenyl methyl ether
MHPME	2-mercapto-4-hydroxyphenyl methyl ether

Animal metabolism

The Meeting received animal metabolism studies with profenofos in lactating goats and laying hens. [U-^{14}C-phenyl]profenofos was used in the metabolism studies.

When two lactating goats were orally dosed with [U-^{14}C-phenyl]-profenofos once daily for 4 consecutive days at 150 mg/animal/day, equivalent to 100 ppm in the feed, most of the administered radioactivity was excreted in the urine (59% and 79%) and faeces (1.7% and 1.2%). None of individual tissues or cumulative milk sample on day 4 contained more than 2% of the administered dose. Residue in milk reached a plateau by days 2–3. Residues of radioactivity were higher in kidney (2.5 mg/kg and 2.3 mg/kg profenofos equivalent) than in other tissues. Metabolite CGA 55960 and its sulfate and glucuronide constituted 22, 40 and 28% of the TRR, respectively in kidney, with no parent profenofos. Parent profenofos was the major component in fat (44% TRR), and was also present in liver (10% TRR). CGA 55960 sulfate was the major component identified in muscle (56% TRR), kidney (40% TRR) and milk (85% TRR). In addition, the major metabolites in liver and kidney were free CGA 55960 (25%, 22% TRR) and its glucuronide (8%, and 28% TRR), respectively.

When two groups of five laying hens were orally dosed with [U-^{14}C-phenyl]profenofos once daily for 8 consecutive days at a dose equivalent to 1 and 10 ppm in the feed, most of the

administered radioactivity was excreted in the excreta (93% and 89%). None of individual tissues or egg samples contained more than 1% of the administered dose. Highest TRR appeared in the kidney (0.12 mg/kg for the 1 ppm dose level and 1.3 mg/kg for 10 ppm dose level). Individual tissue TRR from 10 ppm dose level were approximately 10 times higher than those from 1 ppm dose group. CGA55960 was the major identified component in fat (77% and 89% TRR) and liver (75% and 71% TRR). Parent profenofos accounted for less than 5% TRR in each tissue and egg. For egg, CGA55960 sulfate was the main component of the residue: muscle (85% and 75% TRR), egg yolk (88% and 93% TRR), egg white (98% TRR).

Profenofos was rapidly metabolized following oral administration to animals. Once administered orally, profenofos underwent hydrolysis of the phosphate ester, and then formed either its sulfate or its glucuronide. TRR levels were higher in the kidney than in other tissues. Most of administered dose was rapidly excreted.

The metabolism of profenofos in the lactating goat and the laying hen was qualitatively similar to that described in the toxicology section of the 2007 Report of the JMPR.[39]

Plant metabolism

The Meeting received plant metabolism studies with profenofos in cotton, Brussels sprouts, lettuce and tomatoes. [U-^{14}C-phenyl]profenofos was used in the metabolism studies.

In a greenhouse cotton metabolism study, cotton plants were sprayed at a rate of 1.7 kg ai/ha once to simulate a multiple application of pesticide and maximize metabolites. Immediately after treatment the majority (91%) of the TRR was extractable with organic solvent. The extractable TRR decreased from 19.9mg/kg at day 0 to 1 and 0.55 mg/kg after 6 and 12 weeks. The parent profenofos (89%, 50% TRR) was the major component in the leaves and stems at 0 and 6 weeks after treatment, and then parent profenofos (13% TRR) and CGA 55960 (26% TRR) were identified in the leaves and stems at 12 weeks after treatment.

In a field cotton metabolism study in USA, cotton was sprayed over-the-top at a rate of 2.2 kg ai/ha three times at 2 week intervals. Mature samples of cotton were harvested 7 days after the final application. The TRR of profenofos equivalents was 8.3 mg/kg in the leaves, 0.4 mg/kg in the seeds and 0.2 mg/kg in the cotton fibre. The major compounds identified were parent profenofos (32% TRR) and CGA 55960 glucose conjugate (31% TRR) in mature leaves, and CGA 55960 glucose conjugate (15% TRR) in mature seeds.

In another field cotton metabolism study in USA, cotton was foliar sprayed 6 times at a rate of 2.2 kg ai/ha weekly. Mature samples of stalk, seed and lint were harvested at 61 and 83 days after the final application. Parent profenofos (29% TRR) and CGA 55960 glucosyl sulfate (31% TRR) were major components of the residue (TRR 14 mg/kg) in mature stalk. Mature samples of cotton seed contained parent profenofos (6.5% TRR) and CGA 55960 glucosyl sulfate (17% TRR) as the major part of residue (TRR 0.66 mg/kg).

In a Brussels sprouts metabolism study in Switzerland, Brussels sprouts received 3 foliar sprays at 2 week intervals at a rate equivalent to 1.1 kg ai/ha. In the leaves/stems sampled 21 days after the final treatment, CGA 55960 polysaccharide conjugate (30% TRR) and CGA 55960 monosaccharide conjugate (36% TRR) were major components of the residue (TRR 3.6 mg/kg). Profenofos was rapidly degraded following application to Brussels sprouts, with TRR of 0.3 mg/kg profenofos equivalents in the sprouts at maturity. Parent profenofos was present at 1.9% TRR in the leaves/stems but not found in the sprouts.

[39] In: Pesticide Residues in Food—2007. Report of the JMPR 2007, FAO Plant Production and Protection Paper, 191, pp 210.

In a lettuce metabolism study, two leaves per lettuce plant were treated by smearing 1 mg of ethanol solution of [U-^{14}C-phenyl]profenofos evenly over each leaf surface. Lettuce leaves were sampled at 0, 7, 14 and 21 days after treatment. Parent profenofos was the major component (68–92% TRR) on lettuce leaves, and no metabolite exceeding 3% of the TRR was identified at 0, 7 and 14 days. Parent profenofos (61% TRR) and CGA 55960 (10%) were the major part of the residue on leaves at 21 days after treatment.

In a tomato metabolism study, tomato plants received three foliar applications at a rate of 0.72, 0.82 and 0.81 kg ai/ha, with a week intervals. Mature tomato fruits as well as tomato leaves were harvested just after the last application, and 4, 7 and 14 days. The TRR was 1.1 mg/kg in tomato fruits and 29 mg/kg in leaves at 14 days. About 42% of the TRR was washed off the tomatoes harvested just after treatment, and 6% TRR at 14 days by rinsing with methanol. The parent was the major component of residue amounting to 0.67 mg/kg (63% TRR) in tomato fruits at 14 days later. Other identified components of the residue in tomato fruits were CGA 55960, CGA 55960 disaccharide conjugate and polysaccharide. Although the parent was the major component of residue (72% TRR) just after application in tomato leaves, it decreased to 6% TRR at 14 days later. Metabolite CGA 55960 was the major residue component in the leaves (20% TRR) at 14 days.

Profenofos is slowly absorbed and metabolized. Profenofos was the major residue when harvested several weeks after the last application, and then profenofos underwent hydrolysis of phosphate ester to form CGA 55960 and its sugar conjugate.

Environmental fate in soil

The Meeting received information on aerobic soil metabolism and rotational crop study.

Aerobic soil metabolism studies were conducted using [U-^{14}C-phenyl]profenofos applied to various soils which were then incubated under aerobic conditions at 21 or 25 °C. Aerobic soil degradation rates were influenced by the nature of the soil, temperature, moisture status of the soil and dose applied. Under aerobic conditions, profenofos applied to soil was rapidly degraded. After 28–30 days, only small amounts (< 0.1–1.6%) of applied profenofos remained as the parent. CGA 55960, BCPEE, THPME, MHPME and BCPME were formed and then degraded during study. Unextracted radioactivity, 1.0% of the applied dose in sandy loam on day 0, increased steadily to 10% of the applied dose on day 270. These results indicate that profenofos is not persistent in soil. Under sterile conditions, CGA 55960 was formed as the only degradate, reaching a maximum level of 93% of the applied dose by 360 days.

In confined rotational crop study, mustard, radish and wheat were planted at 30, 60, 90, 180 and 365 days following the application of maximum seasonal use rate of [U-^{14}C-phenyl]profenofos. Profenofos as an 8E formulation was applied to bare ground at the maximum seasonal rate of 6.7 kg ai/ha. Crops were harvested at maturity, and wheat forage was also harvested at intermediate stage.

TRRs for all crops were 0.026–0.157 mg/kg at 30-day plant back interval. Residue levels were slightly lower at 60, 90 and 180-day intervals. Intact profenofos was positively identified only in the mature root of the 30-day radishes, albeit at very low levels (0.001 mg/kg). For all planting intervals, the majority of the residues in rotational crops were in the post-extraction solids and aqueous-soluble fraction. The aqueous soluble residues were characterized as a mixture of neutral, basic and acidic components. A total hydrolysis method indicated these components were CGA 55960 sugar conjugates.

Profenofos residues are not expected to occur in succeeding crops.

Methods of analysis

The Meeting received description and validation data for analytical methods for residues of parent profenofos in raw agricultural commodities, processed commodities, feed commodities, animal

tissues, and milk and eggs. In most of the methods for determination of profenofos, homogenized samples were extracted with methanol or a mixture of methanol and water, and the extract was cleaned up with liquid-liquid partition followed by solid phase column chromatography using silica and florisil singly or in combination. The final residue may be determined by gas chromatography with NPD, FPD or ECD. LOQs were typically in the 0.01–0.05 mg/kg range.

Methods were provided also for residues of parent profenofos, CGA 55960, its sulfate and glucuronide determined as CGA 55960 in raw agricultural commodities and animal tissues, feed commodities, and milk and eggs. Homogenized samples were extracted with methanol or acetonitrile, and the extract was subjected to an acid and a base hydrolysis. The solutions were cleaned up with liquid–liquid partition followed by solid phase column chromatography using silica. The final residue may be determined by gas chromatography with ECD. LOQs were typically in the 0.02–0.05 mg/kg range.

Analytical recovery data were satisfactory for profenofos and total residues determined as CGA 55960 for numerous commodities.

DFG Method S19 (extended version) also demonstrated to be suitable for analysis of profenofos in plant material and foodstuffs of animal origin.

Stability of pesticide residues in stored analytical samples

Information was received on the freezer storage stability of profenofos residues in plant commodities, and of total residues of profenofos determined as CGA 55960 in plant and animal commodities.

Profenofos residues were stable in the following plant commodities for the intervals tested for 1–2 years: cotton seed, cotton seed hulls, cotton seed oil, soap stock and grapes.

Total residues of profenofos determined as CGA 55960 into animal tissues, milk and eggs were stable when stored under freezer storage conditions (approximately –20 °C) for 1 year.

Residue definition

The current residue definition of profenofos is parent profenofos for plant and animal commodities. Parent profenofos is the major component of the TRR in most crops until 2–3 weeks after application. In tomato fruits, profenofos represented 63% of the TRR at 14 days after the last application. Also in lettuce, profenofos (61% TRR) is the major residue component at 21 days after treatment, although CGA 55960 was identified 10% of TRR. No metabolite was found to be more than 10% of the TRR in lettuce leaves and tomato fruits. In Brussels sprouts, however, no parent profenofos was detected in sprouts at 21 days after the last application. Although CGA 55960 and CGA 55960 sugar conjugate were identified in sprouts, concentrations of the metabolites were below the LOQ level.

In cotton seed, parent profenofos and CGA 55960 glucosyl sulfate were identified as the major residue components at 83 days after the final application, although each TRRs were less than 20%. No other metabolites were present higher than 5% of the TRR. Methods of analysis are available for determination of parent profenofos and these metabolites in plants. However, concentrations of these metabolites are expected to be below the LOQ level.

The Meeting decided that parent profenofos is a suitable analyte for enforcement purposes and dietary risk assessment in plant commodities.

Profenofos is rapidly absorbed and eliminated after oral administration in farm animals and is only found in significant amount in goat kidney and hen kidney, liver and eggs. In the lactating goat study, the main components of residue were CGA 55960 sulfate in milk, kidney and muscle, parent profenofos in fat. In the laying hen study, the major residue components were CGA 55960 in fat and liver, CGA 55960 sulfate in muscle and eggs. Methods of analysis are available for determination of parent profenofos and these metabolites in animal tissues, milk and eggs. The metabolites determined

as CGA 55960 by hydrolysis procedure are expected to be detectable as the major compounds in animal tissues, milk and eggs. However, according to farm animal feeding studies, the parent and the metabolites are expected to be present below the LOQ.

The Meeting decided that parent profenofos is suitable analyte for enforcement purposes and dietary risk assessment in animal commodities.

Profenofos may be fat-soluble as it has log P_{ow} of 4.44 at 25 °C. In animal metabolism studies, the TRR in fat (0.07 mg/kg) was much lower than in kidney (2.3 mg/kg), liver (0.51 mg/kg) and milk (0.41 mg/kg). The study results indicated that the parent was rapidly decomposed to water-soluble metabolites, and those metabolites were excreted. Therefore, the Meeting decided the residues would not be fat-soluble.

The Meeting recommended the following as residue definitions for profenofos.

For plants and animals:

Definition of the residue (for compliance with the MRL and for estimation of dietary intake): *profenofos*.

Results of supervised residue trials on crops

The Meeting received supervised trial data for profenofos uses on tropical fruits (mango, mangosteen), cabbages, watermelon, fruiting vegetables (chilli peppers, tomatoes), soya beans and cotton seed. Residue data were also provided on cotton meal and hulls.

Labels (or translation of labels) were available from Australia, Brazil, Chile, Colombia, Indonesia, Malaysia, Philippines, South Africa and USA describing the registered uses of profenofos, and GAP information was also provided from Thailand.

Since no residue data were provided for sweet peppers and potato, the Meeting withdraws its previous recommendations for maximum residue levels for these crops.

Mango

In Thailand, profenofos may be applied to mango trees four times at a spray concentration of 0.075 kg ai/hL, with a 21 days PHI. In six Thai trials conducted in accordance with Thai GAP, profenofos residue in mango whole fruits, were: < 0.01, 0.05, 0.05, 0.06, 0.06 and 0.07 mg/kg. No data were available for residue in edible portion.

The Meeting estimated a maximum residue level, an STMR value and an HR value for profenofos in mango of 0.2, 0.06 and 0.07 mg/kg respectively.

Mangosteen

In Thailand, profenofos may be applied to mangosteen trees three times at a spay concentration of 0.15 kg ai/hL with a 21 days PHI. In four Thai trials conducted in accordance with Thai GAP, profenofos residue in mangosteen whole fruits were 1.9, 1.9, 2.3 and 3.7 mg/kg. No data were available for residue in edible portion.

The Meeting estimated a maximum residue level, an STMR value and an HR value for profenofos in mangosteen of 10, 2.1 and 3.7 mg/kg respectively.

Cabbages

In South Africa, profenofos may be applied to cabbages at a rate of 0.38–0.5 kg ai/ha with a 7 days PHI.

In a South African trial conducted in accordance with South African GAP, profenofos residues were < 0.02, 0.09, 0.13 mg/kg.

The Meeting agreed that insufficient data were available to estimate a maximum residue level for cabbages.

The Meeting withdraws its previous recommendation of 1 mg/kg for cabbages.

Watermelon

In the Philippines, profenofos may be applied to watermelon at a spray concentration of 0.1–0.15 kg ai/hL with a 7 days PHI. Six trials were conducted in the Philippines (0.014–0.075 kg ai/hL with a 13 day PHI) but the spray concentration and PHI did not correspond to Filipino GAP.

The Meeting was unable to estimate residue level as the residue trails conducted do not match the GAP.

Chilli peppers

In Indonesia, profenofos may be applied to chilli pepper crops at a spray concentration of 0.025–0.15 kg ai/hL with no required PHI.

In a Malaysian trial conducted in accordance with Indonesian GAP, profenofos residues on 0 days after the final application was 12 mg/kg. The Meeting agreed that the data matching GAP were insufficient to propose a maximum residue level for chilli peppers.

The Meeting withdraws its previous recommendation of 5 mg/kg for chilli peppers.

Since the Meeting withdraws a maximum residue level in chilli peppers, a maximum residue level in dried chilli peppers, which is estimated using a processing factor of dehydration of chilli peppers, is withdrawn.

Tomatoes

In South Africa, profenofos may be applied to tomato crops at a rate of 0.25–0.75 kg ai/ha with a 4 day PHI. In nine South African trials conducted in accordance with South African GAP, profenofos residues in rank order were 0.18, 0.39, 0.40, 0.81, 1.3, 1.8, 1.9, 4.2 and 4.7 mg/kg. The trials where the samples from control plots contained residues were disregarded.

In Indonesia, profenofos may be applied to tomato crops at a rate of 0.38–1.2 kg ai/ha with no required PHI. In two Indonesian trials conducted in accordance with Indonesian GAP, profenofos residues on 1 day after the final application were 1.3 and 1.6 mg/kg.

Based on the South African trials, the Meeting estimated a maximum residue level, an STMR value and an HR value for profenofos in tomatoes of 10, 1.3 and 4.7 mg/kg respectively.

The Meeting withdraw its previous recommendation of 2 mg/kg for tomato.

Soya beans

In Brazil, profenofos may be applied to soya bean crops at a rate of 0.08–0.1 kg ai/ha with a 21 days PHI. In three Brazilian trials conducted with conditions in line with Brazilian GAP, profenofos residues (ranked order, median underlined) were < 0.02 (3) mg/kg.

In the Philippines, profenofos may be applied at a rate of 0.5–0.75 kg ai/ha with a 7 days PHI. None was conducted in accordance with Filipino GAP.

The Meeting agreed that the data in accordance with GAP were insufficient to propose a maximum residue level for soya beans.

Cotton seed

In Australia, profenofos may be applied to cotton crops at a rate of 0.25–1.0 kg ai/ha, PHI 28 days. In tree Australian trials conducted in accordance with Australian GAP, profenofos residues were 0.04, 0.14 and 0.70 mg/kg.

In a Brazilian trial conducted in accordance with Brazilian GAP (0.25–0.5 kg ai/ha with a 15 day PHI), profenofos residues was < 0.02 mg/kg.

In the USA, profenofos may be applied 2–4 times at a rate of 0.14–0.86 kg ai/ha with a 14 day PHI. In 11 US trials conducted with condition in line with US GAP, profenofos residues in rank order were < 0.05 (2), < 0.10, 0.25, 0.34, 0.35, 0.60, 0.60, 0.92, 0.95 and 1.2 mg/kg.

Based on the US trials, the Meeting estimated a maximum residue level, an STMR value for profenofos in cotton seed of 3 and 0.35 mg/kg respectively.

The Meeting withdraws its previous recommendation of 2 mg/kg for cotton seed.

Animal feedstuffs

Cotton gin trash

In two US trials conducted in accordance with US GAP (0.86 kg ai/ha, PHI of 14 days), profenofos residues in cotton gin trash were 24 and 53 mg/kg respectively.

The Meeting was unable to estimate residue level as the data matching GAP were insufficient to propose a maximum residue level for cotton gin trash.

Fate of residues during processing

The Meeting received information on processing of cotton seed to crude oil and refined oil.

Processing factors were calculated for cotton seed (hulls, meal, crude oil and refined oil) and are shown in the Table below.

Mean processing factors and STMR-P for food and feed

Commodity	Processing factor	Median or best estimate	STMR-P mg/kg
Cotton seed			0.35
Hulls	0.90, 1.1, 1.5, 2.1	1.4	0.49
Meal	0.12, 0.18, 0.35, 1.5	0.54	0.19
Crude oil	1.0, 1.4, 1.5, 1.8, 1.9, 2.0, 2.3, 2.6, 2.7, 3.9, 4.8, 6.5	2.2	0.77
Refined oil	< 0.08, < 0.14, 0.13, 0.15, 0.18, 0.28, 0.40, 0.43, 0.52, 1.2, 1.2, 3.5, 3.6	0.40	0.14
Bleached deodorized oil	< 0.06, < 0.06, < 0.08, < 0.08, 0.08, 0.08, 0.23, 0.33, 0.65, 0.75,	0.08	0.03

Cotton seed oil must be refined to remove a naturally occurring toxin. Therefore the refined oil residues should be used to estimate an STMR for dietary intake.

The Meeting withdraws its previous recommendation of 0.05(*) mg/kg for cotton seed oil, edible.

Farm animal feeding studies

The Meeting received a lactating dairy cow feeding study and a laying hen feeding study, which provided information on likely residues resulting in animal commodities, milk and eggs from profenofos residues in the animal diet.

Lactating dairy cows

Groups of 3 lactating dairy cows were dosed once daily via feed with profenofos at 0.25, 0.75 and 2.5 ppm in the diet for 28 consecutive days. One cow was dosed with profenofos at 25 ppm for 28 days. Milk samples for residue analysis were collected from each cow at 0, 3, 5, 7, 10, 21 and 28 days and samples of liver, kidney, perirenal fat, omental fat, round steak, tenderloin and blood were collected on 14, 21 and 28 days.

Parent profenofos residues did not occur above LOQ in any tissue and milk samples for any of the test doses.

Laying hens

Three groups of 15 laying hens were fed rations treated with profenofos at 0.10, 0.30 and 1.0 ppm for 28 consecutive days. Samples of eggs for residue analysis were collected at 0, 1, 3, 7, 10, 14, 21 and 28 days and samples of liver, fat, breast and thigh were collected.

Parent profenofos residue was not present in the tissues and eggs.

Farm animal dietary burden

The Meeting estimated the dietary burden of profenofos in livestock on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values 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 as dry weight.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6 of the 2006 Report of the JMPR. The calculations were made according to the livestock diets from US-Canada, EU and Australia in the OECD Table (Annex of the 2006 JMPR Report).

	Livestock dietary burden, profenofos, ppm of dry matter diet					
	US-Canada		EU		Australia	
	Max	mean	Max	Mean	Max	mean
Beef cattle	0.11a	0.11b	0.01	0.01	0.11	0.11
Dairy cattle	0.08	0.08c	0.01	0.01	0.05	0.05
Poultry – broiler	0.04d	0.04e	0.01	0.01	0.02	0.02
Poultry – layer	0.04	0.04	0.01	0.01	0.02	0.02

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

Animal commodity maximum residue levels

For MRL estimation, the residue in the animal commodities is profenofos.

In a feeding study, in which profenofos equivalent to 0.75 ppm in the diet was dosed to lactating cows for 28 consecutive days, no total profenofos residues were detected in tissues (< 0.05 mg/kg) and milk (< 0.01 mg/kg). Therefore no residues are to be expected at the maximum estimated dietary burden of 0.11 ppm feed for beef cattle and dairy cattle.

The Meeting estimated a maximum residue level of 0.05(*) mg/kg in mammalian meat and mammalian edible offal, and 0.01(*) mg/kg in milk. The Meeting confirmed its previous recommendations for mammalian meat and milk.

The mean estimated dietary burden for dairy cattle is 0.08 ppm. No profenofos residues (< 0.01 mg/kg) were found in any samples of milk at the 0.75 ppm feeding level. Therefore the Meeting estimated an STMR of 0 mg/kg in milk.

The mean estimated dietary burden for cattle is 0.11 ppm. In muscle, fat, kidney and liver, no profenofos residues (< 0.05 mg/kg) were detectable at the 0.75 ppm feeding level. The Meeting estimated STMRs and HRs of 0 mg/kg in meat, offal and fat.

In a feeding study, in which profenofos equivalent to 0.30 ppm in the diet was dosed to laying hens for 28 consecutive days, no profenofos were detected in any tissues (< 0.05 mg/kg) and eggs (< 0.02 mg/kg). Therefore no residues are to be expected at the maximum estimated dietary burden of 0.04 ppm feed for poultry.

The Meeting estimated a maximum residue level of 0.05(*) mg/kg in poultry meat and edible offal, and 0.02(*) mg/kg in eggs. The Meeting confirmed its previous recommendation for eggs.

The Meeting estimated STMRs and HRs of 0 mg/kg in poultry meat, offal, fat and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of profenofos were calculated for the 13 GEMS/Food cluster diets using STMRs/STMR-Ps estimated by the current Meeting (Annex 3 of the 2007 Report of the JMPR). The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 1–10% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intakes of residues of profenofos, resulting from the uses considered by current JMPR, are unlikely to present a public health concern.

Short-term intake

The IESTI of profenofos calculated on the basis of the recommendations made by the current Meeting represented 0–10% of the ARfD (1 mg/kg bw) for children and 0–6% for the general population. The Meeting concluded that the short-term intakes of residues of profenofos resulting from the uses considered by the Meeting are unlikely to present a public health concern.

5.19 PROTHIOCONAZOLE (232)

TOXICOLOGY

Prothioconazole is the ISO approved common name for the substance for which the IUPAC nomenclature is 2-[(2*RS*)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2*H*-1,2,4-triazole-3(4*H*)-thione (CAS No. 178928-70-6). It is a systemic triazolinthione fungicide, the targets for which are most of the economically important diseases caused by *Ascomycetes*, *Basidiomycetes* and *Deuteromycetes* in cereals, oilseed rape and peanuts. Its mode of action is interference with the synthesis of ergosterol in the target fungi by inhibition of CYP51, which catalyses demethylation at C14 of lanosterol or 24-methylene dihydrolanosterol, leading to morphological and functional changes in the fungal cell membrane.

The residue definition for risk assessment in plant commodities is the metabolite prothioconazole-desthio**,** while in animal commodities it is the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy (M14) and prothioconazole-desthio-4-hydroxy (M15), and their conjugates expressed as prothioconazole-desthio. For the active ingredient prothioconazole and its metabolite prothioconazole-desthio, complete data sets were submitted. Prothioconazole-desthio is considered to be the toxicologically relevant compound. While no independent studies of toxicity with M14 and M15 were available, both metabolites and their glucuronide conjugates were identified and quantified in studies with prothioconazole and prothioconazole-desthio in rats; the toxicology of M14 and M15 can thus be considered to be included in the databases provided for these compounds.

Prothioconazole was reviewed for the first time by the present Meeting at the request of the CCPR.

All critical studies complied with GLP.

Biochemical aspects

In rats given [^{14}C]prothioconazole labelled in either the triazole or phenyl rings as a single oral dose at either 2 or 150 mg/kg bw, the radiolabel was rapidly and extensively (> 90%) absorbed from the gastrointestinal tract, the t_{max} calculated from plasma concentrations being 0.1–0.7 h for males and females. There were no significant differences related to sex, higher or lower dose or multiple doses.

The highest concentrations of radioactivity were found in the gastrointestinal tract and liver, as demonstrated by dissection and liquid scintillation counting and confirmed by whole-body autoradiography. Radioactivity concentrations in the liver were markedly higher in male rats than in females. Relatively high concentrations were also found in the thyroid. Distribution was rapid and was followed by extensive loss of radioactivity from tissues and organs. The highest concentrations of prothioconazole equivalents were recorded in the liver, followed by kidney, fat, thyroid and adrenal gland.

Excretion was initially extensive and relatively rapid, mainly via the faeces, about > 70% being eliminated within 24 h, although the subsequent rate of excretion was low. Extensive biliary excretion (90%) was shown in bile-duct cannulated rats; evidence for enterohepatic recirculation was also seen in these rats.

Study of metabolism using both phenyl- and triazole-ring–labelled molecules indicated that the prothioconazole structural skeleton remained largely intact, although prothioconazole was extensively metabolized. The major types of metabolic reactions identified were conjugation with glucuronic acid, oxidative hydroxylation of the phenyl moiety and desulfuration. The principle metabolites found in the excreta were prothioconazole-*S*-glucuronide, prothioconazole-desthio and prothioconazole itself. Many of the 18 metabolites identified were derived from the desthio metabolite (i.e., in which the triazole sulfur had been eliminated). The desthio metabolite was found

almost exclusively in the faeces and represented between 3.5% and 17.7% of the administered dose. The systemic proportion of radiolabel as prothioconazole-desthio was very low; not more than about 0.07% of the administered dose was found in the urine. The *S*- or *O*-glucuronide conjugates were the principle systemic metabolites and were found in amounts of up to 7.7% of the administered dose in rat urine. These conjugates were also overall the most abundant, occurring at about 46% of the administered dose in bile, followed by the parent compound, prothioconazole (about 1–22%), and prothioconazole-desthio (about 0.4–18%).

Toxicological data

The acute toxicity of prothioconazole is low, the oral LD_{50} being > 6200 mg/kg bw in rats. At this dose, there were no deaths and clinical signs were limited to decreased motility and diarrhoea 1–6 h after dosing. The dermal LD_{50} in rats was > 2000 mg/kg bw and the inhalation LC_{50}, also in rats, was > 4.9 mg/L for a 4-h exposure. Prothioconazole is not irritating to rabbit skin and eyes and is not sensitizing either in the Buehler skin patch test in guinea-pigs or in the local lymph node assay in mice.

Initial studies with repeated doses showed that prothioconazole could be unstable when formulated with diet, hence most studies were performed using dosing by gavage. A 4-week study in rats given prothioconazole by different dosing routes established that plasma concentrations in rats dosed by gavage at 1000 mg/kg bw per day were 3–6-fold those in rats given diets containing prothioconazole at 10 000 ppm, equivalent to 1000 mg/kg bw per day, and this was consistent with the observation of more marked effects in rats dosed by gavage.

The liver was consistently identified as a target organ in short-term studies in rats, mice and dogs, although there were some species differences in the hepatic effects observed. Increased liver weights and increased activities of several liver enzymes were observed in mice, rats (particularly females) and dogs. Microscopic lesions were also observed in the liver, including an increase in pigmented material in dogs, centrilobular fatty change and focal necrosis in mice and cytoplasmic changes and centrilobular hepatocellular hypertrophy in rats and mice. Some of these effects were consistent with induction of hepatic enzymes. None of the effects recorded in the liver persisted after 4- and 8-week recovery periods in rats and dogs, respectively.

The kidney was the primary target organ in dogs and was also identified as a target organ in rats, but not in mice. The effects on the kidneys consisted of increased weights and changes in histology, namely increased incidence and severity of basophilic tubules and tubular dilatation in rats, and interstitial fibrosis and inflammation in dogs. These findings did not persist after a recovery period in rats, but there was only partial recovery in dogs. In rats, these kidney changes correlated with greatly increased water intakes, indicating disturbance of kidney function and systemic water homeostasis.

The following NOAELs were derived from short-term studies in which prothioconazole was administered orally:

— In a 14 week study in mice dosed by gavage, the NOAEL was 25 mg/kg bw per day on the basis of increased liver weights and various histological changes in the liver at 100 mg/kg bw per day;

— In studies of up to 14 weeks in rats dosed by gavage, the NOAEL was 100 mg/kg bw per day on the basis of increased water consumption, decreased urine output, increased liver weights in females, and histological changes in the liver and kidney at 500 mg/kg bw per day;

— In 13-week and 1-year studies in dogs dosed by gavage, the overall NOAEL was 25 mg/kg bw per day on the basis of minimal histological changes in the kidneys at 40 mg/kg bw per day.

In long-term studies in rats and mice dosed by gavage, the primary target organs were the liver and kidney. There was no evidence for any carcinogenic potential in rats or mice. The hepatic effects observed in rats were increased incidences of eosinophilic or clear-cell foci. The other liver effects observed in rats and mice (increased weights, centrilobular hypertrophy with cytoplasmic changes) were consistent with induction of hepatic enzymes. There was slight alteration in the concentrations of plasma thyroid hormones in rats, but there was no associated thyroid histopathology.

The kidney effects in rats were increased organ weight and increased severity of chronic progressive nephropathy accompanied by markedly increased water consumption, effects on urine analysis, crystalline material in the urine sediment and transitional-cell hyperplasia in the urinary bladder. In mice, responses comprised decreased organ weight, tubular degeneration and regeneration and subcapsular tubular degeneration with interstitial fibrosis. The kidney effects were more marked in rats than in mice, and treatment of rats for more than 1 year was associated with prolonged and increasingly severe functional deficit in the kidneys. Males were consistently more markedly affected than females. In rats, the kidney dysfunction and resulting dehydration caused mortality at doses of between 500 and 1000 mg/kg bw per day.

In a long-term study in rats dosed by gavage for 2 years, the NOAEL was 5 mg/kg bw per day on the basis of gross and microscopic changes in the liver and kidneys at 50 mg/kg bw per day. In a long-term study in mice dosed by gavage for 18 months, the NOAEL was 10 mg/kg bw per day on the basis of reduced body weights and gross and microscopic changes in the liver and kidneys at 70 mg/kg bw per day.

Prothioconazole was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. Although genotoxicity was not observed in tests for gene mutation in vitro, there was equivocal evidence for DNA damage and confirmed evidence for the induction of chromosomal aberrations in vitro; however, these observations were not confirmed in the relevant assays conducted in vivo.

The Meeting concluded that prothioconazole is unlikely to be genotoxic.

On the basis of the absence of carcinogenicity in rodents and the absence of genotoxicity in vivo, the Meeting concluded that prothioconazole is unlikely to pose a carcinogenic risk to humans.

In a multigeneration study in rats, effects were observed on the liver and kidneys at higher doses in parental animals. Some of these observations were consistent with the findings of short-term and long-term studies of toxicity. The NOAEL for systemic toxicity in the parental rats was 9.7 mg/kg bw per day on the basis of reduced body weight and effects on organ weights at 95.6 mg/kg bw per day. In the offspring, the NOAEL was 95.6 mg/kg bw per day on the basis of reduced pup-weight gain, reduced spleen weight and delayed preputial separation at 726 mg/kg bw per day. The NOAEL for reproductive effects was 95.6 mg/kg bw per day on the basis of disruption to the oestrus cycle, reduced number of implantation sites and litter size, increased time to insemination and increased duration of gestation at 726 mg/kg bw per day. Although several of these observations were not statistically significantly different, they were consistent features of the group receiving the highest dose in contrast to the other groups, but they did not result in effects on mating, fertility or gestation indices.

The highest dose of 726 mg/kg bw per day caused parental toxicity that was probably related to kidney dysfunction and resulting dehydration, which in other studies in rats given repeated doses were a cause of mortality at doses of between 500 and 1000 mg/kg bw per day. Effects on developing pups also were restricted to the group receiving a dose of 726 mg/kg bw per day.

The Meeting concluded that prothioconazole was toxic to the reproductive system and to developing offspring at a dose that was accompanied by toxicity in parental rats.

In a study of developmental toxicity in which rats were given prothioconazole by gavage on days 6–19 of gestation, the NOAEL for maternal toxicity was 80 mg/kg bw per day on the basis of

reduced body-weight gain and increased water consumption and urination at 500 mg/kg bw per day. Examination of the fetuses revealed an increased incidence of microphthalmia and of rudimentary supernumerary ribs, together with retarded fetal development, at 1000 mg/kg bw per day. Marked maternal toxicity was also recorded at this dose. Although the developmental effects, which included a statistically significant increased incidence in microphthalmia (on a fetal basis) occurred at a dose of 1000 mg/kg bw per day, microphthalmia was also observed in the groups at 500 and 80 mg/kg bw per day, but not in the controls. Rudimentary supernumerary ribs, which occur spontaneously in untreated rats of this strain, were significantly increased in a dose-related manner at all doses, including 80 mg/kg bw per day, the lowest dose tested. The Meeting noted there were indications that the incidence of this variation in the group receiving the vehicle only may have been particularly low in this experiment; however, incidences in all groups treated with prothioconazole were higher than the upper limit of the range for historical controls over the relevant period.

In order to further investigate the occurrence of microphthalmia, a different rat substrain was selected for which the available database on historical controls revealed a virtually-zero background incidence of this malformation. Since the strain was nevertheless sensitive to direct, specific oculo-teratogenic effects, it was well suited for investigation of the specificity of microphthalmia formation caused by prothioconazole. In this second study of developmental toxicity in rats, prothioconazole did not cause microphthalmia or other specific malformations at any dose up to and including 750 mg/kg bw per day. These results would seem to support the hypothesis that the increase in microphthalmia seen in the original study of developmental toxicity was a non-specific enhancement of a common spontaneous effect; however, the mechanism by which microphthalmia was induced has not been investigated or described. There was an increase in the incidence of rudimentary (comma shaped) supernumerary 14th ribs that was significant on a fetal basis at 750 mg/kg bw per day, but not on a litter basis, and was not increased at 80 mg/kg bw per day or at the lower dose. The NOAEL for maternal toxicity was 80 mg/kg bw per day on the basis of reduced body-weight gain, increased water consumption, reduced food consumption and clinical chemical indications for functional impairment of liver and kidney function at 750 mg/kg bw per day. The NOAEL for developmental toxicity was 80 mg/kg bw per day on the basis of a statistically significant increase in the incidence of rudimentary supernumerary 14th ribs at 726 mg/kg bw per day.

In a study of developmental toxicity in which rabbits were given prothioconazole by gavage on days 6–27 of gestation, the NOAEL for maternal toxicity was 80 mg/kg bw per day on the basis of mortality, body-weight loss or reduced body-weight gain and reduced food consumption at 350 mg/kg bw per day. The NOAEL for developmental toxicity was 80 mg/kg bw per day on the basis of abortions, total litter losses, reduced fetal weights and retarded ossification at 350 mg/kg bw, where there was clear evidence of severe maternal toxicity.

In a study of neurotoxicity in rats given a single dose of prothioconazole by gavage, the NOAEL was 218 mg/kg bw per day on the basis of transient clinical signs at 877 mg/kg bw per day. There were no neurohistopathological changes in nerve tissue and no persistent signs of neurobehavioural toxicity.

In a 90-day study of neurotoxicity in rats given prothioconazole by gavage, the NOAEL was 100 mg/kg bw per day on the basis of clinical signs, reduced body weights and reduced motor and locomotor activity at 1000 mg/kg bw per day. The reduced motor and locomotor activity is likely to be secondary to the systemic toxicity evident in these animals rather than clear neurobehavioural toxicity. There were no neurohistopathological changes in nerve tissue or muscle.

The Meeting concluded that prothioconazole is unlikely to cause neurotoxicity in humans.

There were no indications of immunotoxicity in general studies of toxicity in dogs, rats and mice.

Some aspects of the toxicology of certain metabolites of prothioconazole found in wheat (mainly straw), but not necessarily in rats—exceptions being prothioconazole-triazolinone (M03) and prothioconazole-desthio—were investigated.

Triazole (1,2,4-triazole) and its metabolites, triazole alanine and triazole acetic acid, are metabolites of difenoconazole, the toxicology of which was summarized by JMPR 2007 and by the present Meeting. No triazole-free metabolites were found using phenyl-labelled prothioconazole. The other metabolites summarized here were prothioconazole-desthio, prothioconazole-sulfonic acid (M02), prothioconazole-desthio-*alpha*-hydroxy (M18), prothioconazole-desthio-*alpha*-acetoxy (M19), prothioconazole-benzylpropyldiol (M09), prothioconazole-triazolinone (M03). M03 is also found in rat urine in which it represents up to 2% of the administered parent compound. The data submitted on these substances indicate that, except for prothioconazole-desthio and M02, they are not toxicologically relevant metabolites. A single-dose study of oral toxicity indicated that the LD_{50} of prothioconazole-sulfonic acid is > 200 mg/kg bw and < 2000 mg/kg bw. The LD_{50} values for prothioconazole-desthio-*alpha*-hydroxy (M18), prothioconazole-desthio-*alpha*-acetoxy (M19) and prothioconazole-benzylpropyldiol are all > 2000 mg/kg bw. Prothioconazole-sulfonic acid has been tested in a 90-day dietary study of toxicity in rats. The NOAEL was 500 ppm, equal to 34 mg/kg bw per day, on the basis of histomorphological alterations in the urinary bladder at 2000 ppm, equal to 136 mg/kg bw per day. No other repeat-dose studies of toxicity have been conducted with these metabolites.

In a study of developmental toxicity in rats given prothioconazole-sulfonic acid by gavage on days 6–20 of gestation, the NOAEL for maternal toxicity was 150 mg/kg bw per day on the basis of increased mortality, reduced food consumption and reduced body-weight gain at 750 mg/kg bw per day. The NOAEL for developmental toxicity was 150 mg/kg bw per day on the basis of increased incidence of total implantation loss and the occurrence of reduced fetal weight gain and reduced ossification at 750 mg/kg bw per day. Prothioconazole-sulfonic acid did not show any teratogenic potential.

None of the metabolites was active in tests for mutagenicity with strains of *Salmonella typhimurium*.

The most toxicologically significant of the prothioconazole metabolites is prothioconazole-desthio. A largely complete toxicology dossier was available for this compound.

Prothioconazole-desthio was rapidly and almost completely absorbed from the gastrointestinal tract of rats, with a plasma t_{max} of about 1.5 h, but maximum plasma concentrations were low. The plasma t_{max} of prothioconazole-desthio in pregnant rats treated by gavage was similar to that in male rats. The mean concentration of radioactivity in the body minus the gastrointestinal tract was > 3.5% of the administered dose, indicating that there was little distribution to the peripheral tissues; the highest concentrations (about 3% of the administered dose) were found in the liver. Excretion occurred predominantly via the bile, and the elimination half-life and mean residence time were prolonged due to intensive enterohepatic re-circulation. No potential for bioaccumulation was expected. The bile metabolites identified indicated that metabolism proceeded via oxidation only of the phenyl moiety, with subsequent glucuronidation and methylation of the oxidation products. These oxidation reactions yielded metabolites without their former aromatic character; nevertheless, the cyclopropyl and triazole ring structures of prothioconazole-desthio remained intact.

The acute toxicity of prothioconazole-desthio is low, the oral LD_{50} being approximately 2200 mg/kg bw in rats and mice. In both species, deaths were delayed, by 4–13 days in rats and 1–4 days in mice. In rats and mice, no clinical signs were observed at 100 mg/kg bw. The observations recorded for mice given higher doses were apathy, piloerection, laboured breathing, staggering gait and increased urination in males at 500 mg/kg bw and in females at 1000 mg/kg bw. Spastic gait and reduced mobility were also noted in females at > 100 mg/kg bw, but these signs were noted in males only at doses of > 2000 mg/kg bw. Atony, weak reflexes, emaciation, pallor, narrowed palpebral fissures (separation between the upper and lower eyelids), red crusted eyelids, bloody snout, prone position and leg extension occurred in both sexes at high doses. Some clinical signs were evident shortly after treatment but others showed a delayed onset. All signs had resolved by day 13 in male rats and by day 18 in females. In mice, the clinical signs of response were motility and respiratory disturbances, piloerection, staggering gait, narrowed palpebral fissures, lacrimation, a spasmodic

state, temporary rolling over, prostration or lying on the side These were mainly observed at up to moderate intensity, developed shortly after treatment in some cases, and persisted at maximum levels up to the eleventh day of the study in the male mice or up to the seventh day in the females. The dermal LD_{50} in rats was > 5000 mg/kg bw and the inhalation LC_{50}, also in rats, was > 5.08 mg/L for an exposure of 4 h. Prothioconazole-desthio is not irritating to rabbit skin and eyes and is not sensitizing in the Buehler skin patch test in guinea-pigs.

In short-term studies of toxicity, a common target organ in rat, mouse and dog was the liver and effects on this organ formed the basis for the NOAEL in the short-term studies in rats. Effects in the liver (not always adverse and not always at critical doses for those effects that were adverse) included increased organ weight, induction of CYP isoenzymes, hepatocellular hypertrophy, increased hepatocytic fatty vacuolation, single-cell or focal necrosis, hydropic degeneration and increased ploidy. The NOAELs in dietary studies were 2.2 mg/kg bw per day in a 13-week study in rats and 10 mg/kg bw per day in a 30-week study in dogs. No NOAEL was identified in mice, but it was certainly greater than 12 mg/kg bw per day.

Long-term dietary studies in rats and mice of prothioconazole-desthio confirmed that the primary target organ was the liver. The liver effects were increased weights, hypertrophy, cytoplasmic change and a shift in fat storage from the periportal (usual) to the centrilobular region of the liver in rats and increased incidences of periacinar fat accumulation in the liver of mice. Mild alteration in plasma thyroid hormone concentrations in rats was possibly a consequence of induction of hepatic enzymes, but there was no accompanying notable histopathology in the thyroids. In addition, in rats, there were increased incidences of adrenal cortical vacuolization in males at either of the two higher doses. There was no evidence for the carcinogenicity of prothioconazole-desthio in rats or mice. The NOAEL in a 2-year dietary study in rats was 20 ppm, equal to 1.1 mg/kg bw per day, on the basis of microscopic changes in the liver and ovary at 140 ppm, equal to 8.0 mg/kg bw per day. The NOAEL in an 18-month dietary study in mice was 12.5 ppm, equal to 3.1 mg/kg bw per day, on the basis of microscopic changes in the liver at 50 ppm, equal to 12.8 mg/kg bw per day.

Prothioconazole-desthio was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. Genotoxicity was not observed in any of these assays.

The Meeting concluded that prothioconazole-desthio is unlikely to be genotoxic.

On the basis of the absence of carcinogenicity in rodents and the absence of genotoxicity, the Meeting concluded that prothioconazole-desthio is unlikely to pose a carcinogenic risk to humans.

The reproductive toxicity of prothioconazole-desthio was investigated in a one-generation pilot study and a two-generation study of reproduction in rats. One study for potential developmental toxicity after oral dosing was conducted in rats and one in rabbits. In addition, prothioconazole-desthio was tested for developmental neurotoxicity in one study in rats. Reproductive effects of prothioconazole-desthio in rats comprised reduced litter size, reduced pup viability, pre-weaning growth retardation and an increased incidence of cleft palate. In the main two-generation study, a number of females in the parental and F_1 generations exhibited dystocia (difficulty in giving birth). In both the pilot and main study, the NOAELs for parental toxicity were similar to, or lower than, the NOAELs for reproductive and neonatal effects. The NOAEL for systemic toxicity in the parental rats was 40 ppm, equal to 2.7 mg/kg bw per day, on the basis of hepatocellular vacuolation in males at 160 ppm, equal to 10.4 mg/kg bw per day. In the offspring, the NOAEL was 160 ppm, equal to 10 mg/kg bw per day, on the basis of decreased neonatal viability, reduced pup weight gain, and cleft palate at 640 ppm, equal to 41 mg/kg bw per day. The NOAEL for reproductive effects was 40 ppm, equal to 10 mg/kg bw per day, on the basis of dystocia at 640 ppm, equal to 41 mg/kg bw per day.

In a study of developmental toxicity in rats given prothioconazole-desthio by gavage on days 6–15 of gestation, the NOAEL for maternal toxicity was 30 mg/kg bw per day on the basis of reduced body weight gain, reduced food consumption and increased liver weight and histological changes in the liver at 100 mg/kg bw per day. There was no NOAEL for developmental toxicity in this study, in which there were increased incidences of fetuses with supernumerary ribs at all doses, including

10 mg/kg bw per day, the lowest dose tested. In a follow-up to this study, another study of developmental toxicity was conducted in rats given prothioconazole-desthio over a lower dose range by gavage on days 6–15 of gestation. The NOAEL for developmental toxicity was 1 mg/kg bw per day on the basis of increased incidence of supernumerary rudimentary ribs at 3 mg/kg bw per day.

In a study of developmental toxicity in rabbits given prothioconazole-desthio by gavage on days 6–18 of gestation, the NOAEL for maternal toxicity was 2 mg/kg bw per day on the basis of histological changes in the liver at 10 mg/kg bw per day. The NOAEL for developmental toxicity was 2 mg/kg bw per day on the basis of increased incidence of fetuses with any abnormality (primarily arthrogryposis and cleft palate) at 10 mg/kg bw.

In a study of developmental neurotoxicity in rats given prothioconazole-desthio from day 6 of gestation until day 21 of lactation, the NOAEL was 500 ppm, equal to 43.3 mg/kg bw per day, the highest dose tested, on the basis of the absence of effects on neurobehavioural, learning and memory parameters, on brain weight, brain morphometry and on neuropathology parameters at this dose.

In summary, on the basis of the results of the submitted studies of toxicity, the acute oral toxicity of both prothioconazole and its desthio metabolite was low and neither compound showed any mutagenic or carcinogenic potential. The NOAELs for the short-term and long-term studies as well as the studies of reproductive toxicity and developmental toxicity were clearly lower for prothioconazole-desthio than for prothioconazole. In the studies of developmental toxicity, increased incidences of cleft palate in rats and rabbits were observed with prothioconazole-desthio at doses of 100 and 50 mg/kg bw per day, respectively, with no cleft palate induction at 30 and 10 mg/kg bw per day, respectively. Cleft palate was not observed in studies of developmental toxicity with the parent compound, prothioconazole, but was observed in a study of reproductive toxicity in rats given prothioconazole at a dose of 41 mg/kg bw per day.

No adverse effects have been identified in workers involved in the development, production or formulation of prothioconazole. No further information on medical surveillance or poisoning incidents was available.

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

Toxicological evaluation

Prothioconazole

An ADI of 0–0.05 mg/kg bw was established for prothioconazole based on the NOAEL of 5 mg/kg bw per day, identified on the basis of gross and microscopic changes in the liver and kidneys in a 2-year study of toxicity and carcinogenicity in rats treated by gavage, and a safety factor of 100.

An ARfD of 0.8 mg/kg bw was established for women of childbearing age based on a NOAEL of 80 mg/kg bw per day, identified on the basis of a marginally increased incidence of supernumerary rudimentary ribs that might be attributable to a single exposure at 750 mg/kg bw per day in a study of developmental toxicity in rats, and with a safety factor of 100. The Meeting concluded that the establishment of an ARfD for the general population was not necessary on the basis of its low acute toxicity, the lack of evidence for any acute neurotoxicity and absence of any other toxicologically relevant effect that might be attributable to a single dose.

Prothioconazole-desthio

Since the residue definition for risk assessment in all commodities is expressed as prothioconazole-desthio and this metabolite is of higher toxicity than the parent, ARfD values and an ADI were also established for prothioconazole-desthio.

An ADI of 0–0.01 mg/kg bw was established for prothioconazole-desthio based on the NOAEL of 1.1 mg/kg bw per day, identified on the basis of microscopic changes in the liver and ovaries in a 2-year dietary study of toxicity and carcinogenicity in rats, and with a safety factor of 100.

An ARfD of 0.01 mg/kg bw was established for women of childbearing age based on a NOAEL of 1 mg/kg bw per day, identified on the basis of increased incidence of supernumerary rudimentary ribs that might be attributable to a single exposure at 3 mg/kg bw per day in a study of developmental toxicity in rats, and with a safety factor of 100. Although the increased incidence at 3 mg/kg bw per day was only significant on the basis of the number of fetuses, this was the lower limit of a clear dose-related response curve.

The Meeting also established an ARfD of 1 mg/kg bw for the general population based on a NOAEL of 100 mg/kg bw, identified on the basis of clinical signs in studies of toxicity in mice and rats given single doses, and a safety factor of 100.

A toxicological monograph was prepared.

Levels relevant to risk assessment for prothioconazole

Species	Study[a]	Effect	NOAEL	LOAEL
Mouse	18-month study of toxicity and carcinogenicity	Toxicity	10 mg/kg bw per day	70 mg/kg bw per day
		Carcinogenicity	500[b] mg/kg bw per day	—
Rat	Two-year studies of toxicity and carcinogenicity	Toxicity	5 mg/kg bw per day	50 mg/kg bw per day
		Carcinogenicity	750[b] mg/kg bw per day	—
	Two-generation study of reproductive toxicity	Reproductive toxicity	95.6 mg/kg bw per day	726 mg/kg bw per day
		Parental toxicity	9.7 mg/kg bw per day	95.6 mg/kg bw per day
		Offspring toxicity	95.6 mg/kg bw per day	726 mg/kg bw per day
	Developmental toxicity	Maternal toxicity	80 mg/kg bw per day	750 mg/kg bw per day
		Embryo and fetal toxicity	80 mg/kg bw per day	750 mg/kg bw per day
Rabbit	Developmental toxicity	Maternal toxicity	80 mg/kg bw per day	350 mg/kg bw per day
		Embryo and fetal toxicity	80 mg/kg bw per day	350 mg/kg bw per day

[a] In all cases, prothioconazole was administered by gavage.

[b] Highest dose tested.

Levels relevant to risk assessment for prothioconazole-desthio

Species	Study	Effect	NOAEL	LOAEL
Mouse	Single dose LD_{50} study	Toxicity	100 mg/kg bw	500 mg/kg bw
	18-month study of toxicity and carcinogenicity	Toxicity	12.5 ppm equal to 3.1 mg/kg bw per day	50 ppm equal to 12.8 mg/kg bw per day
		Carcinogenicity	200 ppm equal to	—

			51.7 mg/kg bw per day[b]	
Rat	Single-dose LD_{50} study	Toxicity	100 mg/kg bw	500 mg/kg bw
	Two-year studies of toxicity and carcinogenicity	Toxicity	20 ppm equal to 1.1 mg/kg bw per day	140 ppm equal to 8.0 mg/kg bw per day
		Carcinogenicity	980 ppm equal to 57.6[b] mg/kg bw per day	—
	Two-generation study of reproductive toxicity	Reproductive toxicity	160 ppm equal to 10.0 mg/kg bw per day	640 ppm equal to 41.2 mg/kg bw per day
		Parental toxicity	40 ppm equal to 2.7 mg/kg bw per day	160 ppm equal to 10.4 mg/kg bw per day
		Offspring toxicity	160 ppm equal to 10.0 mg/kg bw per day	640 ppm equal to 41.2 mg/kg bw per day
	Developmental toxicity	Maternal toxicity	30 mg/kg bw per day[b]	—
		Embryo and fetal toxicity	1 mg/kg bw per day	3 mg/kg bw per day
Rabbit	Developmental toxicity	Maternal toxicity	2 mg/kg bw per day	10 mg/kg bw per day
		Embryo and fetal toxicity	2 mg/kg bw per day	10 mg/kg bw per day
Dog	30-week study of toxicity	Toxicity	10.1 mg/kg bw per day	69.9 mg/kg bw per day

[b] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.05 mg/kg bw (for prothioconazole)

0–0.01 mg/kg bw (for prothioconazole-desthio)

Estimates of acute reference doses

0.8 mg/kg bw for women of childbearing age (for prothioconazole)

Unnecessary for the general population (for prothioconazole)

0.01 mg/kg bw for women of childbearing age (for prothioconazole-desthio)

1 mg/kg bw for the general population (for prothioconazole-desthio).

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 prothioconazole and prothioconazole-desthio

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and extensively, > 90%
Distribution	Distributed throughout the body; higher concentrations

	in liver and gastrointestinal tract	
Potential for accumulation	No evidence	
Rate and extent of excretion	High, > 70% within 24 h, but subsequently low rate	
Metabolism in animals	18 metabolites identified	
Toxicologically significant compounds (animals, plants and environment)	Parent, prothioconazole-desthio and M02	
Acute toxicity	*Prothioconazole*	*Prothioconazole-desthio*
Rat, LD_{50}, oral	> 6200 mg/kg bw	> 2500 mg/kg bw
Rat, LC_{50}, inhalation	> 4.9 mg/L[a] (4 h)	> 5.08 mg/L[a] (4 h)
Rat, LD_{50}, dermal	> 2000 mg/kg bw[a]	> 5000 mg/kg bw[a]
Rabbit, dermal irritation	Not irritating	Not irritating
Rabbit, ocular irritation	Not irritating	Not irritating
Dermal sensitization	Not sensitizing (Buehler skin patch test in guinea-pigs; lymph node assay in mice)	Not sensitizing (Buehler skin patch test in guinea-pigs)
Short-term studies of toxicity		
Target/critical effect	Liver, kidney	Liver
Lowest relevant oral NOAEL	25 mg/kg bw per day (3-month study in dogs,	2.2 mg/kg bw per day (13-week study in rats
Lowest relevant dermal NOAEL	1000 mg/kg bw per day[a] (4-week study in rats)	No data
Lowest relevant inhalation NOAEC	No data	No data
Genotoxicity		
	Not genotoxic in vivo, but mixed results in vitro	Not genotoxic
Long-term studies of toxicity and carcinogenicity		
Target/critical effect	Liver, kidney	Liver, kidney
Lowest relevant NOAEL	5 mg/kg bw per day (2-year study in rats)	1 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Not carcinogenic	Not carcinogenic
Reproductive toxicity		
Reproductive target/critical effect	Disruption of oestrus cycle; reduced implantation sites and litter size; increased time to insemination; increased gestation time; all associated with severe maternal toxicity	Decreased neonatal viability, reduced pup-weight gain, and cleft palate at maternal toxic doses
Lowest relevant reproductive NOAEL	100 mg/kg bw per day	10 mg/kg bw per day
Developmental target/critical effect	Not teratogenic; abortions, total litter loss, reduced fetal body weight, delayed	Teratogenic (cleft palate, arthrogryposis); abnormal fetuses, increased incidence of supernumerary

	ossifications, rudimentary supernumerary ribs	rudimentary ribs
Lowest relevant developmental NOAEL	80 mg/kg bw per day (rat, rabbit)	1 mg/kg bw per day (rat, rabbit)
Neurotoxicity/delayed neurotoxicity		
	No signs of neurotoxicity	No signs of neurotoxicity
Other toxicological studies		
	Induction of liver xenobiotic metabolizing enzymes	Clinical signs of toxicity in single-dose studies (LD_{50}) in rats and mice
	Several metabolites in addition to prothioconazole-desthio and MO2 have been investigated, but are not considered to be toxicologically significant	
Medical data		
	No reports of toxicity in workers exposed during manufacture or use	

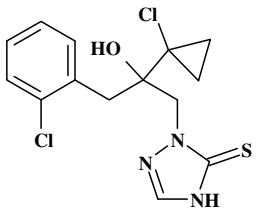
Summary

Prothioconazole	*Value*	*Study*	*Safety factor*
ADI	0–0.05 mg/kg bw	Dog, 1-year study of toxicity; and rat, 2-year study of toxicity and carcinogenicity	100
ARfD	0.8 mg/kg bw for women of childbearing age	Rat, study of developmental toxicity	100
Prothioconazole-desthio	*Value*	*Study*	*Safety factor*
ADI	0–0.01 mg/kg bw	Rat, 2-year study of toxicity and carcinogenicity	100
ARfD	0.01 mg/kg bw for women of childbearing age	Rat, study of developmental toxicity	100
	1 mg/kg bw for the general population	Rat and mouse, LD_{50} studies	100

[a] Only dose tested.

RESIDUE AND ANALYTICAL ASPECTS

Prothioconazole was considered for the first time by the present meeting. It is a systemic fungicide with a triazolinthione structure. The manufacturing process is not enantiomer-selective. All technical quality prothioconazole is produced as a 50:50 racemate.



IUPAC: 2-[(2*RS*)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2H-1,2,4-triazole-3(4H)-thione

CAS: 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione.

The code and descriptive names of metabolites mentioned in the appraisal are:

M01	JAU 6476-S-methyl
M02	JAU 6476-sulfonic acid
M03	JAU 6476-triazolinone
M04	JAU 6476-desthio
M05	JAU 6476-N-glucuronide
M06	JAU 6476-S-glucuronide
M08	JAU 6476-4-hydroxy
M09	JAU 6476-benzylpropyldiol
M11	JAU 6476-disulfide
M12	JAU 6476-thiazocine
M13	1,2,4-triazole
M14	JAU 6476-desthio-3-hydroxy
M15	JAU 6476-desthio-4-hydroxy
M16	JAU 6476-desthio-5-hydroxy
M17	JAU 6476-desthio-6-hydroxy
M18	JAU 6476-desthio-α-hydroxy
M19	JAU 6476-desthio-α-acetoxy
M20	2-chlorobenzoic acid
M21	JAU 6476-desthio-3-hydroxy-glucoside
M22	JAU6476-desthio-4-hydroxy-glucoside
M23	JAU 6476-desthio-6-hydroxy-glucoside
M24	JAU 6476-desthio-hydroxy-dienyl-cysteine
M28	JAU 6476-desthio-hydroxy-methoxy
M29	Triazolylacetic acid (TAA)
M30	Triazolylhydroxypropionic acid (THP)
M31	Triazolylalanine (TA)
M32	JAU 6476-desthio-3,4-dihydroxy-diene
M33	JAU 6476-desthio-3,4-dihydroxy
M34	JAU 6476-desthio-dihydroxy
M36	JAU 6476-desthio-4,5-dihydroxy-diene
M38	JAU 6476-desthio-dihydroxy-diene
M40	JAU 6476-dihydroxy-diene
M44	JAU 6476-desthio-phenyl-cysteine
M45	JAU 6476-triazolyl-ethanol

M46	JAU 6476-triazolyl-ethanol-glucoside
M52	JAU 6476-desthio-3,4-dihydroxy-dienyl-glucuronide
M54	JAU 6476-desthio–3-hydroxy-glucoside-malonic acid
M55	JAU 6476-desthio-4-hydroxy-glucoside-malonic acid
M56	JAU 6476-desthio-6-hydroxy-glucoside-malonic acid
M59	JAU 6476-hydroxy-sulfonic acid glucoside
M60	JAU 6476-hydroxy-disulfonic acid glucoside
M62	JAU 6476-triazolyl-sulfonic acid-ethanol-glucoside
M71	JAU 6476-desthio-glucuronide
M73	JAU 6476-desthio-dihydroxy-dienyl-glucuronide
M74	JAU 6476-desthio-4-hydroxy-glucuronide
M75	JAU 6476-desthio-hydroxy-glucuronide
M80	Thiocyanate
M82	JAU 6476-desthio-hydroxy-methoxy-sulfate
M84	JAU 6476-desthio-hydroxy-sulfate
M85	JAU 6476-desthio-4,5-dihydroxy-dienyl-glucuronide
M87	JAU 6476-desthio-3-hydroxy-glucuronide

The Meeting received comprehensive information for the evaluation of prothioconazole as a new compound in accordance with the data requirements specified in the *FAO Manual*[40].

The metabolism of prothioconazole, in plants and animals was investigated using [phenyl-UL-^{14}C]prothioconazole referred to as phenyl-label, and [3,5-triazole-^{14}C] labelled parent compound referred to as triazole-label. In addition, studies were conducted using [phenyl-UL-^{14}C]- and [3,5-triazole-^{14}C] labelled prothioconazole-desthio *(M04)* which is derived from the parent compound by losing the thione group.

Animal metabolism

Information was provided on the metabolism of prothioconazole in rats, lactating goats and laying hens.

When rats were orally dosed the prothioconazole was rapidly absorbed and excreted mainly via the bile. The major types of metabolic reactions identified were conjugation with glucuronic acid, oxidative hydroxylation of the phenyl moiety and desulfuration. Many of the metabolites were derived from prothioconazole-desthio.

Prothioconazole-S-glucuronide, prothioconazole-desthio and prothioconazole were the principal components, in addition to 10 minor metabolites identified in excreta. The studies with prothioconazole showed that metabolite prothioconazole-desthio, which is the major metabolite of prothioconazole in wheat, amounted to about 18% of the administered dose occurred in the faeces, and a maximum 0.07% in the urine. A study with the metabolite prothioconazole-desthio, which is the major metabolite of prothioconazole in wheat, revealed that about 68% to 74% of the administered dose occurred in the faeces, and a maximum of 10% to 11% in the urine.

The goat metabolism studies followed the same design. In each trial one goat received 10 mg/kg body weight/day dose on three consecutive days in intervals of 24 h. The dose level corresponded to about 195 ppm test substance in the feed. The animals were sacrificed 5 h after administration of the final dose.

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[40] FAO. 2002. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. Appendix IX. Maximum proportion of agricultural commodities in animal feed. *FAO Plant Production and Protection Paper*, 170.

Following the administration of phenyl-, triazole-labelled prothioconazole or phenyl labelled prothioconazole-desthio, the goats excreted about 67, 59 and 74%% administered dose, respectively, within five hours after the last dose. About 0.02–0.05% of the total dose was found in the milk, and about 0.7–1.9% of the total dose was in the organs and tissues.

The TRR values, derived from the administration of labelled parent compound, expressed in mg as equivalents/kg sample material, were 6.1–6.2 mg/kg in liver, 4.5–6.8 mg/kg in kidney, 0.17–0.21 mg/kg in omental fat, 0.11–0.162 mg/kg perirenal fat, 0.11–0.15 mg/kg in subcutaneous fat and 0.08–0.14 mg/kg in muscle.

The metabolic profiles for milk and the edible tissues and organs showed that parent prothioconazole was a major compound in all tissues and organs (> 10% of TRR), but only of minor importance in milk (< 1–3% of TRR or ≤ 0.005 mg/kg). Other metabolites detected in all matrices were prothioconazole-S-glucuronide, prothioconazole–desthio and a number of the hydroxy moiety containing metabolites *(M08, M15, M32, M38, M40,)*, their glucuronides *(M10, M49, M52, M69, M72, M73, M74)* and sulfate conjugates *(M82, M83, M84)*. Following the administration of triazole labelled prothioconazole the only label specific metabolite identified was thiocyanate: 41.1% of TRR, 0.061 mg/kg in milk, 30% in muscle, 12% in fat, 9% in kidney and 2% in liver. Thiocyanate is well known as the main detoxification product after cyanide exposure, and it is a natural constituent of milk.

The administration of phenyl-labelled prothioconazole-desthio resulted in somewhat higher level of total residues. The presence of triazole derivatives or free 1,2,4-triazole at concentrations above 0.01 mg/kg was excluded in each matrix under investigation.

In order to simplify the metabolic pattern, the organs and milk of goat was subjected to acid hydrolysis. The large number of metabolites present in the extracts (M32, M36, M52, M71, M73, M74, M75, M84, M85, *M86 M87, M91*) was reduced to prothioconazole-desthio, *M14*, *M15*, *M33*, *M35* and *M71*.

When prothioconazole-desthio was administered to goat the proportion of identified/characterized metabolites in the TRR after the acid hydrolysis was higher in milk, muscle and kidney than without hydrolysis, and it was practically equal in liver (58.4% and 59.9%) and fat (75% and 74%)

Six laying hens were orally dosed with phenyl or triazole radiolabelled prothioconazole at a dose level of 10 mg/kg body weight. The hens received the doses on three consecutive days at intervals of 24 h. The animals were sacrificed 5 h after the administration of the final dose.

The edible tissues and organs (liver, fat and muscle), pooled excreta and eggs collected daily were analysed by HPLC and TLC. Extractability was high for all tissues and ranged from 77% to 98% of the TRR. The identification rates ranged from 42% and 84%.

About 78% of the phenyl labelled prothioconazole dose administered was already excreted five hours after the last dose. Very low amounts of the total dose were found in eggs during the experimental phase (about 0.01%) and in organs/tissues investigated after sacrifice of the animals (about 0.9%). In the study with the triazole label about 66% of the administered dose was excreted five hours after the last dose. Also very low amounts of the total dose were found in eggs during the experimental phase (about 0.01%) and in organs/tissues investigated after sacrifice of the animals (about 0.8%).

The TRR values, derived from the phenyl- and triazole labelled prothioconazole and expressed in mg as equivalents/kg sample material were, respectively, 4.0–3.5 mg/kg in liver, 0.036–0.05 mg/kg in eggs, 0.45–0.29 mg/kg in subcutaneous fat, 0.089–0.12 mg/kg in muscle.

The parent compound was the major residue component in liver (31% of TRR, 1.1 mg/kg), fat (30% of TRR, 0.14 mg/kg) and muscle (11% of TRR, 0.01 mg/kg). Metabolites exceeding 10% of TRR were prothioconazole-desthio (29.0% of TRR, 0.13 mg/kg) and prothioconazole -S-methyl (20% of TRR, 0.088 mg/kg) in fat, and prothioconazole-S-glucuronide in muscle (15.5% of TRR,

0.014 mg/kg), and liver (*M06*, 15% of TRR, 0.53 mg/kg). The other metabolites occurring in smaller proportion were *M05 M08*, *M10*, *M15, M80* and the label specific metabolites (*M45* and 1,2,4-triazole). All other metabolites identified were either glucuronic acid conjugates derived directly from prothioconazole or from the hydroxylated parent compound or sulfate and glucuronic acid conjugates *(M52, M82, M83, M84)* (in sum 14% of TRR, 0.47 mg/kg).

In eggs the major residue components were prothioconazole-S-glucuronide (24% of TRR, 0.012 mg/kg), prothioconazole-desthio (20% of TRR, 0.007 mg/kg), *M45* (15.6% of TRR, 0.008 mg/kg), 1,2,4-triazole (11% of TRR, 0.006 mg/kg), and thiocyanate (9.8% of TRR, 0.005 mg/kg). Prothioconazole (*3.6% of TRR, 0.002 mg/kg)*, *M15* and *M01* were also detected raging from 1.9% to 3.3% of the TRR.

In summary, the metabolic profile was similar in goats and hens and their edible tissues investigated in the studies with phenyl- and triazole-labelled prothioconazole. The parent compound was one of the major residues in most matrices of goat and hen with the exception of egg in which prothioconazole-desthio was predominant.

The majority of metabolites were derived from the intact parent molecule, retaining the triazolinthione structure, which was detected in all studies with prothioconazole, independent of the radiolabel used. A label specific metabolite common for hen and goat was thiocyanate. This metabolite was detected in all sample materials under investigation. It was a major metabolite in milk and muscle of goat and was detected at about 10% of the TRR in eggs of hens. Two additional label specific metabolites were identified exclusively in laying hen: free 1,2,4-triazole and prothioconazole-triazolyl-ethanol, which were detected in all matrices, including eggs, but they were not present in milk, organs or edible tissues of goat.

The key metabolite in all matrices was prothioconazole-S-glucuronide. Due to the conjugation with glucuronic acid, the sulfur was protected against cleavage. Thus, the metabolic route via prothioconazole-desthio was impeded. Prothioconazole-desthio and all its derivatives accounted in each sample matrix, except in fat and eggs, for less than 20% of the TRR. The major metabolic routes include molecules containing the intact parent compound.

Plant metabolism

The behaviour and metabolism of prothioconazole after spray application in wheat, peanut and sugar beets was investigated using phenyl- and triazole-labelled parent compound. Additionally, the metabolism of phenyl-labelled prothioconazole after seed treatment of wheat and the metabolism of prothioconazole-desthio following spray application were studied.

When phenyl- and triazole-labelled prothioconazole was used for foliar treatment of wheat approximately at the recommended rate (0.2 kg/ha), the total radioactive residue (TRR) levels in forage, hay, straw and grain were 10 and 8.0 mg/kg, 8.9 and 11 mg/kg, 27 and 8 mg/kg and 0.08 and 5 mg/kg (ai equivalents), respectively.

When the seeds were treated at 1× rate the total radioactive residue (TRR) levels were very low and amounted to 0.02 mg/kg in forage, 0.02 mg/kg in hay, 0.03 mg/kg in straw and 0.008 mg/kg (as equivalents) in grain, respectively. Following the 5× treatment the TRR were 0.07 mg/kg in forage, 0.09 mg/kg in hay, 0.28 mg/kg in straw and < 0.01 mg/kg in grain.

Following foliar application with phenyl and triazole labelled parent compounds, the identified metabolites accounted respectively for 73% and 66% of the TRR in forage, 65% and 75% of the TRR in hay, 66% and 61% of the TRR in straw and 34% and 94% of the TRR in grain.

Prothioconazole was extensively metabolized in wheat. Prothioconazole-desthio was found as the main metabolite in all crop parts: forage, (35.4% of the TRR, 3.7 mg/kg), hay (18.5% of the TRR, 1.64 mg/kg), straw (22% of the TRR, 6.0 mg/kg) and grain (16% of the TRR, 0.014 mg/kg).

The hydroxylated metabolites of prothioconazole-desthio *(M14, M15, M17)* and the corresponding glucosides were present in forage, hay and straw, but wheat grain contained only M14, M15.

In addition, the parent compound and the following metabolites were identified in wheat forage, hay and straw: *M02*, *M03*, *M11* and *M18*.

Following the foliar application of prothioconazole-desthio, TRR in forage was 10 mg/kg (day 0) and 11 mg/kg (day 14). The TRRs in straw, and grain were 29 mg/kg and 2.9 mg/kg, respectively.

Identified metabolites in the tested crop parts accounted for 90–94% of the TRR in forage, 84% of the TRR in straw and 94% of the TRR in grain.

The prothioconazole-desthio was slowly metabolized in wheat. It was the dominant constituent of the residue in forage (77% of TRR) and straw (72% of TRR) at harvest. However, it was only detected in small amounts in grain (0.07 mg/kg), where the residue was mainly made up by triazolylacetic acid (0.91 mg/kg) and triazolylalanine (1.72 mg/kg). Free 1,2,4-triazole was not detected in any of the crop parts.

The behaviour and metabolism of phenyl- and triazole-labelled prothioconazole were investigated after 3 spray applications with EC 250 formulation to peanuts at a rate of 297 g as/ha/application.

The total radioactive residue (TRR) levels in peanut hay were 107.5 mg/kg and 47.4 mg/kg (parent equivalents) for the phenyl- and triazole-labelled parent compound, respectively. The TRR in nutmeat was 0.29 mg/kg and 1.4 mg/kg (parent equivalents) for the phenyl- and triazole-label, respectively. Identified metabolites accounted for 74% and 77% of the TRR in peanut hay and 65% and 83% of the TRR in nutmeat for the phenyl- and triazole-label, respectively.

Following the treatments with phenyl-labelled parent compound, the major metabolites in peanut hay included prothioconazole-desthio *(*28% of TRR, 30 mg/kg) and its derivatives *(M14/M15) amounting to* 7.3% of TRR, 7.8 mg/kg and 2.0% of TRR, 2.2 mg/kg, respectively. In addition to the parent compound two other metabolites of prothioconazole were identified as prothioconazole-sulfonic acid and *M03* (2.1% of TRR, 2.3 mg/kg and 1.6% of TRR, 1.7 mg/kg, respectively). None of these compounds were detected in nutmeat. Furthermore, metabolites derived from prothioconazole-desthio and *M02* but lacking the aromaticity of the phenyl ring were detected in the hay and in the case of prothioconazole-desthio derivatives in nutmeat too. But the main portion of radioactivity (48% of TRR in the MSPD extracts) of the nutmeat was characterized as natural occurring oil, and was determined as fatty acids.

When triazole labelled parent compound was applied the metabolites identified in peanut hay included prothioconazole-desthio (as main metabolite, 24% of the TRR, 11 mg/kg) and its hydroxylated derivatives (*M14, M15* amounting to 6.6% of TRR, 3.1 mg/kg and 3% of TRR, 1.4 mg/kg, respectively). Two other metabolites of prothioconazole were identified as *M02* and *M03* (2.7% of TRR, 1.3 mg/kg and 3.6% of TRR, 1.7 mg/kg, respectively). Furthermore, metabolites derived from prothioconazole-desthio and *M02* but lacking the aromaticity of the phenyl ring were detected in the hay. With the exception of prothioconazole-desthio, none of these metabolites were detected in nutmeat.

The major metabolites in nutmeat, are conjugates of 1,2,4-triazole (*M31,* 48% of TRR, 0.67 mg/kg and *M30,* 24% of the TRR, 0.34 mg/kg). However, free 1,2,4-triazole was not detected in peanuts. A small portion of the radioactivity of nutmeat (3.0% of the TRR) was characterized as fatty acids in naturally occurring oil. The detection of radiolabelled fatty acids in nutmeat is assumed to be a consequence of the mineralisation of phenyl-labelled prothioconazole to $^{14}CO_2$ in the soil which is subsequently taken up by the plant and incorporated into natural products.

Four foliar spray applications of prothioconazole were made to sugar beet plants at an average rate of 288 and 289 g as/ha/application for a total rate of 1152 and 1157 g ai/ha of the phenyl- or triazole-labelled parent compound, respectively.

The TRR levels in sugar beet tops were 4.3 mg/kg and 5.2 mg/kg (expressed as mg as equivalents/kg) for the phenyl- and triazole-labelled parent compound, respectively. The TRR in sugar beet roots was 0.12 mg/kg and 0.13 mg/kg for the phenyl- and triazole-label, respectively. Identified metabolites accounted for 65% and 69% of the TRR in sugar beet tops and 60% and 61% of the TRR in the roots for the phenyl- and triazole-label, respectively. Additionally, 33% and 29% of the TRR was characterized in the tops and 32% and 33% in the roots for the phenyl- and triazole-label, respectively.

When the phenyl labelled compound was used the major metabolite identified in sugar beet tops were prothioconazole-desthio *(28% of TRR, 1.2 mg/kg)* and isomers of its hydroxyl-glucosides *(M21/M22/M23)*, *M24* and *M59*. In the sugar beet roots only prothioconazole-desthio (58% of the TRR, 0.068mg/kg) and *M03* were identified. In addition to the parent compound, the following metabolites were identified in sugar beet tops: *M03*, *M24*, *M59* and *M60*. In the sugar beet roots only prothioconazole-desthio (25% of the TRR, 0.033 mg/kg) and *M03* was identified.

In the case of treatment with triazole labelled compound, the metabolites identified in sugar beet tops were prothioconazole-desthio (19% of the TRR, 0.99 mg/kg), and the corresponding hydroxy-glucoside isomers *(M21/M22/M23).*

Prothioconazole was extensively metabolized in sugar beets to numerous components; only a small quantity of unchanged prothioconazole was detected (5–7% of TRR from triazole and phenyl labelled studies). The major metabolite was prothioconazole-desthio arising from oxidation of the sulfur of the triazolinthione ring to form the corresponding sulfonic acid with subsequent elimination of the sulfonic acid group. Hydroxylation of the phenyl ring and/or benzylic carbon to form multiple monohydroxy isomers was observed with subsequent conjugation with glucose or further reaction to produce *M24*. The triazole moiety was released leading to triazolylalanine and triazolylhydroxyl-propionic acid. These metabolites may also have been formed as a result of 1,2,4-triazole uptake from the soil followed by immediate conjugation. Free 1,2,4-triazole was not detected suggesting an immediate conjugation of the released triazole. Additional triazole-label specific metabolites were formed by elimination of the chlorophenyl moiety *(M45, M46* and *M62).* The metabolic pathway is similar to that seen in peanuts and spring wheat conducted with phenyl- or triazole-labelled prothioconazole.

In summary, irrespective of the crop or application mode (foliar or soil), the major metabolites found in all crops were prothioconazole-desthio and, specific to the triazole-label studies, the metabolites triazolylalanine, triazolylhydroxypropionic acid and triazolylacetic acid. Based on the results of these studies it was postulated that 1,2,4-triazole *(M13)* was taken up from the soil and transformed directly in the plants to these metabolites. No free 1,2,4-triazole was detected in any matrix, either in the target plant metabolism studies or in the confined rotational crops study.

Environmental fate

Prothioconazole is a very weak acid and its water solubility is low at pH 4 and increases with increasing pH. It is readily soluble at pH 9. Its log K_{ow} increases from 2.0 at pH 9 to 4.2 at pH 4. Its vapour pressure and volatility are low.

Prothioconazole was found to be stable at pH 7 and 9 while only very low degradation was observed at pH 4. Hydrolysis is of minor importance for its degradation in the environment.

The photodegradation of prothioconazole was studied in sterile aqueous buffer solution at pH 7 and 25 °C using [phenyl-UL-^{14}C] and [3,5-Triazole-^{14}C]prothioconazole. Under the experimental conditions prothioconazole was completely photodegraded. Experimental half-lives were determined to be 48 h (mean of two labels). Prothioconazole-desthio was identified as main degradation product

at a maximum level of 56% of the applied radioactivity. Two further major metabolites were identified as prothioconazole-thiazocine at 15% and 1,2,4-triazole at 12%. Recovery at the latest sampling intervals ranged from 104% to 107% of the applied radioactivity.

The experimental data indicate that the solar radiation contributes to the primary degradation and elimination of prothioconazole in aquatic systems of the environment.

Aerobic degradation of prothioconazole was studied in several soils under laboratory conditions in the dark applying the test substance at about 600 g ai/ha treatment, equivalent to the maximum recommended field application rate for one growing season.

The amount of radioactivity, expressed in percent of applied radioactivity, bound to soil increased during the test period and reached a maximum and then decreased until the end of the test period. In the course of the studies, the amounts of radioactivity which could be extracted decreased. At all sampling intervals, no volatile organic compounds were found (< 0.1% of the applied radioactivity). Prothioconazole was rapidly degraded in soil under aerobic conditions to CO_2, the final degradation product. Parallel to mineralisation, bound residues were formed. The calculated DT_{50} values of prothioconazole determined in the laboratory soil degradation studies were in the range of 0.07 to 1.3 days. The DT_{50} values of the two major metabolites prothioconazole-S-methyl and prothioconazole-desthio determined in the laboratory trials were in the range of 5.9 to 46 days and 7.0 to 34 days, respectively.

A total of eight metabolites were identified or characterized in the soil extracts along with the parent compound and $^{14}CO_2$. The major metabolites (> 10% of the applied radioactivity) were *M01* and prothioconazole-desthio, which were both degradable under aerobic conditions and thoroughly metabolized to carbon dioxide. Prothioconazole -sulfonic acid, *M03*, *M13*, *M14, M15, M16*, *M17* and *M20* were found as minor metabolites.

Eight field trials were conducted at different sites in northern and southern Europe. The DT_{50} values for prothioconazole ranged from 1.3 to 2.8 days (mean: 1.7 days). The corresponding DT_{90} values were in the range of 4.4 to 9.3 days (mean: 5.8 days). The dissipation times for prothioconazole-desthio ranged from 16 to 72 days (mean: 42 days), the corresponding DT_{90} values ranged from 54 to 240 days (mean: 140 days). Prothioconazole-S-methyl concentrations never exceeded the LOQ of 6 µg/kg, corresponding to less than 3% of the initial concentration of the active substance. No residues of prothioconazole or its metabolites were detected at a depth below 10 cm in the soil, with the exception of the day 89 in one trial, where residues of prothioconazole-desthio were detected between the LOD and the LOQ in the 10–20 cm layer.

Crop rotation studies

Two confined rotational crop studies were conducted in wheat, Swiss chard and turnips using phenyl- and triazole-labelled parent compound. The phenyl-labelled prothioconazole was applied once at a rate of 578 g as/ha, while four applications were made to the soil with the triazole-labelled prothioconazole at an average rate of 204 g as/ha/application. The triazole labelled compound gave higher residue concentrations ranging from 0.25 to 0.57 mg/kg in wheat forage, from 2.0 to 2.6 mg/kg in wheat hay, 1.4 to 1.7 mg/kg in wheat straw and from 3.8 to 5.9 mg/kg in wheat grain. The highest residues were observed either in the 2nd or 3rd rotations except wheat straw showing the highest residue in 1st rotation.

In the study using the triazole-labelled prothioconazole the major metabolites found in all matrices were triazolylalanine, triazolylhydroxypropionic acid and triazolylacetic acid. No free 1,2,4-triazole was detected in any matrix. Minor metabolites detected in most matrices were prothioconazole-desthio *(*except wheat grain*))*, *M18*, *M45*, and *M46*. The concentrations of minor metabolites common to both labels were lower than both identification triggers (<< 10% of TRR and < 0.05 mg/kg).

The parent compound was present if detected at all at < 0.005 mg/kg, prothioconazole-desthio was detected in all parts of the wheat plants and amounted to 0.045 mg/kg in wheat straw in the 1st rotation. Conjugation played an important role in the degradation of prothioconazole.

Field rotational crop trials were conducted at three locations in the USA (Georgia, Indiana and Kansas) to measure the magnitude of prothioconazole residues in field crops at 1-, 4-, 8-, and 12-month plant-back intervals (PBIs) following the use of the 480 SC formulation on a target crop.

Each trial contained a control and a treated plot. Two foliar spray applications with the 480 SC were made 14 (±2) days apart to bare soil in the treated plot. The total application rate was about double (800 g/ha) that of the highest label rate for prothioconazole in USA. The total prothioconazole derived residue was less than the LOQ of 0.05 mg/kg (0.02 mg/kg for grain only) in all crop RACs at the 1-month PBI. No further analyses were conducted.

It can therefore be stated that no residues above respective LOQs of 0.02 and 0.05 mg/kg would be expected in rotational crops, for human consumption, following the use of prothioconazole at maximum application rates.

Methods of analysis

The meeting received a number of validated analytical methods for the determination of residues in plant, animal tissue, milk and soils.

The residue components detected and the basic principles of the methods are summarized below.

Prothioconazole-desthio was determined with the extended DFG method S 19 in combination with GPC cleanup and GC/MS detection. The LOQs were for plant commodities were 0.02 mg/kg (tomato, orange, wheat grain, and rape seed), 0.05 mg/kg (wheat forage and straw), and for commodities of animal origin 0.01 mg/kg (milk) and 0.02 mg/kg (meat, egg and fat).

Parent prothioconazole, prothioconazole-desthio and prothioconazole sulfonic acid were extracted from plant materials with a mixture of methanol (MeOH), 30% hydrogen peroxide (H_2O_2), and aqueous sodium bicarbonate ($NaHCO_3$) at 65 °C. This extraction procedure converts prothioconazole to a mixture of prothioconazole-sulfonic acid and prothioconazole-desthio. The unchanged prothioconazole-desthio residues are extracted directly. After cleaning the extracts the residues were determined with HPLC/MS/MS. The method was validated in barley hay, straw, and grain, canola grain, mustard greens, peanut hay and nutmeat, rice straw and grain, turnip tops and roots, wheat forage, hay, straw, and grain, and wheat bran, flour, germ, middlings and shorts. The LOQ ranged between 0.02 and 0.05 mg/kg depending on the sample matrix. The method requires specific instrument setup, and stabile isotopes as internal standards consequently it is not readily applicable for enforcement purposes.

Other methods are also available for the prothioconazole sulfonic acid and prothioconazole-desthio, or prothioconazole and prothioconazole-desthio in various pant matrices with LOQs ranging from 0.01 to 0.05 mg/kg depending on the sample material.

Residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio and prothioconazole-4-hydroxy-desthio, and conjugates that can be converted to one of these compounds via acid hydrolysis in matrices of animal origin can be determined by HPLC-MS/MS (Method 00655 plus modifications). Homogenized sample materials of meat, liver and kidney were extracted twice with a mixture of acetonitrile/water, and centrifuged, each. The supernatant was evaporated to the aqueous remainder, then diluted with water, acidified and refluxed for 2 h. Milk samples were hydrolysed and purified directly after dilution with water. This hydrolysis step was performed to convert non-aromatic precursor compounds and glucuronic acid bound analogues into prothioconazole-desthio-3-hydroxy and prothioconazole-desthio-4-hydroxy. Quantification was carried out with HPLC-MS/MS. The LOQ for milk was 0.004 mg/kg and for meat, liver, kidney and fat 0.01 mg/kg.

Comparison of chromatographic profiles before and after hydrolysis clearly shows that groups of minor unidentified metabolites have disappeared. In their place the compounds with a common moiety, i.e., prothioconazole-desthio, *M14*, *M15*, *M33* and *M35* are emerging or increasing. Since the major part of the radioactivity (58–84%) is recovered, and the proportion of identified/characterized residues is higher after acid hydrolysis than without hydrolysis in milk, kidney and muscle and similar in liver and fat, it can be concluded that a significant proportion of the unidentified compounds are converted to the common moiety products.

Prothioconazole, prothioconazole-desthio, and prothioconazole-4-hydroxy residues in various bovine matrices can also be determined by LC-MS/MS (Method JA006-A04-02). This method is based on extraction with acetonitrile/water containing 250 mg/mL L-cysteine HCl (4:1 v/v), and hydrolysis of the extracts with 5N HCl under reflux for 2 hours. Prothioconazole, prothioconazole-desthio prothioconazole-4-hydroxy are quantified individually. The LOQ for each of the three analytes are: 0.004 mg/kg for milk; 0.010 mg/kg for skim milk, cream, and muscle; 0.010 mg/kg for liver; 0.010 mg/kg for kidney; and 0.050 mg/kg for fat.

Stability of pesticide residues in stored analytical samples

Freezer storage stability of metabolite prothioconazole-desthio, the main residue component in plants was examined in wheat, canola (seed, pod, straw), spinach (leaves), sugar beet (root, leaf with root collar), tomato (fruit), and field pea (field pea dried) at about minus 18 °C or below. The results demonstrate that, under freezer conditions, residues of prothioconazole-desthio were stable over a storage period of up to 36 months in wheat and at least 24 months for the other crops.

The storage stability periods are longer than the longest period of time for which samples from European field residue trials presented in this dossier were stored prior to analysis (cereals and oil seed rape).

The prothioconazole and prothioconazole-desthio residues were found to be stable (< 30% decomposition) in wheat hay, wheat straw, canola seeds, mustard greens, turnip root and tomato fruit during 36–42 months of freezer storage.

Residue definition

Prothioconazole is extensively metabolized and the most important pathways for metabolism are common to wheat, peanut and sugar beet. The nature of the residue found in wheat after foliar spray application, seed treatment and as a rotational crop was similar.

The majority of the metabolites are simply multiple structural isomers of monohydroxylated prothioconazole-desthio *(M14-M17)* and their conjugates [glucosides *(M21-M23)* and malonyl-glucosides*(M54-M56)*], and prothioconazole-dihydroxy-olefin and its conjugates. Oxidative hydroxylation led to isomers of prothioconazole-dihydroxy-diene and their conjugates. Although the sum of these compounds and their conjugates were as high as 42% of the TRR in an individual crop matrix, these conjugated and/or hydroxylated metabolites represented individually < 10% of the TRR in the plant matrices.

The proportion of parent prothioconazole was low in wheat grain, wheat forage, wheat hay, straw, peanut hay, peanut nutmeat , sugar beet tops, sugar beet roots, sugar beet forage and in rotational crops if detected at all.

Irrespective of the crop or application mode, the major metabolites found in all crops were prothioconazole-desthio and triazolylalanine, triazolyl-hydroxy-propionic acid and triazolylacetic acid. The major plant metabolite, prothioconazole-desthio was slowly metabolized in wheat. It was the dominating constituent of the residue in forage and straw at harvest. However, it was only detected in small amounts in grain where the residue was mainly made up by triazolylacetic acid and triazolylalanine. No free 1,2,4-triazole was detected in any matrix either in the target plant metabolism studies or in the confined rotational crops study.

The metabolic profiles for milk and the edible tissues and organs showed that parent prothioconazole was a major compound in all tissues and organs but only of minor importance in milk. Compounds detected in all matrices in the study with phenyl-labelled prothioconazole-desthio were prothioconazole-desthio (except for milk), *M32*, *M74, M52*, and sulfate conjugates of prothioconazole-desthio-hydroxy, prothioconazole-desthio-dihydroxy, prothioconazole-desthio-hydroxy-methoxy in laying hens.

Following the administration of triazole labelled prothioconazole the only label specific metabolite identified was thiocyanate. Triazole derivatives or free 1,2,4-triazole were not found at concentrations above 0.01 mg/kg in any goat matrix. Free triazole did not exceed a residue level of 0.04 mg/kg in laying hen matrices.

The most abundant metabolite was prothioconazole-S-glucuronide. Prothioconazole-desthio was also present in all sample materials, but in much lower concentrations than prothioconazole-S-glucuronide. An exception was fat in hen and goat and eggs in hen, in which prothioconazole-desthio was predominant. In eggs and all edible tissues of hen metabolite prothioconazole-S-methyl was additionally identified. Animal feeding studies showed that the residues are not concentrated in fat of meat or milk cream. As the total residue composed of several hydroxy derivatives and their conjugates, the Meeting concluded that the residues of prothioconazole are not fat soluble.

There are analytical procedures for the determination of prothioconazole residues in various combinations. A GC/MS multi residue method has been validated for the determination of prothioconazole-desthio. An LC-MS/MS total residue method converts prothioconazole, its metabolites and their conjugates to a mixture of prothioconazole sulfonic acid and prothioconazole-desthio. Another method is suitable for the determination of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio and prothioconazole-4-hydroxy-desthio and conjugates that can be converted to one of these compounds via acid hydrolysis in/on matrices of animal origin by HPLC-MS/MS. The major part of the TRR (58–84%) is recovered with this method.

Supervised trials indicated that residues measured as the sum of prothioconazole sulfonic acid and prothioconazole-desthio were higher than the prothioconazole-desthio alone.

The Meeting noted that 1,2,4-triazole, triazolyl-acetic acid and triazolyl-alanine may be derived from several sources. Field trials performed in USA indicated that the sum of the conjugates of triazolyl-alanine and triazolyl-acetic acid amounted to a maximum of 0.92 mg/kg and 1.76 mg/kg in barley and wheat grain, 0.66 mg/kg in canola seed and 3.39 in peanut meat. However, free 1,2,4 triazole was not detected in any of the samples above the LOQ. These findings agree with the information obtained from metabolism studies. As these compounds may be present in food commodities from different sources they are not suitable for enforcement purposes. The relatively low level of conjugated residues in food commodities and the low toxicity of triazolyl-acetic acid and triazolyl-alanine (max ADI of 1 mg/kg) do not justify their inclusion for dietary risk assessment.

Taking into consideration the toxicological significance of the metabolites, the major residues in plant (including the fact that animal feed commodities are almost free of the parent prothioconazole) and animal commodities and the practicality of enforcing the residue limits, the Meeting recommends the following residue definition: for both enforcement and dietary risk assessment:

for plant commodities for enforcement and dietary risk assessment: *prothioconazole-desthio*,

for animal commodities for enforcement: prothioconazole-desthio; and for dietary risk assessment: *the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio*.

Results of supervised residue trials on crops

The meeting received supervised trial data for prothioconazole uses on barley, wheat, triticale (one seed dressing trial), dried beans and peas, oil seed rape and canola, sugar beet, soya bean and peanut.

Prothioconazole was applied as a foliar spray using an EC (emulsifiable concentrate), SC (suspension concentrate) formulation, and for seed dressing of cereals using a FS (flowable concentrate) formulation. The both use patterns are permit for use on cereals.

The trials were performed in Brazil, Canada, Europe and USA. Labels and English translations, where necessary, were provided from 20 countries.

The trials were performed in compliance with GLP and good documentation was provided.

In the Brazilian and European trials the main plant metabolite prothioconazole-desthio was determined. In the Canadian and US trials the residues of parent prothioconazole and its metabolites were converted to a mixture of prothioconazole-desthio and prothioconazole-sulfonic acid (both expressed as parent molar equivalents) and summed with unchanged prothioconazole-desthio (expressed as parent molar equivalents) to give a total prothioconazole derived residue. The methods applied were validated by recovery experiments prior to and concurrent with the residue analyses. The performance of the methods concurred with the current quality requirements.

In trials from Brazil, Canada and USA only the total residue was reported, though the individual residue components were measured separately. Thus the presentation of the results did not comply with the *FAO Manual* specifying that individual residue data should be reported separately (Analysis of samples, page 25) and could not be used for estimation of residue levels.

Pulses (dried beans and peas)

Supervised trials on dried peas (13) and dried beans (10) were carried out with 3 foliar applications of a SC 480 formulation at a target rate of 200 g/ha/application in Canada (9) and USA (14) corresponding to US GAP.

Only total residues were reported.

Sugar beet

The Meeting received reports of 12 residue trials on sugar beets from the USA complying with the US GAP.

Only total residues were reported.

Cereal grains

A total of 123 trials were carried out on cereals (wheat, triticale and barley) with the SC 480, EC250 and FS200 formulations in Canada, Europe and the USA. Only total residues were reported from the USA and Canadian trials.

In Germany, Ireland, and the UK one seed dressing and up to 3 foliar applications for wheat and rye, and a maximum of 2 applications for barley and oat can be made at a rate of 200 g ai/ha. The PHI is 35 days in Germany, and the last treatment should be made at growing stage of BBCH 69–71 in the UK.

The maximum registered application rates for barley, oat, triticale and wheat seed treatments are 100 mg ai/kg of seed in the UK, 75 mg/kg in France and 25–50 mg/kg in Germany. The registered rates in other European countries are within this range or lower in few cases.

A total of 17 trials on barley were reported from Germany, France, Italy, Spain ,Sweden and the UK, where three applications were made at each site: one seed dressing with a nominal rate of 150 mg ai/kg seed and two foliar applications with 200 g ai/ha. The seed dressing rate was 1.5 times higher than the recommended label rate.

The prothioconazole-desthio residues in barley grain at 35–57 days, matching the PHI or growing stage specified on the label, were: < 0.01 (10), 0.01, 0.01, 0.02 (4) mg/kg.

In 19 European trials on wheat, the application rate for seed dressing was approximately double the GAP rate and 3 foliar applications were made instead of two in South European trials. Nevertheless, no prothioconazole-desthio residue could be detected (< 0.01 mg/kg) in any of the 16 grain samples taken at 35 days post application, or 16 samples taken between 42–64 days after last application, except in one trial conducted in the UK where 0.32 mg/kg residue was found.

Taking into account the total residues derived from similar application rates (0.6 mg/kg in barley and 0.061 mg/kg in wheat) the Meeting concluded that the 0.32 mg/kg residue value was atypical and was not considered.

Based on the similar residue data on barley and wheat available from European trials and the similar use patterns for cereals, the Meeting estimated an STMR value of 0.01 mg/kg and a maximum residue level of 0.05 mg/kg for barley, oat, rye, triticale and wheat.

Oils seeds

A total of 34 trials on rape/canola were carried out with either an EC250 or SC 480 formulations. The trials were performed in Canada (16), France (7), Germany (2), the UK (2), Sweden (1) and the USA (6).

In the 22 Canadian and USA trials only the total residue was reported.

In France, Germany, the UK and several other countries in Europe the application rate is within 125–175 g/ha and the PHI ranges between 35 and 56 days.

The European trials were performed with 2 applications at 175 g ai/ha nominal rate and samples were collected 56 to 67 days after the second treatment, which correspond to the GAP of the UK.

The prothioconazole-desthio residues derived from trials evaluated against the UK GAP were: < 0.01 (7), 0.01 (3) and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and STMR of 0.01 mg/kg for rape seed.

Peanut

The GAP in the USA permits 4 applications at a rate of 200 g ai/ha (800 g ai/ha/season) at 14 days intervals and 14-day PHI. The hay and by-products cannot be fed to animals.

In 12 trials from the USA, performed according to GAP, the total residues in nutmeat were below the LOQ (< 0.02 mg/kg) in all samples.

The Meeting noted that the metabolism studies indicated very low residues in nutmeat and no total residue was detected in any of the samples, and decided to use the total residue data for estimating a maximum residue level of 0.02* mg/kg and an STMR of 0.01 mg/kg.

Soya bean

The GAP of the USA specifies 3 applications at a maximum rate of 105 g/ha and 21 days PHI. No information was available on permitted Brazilian uses. Nineteen US trials did not comply with GAP, and only the total residue was reported.

Primary feed commodities

The basic information on registered uses is provided under food commodities. Only the relevant residue data are summarized below.

Total residues in soya bean forage and hay and sugar beet tops derived from supervised trials were recorded, but not evaluated by the Meeting. The total residues in peanut hay were not considered as it is not allowed to be used as an animal feed in the USA where the trials were conducted.

Cereal forage and straw

The Meeting noted that forage samples were taken up to 28 days after last application. However, several countries labels do not contain any restriction on grazing. As the 7-day sampling interval was considered the shortest under practical conditions, residues measured at 7 days were used for estimation of animal dietary burdens.

In North European trials the prothioconazole-desthio residues in wheat forage at 7 days post-application were: 0.11, 0.32, 0.57, 0.65, 0.78, 0.89, 0.92, 1.0, 1.1, and 1.8 mg/kg.

In barley forage at the 7 day sampling the residues were: 0.6, 0.85, 1.0, 1.2, 1.7(2), 2.0 and 2.6 mg/kg.

The Meeting noted that the residues in barley and wheat forage were in the same range, and based on the combined data (0.11, 0.32, 0.57, 0.60, 0.65, 0.78, 0.85, 0.89, 0.92, 1.0, 1.0, 1.1, 1.2, 1.7, 1.7, 1.8, 2 and 2.6 mg/kg) estimated a STMR of 0.96 mg/kg and a highest residue of 2.6 mg/kg for barley, oat, rye, triticale and wheat forage.

In wheat straw (between 35 and 64 days after last treatment) the residues were: 0.08, 0.09, 0.11, 0.14, 0.15, 0.19, 0.20, 0.25, 0.27, 0.31, 0.42, 0.47, 0.52, 0.53, 0.72 (3), 0.77 and 1.0, mg/kg.

In barley straw (between 35–57 days) the residues were: 0.08, 0.1, 0.1, 0.13, 0.13, 0.14, 0.14, 0.16, 0.19, 0.24, 0.3, 0.38, 0.53, 0.75, 1.1, 1.1 and 1.2 mg/kg.

The Meeting considered the barley and wheat straw residue data were from the same population and based on the combined residue data (0.08, 0.08, 0.09, 0.1, 0.1, 0.11, 0.13, 0.13, 0.14, 0.14, 0.14, 0.15, 0.16, 0.19, 0.19, 0.20, 0.24, 0.25, 0.27, 0.3, 0.31, 0.38, 0.42, 0.47, 0.52, 0.53, 0.53, 0.72(3), 0.75, 0.77, 1.0, 1.1, 1.1, and 1.2 mg/kg) estimated on dry weight basis a STMR of 0.30 mg/kg (median value of 0.26 uncorrected for moisture content) and highest residue of 1.36 and a maximum residue level of 2 mg/kg, for barley, oat, ray, triticale and wheat straw.

Rape forage

Samples of green forage were only taken at day 0. The residues present in day 0 samples do not represent the practical situation and cannot be used for estimation of animal burden.

Fate of residues during processing

A hydrolysis study with [Phenyl-UL-^{14}C]prothioconazole in buffered drinking water was conducted under conditions representative for core processing procedures in order to determine their possible influence on the nature of the residues. The samples were incubated at 90 °C at pH 4 for 20 minutes (pasteurisation), l00 °C at pH 5 for 60 minutes (baking, brewing and boiling) and l20 °C at pH 6 for 20 minutes (sterilisation).

HPLC analyses of incubated samples demonstrated that prothioconazole degraded slightly (≤ 11%) to prothioconazole-desthio at l20 °C at pH 6.

A field trial was conducted to measure the magnitude of prothioconazole residues in/on wheat grain, aspirated grain fractions, bran, flour, germ, middling, and shorts following two foliar spray applications of prothioconazole 480 SC to wheat at five-fold exaggeration of the maximum recommended label use rate.

Mature wheat grain was harvested 47 days after the last treatment, and processed with a procedure which simulated commercial processing practices.

The residues of prothioconazole and prothioconazole-desthio were measured as prothioconazole-desthio and prothioconazole sulfonic acid. The individual residues were summed to give a total prothioconazole derived residue. The LOQ for total residue was 0.02 mg/kg for wheat grain, bran, flour, germ, middling, and shorts, and 0.25 mg/kg for aspirated grain fractions.

The total residues of prothioconazole in grain at harvest were 0.05 mg/kg. The corresponding residues in aspirated grain fraction were 12.5 mg/kg.

The residues in the processed products were up to 0.12 mg/kg in bran, < 0.02 mg/kg in flour, 0.10 mg/kg in germs, 0.03 mg/kg in middling and 0.05 mg/kg in shorts. No control interferences were detected. The calculated processing factors were 250 for aspirated grain fraction, 2.4 for wheat bran, 0.4 for flour, 2 for germ, 0.6 for middling and 1 for shorts.

A field trial was conducted to measure the magnitude of prothioconazole residues in canola seed, canola meal and canola refined oil following two foliar spray applications with 480 SC at 1.0 kg ai/ha, which corresponded to a five-fold (5×) exaggeration of the maximum recommended label use rate. Mature canola plants were cut 47 days after the second treatment, dried on the field for 5 days, then processed using procedures which simulated commercial processing practices.

The residues of prothioconazole and prothioconazole-desthio were measured as prothioconazole-desthio and prothioconazole sulfonic acid. The LOQ for total prothioconazole residue was 0.02 mg/kg for canola seed, meal and refined oil. The results indicated that no concentration (< 0.7×) of the total prothioconazole derived residue was seen in canola meal and refined oil.

Field trials were conducted to measure the magnitude of prothioconazole residues in peanut nutmeats, peanut meal, peanut refined oil, dry roasted peanuts and peanut butter as well as in soya bean processed commodities of meal, hulls and refined oil. The total amount of prothioconazole 480 SC applied represented a five-fold (5×) exaggeration of the maximum recommended label use rate. The processed fractions were analysed for total residues. The total prothioconazole derived residue did not concentrate (<1×) either in the peanut refined oil, dry roasted peanuts and peanut butter, or in soya bean meal and refined oil.

Farm animal feeding studies

The cattle feeding studies were conducted administering prothioconazole-desthio or the parent compound via capsules to lactating dairy cows at three dose levels for 28 or 29 consecutive days. At the end of the dosing period, the cows were sacrificed within 24 h after the last capsule treatment. The liver, kidney, fat (composite omental and perirenal), and muscle (composite of loin, elbow and flank) were collected for analysis.

Milk was collected for analysis twice daily at regular intervals during the dosing period and composited for each cow. In addition, a portion of the morning milk from one cow of the highest dose level was subjected to an accumulation test in milk fat on the day before sacrifice.

Following the administration of prothioconazole-desthio at rates of 4 mg/kg feed, 25 mg/kg feed, or 100 mg/kg feed the samples were analysed for prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio , and prothioconazole-desthio. The LOQ were 0.01 mg/kg for muscle, liver, kidney and fat, and 0.004 mg/kg for milk.

Prothioconazole-desthio total residues, expressed as mg/kg prothioconazole-desthio equivalents, were observed in liver and kidney at all feeding levels with a linear dose relationship.

- In liver total residues ranged from 0.02 to 0.05 mg/kg at the 4 mg/kg feeding level, from 0.18 to 0.26 mg/kg at the 25 mg/kg feeding level, and from 0.61 to 1.6 mg/kg at the 100 mg/kg feeding level.

- In kidney total residues ranged from 0.01 to 0.04 mg/kg at the 4 mg/kg feeding level, from 0.11 to 0.17 mg/kg at the 25 mg/kg feeding level, and from 0.41 to 1.1 mg/kg at the 100 mg/kg feeding level. In muscle and fat, total residues were considerably lower.
- In muscle, total residues were below the LOQ (0.01 mg/kg) at the 4 mg/kg and 25 mg/kg feeding levels, and ranged from 0.01 to 0.03 mg/kg at the 100 mg/kg feeding level.
- In fat, total residues were below the LOQ (0.01 mg/kg) at the 4 mg/kg feeding level, and ranged from 0.01 to 0.02 mg/kg at the 25 mg/kg feeding level, and from 0.03 to 0.14 mg/kg at the 100 mg/kg feeding level.
- from a single population or the equivalent of a single population;

Prothioconazole-desthio total residues in milk at the highest dose level increased from < 0.004 mg/kg (day 1) to a plateau level (day 4 to day 29) of 0.006 to 0.010 mg/kg for two animals and of 0.013 to 0.021 mg/kg for one animal, while no residue could be detected at lower dose levels. Liquid-liquid-partitioning of whole milk against n-hexane showed that prothioconazole-desthio was in milk fat and the 3-hydroxy and 4-hydroxy metabolites (M14 and M15) remained in the aqueous phase. However, the total residues remained preferentially in the aqueous phase, i.e., 0.015 mg/kg with only 0.004 mg/kg in the n-hexane phase, indicating no accumulation in milk fat.

When cows were dosed with the parent compound at levels of 9.9 mg/kg feed, 29.5 mg/kg feed, and 98.4 mg/kg feed, the samples were analysed for prothioconazole, prothioconazole-desthio and prothioconazole-4-hydroxy. The LOQ for the total residue was 0.005 mg/kg in milk; 0.01 mg/kg in skim milk, milk cream, liver, kidney, and muscle; and 0.05 mg/kg in fat.

The total average prothioconazole-desthio residues (prothioconazole, prothioconazole-desthio and prothioconazole-4-hydroxy) at the dose groups of 9.9 mg/kg feed, 29.5 mg/kg feed, and 98.4 mg/kg feed were respectively: < 0.05 mg/kg in fat, 0.07, 0.21, and 0.80 mg/kg in kidney, 0.10, 0.28 and 0.8 mg/kg in liver, and < 0.01, 0.01 mg/kg in muscle.

The highest total prothioconazole residue in the milk from the highest (5×) dose group was equal to or less than 0.006 mg/kg. All milk samples from the 29.5 mg/kg (1.5×) dose group contained < 0.005 mg/kg (< LOQ) total prothioconazole residue. Minimal concentration (1.1× concentration) of prothioconazole residues occurred in cream and no concentration (<1× concentration) occurred in skim milk.

Poultry

A summary of a feeding study with laying hens was provided. In this study three groups of laying hens were dosed via capsule for 29 consecutive days with 0.26, 0.79, and 2.6 mg/kg feed/day. Following the administration of the highest dose, the total prothioconazole residues (sum of prothioconazole-desthio, prothioconazole-4-hydroxy and prothioconazole) were below the LOQ in eggs (< 0.005 mg/kg) and liver, muscle and fat (< 0.01 mg/kg) samples.

Farm animal dietary burden

The Meeting noted that the feeding study conducted with parent prothioconazole does not represent the practical residue situations where the feed items contained only low levels (< 5%) of the parent compound while the major part of the residue was the prothioconazole-desthio. Consequently, the dietary burden was calculated from the prothioconazole-desthio residues measured in feed commodities and it was compared to the residues found in animal commodities after the administration of prothioconazole-desthio.

The Meeting estimated the dietary burden in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from highest residue, STMR for some bulk commodities and STMR-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 are provided in Annex 6.

		Animal dietary burden, total prothioconazole ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	2.61	2.61	**10.40**[a]
	mean	0.96	0.96	**3.84**[b]
Dairy cattle	max	4.17	2.60	**7.80**[c]
	mean	1.55	0.96	2.75

[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 dairy cattle dietary burden suitable for STMR estimates for mammalian milk.

Dietary burden calculations for poultry

		Animal dietary burden, total prothioconazole ppm of dry matter diet		
		US-Canada	EU	Australia
Broiler chicken	max	0.009	0.008	0.008
	mean	0.009	0.008	0.008
Laying	max	0.009	1.050[a]	0.006
	mean	0.009	0.39[b]	0.006

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

[b] Highest mean dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodity maximum residue levels

Based on the linear relationship observed for the maximum residues in various tissues of cattle and the results of the metabolism studies, the expected maximum prothioconazole-desthio residue derived from feeding 10.4 mg/kg feed were: 0.095 mg/kg in liver, 0.065 mg/kg in kidney, 0.009 mg/kg in meat, and 0.01 mg/kg in fat.

In milk the highest dose resulted in a maximum of 0.02 mg/kg residue, and no residue (< 0.004 mg/kg) could be detected at lower dose levels. Consequently, no residue is expected in milk where the feed contains residues up to 7.8 mg/kg.

The STMR residues estimated from the 3.84 mg/kg median residue intake are: < 0.01 in liver and kidney, meat and fat.

The Meeting estimated maximum residue levels of 0.2 mg/kg for edible offal, 0.01 mg/kg in meat and fat and 0.004* mg/kg in milk. The STMR and HR values are 0.01 mg/kg for meat, 0.004 mg/kg for milk and edible offal the values are 0.05 and 0.1 respectively.

A metabolism study was carried out on laying hens with the parent prothioconazole at an exaggerated rate of 171 mg/kg feed indicated a total residue of 4 mg/kg in liver. Assuming a proportional residue level the 1.05 mg/kg residue in feed would result in 0.025 mg/kg residue in the liver.

A feeding study performed with parent prothioconazole at maximum rate of 2.59 mg/kg feed showed that the total residue would be below the LOQ in eggs (0.005 mg/kg), liver, meat and fat

(0.01 mg/kg). The Meeting also noted that the study designs do not reflect the residue composition in feed and the results cannot be used for estimation of maximum residue levels or STMR values.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for prothioconazole-desthio was calculated from the recommendations for STMR-s for raw agricultural commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

The IEDI of the 13 GEMS/Food cluster diets were in the range of 0-1% of the maximum ADI of 0.01 mg/kg bw. The Meeting concluded that the long-term intake of residues from uses of prothioconazole considered by the Meeting is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for prothioconazole-desthio was calculated from the recommendations for STMRs and HRs for raw agricultural commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 4.

The IESTI for women of child bearing age is 0–6% of the ARfD of 0.01 mg/kg bw. The IESTI for children and general populations is 0% of the ARfD of 1 mg/kg bw.

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

5.20 SPINETORAM (233)

TOXICOLOGY

Spinetoram, also known as XDE-175 or XR-175, is a fermentation product derived from the actinomycete bacterium *Saccharopolyspora spinosa,* which has been slightly modified by chemical reaction. Spinetoram is a macrocyclic lactone insecticide. It acts by causing persistent activation of insect nicotinic acetylcholine receptors.

Spinetoram is composed of numerous spinosyns, known as "factors", which differ slightly from each other. Each spinosyn consists of a large complex hydrophobic ring, a basic amine group, and two sugar moieties. The insecticidal activity of spinetoram is attributed to two spinosyns, identified as XDE-175-J ("factor J") and XDE-175-L ("factor L"), which comprise the overwhelming majority of the technical material. The ratio of factor J to factor L ranges from 70 : 30 to 90 : 10.

The remaining components of spinetoram comprise a number of additional spinosyns (that have minor substitutions at various locations in the spinosyn molecule) and other impurities consisting of inorganic salts, carbohydrates and proteinaceous material that would be expected to be produced during a fermentation process.

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

All the pivotal studies met the basic requirements of the relevant OECD or national test guidelines and included certificates of compliance with GLP.

Biochemical aspects

The toxicokinetics and metabolism of the two insecticidally active factors in spinetoram, factor J and factor L, are quite similar. In rats, the factors were rapidly and extensively (≥ 70%) absorbed. Peak plasma concentrations of radiolabel were achieved within 2–4 h. Systemic bioavailability was at least 26–29% for factor J and 39–57% for factor L. The factors were extensively distributed in the tissues, with highest concentrations in the gastrointestinal tract, fat, carcass and the liver. Excretion was primarily via the faeces (85%), mainly as metabolites, with only 3–4% of the administered dose excreted in the urine. Most of the administered dose was recovered within 24 h. The plasma half-lives for radiolabelled factor J and factor L were 4–11 h and 8–24 h, respectively. Very little radiolabel remained in the carcass after 7 days: 0.6–1.4% with factor J and 3–7% with factor L. Pre-treatment of rats with a low dose of either factor for 14 days did not affect the subsequent absorption and excretion of the respective factor.

Both factor J and factor L were extensively metabolized. The major metabolic pathway was glutathione conjugation, either of the parent, or of the products of *N*-demethylation, *O*-deethylation and deglycosylation of each factor, as well as hydroxylation of parent factor J. The aglycone of factor L was also subject to sulfate and glucuronide conjugation. The major metabolite was the cysteine conjugate of the parent factor.

Toxicological aspects[41]

Spinetoram was of low acute toxicity in rats: oral LD_{50} > 5000 mg/kg bw; dermal LD_{50} > 5000 mg/kg bw; and 4-h inhalational LC_{50} > 4.44 mg/L. There was no mortality at limit doses of 5000 mg/kg bw and 4.4 mg/L, respectively. Spinetoram is not a skin or eye irritan**t.**

In a local lymph node assay in BALB/c mice, spinetoram was shown to be a moderate skin sensitizer, while in a second assay in CBA/J mice (the recommended strain for this assay according to OECD TG 429 guidelines), spinetoram was not a skin sensitizer.

A range of effects was observed in short- and long-term studies with repeated dosing, and the effects were broadly similar in mice, rats and dogs. In short-term studies in mice, rats and dogs, cytoplasmic vacuolation of parenchymal cells, epithelial cells, macrophages and fibroblasts of a variety of tissues was observed, with some degeneration of muscle. There was also an increase in the incidence and/or severity of aggregates of macrophages/histiocytes in the lymphoid structures of numerous tissues. In mice, the NOAEL was 150 ppm, equal to 24.5 mg/kg bw per day, in a 28-day study. The NOAEL was 50 ppm, equal to 7.5 mg/kg bw per day, in a 90-day study in which there was also slight splenic extramedullary haematopoiesis in females at the LOAEL. In rats, the NOAEL was 500 ppm, equal to 48 mg/kg bw per day, in a 28-day study in which there was vacuolation of the thyroid follicular epithelium and the renal tubular epithelium at the LOAEL. In three 90-day studies in which rats were exposed to spinetoram at two different ratios of factor J to factor L (75 : 25 and 85 : 15), the overall NOAEL was 10 mg/kg bw per day, the factor ratio having little effect on sensitivity. There was also an increase in reticulocyte and leukocyte counts at the LOAEL in one of these studies. In beagle dogs, the NOAEL was 200 ppm, equal to 5.9 mg/kg bw per day, in a 28-day study. In addition to vacuolation of numerous tissues, there was extramedullary splenic haematopoiesis at the LOAEL. In a 90-day study, the NOAEL was 150 ppm, equal to 5.0 mg/kg bw per day. Arteritis or perivascular inflammation and extramedullary haematopoiesis were also observed at the LOAEL in this study. The NOAEL in a 1-year study was 100 ppm, equal to 2.5 mg/kg bw per day, on the basis of arteritis, accompanied by necrosis of the arterial walls at the LOAEL of 200 ppm. The incidence of arteritis in the group receiving spinetoram at 200 ppm was low (one out of four males and one out of four females), and may have reflected the normal background incidence of lesions often seen in beagle dogs; however, the fact that more severe effects that were considered to be treatment-related were noted in dogs given spinetoram at 300 or 900 ppm for 90 days suggested that these changes in the 1-year study may be treatment-related. The overall NOAEL was 5 mg/kg bw per day in dogs.

In long-term studies in rats and mice, tissue vacuolation was again commonly observed at doses at and above the LOAEL. In an 18-month study in mice, the NOAEL was 150 ppm, equal to 18.8 mg/kg bw per day, on the basis of histopathological changes in the stomach, lungs and epididymides at the LOAEL. In addition to cytoplasmic vacuolation of the epithelium of the ducts lining the head of the epididymides and aggregates of alveolar macrophages in the lungs, hyperplasia and inflammation of the glandular mucosa of the stomach, with dilatation of the mucosal glands were also observed. In a 2-year study in rats, the NOAEL was 250 ppm, equivalent to 10.8 mg/kg bw per day.

Selected tissues from short-term studies of toxicity with spinetoram and with the structurally related compound spinosad in rats (both compounds) and in mice (spinosad only) were examined by electron microscopy. Vacuolation was shown to be associated with cytoplasmic lamellar inclusion bodies, reflecting dysregulation of lysosomal storage (i.e., phospholipidosis). While such effects may arise through a variety of mechanisms that prevent degradation of cell constituents usually processed

[41] Most of the studies of toxicity were conducted with factor J and factor L in a ratio equal to 75 : 25. Some studies were repeated with factor J and factor L in the ratio of 85 : 15; this was done to demonstrate that the 85 : 15 ratio produces a toxicity profile that is essentially the same as that seen with the 75 : 25 ratio.

in the lysosomes, it is most likely that spinetoram acts through a physicochemical mechanism associated with its cationic amphiphilic structure, in common with other such compounds.

In long-term studies of toxicity and carcinogenicity, there was no evidence of treatment-related tumourigenicity in rats or mice. The Meeting concluded that spinetoram was not carcinogenic.

Spinetoram gave negative results in an adequate range of studies of genotoxicity in vitro and in vivo. The Meeting concluded that spinetoram had no genotoxic potential.

On the basis of the absence of carcinogenicity and genotoxicity, the Meeting concluded that spinetoram is unlikely to pose a carcinogenic risk to humans

The reproductive effects of spinetoram have been investigated in a two-generation study in rats. Cytoplasmic vacuolation of thyroid follicular epithelial cells was observed in adults of both generations at the highest dose (75 mg/kg bw per day). Among females at this dose, three parental (F_0) and three F_1 females had complications of parturition (dystocia), in most cases evidenced by the protracted delivery of pups over several days. These females also exhibited clinical signs (e.g., postpartum vulvar discharge, pale skin/mucous membranes, perinasal/perineal soiling), had reduced body weights and feed consumption during lactation, and associated decreases in survival and body weight of their pups. The dystocia occurred in a few females (about 13%) at the highest dose of 75 mg/kg bw per day. A similar effect (in up to about 24% of litters) was seen with spinosad at a higher dose of 100 mg/kg bw per day. For both substances, the NOAEL for this effect was 10 mg/kg bw per day, which was also the NOAEL for maternal toxicity, For females at the highest dose without dystocia, gestational survival was slightly decreased, with an associated increase in postimplantation loss. No other measures of reproductive performance were affected in either males or females. The NOAELs for parental, reproductive and offspring toxicity were 10 mg/kg bw per day on the basis of slight thyroid vacuolation in adult males and females, dystocia in females and decreased gestation survival in pups at 75 mg/kg bw per day

The developmental toxicity of spinetoram had been investigated in rats and rabbits. In rats, maternal body weight and feed consumption were reduced at 300 mg/kg bw per day, with a NOAEL of 100 mg/kg bw per day. There was no treatment-related embryo/fetal toxicity or teratogenicity at doses up to and including 300 mg/kg bw per day. The NOAEL for developmental toxicity was 300 mg/kg bw per day, the highest dose tested.

In a preliminary study of developmental toxicity in rabbits, dams given doses of 150 or 100 mg/kg bw per day showed decreased feed consumption, decreased faecal output, and decreased body-weight gain from the beginning of the treatment period. No other clinical findings were present in these two groups.

The effect on body weight and faecal output, which were associated with a marked and consistent decrease in feed consumption, were most likely a consequence of local irritation of the gastrointestinal tract.

Owing to severe inanition and subsequent weight loss, all rabbits from these groups were killed by day 15 of gestation with no further data collection.

In the main study of developmental toxicity in rabbits, treatment with spinetoram resulted in decreases in feed consumption, faecal output, and body-weight gain, and increased mean absolute and relative liver weights at a dose of 60 mg/kg bw per day. In addition, one dam at 60 mg/kg bw per day was killed on day 21 of gestation owing to inanition and subsequent weight loss, considered to be treatment-related. There were no signs of developmental toxicity at any dose. The NOAEL for maternal toxicity was 10 mg/kg bw per day. The NOAEL for developmental toxicity was 60 mg/kg bw per day, the highest dose tested.

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

Neurotoxicity was investigated in rats given single doses of up to 2000 mg/kg bw, or repeated doses of up to 750 ppm (36.7 mg/kg bw per day) for 12 months. Comprehensive behavioural and histopathological investigations revealed no evidence of neurotoxicity.

The plant metabolites *N*-formyl-XDE-175-J and *N*-formyl-XDE-1175-L were evaluated in a test for acute oral toxicity and in an Ames test for genotoxicity. Both metabolites were of low acute oral toxicity (LD_{50} > 5000 mg/kg bw) and gave negative results in the Ames test.

The development of spinetoram as a commercial product had been too short for any information from medical surveillance of manufacturing-plant personnel to be available. There were no documented cases of intoxication or of any other clinical effects associated with its use.

Toxicological evaluation

The Meeting established an ADI 0–0.05 mg/kg bw based on an overall NOAEL of 5.0 mg/kg bw per day, identified on the basis of arteritis, accompanied by necrosis of the arterial walls in the affected organ(s), in studies of toxicity in dogs, and with a safety factor of 100. Although arteritis was observed only in some dogs, at an incidence that was within the range for historical controls, the incidence of arteritis at the LOAEL was greater in the concurrent controls and clear effects were found at higher doses in another study. Additionally, the structurally related compound spinosad had also been observed to cause arteritis in dogs given spinosad for 1 year, at doses not dissimilar to the LOAEL for the present study. Hence, the Meeting concluded that while there was some uncertainty as to the toxicological significance of the finding of arteritis at the LOAEL for spinetoram, use of the overall NOAEL from studies of toxicity in dogs as a basis for establishing the ADI was scientifically justified.

The Meeting concluded that it was not necessary to establish an acute reference dose for spinetoram on the basis of its low acute toxicity, the absence of neurotoxic potential and of developmental or any other effects of relevance for acute exposure in studies of longer duration. Effects on gestational survival of pups observed in the multigeneration study in rats were most likely to be secondary to maternal toxicity, which was not a consequence of acute exposure.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month combined toxicity and carcinogenicity[a]	Toxicity	150 ppm, equal to 18.8 mg/kg bw per day	300 ppm, equal to 37.5 mg/kg bw per day[c]
		Carcinogenicity	300 ppm, equal to 37.5 mg/kg bw per day[c]	—
Rat	2-year combined study of toxicity and carcinogenicity[a]	Toxicity	250 ppm, 10.8 mg/kg bw per day	500 ppm, equal to 21.6 mg/kg bw per day
		Carcinogenicity	750 ppm, equal to 32.9 mg/kg bw per day[c]	—
	Two-generation study[a]	Parental	10 mg/kg bw per day	75 mg/kg bw per day[c]
		Offspring toxicity	10 mg/kg bw per day	75 mg/kg bw per day[c]
		Reproductive toxicity	10 mg/kg bw per day	75 mg/kg bw per day[c]
	Developmental toxicity[b]	Maternal toxicity	100 mg/kg bw per day	300 mg/kg bw per day[c]
		Foetotoxicity	300 mg/kg bw per day[c]	—

Rabbit	Developmental toxicity[b]	Maternal toxicity	10 mg/kg bw per day	60 mg/kg bw per day[c]
		Foetotoxicity	60 mg/kg bw per day[c]	—
Dog	Oral 90-day and 1-year studies	Toxicity	150 ppm, equal to 5.0 mg/kg bw per day	200 ppm, equal to 5.4 mg/kg bw per day)[42]

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.05 mg/kg bw

Estimate of acute reference dose

Unnecessary

Information that would be useful for 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 spinetoram

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid (t_{max} 2–4 h) and extensive (> 70%). Systemic bioavailability of factor J (26–29%) < factor L (39–57%)
Distribution	Rapidly and extensive. Highest concentrations of radioactivity in the gastrointestinal tract, followed by fat, carcass and liver
Potential for accumulation	Tissue and carcass concentrations low after 7 days (0.6–1.4% of administered dose).
Rate and extent of excretion	Rapidly excreted, plasma half-lives 4–24 h; 85% of dose in faeces, mainly as metabolites; 3–4% in urine, mostly in first 24 h
Metabolism in animals	Extensively metabolized, primarily by glutathione conjugation of parent and products of phase-one metabolism. Some sulfate and glucuronide conjugation of aglycone of factor L
Toxicologically significant compounds (animals, plants and environment)	Spinetoram, comprising factors J and L

[42] Marginal differences out of concurrent controls but within the historical control range.

Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.44 mg/L for 4 h (nose only)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Transient irritation
Mouse, dermal sensitization	Not sensitizing (local lymph node assay in CBA/J mice)[43]
Short-term studies of toxicity	
Target/critical effect	Mice, rats, dogs: vacuolation of macrophages in a wide range of lymphoid tissues within numerous organs and aggregates of macrophages/histiocytes in a number of tissues, non-regenerative anaemia, arteritis (dogs)
Lowest relevant oral NOAEL	5.0 mg/kg bw per day (90-day and 1-year study in dogs)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (28-day study in rats, highest dose tested)
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	Negative in vitro and in vivo
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Mice, rats: vacuolation of cells (thyroid in rats; epididymes in mice) and increases in aggregates of macrophages/histiocytes in lymphoid tissues in numerous organs, hyperplasia of the glandular mucosa of the stomach and inflammation of the glandular submucosa (mice)
Lowest relevant NOAEL	2-year study, rat: 10.8 mg/kg bw per day
Carcinogenicity	Not carcinogenic
Reproductive toxicity	
Reproduction target/critical effect	Dystocia (difficulty in delivery), decrease in gestation survival of pups.
Lowest relevant reproductive NOAEL	10 mg/kg bw per day (rats)
Developmental target/critical effect	None
Lowest relevant developmental NOAEL	60 mg/kg bw per day (rabbit; highest dose tested)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity and short-term studies of neurotoxicity	No indications of neurotoxicity in single- or repeat-dose studies
Medical data	
	No data available on manufacturing-plant personnel (production-scale manufacturing has yet to start). No

[43] Recommended strain.

reports of adverse health effects in exposed subjects.

Summary

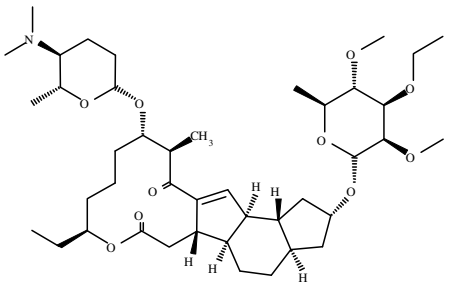
	Value	*Study*	*Safety factor*
ADI	0–0.05 kg bw	Dog, 90-day and 1-year study	100
ARfD	Unnecessary	—	—

Factor J, XDE-175-J

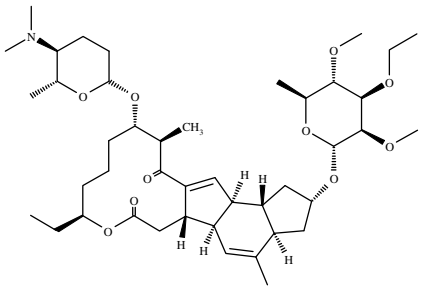
Factor L, XDE-175-L

RESIDUE AND ANALYTICAL ASPECTS

Spinetoram, a multi-component tetracyclic macrolide in the class of spinosyn insecticides, consists of two components shown below, present approximately in a three to one ratio. It was identified as a priority new compound at the 39th Session of the CCPR in 2007 (ALINORM 07/30/24—Rev.1) for evaluation by the 2008 JMPR. The Meeting received information on physical and chemical properties, animal and plant metabolism, environmental fate, analytical methods, storage stability, use patterns, supervised trials, processing and farm animal feeding.

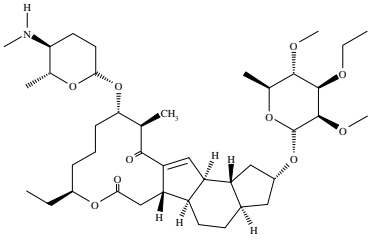


XDE-175-J (Major component)

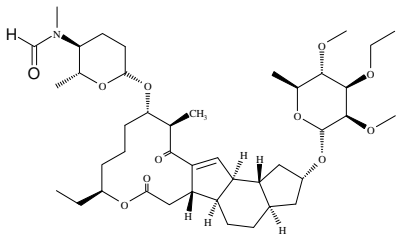


XDE-175-L (Minor component)

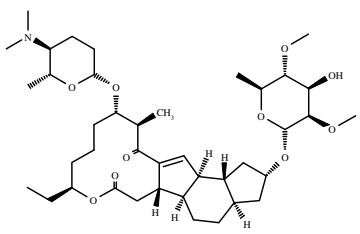
In this appraisal, the following abbreviated names were used for metabolites:



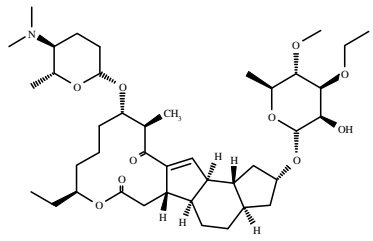
N-demethyl-175-J



N-formyl-175-J



3'-O-deethyl-175-J



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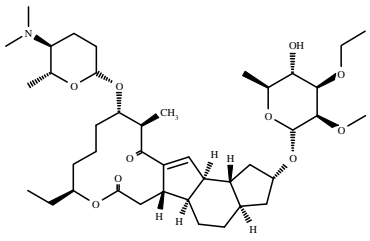
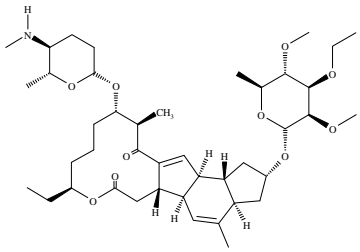
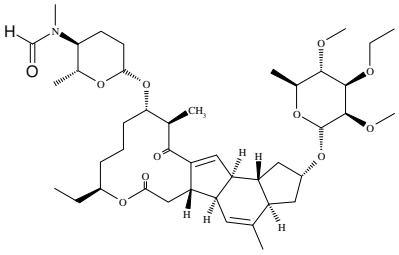


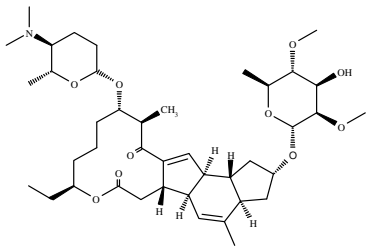
4'-O-demethyl-175-J



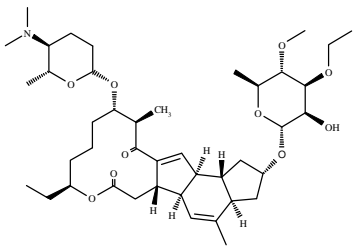
N-demethyl-175-L



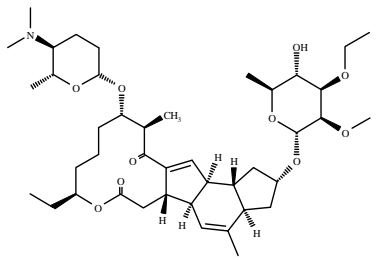
N-formyl -175-L



3'-O-deethyl-175-L



2'-O-demethyl-175-L



4'-O-demethyl-175-L

Animal metabolism

The Meeting received information on the fate of orally-dosed spinetoram in lactating goats and laying hens.

When either ^{14}C-XDE-175-J or ^{14}C-XDE-175-L, uniformly labelled with ^{14}C in the macrolide ring, was administered orally at a dose equivalent to a dietary concentration of 10–11 ppm to a lactating goat once a day for five consecutive days, 51% or 78% of the administered dose of ^{14}C-XDE-175-J or ^{14}C-XDE-175-L, respectively, were recovered in faeces. Radioactivity recovered in urine was insignificant; less than 0.2% of the administered dose.

Radioactivity started to appear in milk within 24 hours after the first application but cumulative milk sample contained only about 0.3% of the total administered dose of ^{14}C-XDE-175-J or 0.2% of that of ^{14}C-XDE-175-L. The maximum total radioactive residues were 0.047 mg/kg in parent equivalents for ^{14}C-XDE-175-L and 0.039 mg/kg ^{14}C-XDE-175-L.

Total radioactive residues (TRR) in tissues after sacrifice (21 h after the last dose) showed the tendency to be higher in fatty tissues, with 0.235 mg/kg and 0.119 mg/kg in parent equivalents in fat (after the administration of ^{14}C -XDE-175-J and ^{14}C-XDE-175-L, respectively), and 0.116 mg/kg and 0.099 mg/kg in liver. TRR in kidney, muscle and milk were much lower.

The primary residue was XDE-175-J or XDE-175-L (42–84% of TRR) in all tissues and milk, except liver, indicating that minimal metabolism had occurred. In liver, XDE-175-J or XDE-175-L was the primary residue but at lower levels (30 or 26% of TRR) with N-demethyl-175-J or -L at very low levels (< 2% of the TRR), and an unidentified metabolite. No residue components other than the unchanged parent compounds were identified in milk, kidney or fat. Radioactive residues in muscle also consisted primarily of XDE-175-J or XDE-175-L and much lesser amounts of what seemed to be the same unidentified metabolite as found in liver. There were many minor metabolites detected but all were less than 10% of the TRR. Unextracted radioactivity was less than 15% of the TRR in all samples except liver in which it was around 25%.

When either ^{14}C-XDE-175-J or ^{14}C-XDE-175-L, (uniformly labelled with ^{14}C in the macrolide ring), was administered orally at a dose equivalent to a dietary concentration of 10 ppm to a group of laying hens once a day for seven consecutive days, 93% or 91% of the administered dose of ^{14}C-XDE-175-J or ^{14}C-XDE-175-L, respectively, were recovered in excreta.

Eggs and tissues contained a low proportion of the administered dose (< 3%) for both ^{14}C-XDE-175–J and ^{14}C-XDE-175-L. TRR in eggs increased over the experimental period and reached a maximum of 0.20 and 0.49 mg/kg for ^{14}C-XDE-175-J and ^{14}C-XDE-175-L, respectively, on day 7. TRR in the tissues were highest in abdominal fat (1.04 mg/kg for XDE-175-J, and 2.46 mg/kg for XDE-175-L), followed by skin with subcutaneous fat, liver, eggs and muscle. There is a tendency for radioactivity to be found at higher levels in tissues with higher fat content.

Unchanged XDE-175-J or XDE-175-L remained as the primary residue in the egg (58–49%) and tissues (45–70% of TRR) other than liver (13–12%). 3'-O-deethyl-175-J was detected in abdominal fat (1.8% of TRR) and in liver (18%) and O-demethyl-175-J was present in all tissues (3.2–6.5% of TRR) while 3'-O-deethyl-175-L and O-demethyl-175-L were found in all tissues and eggs (5.2–13% and 13–20% of TRR respectively). Unextracted radioactivity was less than 7% of the TRR in all samples except muscle and eggs in which it was 12–20%.

Limited metabolism of spinetoram was observed in ruminants and hens as the unchanged parent compound was the primary residue component in milk and all ruminant tissues as well as eggs and all avian tissues except liver for both XDE-175-J and XDE-175-L. Metabolism of spinetoram appears to be primarily through demethylation of the N-dimethyl moiety on the forosamine sugar to give the N-demethyl metabolite (goat) and dealkylation of the rhamnose sugar to give the O-deethyl and/or O-demethyl (two possible isomers) metabolites (hen).

Plant metabolism

The Meeting received information on the fate of spinetoram after foliar applications of ^{14}C-XDE-175-J or ^{14}C-XDE-175-L, uniformly labelled with ^{14}C in the macrolide ring, on apple, lettuce and turnip representing the fruits, leafy crops and root crops respectively.

In all three crops tested, applied parent compounds decreased over test period. Among the two spinetoram components, XDE-175-L tended to be metabolized faster than XDE-175-J.

Apple

When a branch of apple tree with immature fruits was treated with single foliar application of either ^{14}C-XDE-175-J or ^{14}C-XDE-175-L at the rate of 1.8 kg ai/ha (4.8×) or 1.1 kg ai/ha (8.9×), respectively, apple fruits harvested seven days (PHI in US GAP) after the application contained 1.2 mg/kg or 0.36 mg/kg of radioactive residues. Washing of fruits (0–30 DAT) with acetonitrile and then dichloromethane removed 63–97% of TRR.

In the case of XDE-175-J application, in apples taken seven DAT, the parent compound was the major residue at 43% of the TRR with N-demethyl-175-J at 9.5% and N-formyl-175-J at 5.1% of the TRR. After the treatment with XDE-175-L, the parent compound was extensively degraded and

metabolized and only 1.3% of the TRR remained as the parent compound with 1.0% of the TRR as N-demethyl-175-L and another 1.0% as N-formyl-175-L.

In the washed fruits obtained from the ^{14}C-XDE-175-J treated branch, peels contained 2–11% of TRR while pulp contained less than 1% (≤ 0.007 mg/kg). In washed fruits from ^{14}C-XDE-175-L treated branch, peel contained 6–33% of TRR while pulp contained less than 4%.

Unextractable radioactive residues were < 10% of TRR in or on all samples after extraction with a mixture of acetonitrile and water (80:20, v/v). Several minor metabolites were also detected in the treated apples and leaves, each at ≤ 7.5% of TRR. A multi-component mixture of extensively degraded compounds represented up to 39–77% of TRR but each component was less than 1% of TRR.

Comparison of radioactivity in treated fruits and shielded fruits indicates that translocation was negligible.

Lettuce

Red leaf lettuce was treated with either single or multiple foliar spray applications of ^{14}C-XDE-175-J or ^{14}C-XDE-175-L. For ^{14}C-XDE-175-J, single applications were made at rates equivalent to 0.90 kg ai/ha while the same amount of the test compound was sprayed in three separate applications with the equal rate at weekly intervals. For ^{14}C-XDE-175-L, plants were treated in a similar fashion but at a rate equivalent to 0.30 kg ai/ha. For both compounds, the applied amounts approximately correspond to four times the maximum seasonal rate on the label and reflect the ratio between XDE-175-J and XDE-175-L in spinetoram formulations.

Washing leaves (0-7 DAT) with dichloromethane and then acetonitrile removed 76–96% of TRR.

The lettuce samples taken one day (PHI in US GAP) after the single application of XDE-175-J or XDE-175-L contained 34 mg/kg in parent equivalents or 7.6 mg/kg of radioactive residues, respectively. For treatment with XDE-175-J, the parent was 31%, N-demethyl-175-J was 20% and N-formyl-175-J was 11% of the TRR. For treatment with XDE-175-L, the parent was 12%, N-demethyl-175-L was 7.2% and N-formyl-175-L was 4.0% of the TRR. With the multiple applications, both TRR and percentage of these three compounds tended to be lower than with single applications of the same total rate for both parent compounds. Only 0.2–5.2% of TRR remained unextractable in all treated lettuce samples after extraction with acetonitrile/water (75:25, v/v).

Several minor metabolites were observed in the 14C-XDE-175-J and 14C-XDE-175-L treated lettuce at ≤ 6% of TRR. A multi-component mixture of extensively degraded compounds represented up to 13–78% of TRR, each component at less than 3% of TRR.

Turnip

Turnips were treated with either a single or multiple foliar applications of ^{14}C-XDE-175-J or ^{14}C-XDE-175-L in the same manner as in the lettuce study. In turnip roots harvested three days after the application, TRR was quite low at 0.12 mg/kg for XDE-175-J treatment and 0.031 mg/kg for XDE-175-L treatment.

In ^{14}C-XDE-175-J treated turnip tops, 59–91% of TRR were surface residues found in the dichloromethane and acetonitrile washings. In ^{14}C-XDE-175-L treated turnip tops, surface residues were 39–80% of TRR.

Major components identified at three DAT were the parent compounds (XDE-175-J and –L), N-dimethyl-175-J and N-formyl-175-J in roots and tops but all less than 25% of the TRR.

Several minor metabolites assumed to be structurally similar to the parent compound were also observed in treated turnip roots and tops, each less than 4% of TRR. A multi-component mixture

of extensively degraded compounds represented 10–74% of TRR; each compound at less than 1% TRR.

Metabolism of spinetoram was observed to be similar in the three crops studied—apple, lettuce and turnip—indicating that a common metabolism is expected for not only fruits, leafy vegetables and root vegetables but also other plants. It appears that three metabolic pathways are responsible for the breakdown of spinetoram in plants. The first one involves changes to the N-demethyl moiety on the forosamine sugar to give the N-demethyl and N-formyl metabolites. N-formyl metabolites were found only in plants. The second involves cleavage of the macrolide ring system at one or more positions, ultimately resulting in a complex residue mixture consisting of numerous components. The third, (applicable only to XDE-175-J), involves changes to the rhamnose sugar producing the 3-O-deethyl and C9-pseudoaglycone-175-J metabolites. All the metabolites occurring as a result of changes in forosamine and rhamnose are further degraded via the second pathway.

Environmental fate in soil

The Meeting reviewed information on aerobic soil metabolism, aqueous photolysis and hydrolysis, and rotational crop study, as spinetoram was intended for protection of root vegetables.

Aerobic soil metabolism

Aerobic soil metabolism studies were conducted using ^{14}C-XDE-175-J or ^{14}C-XDE-175-L, uniformly labelled with ^{14}C in the macrolide ring applied to various soils and incubated under aerobic conditions at 25, 20 or 10 °C. Under aerobic conditions, spinetoram applied to soil was degraded relatively rapidly. In all soils tested, XDE-175-L was degraded faster than XDE-175-J. After one year of incubation at 25 °C, 1.2–2.8% and 0.3–2.9% of applied XDE-175-J and XDE-175-L respectively, remained as the parent in US soils tested. In European soils (except the loamy sand), after 127 days of incubation at 20 °C, 2.0–4.9% and 1.4–5.0% of applied XDE-175-J and XDE-175-L respectively remained as the parent. Carbon dioxide was evolved slowly from all soils and accounted for 5.0–35% and 9.5–32% of the applied XDE-175-J and XDE-175-L respectively after one year at 25 °C, and 0.8–1.1% and 1.2–3.2% of the applied XDE-175-J and XDE-175-L respectively after 127 days at 20 °C.

Major degradation products, N-demethyl-175-J and N-demethyl-175-L were formed and then degraded during the study periods. As minor products (at or less than 10% of the applied dose), N-demethyl-N-nitroso-175-J, N-demethyl-N-nitroso-175-L, N-succinyl-175-J and N-succinyl-175-L were also formed and degraded. Many other degradates were formed but at very low concentrations.

While extractable radioactivity decreased, non-extractable radioactivity steadily increased to reach 22–29% and 32–37% of the applied XDE-175-J and XDE-175-L respectively after one year at 25 °C; and 5–15% and 11–24% of the applied XDE-175-J and XDE-175-L respectively after 127 days at 20 and 10 °C.

Aqueous photolysis

Under xenon light (simulating 40°N latitude summer sunlight) in aqueous buffer solution at pH 7 at 25 °C, XDE-175-J and XDE-175-L degraded rapidly with DT_{50} of 0.5 days and 0.3 days respectively. Numerous (more than 70) minor degradates were observed after irradiation of XDE-175-J and -L. N-demethyl-175-L was observed as a major photodegradation product of XDE-175-L.

At test termination, greater than 90% of the applied amount remained as parent in the dark controls indicating that negligible transformation of the parent compounds occurred in the dark. No degradates were observed in the dark controls.

Aqueous hydrolysis

In sterile aqueous buffer solutions at pH 5 and 7, no degradation was observed for both XDE-J and XDE-175-L for 30 days at 20 °C. At pH 9, a degradate of XDE-175-J was observed but the concentration of XDE-175-J did not decrease below 89% and therefore, XDE-175-J can be regarded to be relatively stable, also at pH 9. After 30 days at pH 9, XDE-175-L decreased from 92% to 82% with N-demethyl-175-L as the major degrade at 12% at the end of the testing period. No minor degradates were detected. DT_{50} of XDE-175-L at pH 9 was calculated to be 154 days.

Residues in succeeding crops

In an outdoor confined rotation study, radish, lettuce and wheat were planted at 30, 120 and 365 days after the application of ^{14}C-XDE-175-J or ^{14}C-XDE-175-L at rate of 405 or 135 g ai/ha respectively to soil corresponding to the maximum seasonal rate and reflecting the ratio of these two active ingredients in spinetoram formulations.

TRRs were very low for all samples at all plant back intervals with the maximum at 0.085 mg/kg in parent equivalents. Unextractable residues in crops were less than 0.019 mg/kg.

Extraction of residues indicated that no greater than 0.065, 0.004 and 0.007 mg/kg were found in the neutral organic phases, acidic organic phases, and in the extracted aqueous phase, respectively. In any immature or mature sample, no single component exceeded 0.025 mg/kg or 0.007 mg/kg, respectively. At 120 DAT and 365 DAT, no radioactive residues were associated with any of XDE-175-L, N-demethyl-175-L or N-formyl-175-L. Of the XDE-175-J treated 120 DAT and 365 DAT crop samples, radish (immature tops and mature tops), lettuce (immature), and wheat forage, hay, and straw contained TRR greater than 0.010 mg/kg, but the concentrations were too low for identification. The lower residues in 30 DAT samples were characterized, but could not be identified.

The levels of radioactivity taken up from soil treated with [^{14}C]spinetoram into the three succeeding crops (radish, lettuce, and wheat) planted 30, 120, or 365 days after treatment, were below 0.085 mg/kg spinetoram equivalents. Since such low radioactive residues were found in analysed fractions of these rotational crop samples, spinetoram is unlikely to be taken up readily by succeeding crops.

Methods of analysis

Analytical methods for determination of residues of spinetoram and its metabolites were developed for a wide range of matrices of plant and animal origin. In general, these methods employ extraction of spinetoram and its metabolites with a mixture of acetonitrile and water (80:20, v/v), addition of a stable isotope internal standard solution containing XDE-175 and metabolites, and then, without any clean-up or with solid phase clean-up using a C18 cartridge, analysis with HPLC with positive-ion electrospray tandem mass spectrometry (LC-MS/MS). Three methods, two for plant matrices and one for animal matrices, are capable of determining XDE-175-J, XDE-175-L, N-demethyl-175-J and -L, and N-formyl-175-J and -L. One method for animal matrices, however, determines XDE-175-J, XDE-175-L, N-demethyl-175-J and -L, and 3'-O-deethyl-175-J and -L.

The methods for plant matrices were validated for each analyte at 0.01–1.0 mg/kg, and in the case of lettuce at 0.01–10 mg/kg. Mean recovery was in a range of 82–111%. The validated limit of quantification was 0.01 mg/kg for all matrices.

The methods for animal matrices were validated for each analyte at 0.01–15 mg/kg in bovine muscle and kidney; 0.01–0.10 mg/kg in poultry muscle; 0.01–50 mg/kg in liver, milk and cream, and eggs; and 0.01–150 mg/kg in fat. Mean recovery ranged between 83 and 119%. The validated limit of quantification was 0.01 mg/kg for all matrices.

The existing multi-residue enforcement methods, FDA PAM I screen methods, were found to be unsuitable for the determination of spinetoram and its metabolites in plant and animal matrices. The DFG S19 multi-residue method was validated successfully only for the determination of spinetoram and its N-demethyl and N-formyl metabolites in apples, grapes and oranges.

Stability of pesticide residues in stored analytical samples

Stability of spinetoram and its N-demethyl and N-formyl metabolites (each at a fortification level of 0.10 ppm) in homogenized orange, lettuce, sugar beet, soya bean and wheat grain stored in deep freezer at –20 °C was investigated over 12 months. No significant decrease of spinetoram was observed in all samples, except lettuce, during the test period. In lettuce, remaining XDE-175-L and N-dimethyl-175-L were 60 and 65% respectively (unadjusted for procedural recovery) at 372 days after initiation of the study.

The Meeting concluded that at –20 °C, spinetoram and its N-demethyl and N-formyl metabolites were stable for 12 months in orange, sugar beet, soya bean and wheat. In lettuce, XDE-175-J, the major component, and its N-demethyl and N-formyl metabolites were also stable for 12 months but XDE-175-L and N-dimethyl-175-L were stable only up to eight months.

As samples of animal tissues, milk and eggs from the metabolism and feeding studies were analysed within 20 days of sample collection in supervised trials, no information was provided to the Meeting on storage stability of spinetoram in animal commodities.

Residue definition

Spinetoram consists of two closely related active ingredients, XDE-175-J and XDE-175-L, present approximately in a three to one ratio.

In apple, lettuce and turnip receiving 4× to 9× the rate of either of the two active ingredients, major metabolites were the parent compounds (XDE-175-J and XDE-175-L), N-demethyl-175-J and N-formyl-175-J. In most cases, PHI XDE-175-J was the primary component of residues. N-demethyl-175-L and N-formyl-175-L were also detected but no more than 7.2% and 4.0% respectively of TRR on one DAT or thereafter.

In goats and hens, metabolism of spinetoram was limited. The parent compounds remained as major components in milk and all ruminant tissues as well as eggs, and all avian tissues except liver, in which 3'-O-deethyl metabolites were detected at similar levels as the parent, but less than 20%.

Sufficiently validated LC-MS/MS methods were available for determining the parent compounds and their N-demethyl and N-formyl metabolites in a wide range of plant commodities and animal tissues, milk and eggs.

Based on the above findings, the Meeting considered that the two parent compounds, XDE-175-J and XDE-175-L, were suitable residues for enforcement. However, as N-demethyl-175-J is a major metabolite in both plants and animals and covered by the ADI, and N-formyl-175-J, a major metabolite in plants, is also found in crops after application of spinetoram, the Meeting decided to include these two metabolites as well as the two spinetoram components in the residue definition for estimation of dietary intake.

XDE-175-J and XDE-175-L have logPow of 4.09 and 4.49 respectively at pH 7 at 20 °C, implying that spinetoram may be fat-soluble. In animal metabolism studies, residue concentrations were found to be higher in tissues with higher fat content. In addition, an animal feeding study with lactating cows indicates that spinetoram residue concentrations in milk fat were 4.4–9.5 times higher than those in whole milk and those in composite fat were 14–24 times higher than in muscle. The Meeting agreed that spinetoram residue is fat-soluble.

The Meeting recommended the following residue definition for plant and animal commodities:

- 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.

Results of supervised residue trials on crops

The Meeting received supervised trial data for spinetoram on orange, pome fruits, stone fruits, leaf lettuce, tomato, sugar beet and tree nuts.

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.

Citrus fruits

Twelve supervised trials were conducted on oranges in the USA.

Six trials conducted using low spray volume applications (approximately 700 L/ha) were in accordance with 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). Spinetoram residues from these trials in rank order were: < 0.01 (2), 0.012, 0.022, 0.028 and 0.03 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were: < 0.02, 0.022, 0.03, 0.052, 0.052 and 0.066 mg/kg.

Six other trials conducted using high spray volume applications (approximately 3300 L/ha) were in accordance with US GAP. Residues from these trials in rank order were: < 0.01, 0.012, 0.015, 0.018, 0.021 and 0.02 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were: < 0.02, 0.039, 0.041, 0.046, 0.047 and 0.069 mg/kg.

The Meeting considered that these two sets of trials conducted in the same locations could not be regarded as independent from each other and decided to use one data set for the estimation of maximum residue level. Taking into consideration the results of the two data sets being mutually supportive, the Meeting estimated a maximum residue level based on spinetoram residues and an STMR based on the total residues of spinetoram and the two metabolites for oranges at 0.07 and 0.0435 mg/kg.

Pome fruits

Numerous supervised trials were conducted on apple in Australia (20), Canada (8), New Zealand (20) and the USA (12).

Six trials conducted in the USA using low spray volume applications (approximately700 L/ha) were in accordance with US GAP for pome fruits (maximum rate of 123 g ai/ha, five applications, maximum seasonal rate of 500 g ai/ha, PHI seven days). Spinetoram residues from these trials in rank order were: < 0.01 (3), 0.01, 0.013 and 0.028 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02 (3), 0.023, 0.036 and 0.038 mg/kg.

Six other trials conducted in the USA using high spray volume applications (approximately 3300 L/ha) were in accordance with US GAP. Spinetoram residues from these trials in rank order were < 0.01 (4), 0.012 and 0.02 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02 (2), 0.022, 0.022, 0.026 and 0.037 mg/kg.

Supervised trials were conducted in four locations in Canada and in the USA in accordance with Canadian GAP for pome fruits (maximum rate of 103 g ai/ha, three applications, maximum seasonal rate of 315 g ai/ha, PHI seven days). Since two plots were in each location, only higher residues were selected for each location. Spinetoram residues from these trials in rank order were < 0.01, 0.015, 0.017 and 0.028 mg/kg. These trials were also in compliance with US GAP. Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02, 0.025, 0.038 and 0.038 mg/kg.

Two trials conducted in Australia and five trials in New Zealand were according to GAP in New Zealand for pome fruits (maximum 2.5 g ai/hL, minimum 50 g ai/ha, four applications and PHI seven days). Spinetoram residues from these trials in rank order were < 0.01 (7) mg/kg. Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02 (7) mg/kg.

Although application rates were different (PHI in all related GAPs is seven days), results of trials matching three different GAPs were mutually supportive. In ten trials conducted in the USA and Canada following US GAP, which would lead to the highest residues, spinetoram residues were in rank order: < 0.01 (4), 0.01 0.013 0.015 0.017 and 0.028 (2) mg/kg. Corresponding total residues of spinetoram and the two metabolites in rank order were: <0.02 (3), 0.023, 0.025, 0.036, 0.038 (3) mg/kg.

Eight trials were conducted on <u>pear</u> in Australia and eight other in New Zealand. No trials in Australia matched GAP of New Zealand for pome fruits. Spinetoram residues from two trials conducted in New Zealand in accordance with GAP of New Zealand in rank order were < 0.01 and 0.02 mg/kg. Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02 and 0.03 mg/kg.

Since the results from trials on apple and pear were similar, the Meeting estimated a maximum residue level based on spinetoram residues and an STMR based on the total residues of spinetoram and the two metabolites, for pome fruits on a basis of apple trials, at 0.05 and 0.025 mg/kg respectively.

Stone fruits

A large number of supervised trials were conducted on cherry, peach and apricot in Australia and New Zealand. A few trials on nectarines were also conducted in Australia.

However, since proposed GAP in Australia for stone fruits has not been approved, no maximum residue level could be estimated.

Tomato

Six supervised trials conducted in the USA were according to US GAP for fruiting vegetables (maximum rate of 88 g ai/ha, six applications, maximum seasonal rate of 298 g ai/ha and PHI one day). Residues from these trials in rank order were < 0.01 (2), <u>0.01</u>, 0.0156, 0.024 and 0.025 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02 (3), <u>0.02</u>, 0.025, 0.034 and 0.035 mg/kg.

The Meeting estimated a maximum residue level based on spinetoram residues and an STMR based on the total residue of spinetoram and the two metabolites in tomato at 0.06 and 0.02 mg/kg respectively.

Lettuce

Six supervised trials were conducted on leaf lettuce in the USA in accordance with US GAP for leafy vegetables (maximum rate of 88 g ai/ha, six applications, maximum seasonal rate of 298 g ai/ha and PHI one day). Residues in rank order were 0.15, 0.31, 0.32, 0.34, 0.55 and 7.80 mg/kg.

Corresponding total residues of spinetoram and the two metabolites in rank order were 0.28, 0.56, 0.64, 1.16, 1.35 and 9.55 mg/kg.

The residue values of 7.80 and 9.55 mg/kg were very high compared to the rest of results. The study report indicates that the trial was conducted in the same manner as the other trials and there was no indication for this trial being invalid. Using all the residue values, the Meeting estimated a maximum residue level based on spinetoram residues and an STMR for spinetoram in lettuce at 10 and 0.895 mg/kg.

As foliar applications on leaf lettuce were expected to result in higher residues than those on head lettuce, the Meeting agreed that these maximum residue level and STMR are applicable also to head lettuce.

Sugar beet

Six supervised trials were conducted in the USA. In one trial according to US GAP (maximum rate of 70 g ai/ha, four applications, maximum seasonal rate of 281 g ai/ha and PHI seven days) for tuberous vegetables, e.g., potato and sugar beet, the residue was < 0.01 mg/kg. In the other five trials, root samples were taken three days after the last application, earlier than the required PHI of seven days in GAP. Residues in these five trials were < 0.01 mg/kg (5).

Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02 (6) mg/kg.

The Meeting estimated a maximum residue level based on spinetoram residues and an STMR for spinetoram in sugar beet at 0.01 (*) and 0.02 mg/kg respectively.

Tree nuts

Six supervised trials were conducted on almonds in the USA. One trial was in accordance with US GAP for tree nuts (maximum rate of 123 g ai/ha, four applications, maximum seasonal rate of 490 g ai/ha and PHI 14 days), and residues were < 0.01 mg/kg. In the other five trials, nut samples were taken seven days after the last application rather than the required PHI of 14 days in GAP. Residues in these five trials were < 0.01 mg/kg (5).

Corresponding total residues of spinetoram and the two metabolites in rank order were < 0.02 (6) mg/kg.

Six supervised trials were also conducted on pecan in the USA. In one trial according to US GAP for tree nuts, residues were < 0.01 mg/kg. In the other five trials, nut samples were taken seven days after the last application rather than the required PHI of 14 days in GAP. Residues in these five trials were < 0.01 mg/kg (2) and 0.01 (3) mg/kg. A decline study indicates that it is likely that residues would be less than 0.01 mg/kg if samples were taken on the required PHI of 14 days and in general residues were not expected to occur in edible portions of tree nuts due to negligible translocation of spinetoram.

From the results of trials on almonds and pecan, the Meeting estimated a maximum residue level based on spinetoram residues and an STMR based on the total residue of spinetoram and the two metabolites in tree nuts at 0.01 and 0.02 mg/kg.

Sugar beet leaves or tops

Among six supervised trials conducted in the USA, only one was in compliance with US GAP and residues were 0.024 mg/kg. In other trials, samples were collected only three days after the last application instead of the required PHI of seven days and they contained finite level of residues. However, these trials were in compliance with US GAP for leaf of root and tuberous vegetables for forage (maximum rate of 80 g ai/ha, four applications, maximum seasonal rate of 281 g ai/ha and PHI of three days). Residues from these trials were 0.086, 0.099, 0.11, 0.16 and 0.20 (2) mg/kg.

The Meeting estimated an STMR and a highest residue in sugar beet leaves or tops based on spinetoram residues for calculation of animal burden at 0.135 and 0.20 mg/kg.

Almond hulls

Among six supervised trials conducted in the USA, only one trial was in accordance with US GAP and residues are 0.75 mg/kg. In other trials, samples were collected seven days after the last application instead of the required PHI of 14 days and they contained finite level of residues. The Meeting concluded that it was not possible to estimate a maximum residue level for spinetoram in almond hulls from the results of these trials.

Fate of residues during processing

The Meeting received information on processing of oranges to juice and oil, and apples to juice and puree (sauce).

Processing factors were calculated for oranges (juice, peel and pulp after juicing, dried pulp and oil) and for apples (juice, dry pomace and puree (sauce)).

Processed Orange Product	Processing factor		STMR/STMR-P (mg/kg)
	Spinetoram residues	Spinetoram+2 metabolites	
Orange	-	-	0.045
Juice	< 0.05	< 0.07	0.003
Dried pulp	2.4	2.3	0.105
Apple	-	-	0.025
Juice	< 0.37	< 0.44	0.011
Dry pomace	8.1	6.0	0.15
Puree (sauce)	0.45	0.47	0.012

For the purpose of calculating animal dietary burden for estimating maximum residue levels for commodities of animal origin, STMR-P for citrus pulp, dry and apple pomace, dry were calculated based on spinetoram residues to be 0.048 and 0.081 mg/kg.

Farm animal dietary burden

Dry apple pomace, dry citrus pulp and sugar leaves or tops may be fed to dairy cattle and beef cattle but not as a major ingredient. The dietary burdens were calculated from the highest residue and STMR of sugar beet leaves or tops, and the STMRs of apple pomace, dry, using the OECD feedstuffs tables (Annex 6 of the 2006 Report of the JMPR).

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

	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	0.018	0.018	0.192[a]	0.135[b]	0.018	0.018
Dairy cattle	0.0089	0.0089	0.270[c]	0.185[d]	0.0089	0.0089

[a] Suitable for estimating maximum residue levels for meat and edible offal.

[b] Suitable for estimating STMRs for meat and edible offal.

[c] Suitable for estimating a maximum residue level for milk and fat.

[d] Suitable for estimating an STMR for milk and fat.

Residues in milk and cattle tissues

Lactating dairy cows were dosed daily for 29 consecutive days via gelatin capsules containing a mixture of spinetoram and N-demethyl and N-formyl metabolites of XDE-175-J (1.2–38.6 ppm in diet) or spinetoram only (37.6 ppm).

Residues in the milk in 1.2 ppm (equivalent to 0.4 mg XDE-175-J and -L) dose group were generally between the LOD (0.003 mg/kg) and LOQ (0.01 mg/kg) throughout the dosing period.

No or low concentration residues were detected in skim milk; even in 11.5 and 38.6 ppm (total) doses groups, mean total residues of the four compounds in skim milk ranged from just below the LOQ to 0.075 mg/kg. In all of the dose groups on day 14 and 28, total residues in cream were much higher than the residues in skim milk at 0.187 and 0.237 mg/kg in the 1.2 ppm doses groups. The mean total residues in cream from the 11.5 and 38.6 ppm doses groups ranged from 0.64 to 5.84 mg/kg. The average ratio of residues in cream to those in whole milk is 6:6.

All tissues from treated cows contained residues and they increased from the lowest to highest dose groups. Residue concentrations were lowest in the muscle followed by kidney, liver, and fat. Residues in fat were significantly higher than residues in the other tissues. These results indicate that residues of spinetoram tend to accumulate in fatty tissue.

With one exception, residues were not detectable in milk by the fourth day after the last dose was administered. Concentrations just above the LOD were detected in one cow through day nine after the final dose. No further residue was detected beyond that point.

Residues in tissues continuously declined through 28-day depletion period after the last dose. No residue was detected in kidney, liver or muscle from any cow by 28 days after the final dose or in fat 56 days following the final dose.

The dietary burdens for beef and dairy cattle are both lower than the lowest feeding level (1.2 ppm, equivalent to 0.4 ppm of spinetoram only) in the feeding study. Therefore the MRL and STMR were estimated using the residue concentrations in milk and tissues at the lowest feeding level and the dietary burden. The calculated residues in cattle tissues and milk are summarized below.

Dietary burden mg/kg Feeding level [mg/kg]	Spinetoram residues, mg/kg				
	Milk	Muscle	Liver	Kidney	Fat
MRL	highest	highest	highest	highest	highest
0.270/0.192	< 0.00675	< 0.00480	< 0.00480	< 0.00480	0.0743
[0.4]	[< 0.01]	[< 0.01]	[< 0.01]	[< 0.01]	[0.11]
	Spinetoram, N-demethyl-175-J and N-formyl-175-J, mg/kg				
STMR	mean	mean	mean	mean	mean
0.185/0.135	< 0.00925	< 0.00625	< 0.00625	< 0.00625	0.0463
[0.4]	[< 0.02]	[< 0.02]	[< 0.02]	[< 0.02]	[0.10]

The Meeting estimated a maximum residue level for spinetoram in edible offal (mammalian) and whole milk at 0.01(*) mg/kg and in mammalian fats at 0.2 mg/kg. STMRs were estimated to be 0.00925 mg/kg for whole milk, 0.00625 mg/kg for meat (muscle) and edible offal (mammalian), and 0.046 mg/kg for mammalian fats.

The Meeting estimated a maximum residue level for spinetoram and an STMR for spinetoram and the two metabolites in milk fat, using the median ratio between residues in cream and whole milk of 6:6 and assuming that cream contains 50% fat, at 0.1 mg/kg and 0.12 mg/kg respectively.

Poultry

No data were provided on poultry feeding study. Since there was no treated commodities that can be fed to hens, the Meeting considered that it was unnecessary to estimate maximum residue levels for poultry tissues or eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Dietary Intakes (IEDIs) of spinetoram were calculated for the 13 GEMS/Food cluster diets using STMRs estimated by the current Meeting (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 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.

5.21 SPINOSAD (203)

Spinosad, an insecticide, was first evaluated by the 2001 JMPR (T, R), which established an ADI of 0–0.02 mg/kg bw. An ARfD was judged to be unnecessary. MRLs were recommended for fruits, vegetables, nuts, oil seeds, cereal grains, animal feeds and animal commodities. The 2004 JMPR recommended several additional MRLs. In 2007, on the request of the Delegation of the United States, the 39the Session of the CCPR scheduled the evaluation of additional MRLs on banana, cranberry and hops for the 2008 JMPR.

The meeting received information from the IR-4 project[44] on registered uses and data from supervised residue trials.

Methods of analysis

All methods are immunoassays that were previously reported and evaluated by the 2001 JMPR. These methods do not differentiate between individual spinosyns, but measure the total residue of spinosad and its metabolites LOQs were 0.005 mg/kg for leafy vegetables and 0.01 mg/kg for banana, cranberry and basil.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of residues in samples stored frozen. JMPR 2001 evaluated a large amount of storage stability data and found no indications for instability during storage.

Results of supervised residue trials on crops

The Meeting received supervised trials data for spinosad on banana, cranberry, basil, mustard greens, spinach and legume forage. No data on hops was submitted.

Cranberry

Field trials were conducted in the USA and Canada using the SC formulation at a rate of 3 times 0.18 kg ai/ha, with a PHI of 20–21 days. USA GAP indicates a rate of 0.07–0.17 kg ai/ha with no more than a total of 0.50 kg ai/ha per crop, with a PHI of 3 days. In all six trials the residues were < 0.01 (6) mg/kg.

The Meeting decided that since none of the trials matched GAP, no estimate could be made for a maximum residue limit for spinosad in cranberries.

Banana

Field trials were conducted in Hawaii (USA) using the SC formulation at a rate of 4 times 0.015 kg ai/hL, with a PHI of 53–56 days. USA GAP indicates using a rate of 4 times a spray concentration of 0.006 kg ai/hL, with a PHI of 56 days. In one of the trials banana bunches were bagged following the final application once the spray mixture deposits had dried; this trial yielded a residue of 0.026 mg/kg (whole banana). In the other four trials the banana bunches remained unbagged, residues were: 0.033, 0.042, 0.13, 0.19 mg/kg (whole banana). No information was available on the residue in the edible portion.

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[44] The Interregional Research Project Number 4 (IR-4) is a publicly funded program in the USA that was established in 1963 to help minor acreage, specialty crop producers obtain EPA tolerances and new registered uses for pest control products.

The Meeting decided that as no trials matched GAP, no estimate could be made for a maximum residue limit for spinosad in bananas.

Leafy vegetables

Four field trials were conducted in the USA in mustard greens and cowpea forage (Georgia) and in spinach and snap bean forage (California) using the GF fruit fly bait formulation. The application rates were approximately 0.03 kg ai/ha (base rate = 1×), 0.10 kg ai/ha (3×), and 0.33 kg ai/ha (10×). Samples of commercially mature greens were collected on day 0. USA GAP indicates 0.01–0.02 kg ai/ha without specifications on the number of applications or PHI. Residues at 1× rate were < 0.005 (3), 0.0063 mg/kg, at 3× rate < 0.005(2), 0.0058, 0.0072 mg/kg, and at 10× rate 0.019, 0.026, 0.046, 0.070 mg/kg.

The Meeting decided not to estimate a new maximum residue level for spinosad in leafy vegetables.

Dried herbs

Two field trials were conducted on basil, one each in Washington and California (USA), using the SC formulation with 5 applications at approximately 0.11 kg ai/ha, for a total of approximately 0.5 kg ai/ha, with a PHI of 1 day. In the Californian trial, residues were determined both in fresh and dry basil. The US GAP for herbs and hops indicates a maximum of 5 applications per crop at a rate of 0.07–0.10 kg ai/ha, PHI 1 day. Residues were 0.66 and 1.90 mg/kg in fresh basil and 6.3 mg/kg in dry basil.

The Meeting agreed that the data was insufficient to estimate a maximum residue level for spinosad in dried herbs (basil and hops).

5.22 SPIROTETRAMAT (234)

TOXICOLOGY

Spirotetramat is the ISO approved name for *cis*-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4,5]dec-3-en-2-one (IUPAC). The CAS No. is 203313-25-1. Spirotetramat belongs to the chemical class of ketoenols, subclass tetramic acid derivatives, intended for use as an insecticide on a range of agricultural crops. The pesticidal mechanism of action is disruption of lipogenesis as a result of inhibition of acetyl CoA carboxylase.

The JMPR has not previously evaluated spirotetramat. Spirotetramat was reviewed by the present Meeting at the request of CCPR under the new compounds review programme.

The batches of spirotetramat used in studies of toxicity had a variable impurity profile. Some impurities were absent in the material used in long-term studies of toxicity and studies of genotoxicity, or were present at a low concentration. However, the results of studies with impurities indicated that this is not a critical issue in the toxicological evaluation. All critical studies complied with GLP.

Biochemical aspects

After oral administration at a dose of 2 or 100 mg/kg bw, spirotetramat was rapidly absorbed in rats. The extent of absorption in the single low-dose test was 95%. The maximum plasma concentration of radiolabel was reached 0.1–2.0 h after dosing. Concentrations of radiolabel in tissues and organs at 48 h were very low (< 0.2%). Excretion was mainly urinary and was very rapid (essentially complete within 24 h). Faecal excretion accounted for 2–11% of the administered dose in rats. No parent compound was detected in the excreta. Only very minor metabolites (< 0.7% of the administered dose) were not identified. The main metabolic reaction was cleavage of the ester group, producing the enol that is subsequently metabolized to a range of metabolites.

In male rats given a high dose of spirotetramat at 1000 mg/kg bw, it was found that only 27% of the administered dose was excreted in the urine after 24 h. In addition, concentrations of radiolabel in the plasma were slightly higher than in the liver and kidney, and the decline in concentrations of radiolabel found in the tissues was minimal from 1 h to 8 h after dosing, with considerable quantities still remaining at 24 h (approximately 25%). These findings were consistent with saturation of cellular transport mechanisms, which may result in decreased excretion via urine and faeces and a potential for the accumulation of spirotetramat metabolites in the body after repeated high doses. The results of physiologically based pharmacokinetic simulations supported this conclusion and suggested that repeated daily doses of spirotetramat at > 500 mg/kg bw lead to non-linear elimination kinetics, resulting in a higher-than-expected body burden in studies with repeated doses, despite some evidence of reduced absorption at such high doses.

In a comparative study of metabolism in vitro in hepatocytes from male rats, mice, and humans, differences in the proportions of several metabolites were observed; however, BYI 08330-enol was the first and most prominent metabolite detected and accounted for 66% and 100% of all metabolites in these studies, in mice and rats respectively. The relative efficiency of enol glucuronidation in isolated hepatocytes was: mouse > human > rat.

Toxicological data

Spirotetramat has low acute toxicity: oral and dermal LD_{50}s in rats were > 2000 mg/kg bw; the inhalation LC_{50} was > 4.18 mg/L of air. Spirotetramat is not a skin irritant in rabbits, although it is an irritant to rabbit eyes. Spirotetramat exhibited a skin sensitization potential in guinea-pigs (Magnussen & Kligman test) and mice (local lymph node assay).

In general, there were no target organs or effects that were common to all species. However, it should be noted that there were indications of immune-related effects in several species.

Mice appeared to be insensitive to toxicity caused by spirotetramat. In repeat-dose studies, mice given diets containing spirotetramat at the highest dose of 5000 ppm (equal to 1415 mg/kg bw per day), 7000 ppm (equal to 1305 mg/kg bw per day) or 7000 ppm (equal to 1022 mg/kg bw per day) for 4 weeks, 14 weeks or 18 months, respectively, showed no toxicological effects.

In a 14-week dietary study of toxicity in rats, the NOAEL was 2500 ppm (equal to 148 mg/kg bw) on the basis of decreased body-weight gain, an increased incidence of abnormal spermatozoa and hypospermia, an increased incidence of tubular degeneration, decreased absolute testicular weight, and accumulation of alveolar macrophages in the lungs of rats at 10 000 ppm (equal to 616 mg/kg bw per day). However these effects were reversible within 4 weeks in most rats after cessation of treatment. In the 1-year dietary study in rats, the NOAEL was 250 ppm (equal to 13.2 mg/kg bw per day) on the basis of an increased incidence of accumulation of alveolar macrophages in the lungs of males at 3500 ppm (equal to 189 mg/kg bw per day). Effects on body weight, and testes and sperm were observed at 7500 ppm.

The thymus and the thyroid were the main target organs in dogs. Reduced weight accompanied with histological evidence of involution and atrophy of the thymus were observed at 6400 ppm in the 4-week dose range-finding study, at 4000/2500 ppm in the 13-week study, and at 600 and 1800 ppm in the 1-year study. Although there was no clear dose–response relationship in the 1-year study, these findings were considered toxicologically significant because they occurred in all studies and because there were other indications that spirotetramat interferes with the immune system (skin sensitization, effect on lungs in rats, and allergic contact dermatitis in humans). Decreases in T4 and T3 concentrations were also observed, with an overall NOAEL of 600 ppm. Changes at this dose were inconsistent. Reduced body weight and haematological effects were observed at higher doses.

The occasional brain ventricular dilatation observed at 600 ppm (one male and one female) and at 1800 ppm (one male) in the 1-year study was not accompanied by any clear histopathological alterations. In addition, brain ventricular dilatation is occasionally reported to occur spontaneously in the strain of dogs used in the test. Consequently, the Meeting considered that this finding was of uncertain toxicological significance.

The Meeting concluded that the NOAEL in the 1-year study in dogs was 200 ppm, equal to 5 mg/kg bw per day, on the basis of effects on the thymus. This NOAEL is also protective for the equivocal findings of changes in thyroid hormones, and the brain ventricular dilatation of uncertain significance seen at 600 ppm.

Spirotetramat was tested in an extensive range of studies of genotoxicity. Negative results were found in studies in vivo and in vitro, except for one weakly and equivocally positive result in a study for chromosomal aberrations in vitro that was not reproduced in a second study using higher concentrations. The Meeting concluded that spirotetramat was unlikely to be genotoxic.

The carcinogenic potential of spirotetramat was studied in mice and rats. Spirotetramat was not found to be carcinogenic in either species. In rats, the NOAEL was 250 ppm, equal to 12.5 mg/kg bw per day, on the basis of structural changes in the kidney (renal tubular dilatation) at 3500 ppm. In this study, effects on the lungs were characterized by an increased incidence of accumulation of alveolar macrophages and of interstitial pneumonia at 7500 ppm and inconsistently at lower doses. These changes were of uncertain significance, possibly being indicative of effects of spirotetramat on the immune system. Effects on body-weight gain, the testes, epididymis and bile duct were also observed at 7500 ppm.

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

Further support for findings of testicular effects in rats given spirotetramat at a high dose was provided by the results of a dose range-finding one-generation study and a two-generation study of

reproductive toxicity. In the one-generation dietary study of reproductive toxicity in rats, severe toxicity was observed in sperm (motility and malformation) of parental males at 10 000 ppm (equal to 538 mg/kg bw per day), resulting in no pregnancies with a NOAEL of 6000 ppm (equal to 320 mg/kg bw per day). However, minimal effects on sperm parameters were observed in the F_1 generation at 6000 ppm (equivalent to 400 mg/kg bw per day in parents) with a NOAEL of 500 ppm (equal to 27.8 mg/kg bw per day in parents). At this dose, a significant (–14%) decline in pup weight gain, possibly secondary to decreases in maternal body weight was observed. In the two-generation study of reproductive toxicity, abnormal sperm cells were reported in the F_1 generation, but not in parental male rats at 6000 ppm (equal to 487 mg/kg bw per day) and decreased reproductive performance was also observed in one of these males. Offspring toxicity also included decreased body weight in F_1 and F_2 pups in both sexes during lactation at 6000 ppm (equal to 419 mg/kg, bw per day). Effects observed in parental generation were reduction of body weight and/or body-weight gain, reduced terminal body weight, reduced food consumption (females) and increased multifocal tubular dilatation in the kidneys in rats at 6000 ppm. The NOAEL for parental toxicity was 1000ppm (equal to 70.7 mg/kg bw per day) on the basis of decreases in body-weight gain in the parental generation. The NOAEL for reproductive toxicity was 1000 ppm (equal to 79.5 mg/kg bw in F_1 males) on the basis of abnormal sperm-cell morphology in the F_1 generation. The NOAEL for offspring toxicity was 1000 ppm on the basis of growth retardation at 6000 ppm.

Two studies of developmental toxicity in rats treated by gavage had been performed. Inconsistent and equivocal effects on the offspring, including retarded ossification and increased wavy ribs, were observed in one study at doses of 140 and 20 mg/kg bw per day. Maternal effects consisting mainly of reduced body-weight gain were observed at 1000 mg/kg bw per day and were associated with reduced offspring weight, reduced fetal weight, retarded ossification and a slight increase in the frequency of fetuses with any malformations. The overall NOAEL for maternal toxicity was 140 mg/kg bw per day and the overall NOAEL for developmental toxicity was 140 mg/kg bw per day.

In a study of developmental toxicity in rabbits treated by gavage, severe maternal toxicity was observed, including death and abortion, at 160 mg/kg bw per day. No effects were observed at 40 mg/kg bw per day, except one abortion, which was considered to be incidental. No significant effects were observed in the offspring and the NOAEL was 160 mg/kg bw per day, the highest dose tested. The NOAEL for maternal toxicity was 40 mg/kg bw per day.

The effect on sperm, testes and epididymis were studied in more detail in rats given spirotetramat at a dose of 1000 mg/kg bw per day. It was observed that the decreased epididymal sperm counts occurred after 21 days and not after 10 days of treatment. In another study in rats given the enol metabolite, testicular/sperm toxicity similar to that caused by spirotetramat was observed. Thus these effects are unlikely to be due to the presence of the acyl chain of this compound.

The Meeting concluded that spirotetramat causes toxicity in the testes and sperm that, at higher doses, affects reproductive performance in rats. The NOAEL for testes and sperm effects was 169 mg/kg bw per day, with a LOAEL of 370 mg/kg bw per day in a 2-year study in adult rats, and a NOAEL of 79.5 mg/kg bw per day and a marginal LOAEL of 400 mg/kg bw per day in young rats, respectively. The Meeting observed that these effects occurred at dose higher than those causing other types of systemic toxicity, on which the ADI and ARfD were based.

Two studies of acute oral neurotoxicity in rats had been conducted. The overall NOAEL was 100 mg/kg bw per day on the basis of urine staining and slight declines in motor and locomotor activity in male rats at 200 mg/kg bw per day.

Studies with four metabolites found in animals and plants—BYI 08330-*cis*-ketohydroxy, BYI 08330-desmethyl-ketohydroxy, BYI 08330-mono-hydroxy and BYI 08330-di-hydroxy—showed that these substances were of low acute oral toxicity in female rats (LD_{50} > 2000 mg/kg bw) and not mutagenic in an assay for gene mutation in strains of *Salmonella typhimurium*. The plant-specific metabolite BYI 08330-enol-glucoside is rapidly absorbed from the gastrointestinal tract and

extensively metabolized and excreted within 24 h. The metabolites formed from this compound in rats do not differ from those found in the metabolism study with spirotetramat in rats.

Spirotetramat caused two proven cases of allergic contact dermatitis in workers handling undiluted active ingredient. Neither a questionnaire survey among staff exposed to spirotetramat nor yearly surveillance of 12 workers exposed to spirotetramat revealed any further cases of sensitization.

The Meeting concluded that the existing database on spirotetramat was adequate to characteri ze the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.05 mg/kg bw per day based on a NOAEL of 200 ppm (equal to 5 mg/kg bw per day) identified on the basis of thymus involution in a 1-year study in dogs and with a safety factor of 100.

The Meeting established an ARfD of 1 mg/kg bw based on a NOAEL of 100 mg/kg bw identified on the basis of altered motor and locomotor activity and FOB changes in a single-dose study in rats treated by gavage and with a safety factor of 100. This ARfD provides adequate protection from maternal toxicity and abortion observed at 160 mg/kg bw per day in the study of developmental toxicity in rabbit, even in the unlikely event that the observed effect could be attributed to a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month study of carcinogenicity [a]	Toxicity and carcinogenicity	7000 ppm, equal to 1022 mg/kg bw per day[c]	—
Rat	Two-year study of carcinogenicity [a]	Toxicity	250 ppm, equal to 12.5 mg/kg bw per day	—
		Carcinogenicity	7500 ppm, equal to 373 mg/kg bw per day [c]	3500 ppm, equal to 169 mg/kg bw per day
	Multigeneration reproductive toxicity [a d]	Parental	1000 ppm, equal to 70.7 mg/kg bw per day	6000 ppm, equal to 419 mg/kg bw per day
		Offspring	1000 ppm, equal to 79.5 mg/kg bw per day	6000 ppm equivalent to 400 mg/kg bw per day
		Reproductive	1000 ppm, equal to 79.5 mg/kg bw per day	6000 ppm, equal to 486.7 mg/kg bw per day
	Developmental toxicity[b]	Maternal toxicity	140 mg/kg bw per day	1000 mg/kg bw per day
		Embryo and fetal toxicity	140 mg/kg bw per day	1000 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	Acute oral neurotoxicity[b,d]		100 mg/kg bw (overall)	200 mg/kg bw
Rabbit	Developmental toxicity [b]	Maternal toxicity	40 mg/kg bw per day	160 mg/kg bw per day
		Embryo and fetal toxicity	160 mg/kg bw per day[c]	—
Dog	1-year study of toxicity [a]	Toxicity	200 ppm, equal to 5 mg/kg bw per day	600 ppm, equal to 19 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

[d] Two studies were combined.

Estimate of acceptable daily intake for humans

0–0.05 mg/kg bw

Estimate of acute reference dose

1 mg/kg bw

Information that would be useful for continued evaluation of the compound

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

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

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid and nearly complete absorption,
Distribution	Extensive, highest in liver and kidney
Potential for accumulation	No evidence of significant accumulation at low doses
Rate and extent of excretion	Very fast and almost complete within 48 h.
Metabolism in animals	Extensive. Main metabolite BYI08330-enol was formed by cleavage of ester bond. Other minor metabolites are formed by oxidative transformation or conjugation.
Toxicologically significant compounds (animals, plants and environment)	Spirotetramat and BYI08330-enol
Acute toxicity	
Rat, LD_{50}, oral	> 2000 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 4.18 mg/L air (nose only)
Rabbit, dermal irritation	Not irritating

Rabbit, ocular irritation	Irritating
Skin sensitization	Skin sensitization potential (Magnussen & Kligman test) in guinea-pigs and local lymph node assay in mice
Short-term studies of toxicity	
Target/critical effect	Thymus involution
Lowest relevant oral NOAEL	200 ppm (equal to 5 mg/kg bw per day) 1-year study in dogs
Lowest relevant dermal NOAEL	> 1000 mg/kg bw per day
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	No genotoxic potential
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Kidney (tubular dilatation), decreased absolute weight
Lowest relevant NOAEL	2-year, rat, 250 ppm (equal to 12.5 mg/kg bw per day)
Carcinogenicity	No carcinogenic potential in mice and rat
Reproductive toxicity	
Reproduction target/critical effect	Abnormal sperm in F_1 at parentally toxic dose
Lowest relevant reproductive NOAEL	Parental toxicity: 1000 ppm (equal to 70.7 mg/kg bw per day)
	Offspring toxicity: 1000 ppm (equal to 79.5 mg/kg bw per day)
	Reproductive toxicity: 1000 ppm (equal to 79.5 mg/kg bw per day)
Developmental target/critical effect	Increase incidence of retarded ossification in fetuses at maternally toxic doses in rats. None in rabbits.
Lowest relevant developmental NOAEL	Maternal toxicity: 40 mg/kg bw per day (rabbit)
	Developmental toxicity: 140 mg/kg bw per day (rat)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity	Based on behavioural effects, NOAEL was 100 mg/kg bw per day in rats
Medical data	
	Two proven cases of allergic contact dermatitis in workers handling undiluted active ingredient. No other effects were observed.

Summary

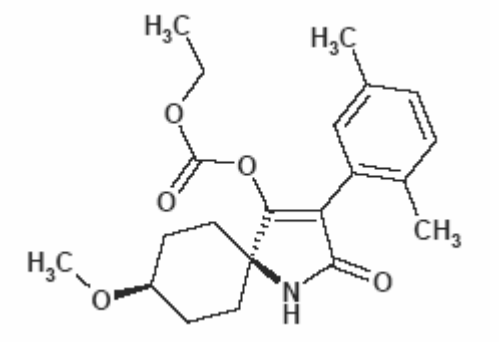
	Value	*Study*	*Safety factor*
ADI	0–0.05mg/kg bw	Dog, 1-year study of oral toxicity	100
ARfD	1 mg/kg bw	Rat, studies of acute oral neurotoxicity	100

RESIDUE AND ANALYTICAL ASPECTS

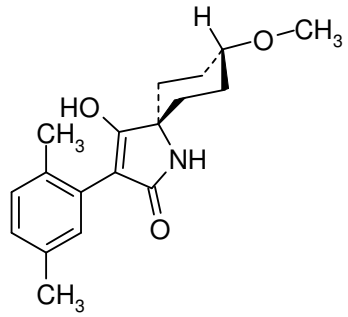
Spirotetramat belongs to the chemical class of ketoenols and acts as a systemic insecticide for the control of a broad spectrum of sucking insects. At the 39th session of the CCPR (ALINORM 07/30/24), it was listed as a candidate for evaluation of new compounds by the 2008 JMPR.

Chemical name

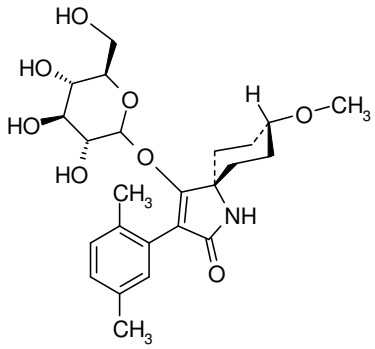
cis-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate



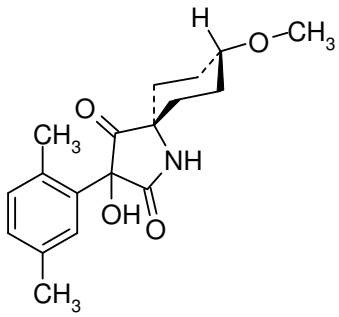
Chemical structures of major metabolites:



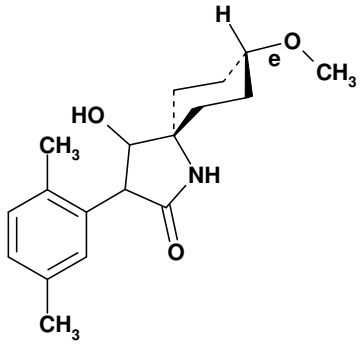
Spirotetramat Enol



Spirotetramat Enol Glucoside (Glc)



Spirotetramat Ketohydroxy



Spirotetramat Monohydroxy

Animal metabolism

The Meeting reviewed studies on the metabolism of [azaspirodecenyl-3-^{14}C]spirotetramat in goats and hens. A lactating goat received 4 daily oral administrations of spirotetramat at a mean dose rate of 2.22 mg/kg bw/day (73.0 ppm in the diet). The urine and faeces contained about 90% of the

administered dose of radioactivity. The levels of radioactive residue in milk and tissues were as follows: milk (day 4), 0.008 mg/kg; muscle, 0.011 mg/kg; fat, 0.003 mg/kg; liver 0.050 mg/kg; and kidney 0.184 mg/kg. Spirotetramat was absent in all samples. The major metabolites in all matrices were spirotetramat-enol (34–72% TRR) and spirotetramat-enol GA (glucuronic acid conjugate of 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one , 14–37% TRR). Minor metabolites were spirotetramat desmethyl enol (3-(2,5-dimethylphenyl)-4,8-dihydroxy-1-azaspiro[4.5]dec-3-en-2-one, 0–8% TRR), spirotetramat ketohydroxy (0–10% TRR) and spirotetramat monohydroxy (0–4% TRR). The degree of identification ranged from 79% TRR in fat to 99% TRR in kidney.

Six laying hens were administered 14 oral doses of [azaspirodecenyl-3-^{14}C]spirotetramat at a daily dose rate of 1.01 mg/kg bw/day (12.86 ppm in the diet). The TRR levels were as follows: eggs (pool day 2–14), 0.015 mg/kg, fat, 0.0038 mg/kg; kidney, 0.039 mg/kg; liver, 0.017 mg/kg; and muscle, 0.0034 mg/kg. The residue level in eggs appears to reach a plateau by day 10. The residue profile was qualitatively similar to that of the goat. Spirotetramat was not found in any matrix. The major metabolites were spirotetramat enol (18–84% TRR) and spirotetramat enol GA (4–15% TRR), with no other metabolites identified. The identifications ranged from 18% TRR (fat, with low TRR) to 84% (egg). About 30% of the TRR in liver was not released after exhaustive extractions.

Spirotetramat was completely metabolized by the rat, with no parent compound found in the excreta. Identified metabolites accounted for ≥ 87% of the administered dose. The major metabolite was spirotetramat-enol, accounting for about 53–87% of the administered dose. The second most abundant metabolite was spirotetramat-desmethyl-enol, at 5–37% of the administered dose. Minor metabolites included spirotetramat-ketohydroxy, spirotetramat-desmethyl-ketohydroxy (3-(2,5-dimethylphenyl)-3,8-dihydroxy-1-azaspiro[4.5]decane-2,4-dione), spirotetramat-enol-GA, and spirotetramat-enol-alcohol (4-hydroxy-3-[5-(hydroxymethyl)-2-methylphenyl]-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one).

The metabolism in ruminants and poultry is adequately defined. The biodegradation of spirotetramat in livestock can be characterized as cleavage of the carbonate ester group to the primary metabolite spirotetramat-enol followed by conjugation of the enol hydroxy group with glucuronic acid to spirotetramat-enol-GA. Oxidation of the azaspirodecenyl moiety to spirotetramat-ketohydroxy and demethylation of the methoxy group to spirotetramat-desmethyl-enol were minor metabolic reactions in ruminants as well as reduction of the azaspirodecenyl moiety to spirotetramat-monohydroxy. This pathway is consistent with the metabolism found in the rat.

Plant metabolism

The metabolism of [azaspirodecenyl-3-^{14}C]spirotetramat on four distinct crop types was reported to the Meeting: apple, cotton, lettuce and potato. The metabolism results were qualitatively similar across the crops studied. The major metabolic reaction involves the hydrolytic cleavage of the carbonate ester parent bond of the parent compound to form spirotetramat-enol. Further reduction of the enol moiety double bond of spirotetramat-enol occurs to form the spirotetramat-mono-hydroxy metabolite. Hydroxylation of spirotetramat enol results in spirotetramat-ketohydroxy. Demethylation of the methoxy group of the cyclohexyl ring results, via a proposed intermediate (spirotetramat-desmethyl-enol), in spirotetramat-desmethyl-ketohydroxy (after the corresponding hydroxylation). Partly, metabolites bearing a hydroxy group were conjugated with glucose.

Spirotetramat occurs at various concentration levels: 51% TRR apple fruit, 56% TRR head lettuce, 0% TRR potato tuber, 0% cotton seed, 49% potato foliage, 32% cotton lint, 47% immature cotton plant. Spirotetramat-enol varied from 2% TRR in apple fruit to 66% TRR in the potato tuber and 40% in cotton seed. Spirotetramat enol glucoside was found only in cotton lint (5% TRR), lettuce (11% TRR), and potato tuber (2% TRR). Spirotetramat monohydroxy was 16% TRR in apple fruit, but insignificant in other commodities. Spirotetramat ketohydroxy was more widely distributed: 6% TRR lettuce, 9% TRR cottonseed and 8% TRR in apple. Other metabolites were consistently below 10% TRR in raw agricultural commodities. More extensive metabolism of spirotetramat was noted in cotton lint.

Environmental fate

Soil

Aerobic degradation in various soil types was rapid, with 90% of the applied spirotetramat degraded within one day of application. Spirotetramat enol and/or spirotetramat ketohydroxy were the major identified degradates. Carbon dioxide was a maximum of 15% of applied radioactivity at 50–86 days after application to the soil. Additional studies with radiolabelled spirotetramat-enol showed that spirotetramat-enol dissipated in soil and was mineralized, with $^{14}CO_2$ accounting for about 40% of applied radioactivity at day 100.

Anaerobic degradation was equally rapid, with 90% of the applied spirotetramat degraded within one day of application. The major identified degradates were spirotetramat-enol and spirotetramat ketohydroxy. Carbon dioxide was 20% of applied radioactivity at day 50 after application.

Under soil photolysis conditions, the dark control degraded more rapidly than the illuminated soil. It is speculated that the light inhibited bacteria that facilitate the breakdown of spirotetramat.

Water

Spirotetramat is hydrolytically labile under neutral and alkaline conditions at ambient temperature, with half-lives at 25 °C of 9 days and 8 h, respectively. One major degradation product occurred: spirotetramat-enol. Under acidic conditions, degradation was slower (half life 32 days), but spirotetramat-enol was again the degradate.

Under photolysis in sterile buffer at pH 5, 85% of the spirotetramat is degraded within 7 days. The major degradates are a cyclopentyl derivative (35% applied radioactivity), a methyl carbonate derivative (17% applied radioactivity), and a 2-hydroxymethyl derivative (15% applied radioactivity). Under control (dark) conditions, only spirotetramat-enol forms. These degradates are not observed when the photolysis is conducted with sterile natural water.

In water/sediment systems maintained under aerobic conditions, radiolabelled spirotetramat degraded rapidly, with 60% (water fraction) lost within one day. The major degradate was spirotetramat-enol (> 40% of applied radioactivity).

Spirotetramat degrades rapidly in soil and water, with the initial product being spirotetramat-enol.

Rotational crops

The metabolism in rotational crops (spring wheat, Swiss chard and turnips) was investigated following spray application of [azaspirodecenyl-3-^{14}C]spirotetramat onto bare soil (day 0) at an application rate of 406 g ai/ha. Significant TRRs (≥ 0.01 mg/kg) persisted in wheat matrices, Swiss chard, and turnip tops at a 135 day plantback interval. Significant TRRs were found in wheat hay (0.014 mg/kg) and straw (0.036 mg/kg) at a 260 day plantback interval.

At a 31 day plantback interval, parent spirotetramat was not found in any commodity (at maturity). Two of the principle degradates/metabolites were spirotetramat ketohydroxy in wheat forage (31% TRR), Swiss chard (17% TRR) and turnip root (30% TRR) and spirotetramat desmethyl ketohydroxy Glc in wheat forage (32% TRR), hay (18% TRR), and Swiss chard (24% TRR). Spirotetramat-enol was not found, except at 3% TRR in wheat grain.

A field rotational crop study was conducted in three sites applying spirotetramat formulated as 100 g/kg OD (oil dispersion) to a primary crop (leafy, *Brassica*, or fruiting vegetables) at a total rate of 172–180 g ai/ha. After primary crops were removed, rotational crops (mustard greens, turnips and wheat) were planted at a 30-day plant-back interval (PBI). At maturity, samples of mustard greens, turnip (tops and roots), wheat (forage, hay, straw and grain) were collected and analysed for residues of spirotetramat, spirotetramat-ketohydroxy, spirotetramat-desmethyl-ketohydroxy, spirotetramat-desmethyl-di-hydroxy and spirotetramat-ketohydroxy-alcohol. The analytical method included an acid hydrolysis step to release metabolite conjugates, such as glucosides. None of the target compounds were found at the LOQ of 0.01–0.02 mg/kg per component.

Quantifiable residues from the foliar application of spirotetramat are unlikely to occur in succeeding (rotational crops) at a minimum plantback interval of 30 days after the final application of spirotetramat to the primary crop at typical current application rates.

Methods of analysis

The methods used for data collection and proposed for enforcement for plant matrices and livestock commodities are based on HPLC/MS-MS. All methods involve extraction with acetonitrile/water and clean-up with solid phase extraction columns. Analytical method 00857 was developed for the determination of residues of spirotetramat, the metabolites spirotetramat -enol, spirotetramat -ketohydroxy, spirotetramat -mono-hydroxy and spirotetramat enol-Glc in plant matrices by HPLC-MS/MS. The analytical method 00966 was developed for the determination of residues of spirotetramat and the metabolites spirotetramat -enol and spirotetramat -enol-GA in livestock matrices by HPLC-MS/MS. These methods were used as the data-collection methods in the analysis of samples for residues from the various studies submitted to the Meeting. These methods used isotopically labelled internal standards, whereas variants of the methods were developed (and validated) with external standards. Each method has been adequately validated by the manufacturer as well as by independent laboratories Method 00857 was also adequately radiovalidated using samples obtained from metabolism studies.

The limits of quantitation (LOQ) for plant commodities are as follows:

For hops: spirotetramat: 0.1 mg/kg; -enol: 0.12 mg/kg; -ketohydroxy: 0.12 mg/kg; monohydroxy: 0.12 mg/kg; -enol-glucoside: 0.08 mg/kg; total residue calc: 0.55 mg/kg

All other matrices: spirotetramat: 0.01 mg/kg; -enol: 0.012 mg/kg; -ketohydroxy: 0.012 mg/kg; -monohydroxy: 0.012 mg/kg; -enol-glucoside: 0.008 mg/kg; total residue calc.: 0.055 mg/kg.

The limits of quantitation (LOQ) for animal commodities are as follows:

For milk: spirotetramat: 0.005 mg/kg; -enol: 0.005 mg/kg; -enol-glucuronide: 0.005 mg/kg

For tissues and eggs: spirotetramat: 0.01 mg/kg; enol: 0.01 mg/kg; -enol-glucuronide: 0.01 mg/kg.

Multiresidue methods were tested and found not applicable to spirotetramat.

The methods are suitable for data collection and for enforcement of MRLs for plant and animal commodities.

Stability of pesticide residues in stored analytical samples

The stability of spirotetramat in frozen (–18 °C) samples of various commodities was reported. Spirotetramat including its enol metabolite was stable (≥ 80%) remaining for about 2 years in tomato, potato, lettuce, almond nutmeat, climbing French beans and tomato paste. A stability of up to 5 months was demonstrated for orange juice and dried prunes. The Meeting noted that in certain commodities spirotetramat did convert to the enol during storage. For example, in potatoes about 50% of the residue was enol and 50% spirotetramat after 6 months' storage. A similar situation occurs in lettuce at one year and in almonds in 26 days. No other metabolites were found in any commodity accept beans, where up to 8% of the remaining residue was spirotetramat ketohydroxy.

The stability of various metabolites (spirotetramat enol, spirotetramat ketohydroxy, spirotetramat monohydroxy, spirotetramat enol Glc) was reported for the above commodities for the above intervals. All metabolites were stable (≥ 70% remaining) except for spirotetramat enol glucoside on dried prunes, where recovery was only 60% for intervals above 30 days.

Spirotetramat, when determined as the sum of spirotetramat and its enol, is stable on various commodities stored frozen for intervals typical of storage prior to analysis. Considered alone, however, spirotetramat may show significant loss (to spirotetramat enol). Likewise, the metabolites spirotetramat enol, spirotetramat ketohydroxy, spirotetramat monohydroxy, spirotetramat enol Glc (glucuronide) are stable.

Stability of the spirotetramat residue in frozen livestock commodity samples was not demonstrated, but all livestock commodity samples were analysed within 30 days of collection.

Residue definition

The plant metabolism studies indicate that significant portions of spirotetramat are converted to spirotetramat enol, and in some cases there may be no measurable parent (e.g., potato tubers). The analytical methods, all based on HPLC/MS-MS, are capable of determining spirotetramat, and the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy. With the exception of the enol, the metabolites were not distributed through all plant metabolism studies and where present, were typically ≤ 15% TRR each.

In the field trials (see below), spirotetramat and the four metabolites mentioned were always determined.

The Meeting concluded that the residue definition for plant commodities for purposes of enforcement is spirotetramat plus its enol metabolite, expressed as spirotetramat. The Meeting also concluded that for purposes of dietary intake considerations, the residue definition is spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat.

The ruminant and poultry metabolism studies indicated that spirotetramat was totally converted to the enol metabolite. Significant quantities of the glucuronide conjugate of the enol were also found; other metabolites were minor (goat) or absent (hen). The ruminant feeding study conducted at levels up to 30 ppm for 29 days revealed only the enol metabolite, except for low levels of the enol glucuronide in liver and kidney (0.030 mg/kg maximum).

The Meeting concluded that the residue definition for animal commodities for purposes of enforcement and dietary intake considerations is spirotetramat enol, expressed as spirotetramat.

The log of the octanol/water partition coefficient for spirotetramat is 2.5. The log of the octanol/water partition coefficient for spirotetramat enol varies from 2.0 at pH 5 to –1.3 at pH 9. The spirotetramat enol showed no propensity to concentrate in ruminant or poultry fat. Therefore, the Meeting concluded that spirotetramat/spirotetramat enol are not fat soluble.

Residue for enforcement plant commodities: spirotetramat plus spirotetramat enol, expressed as spirotetramat.

Residue for dietary intake plant commodities: *spirotetramat plus the metabolites enol, ketohydroxy, enol glucoside, and monohydroxy, expressed as spirotetramat*.

Residue for enforcement and dietary intake animal commodities: *spirotetramat enol, expressed as spirotetramat*.

The residue is not fat soluble.

Results of supervised residue trials on crops

The Meeting received supervised trials data for the foliar application of spirotetramat as a suspension concentrate formulation (SC) or oil dispersion (OD) to a variety of fruit, vegetable, nut crops and hops.

Citrus

Field trials were conducted on oranges and mandarins in South Europe. No applicable GAP was available.

Field trials were conducted on oranges, lemons, and grapefruits in the USA. The GAP is 0.18 kg ai/ha/application, 0.36 kg ai/ha/season, 1 day PHI, SC and OD formulations. The ranked order of residues (spirotetramat plus enol, whole orange) from 12 trials on oranges were: < 0.10 (3), 0.10, 0.17, 0.19 (2), 0.20, 0.23, 0.26 (2), 0.27 mg/kg.

The ranked order of residues (spirotetramat plus four metabolites, whole orange) from 12 trials on oranges, median underlined, were: < 0.25 (3), 0.25, 0.32, <u>0.34</u> (2), 0.35, 0.38, 0.41, 0.42, 0.43 mg/kg.

The ranked order of residues (spirotetramat plus enol, whole lemon) from five trials on lemons were: 0.13, 0.18, 0.19, 0.21, 0.32 mg/kg.

The ranked order of residues (spirotetramat plus 4 metabolites, whole lemon) found from five trials were: 0.28, 0.33, 0.34, 0.36, 0.47 mg/kg.

The ranked order of residues (spirotetramat plus enol, whole grapefruit) found from six trials were: < 0.10 (3), < 0.11, 0.11, 0.20 mg/kg.

The ranked orders of residues (spirotetramat plus 4 metabolites, whole grapefruit) from six trials were: < 0.25 (3), < 0.26, 0.26, 0.35 mg/kg.

The residues on the various citrus from US trials were considered to be from similar populations and were combined. The ranked order of residues (parent plus enol) found on citrus were:

The ranked order of residues (spirotetramat plus enol, n = 23) on citrus were: 0.10 (7), 0.11 (2), 0.13, 0.17, 0.18, 0.19 (3), 0.20 (2), 0.21, 0.23, 0.26 (2), 0.27, 0.32 mg/kg. The Meeting estimated a maximum residue level maximum residue level of 0.5mg/kg.

The ranked order of residues (spirotetramat plus 4 metabolites, n = 23), median underlined, found on whole citrus fruit were: 0.25 (7), 0.26 (2), 0.28, 0.32, <u>0.33,</u> 0.34 (3), 0.35 (2), 0.36, 0.38, 0.41, 0.42, 0.43, 0.47 mg/kg. The Meeting estimated an STMR of 0.33 mg/kg and an HR of 0.47 mg/kg.

Pome fruit

The Meeting received supervised field trial studies for apples and pears in Europe. No relevant GAP was available.

Supervised field trials on apples and pears were reported from Canada and the USA. Twelve apple trials were reported, including one in Canada, and six pear trials were reported, with all trials

conducted at the GAP of 0.14 kg ai/ha (Canada) or 0.16 kg ai/ha (US), with a maximum seasonal rate of 0.45 kg ai/ha and a PHI of 7 days. Both OD and SC formulations and high and low spray volumes were tested.

The ranked order of residues (spirotetramat plus enol, *n* = 12) on apples were: 0.038, 0.042, 0.051, 0.072 (2), 0.077, 0.13 (2), 0.14, 0.21, 0.33, 0.49 mg/kg.

The ranked order of residues (spirotetramat plus 4 metabolites, *n* =12) on apples were: 0.073, 0.076, 0.085, 0.11 (2), 0.13, 0.17 (2), 0.18, 0.37, 0.38, 0.55 mg/kg.

The ranked order of residues (spirotetramat plus enol, *n* =6) on pears were: 0.075, 0.084, 0.16, 0.17, 0.22, 0.32 mg/kg.

Residues, in ranked order, of (spirotetramat plus 4 metabolites, *n* = 6) found on pears were: 0.10, 0.16, 0.20, 0.21, 0.26, 0.37 mg/kg.

The Meeting considered that the residue values for apples and for pears are from similar populations and combined them for estimation of pome fruit.

Residues in ranked order of (spirotetramat plus enol, *n* = 18) found on pome fruit were: 0.038, 0.042, 0.051, 0.072 (2), 0.075, 0.077, 0.084, 0.13 (2), 0.14, 0.16, 0.17 (2), 0.21, 0.23, 0.31, 0.33, 0.49 mg/kg. The Meeting estimated a maximum residue level of 0.7 mg/kg for pome fruit.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites, *n* = 18) found on pome fruit were: 0.073, 0.076, 0.085, 0.10, 0.11 (2), 0.13, 0.16, 0.17, 0.18, 0.20, 0.21, 0.26, 0.37 (2), 0.38, 0.55 mg/kg. The Meeting estimated an STMR of 0.17 mg/kg and an HR of 0.55 mg/kg for pome fruit.

Stone fruit

The Meeting received Stone Fruit trial data from Europe for apricots, plums and cherries. No relevant GAP was available. The Meeting also received Stone fruit trials from Canada and the USA for peaches, plums and cherries. The Canada/US GAP were: OD and SC formulations, 0.14 kg ai/ha (Canada) or 0.16 kg ai/ha (USA), 0.27 kg ai/ha/season, with a 7 day PHI.

Nine peach trials at maximum GAP were reported, including one trial from Canada. Both OD and SC formulations and low volume and high volume foliar applications were tested in side-by-side plots at several locations.

Residues in ranked order of (spirotetramat plus enol, *n* = 9) found on peaches were: 0.38, 0.49, 0.53, 0.55, 0.58, 0.60, 0.68, 0.72, 1.0 mg/kg.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites, *n* = 9) found on peaches were: 0.51, 0.56, 0.69 (2), 0.70, 0.77, 0.81, 0.82, 1.2 mg/kg.

The Canada and USA GAPs for plums are the same as for peaches. Six trials were conducted at maximum GAP in the USA, with both low volume and high volume foliar applications in side-by-side plots.

The ranked order of residues (spirotetramat plus enol, *n* = 6) for plums were: 0.066, 0.16, 0.26, 0.32, 0.34, 0.59 mg/kg.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites, *n* = 6) found on plums were: 0.11, 0.36, 0.37, 0.46, 0.57, 0.84 mg/kg.

The Canada and USA GAPs for cherries (sweet and sour) are the same as for peaches. Six trials were conducted at the maximum GAP, including one trial from Canada.

The ranked order of residues (spirotetramat plus enol, *n* = 6) for cherries were: 0.68, 1.3 (3), 1.4, 1.6 mg/kg.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites, *n* = 6) found on cherries were: 0.74, 1.6 (3), 2.1 (2) mg/kg.

The Meeting noted that the residue population for cherries is not from the same population as peaches and plums and therefore did not combine the various stone fruit data sets.

The Meeting decided to use the residue data set with highest residues (cherry, *n* = 6) to estimate a stone fruit group maximum residue level. The Meeting estimated a maximum residue level of 3 mg/kg for stone fruit, an STMR of 1.6 mg/kg and an HR of 2.1 mg/kg.

Small berries and grapes

Supervised trials were reported from Europe for the foliar treatment of strawberries in glasshouses, but no GAP was available.

Supervised trials were reported from Europe (South) for the foliar treatment of grapes, but no GAP was available

Supervised trials for grapes were also reported from the USA. The GAP of the USA and of Canada were: OD or SC, 0.14 kg ai/ha, 0.22 kg ai/ha/season, with a 7 day PHI.

The ranked order of residues (spirotetramat plus enol, *n* = 15) for grapes were: 0.057, 0.14, 0.21, 0.23, 0.24, 0.26, 0.31, 0.32, 0.34, 0.36, 0.44, 0.49, 0.58, 0.62, 1.0 mg/kg.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites *n* = 15) found on grapes were: 0.11, 0.26, 0.29, 0.32 (2), 0.36, 0.40, 0.41, 0.48 (2), 0.55, 0.65, 0.79, 0.85, 1.3 mg/kg.

The Meeting estimated for grapes an STMR of 0.41 mg/kg, an HR of 1.3 mg/kg, and a maximum residue level of 2 mg/kg.

Bulb vegetables

The Meeting received field trial reports for bulb onions in Europe. However, as no GAP information was provided the Meeting was unable to estimate a maximum residue level for Bulb vegetables.

Brassica vegetables

The Meeting received field trial reports for head cabbage in Europe. None of the trials were at the maximum GAP of Austria (OD; 0.075 kg ai/ha, 0.015 kg ai/ha, 2 applications at 14 day interval, PHI 3 days).

The Meeting also received field trial reports for head cabbage in Australia. There was no finalized GAP in Australia.

The Meeting received field trial reports for head cabbage in the USA. The GAPs for brassica vegetables, including cabbage, in Canada and the USA are: SC, OD; 0.088 kg ai/ha/application, 0.175 kg ai/ha per season, 1 day PHI. Six trials were conducted at maximum GAP in the USA.

The ranked order of residues of (spirotetramat plus enol, *n* = 7) for cabbage was: 0.020, 0.023, 0.095, 0.15, 0.27, 0.50, 0.89 mg/kg.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites *n* = 7) found on cabbage were: 0.060, 0.067, 0.19, 0.23, 0.45, 0.64, 0.92 mg/kg.

The Meeting estimated for cabbage heads a maximum residue level of 2 mg/kg, an STMR of 0.23 mg/kg, and an HR of 0.92 mg/kg.

The Meeting received field trial reports for broccoli and cauliflower in Europe, but no GAPs were available. The Meeting also received field trial reports for broccoli and Brussels sprouts in

Australia, but no GAP was available. The Meeting received field trial reports for kohlrabi in Europe, but no GAPs were available.

The Meeting received field trial reports for cauliflower and broccoli from the USA. The GAPs in Canada and the USA are: OD, SC; 0.088 kg ai/ha/application, 0.175 kg ai/ha per season, 1 day PHI. Four trials on broccoli and four trials on cauliflower were conducted at the maximum GAP.

The ranked order of residues of (spirotetramat plus enol, n = 4) for broccoli were: 0.095, 0.21, 0.28, 0.39 mg/kg.

The ranked order of residues of (spirotetramat plus 4 metabolites n =4) for broccoli were: 0.17, 0.54, 0.84, 0.87 mg/kg.

The ranked order of residues of (spirotetramat plus enol, n = 4) for cauliflower were: 0.076, 0.10, 0.11, 0.28 mg/kg.

The ranked order of residues of (spirotetramat plus 4 metabolites n = 4) for cauliflower were: 0.22, 0.34, 0.45, 0.54 mg/kg.

The Meeting decided to combine the broccoli and cauliflower results for mutual support. The ranked order of residues (spirotetramat plus enol, n = 8) for flowerhead brassica were: 0.076, 0.095, 0.10, 0.11, 0.21, 0.28 (2), 0.39 mg/kg.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites n = 8) for flowerhead brassica were: 0.17, 0.22, 0.34, <u>0.45, 0.54</u> (2), 0.84, 0.87 mg/kg.

The Meeting estimated for flowerhead brassica a maximum residue level of 1 mg/kg, an HR of 0.87 mg/kg, and STMR of 0.50 mg/kg.

Fruiting vegetables, Cucurbits

The Meeting received supervised trial data for both glasshouse and field sites for melons in Europe. There was no relevant GAP.

The Meeting also received field trial data for melons in the USA. The GAPs in Canada and the USA for cucurbits are: OD and SC, 0.088 kg ai/ha, 0.175 kg ai/ha/season, 1 day PHI. Eight trials in the USA were conducted at the maximum GAP.

The ranked order of results (spirotetramat plus enol, n = 8) for melons were: < 0.02 (2), 0.023, 0.026, 0.027, 0.053, 0.10, 0.13 mg/kg.

The ranked order of results (spirotetramat plus 4 metabolites, n = 8) for melons were: < 0.05 (2), 0.056, 0.057 (2), 0.083, 0.13, 0.16 mg/kg.

The Meeting received reports of trials in glasshouses and the fields for cucumbers in Europe. There was no relevant GAP.

The Meeting also received field trial data for cucumbers from the USA. The GAPs in Canada and the USA for cucurbits are: OD and SC, 0.088 kg ai/ha, 0.175 kg ai/ha/season, 1 day PHI. Eight trials were conducted at the maximum GAP.

The ranked order of results (spirotetramat plus enol, n = 8) for cucumbers were: < 0.02 (7), 0.044 mg/kg.

The ranked order of results (spirotetramat plus 4 metabolites, n = 8) for cucumbers were: < 0.050 (6), 0.073, 0.076 mg/kg.

Field trials were conducted on summer squash (zucchini) in the USA. The GAPs in Canada and the USA for cucurbits are: OD and SC, 0.088 kg ai/ha, 0.175 kg ai/ha/season, 1 day PHI.

The ranked order of results (spirotetramat plus enol, n = 5) for summer squash were: < 0.020 (3), 0.088, 0.13 mg/kg.

The ranked order of results (spirotetramat plus 4 metabolites, *n* = 5) for summer squash were: < 0.05, 0.059, 0.060, 0.16, 0.18 mg/kg.

The Meeting considered the data for summer squash, cucumber, and melons not to be from different populations and combined the data to make estimates for the cucurbit vegetable group.

The ranked order of results (spirotetramat plus enol, *n* = 21) for cucurbits were: < 0.020 (12), 0.023, 0.026, 0.027, 0.044, 0.053, 0.088, 0.10, 0.13 (2) mg/kg.

The ranked order of results (spirotetramat + 4 metabolites, *n* = 21) for cucurbits were: < 0.050 (9), 0.056, 0.057 (2), 0.059, 0.060, 0.073, 0.076, 0.083, 0.13, 0.16 (2), 0.18 mg/kg.

For cucurbit vegetables, the Meeting estimated an STMR of 0.057 mg/kg, an HR of 0.18 mg/kg, and a maximum residue level of 0.20 mg/kg.

Fruiting vegetables other than Cucurbits

Supervised trials were conducted on tomatoes in both glasshouses and the field in Europe. The GAP of Austria is for glass house use and specifies: OD; 0.075 kg ai/ha, 0.01 kg ai/ha per 1 metre plant height, 4 applications at 7 day interval, 3 day PHI. Eight trials in glass house were conducted at this GAP.

The ranked order of residue results (spirotetramat plus enol, *n* = 8) for tomato were: 0.16, 0.19, 0.26, 0.28, 0.32, 0.45, 0.48, 0.49 mg/kg.

The ranked order of residue results (spirotetramat plus 4 metabolites, *n* = 8) for tomato were: 0.22, 0.29, 0.34, 0.44 (2), 0.51, 0.68, 0.70 mg/kg.

Additionally, field trials were conducted on tomatoes in the USA. The GAPs for Canada and the USA are OD and SC, 0.088 kg ai/ha, 0.18 kg ai/ha/season, 1 day PHI. Thirteen trials were conducted at maximum GAP. Also, both OD and SC formulations were tested in side-by-side plots at some trial locations.

The ranked order of residue results (spirotetramat plus enol, *n* = 15) for tomato were: 0.040, 0.046, 0.078, 0.096, 0.12 (2), 0.14 (2), 0.17, 0.20 (2), 0.21, 0.22, 0.23, 0.24 mg/kg.

The ranked order of residue results (spirotetramat plus 4 metabolites, *n* = 15) for tomato were: 0.070, 0.081, 0.12, 0.14, 0.15, 0.16, 0.17, 0.19, 0.21, 0.23, 0.24 (2), 0.25, 0.27, 0.30 mg/kg.

Supervised trial data were received for foliar application of spirotetramat to sweet peppers in both glasshouses and the field in Europe. The GAP of Austria is for glass house use and specifies: OD; 0.075 kg ai/ha, 0.01 kg ai/ha per 1 meter plant height, 4 applications at 7 day interval, 3 day PHI.

The ranked order of residue values (spirotetramat plus enol, *n* = 12) for sweet peppers in (EU glass houses) were: 0.23, 0.25, 0.27, 0.30, 0.36, 0.40, 0.42, 0.46, 0.47, 0.49, 0.50 (2) mg/kg.

The ranked order of residue values (spirotetramat plus 4 metabolites, *n* = 12) for sweet peppers were: 0.27, 0.29, 0.31, 0.35, 0.43, 0.48 (2), 0.54, 0.55, 0.56, 0.57, 0.58 mg/kg.

Also, supervised field trial data were received for peppers from the USA. The GAPs in Canada and the USA for fruiting vegetables are: OD and SC, 0.088 kg ai/ha, 0.18 kg ai/ha/season, 1 day PHI.

The ranked order of residue values (spirotetramat plus enol, *n* = 8) for sweet peppers were: 0.20, 0.27, 0.29, 0.33, 0.40, 0.44, 0.51, 0.76 mg/kg.

The ranked order of residue values (spirotetramat plus enol, *n* = 4) for Chilli (non-bell) peppers were: 0.67, 0.75, 0.82, 1.3 mg/kg.

The ranked order of residue values (spirotetramat plus 4 metabolites, *n* = 8) for sweet peppers were: 0.29, 0.36, 0.39, 0.43, 0.49, 0.55, 0.78, 1.1 mg/kg.

Residues in ranked order, median underlined, of (spirotetramat plus 4 metabolites, *n* = 4) found on Chilli (non-bell) peppers were: 0.72, 0.92, 0.97, 1.5 mg/kg.

The Meeting concluded that the US residue values for sweet peppers and for Chilli peppers are not from the same population. The Meeting further concluded that the residue values for tomatoes and for sweet peppers in the US are not from the same population. The Meeting concluded that the EU glasshouse values for peppers and for tomatoes are from similar populations and therefore combined them.

The combined residue values (spirotetramat plus enol, *n* = 20) for fruiting vegetables (non-cucurbit) for glass houses (EU) in ranked order were: 0.16, 0.19, 0.23, 0.25, 0.26, 0.27, 0.28, 0.30, 0.32, 0.36, 0.40, 0.42, 0.45, 0.46, 0.47, 0.48, 0.49 (2), 0.50 (2) mg/kg.

The combined residue values (spirotetramat plus 4 metabolites, *n* = 20) for fruiting vegetables (non-cucurbit) for glass houses (EU) in ranked order were: 0.22, 0.27, 0.29 (2), 0.31, 0.34, 0.35, 0.43, 0.44 (2), 0.48 (2), 0.51, 0.54, 0.55, 0.56, 0.57, 0.58, 0.68, 0.70 mg/kg.

However, the Meeting noted that the highest residue set, excluding the limited data set (*n* = 3) for non-bell peppers, was that for US sweet peppers. Using this set, the Meeting estimated for fruiting vegetables (non-cucurbit) an STMR of 0.43 mg/kg, an HR of 1.1 mg/kg, and a maximum residue level of 1 mg/kg for fruiting vegetables, except Chilli peppers, except mushrooms, except sweet corn.

The Meeting estimated an STMR 0.95 mg/kg, an HR of 1.5 mg/kg, and a maximum residue level of 2 mg/kg for Chilli peppers. The Meeting also estimated a maximum residue level of 15 mg/kg for dried Chilli peppers based on a standard dehydration factor of 7 (General Considerations, 2008 JMPR).

Leafy vegetables (including Brassica leafy)

Lettuce trials from both glasshouses and fields were reported for Europe. Four glasshouse trials were conducted at the maximum GAP of Austria: OD; 0.075 kg ai/ha, 2 applications at 14 day interval, 7 day PHI.

The residue values (spirotetramat plus enol, *n* = 4) in ranked order for head lettuce were: 0.11, 1.3, 1.6, 1.7 mg/kg, and for leaf lettuce (*n* = 4): 0.27, 0.29, 0.96, 2.2mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 4) in ranked order for head lettuce were: 0.16, 1.4, 1.8, 1.9 mg/kg, and for leaf lettuce (*n* = 4): 0.37, 0.39, 1.0, 2.4 mg/kg.

Also, lettuce trials were reported from the USA. The GAPs in Canada and the USA for non-Brassica leafy vegetables were: SC, OD; 0.088 kg ai/ha, 0.175 kg ai/ha/season, 3 day PHI. Six trials were conducted at maximum GAP on head lettuce, and six trials were conducted at maximum GAP on leaf lettuce.

The residue values (spirotetramat plus enol, *n* = 8) in ranked order for head lettuce were: 0.14, 0.15, 0.18, 0.60 (2), 0.66, 0.69, 0.84 mg/kg, and for leaf lettuce (*n* = 7): 0.11, 0.14, 0.53, 0.60, 0.66, 0.96, 1.5 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 8) in ranked order for head lettuce were: 0.26, 0.29, 0.33, 0.73, 0.82, 0.84, 0.92, 1.0 mg/kg, and for leaf lettuce (*n* = 7): 0.21, 0.23, 0.73, 0.75, 1.0, 1.2, 1.7 mg/kg.

The Meeting received trials for spinach conducted in the USA. Seven trials were conducted at the maximum GAP for leafy vegetables (excluding Brassica).

The residue values for (spirotetramat plus enol, *n* = 7) in ranked order for spinach were: 0.13, 0.82, 1.1, 1.2, 1.4, 1.5, 3.0 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 7) in ranked order for spinach were: 0.24, 1.0, 1.2, 1.5, 1.6 (2), 3.4 mg/kg.

Residue trials were reported from Europe from several leafy vegetables: curly kale, Chinese cabbage, Chinese kale. However, no GAP was available.

Residue trials were reported from the USA for mustard greens. Ten trials were conducted at the maximum GAP for Brassica vegetables (including leafy), where the application rate is the same as for leafy vegetables, but the PHI is 1 day.

The residue values (spirotetramat plus enol, *n* = 10) in ranked order for mustard greens were: 0.61, 0.63, 1.3, 1.6, 2.6, 3.0 (2), 3.3, 4.2, 5.0 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 10) in ranked order for mustard greens were: 0.85, 0.86, 1.7, 2.0, 3.4, 4.0, 4.4, 4.5, 4.6, 5.5 mg/kg.

The Meeting decided to combine the residue values for head lettuce and leaf lettuce from the EU (glass house). The residue values (spirotetramat plus enol, *n* = 8) in ranked order for lettuce were: 0.11, 0.27, 0.29, 0.96, 1.3, 1.6, 1.7, 2.2 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 8) in ranked order for lettuce from the EU were: 0.16, 0.37, 0.39, 1.0, 1.4, 1.8, 1.9, 2.4 mg/kg.

The Meeting decided to combine the residue values for head lettuce and leaf lettuce from the USA. The residue values (spirotetramat plus enol, *n* = 15) in ranked order for lettuce were: 0.11, 0.14 (2), 0.15, 0.18, 0.53, 0.60 (3), 0.66 (2), 0.69, 0.84, 0.96, 1.5 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 15) in ranked order for lettuce were: 0.21, 0.23, 0.26, 0.29, 0.33, 0.73 (2), 0.75, 0.82, 0.84, 0.92, 1.0 (2), 1.2, 1.7 mg/kg.

The Meeting decided that the trials from the EU and the USA should not be combined because of substantial differences in the GAPs (glass house vs field, 7 day PHI vs 3 day PHI).

Using the trial data for mustard greens, the Meeting estimated for leafy vegetables an HR of 5.5 mg/kg, an STMR of 3.7 m/kg, and a maximum residue level of 7 mg/kg.

Legume vegetables

The Meeting received a study on field trials for French climbing beans conducted in glasshouses in Europe. However, no GAP was available.

Root and tuber vegetables

Trials on potatoes were reported from the USA. The GAPs in Canada and the USA for tuberous and corm vegetables were: OD, SC; 0.088 kg ai/ha, 0.175 kg ai/ha/season, 7 day PHI. Seventeen trials were conducted at the maximum GAP.

The residue values (spirotetramat plus enol, *n* = 20) in ranked order for potato were: 0.020, 0.034, 0.039, 0.041, 0.046 (2), 0.050, 0.052, 0.053, 0.080, 0.091, 0.11 (2), 0.16, 0.17, 0.18, 0.23, 0.30, 0.37 (2) mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 20) in ranked order for potato were: 0.055, 0.064, 0.069, 0.071, 0.076 (2), 0.080, 0.082, 0.083, 0.11, 0.12 (2), 0.14 (2), 0.19, 0.22, 0.29, 0.36, 0.43, 0.46 mg/kg.

The Meeting estimated an STMR of 0.12 mg/kg for potato, an HR of 0.46 mg/kg and a maximum residue level of 0.8 mg/kg.

Stalk and stem vegetables

Supervised field trials for celery were reported from the USA. The GAPs for leafy vegetables, which include celery in the NAFTA classification, were: OD, SC; 0.088 kg ai/ha, 0.75 kg ai/ha/season, 3 day PHI.

Six trials were conducted at the maximum GAP. The residue values (spirotetramat plus enol, *n* = 8) in ranked order for celery were: 0.26, 0.29, 0.33, 0.38, 0.45, 0.46, 1.9, 2.4 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 8) in ranked order for celery were: 0.40, 0.41, 0.49 (2), 0.66, 0.76, 2.2, 2.6 mg/kg.

The Meeting estimated for celery an STMR of 0.58 mg/kg, an HR of 2.6 mg/kg, and a maximum residue level of 4.

Tree nuts

Supervised field trials were reported from the USA for almonds and pecans. The GAPs in Canada and the USA are: SC, OD; 0.14 kg ai/ha, 0.38 kg ai/ha/season, 7 day PHI.

Six trials on almonds were conducted at the maximum GAP. The residue values (spirotetramat plus enol, *n* = 6) in ranked order for almond nutmeats were: 0.020, 0.031, 0.054, 0.082, 0.089, 0.094 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 6) in ranked order for almond nutmeats were: 0.050, 0.061, 0.084, 0.14 (3) mg/kg.

Five trials on pecans were conducted at the maximum GAP. The residue values (spirotetramat plus enol, *n* = 5) in ranked order for pecan nutmeats were: 0.020 (2), 0.048, 0.13, 0.25 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 5) in ranked order for pecan nutmeats were: 0.050 (2), 0.076, 0.16, 0.29 mg/kg. The Meeting combined the residue values for pecan and almond nutmeats. The residue values (spirotetramat plus enol, *n* = 11) in ranked order for tree nut nutmeats were: 0.020 (3), 0.031, 0.048, 0.054, 0.082, 0.089, 0.094, 0.13, 0.25 mg/kg. The residue values (spirotetramat plus 4 metabolites, *n* = 11) in ranked order for tree nut nutmeats were: 0.050 (3), 0.061, 0.076, 0.084, 0.14 (3), 0.16, 0.29 mg/kg.

The Meeting estimated for the tree nuts group an STMR of 0.084 mg/kg, an HR of 0.29 mg/kg and a maximum residue level of 0.5 mg/kg.

Secondary food commodities of plant origin – Dried Herbs

Supervised field trials were received from France and Germany for green hops and dried cones. The GAP of Austria specifies for hops: OD; 0.15 kg ai/ha, 0.005 kg ai/hL, 1 application, 14 day PHI. Four trials were conducted according to this GAP. The residue values (spirotetramat plus enol, *n* = 4) in ranked order for dried hops cones were: 0.73, 1.1, 1.7, 1.8 mg/kg.

The residue values (spirotetramat plus 4 metabolites, *n* = 4) in ranked order dried hops cones were: 1.1, 1.8, 2.0, 3.1 mg/kg.

Supervised field trials were received from the USA for dried hops cones. The GAPs in Canada and the USA are: OD, SC; 0.105 kg ai/ha, 0.220 kg ai/ha/season, 7 day PHI. Four trials were conducted at maximum GAP.

The residue values (spirotetramat plus enol, *n* =4) in ranked order for dried hops cones were: 2.2, 3.7, 4.8, 4.9 mg/kg. The residue values (spirotetramat plus 4 metabolites, *n* = 4) in ranked order dried hops cones were: 2.8, 4.5, 5.8 (2) mg/kg.

Based on the US trial data, the Meeting estimated for dried hops cones an STMR of 5.2 mg/kg and a maximum residue level of 15 mg/kg.

Almond hulls

Supervised field trials were reported from the USA for almonds. The GAPs in Canada and the USA are: SC, OD; 0.14 kg ai/ha, 0.38 kg ai/ha/season, 7 day PHI. Six trials on almonds were conducted at the maximum GAP. The residue values (spirotetramat plus enol, $n = 6$) in ranked order for almond hulls were: 1.3, 2.0, 3.9, 4.2, 4.4, 4.7 mg/kg. . The residue values (spirotetramat plus 4 metabolites, $n = 6$) in ranked order for almond hulls were: 1.9, 2.6, 4.8, 5.0, 5.2, 5.3 mg/kg.

The Meeting estimated for almond hulls an STMR of 4.9 mg/kg. The Meeting estimated a maximum residue level of 10 mg/kg for almond hulls.

Fate of residues during processing

The Meeting received processing studies for apple, bean with pod, cheery, orange, grape, hops, plum, potato and tomato. Some information was supplied on the fate of radiolabelled spirotetramat under general processing conditions.

The nature of the residue under simulated processing conditions was reported for radiolabelled spirotetramat and radiolabelled metabolites spirotetramat-enol, spirotetramat-enol-glucoside, spirotetramat-ketohydroxy and spirotetramat-monohydroxy.

Spirotetramat was resistant to hydrolysis under conditions being representative for pasteurization. Under conditions representative for baking, boiling and brewing 15% of spirotetramat degraded to spirotetramat-enol. Under conditions of sterilization the active substance was nearly completely hydrolysed to spirotetramat-enol. Spirotetramat-enol was detected as the only hydrolysis product.

Spirotetramat-enol was resistant to hydrolysis under all test conditions.

Spirotetramat-enol-glucoside was resistant to hydrolysis under conditions representative for pasteurisation. Under conditions representative for baking, brewing and boiling ca.10% of the test substance was hydrolysed to spirotetramat-enol. Under conditions of sterilization ca. 40% of the spirotetramat-enol-glucoside was hydrolysed to the enol metabolite.

Spirotetramat-ketohydroxy was resistant to hydrolysis under conditions of pasteurisation. Under conditions of baking, brewing and boiling a slight (5%) degradation occurred; under conditions of sterilisation spirotetramat-ketohydroxy was completely hydrolysed.

Spirotetramat-monohydroxy was resistant under all test conditions.

Spirotetramat is unstable under some processing conditions, yielding the enol metabolite. Likewise, the spirotetramat enol glucoside metabolite may hydrolyse to the enol under some processing conditions. Additionally, the spirotetramat ketohydroxy metabolite is unstable under sterilization conditions. However, this metabolite is generally a very small portion of the residue. The residue definitions recommended for plant commodities will suffice for processed plant commodities.

The processing (or transfer) 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. The factors are the ratio of the total residue in the processed commodity divided by the total residue in the raw agricultural commodity (RAC). Where the apparent factor was > 1, the factor was also calculated based on the ratio of parent plus enol metabolite in the processed fraction to the parent plus enol metabolite in the RAC. These were generally comparable.

Processing (Transfer) Factors from the Processing of Raw Agricultural Commodities (RACs) with Field-Incurred Residues from Foliar Treatment with Spirotetramat

RAC	Processed Commodity	Processing Factor[a]	RAC mrl	Processed Commodity mrl	RAC STMR	Processed Commodity STMR-P	RAC HR	Processed Commodity HR-P
Orange	Juice	< 0.86 < 0.83 < 0.56 < 0.56 < 0.30 < 0.40 MEDIAN 0.56	0.5		0.33	0.18	0.47	
Orange	Marmalade	< 0.83 < 0.83 < 0.56 0.37 MEDIAN 0.56	0.5		0.33	0.19	0.47	
Orange (citrus)	Pulp, dry	1.3	0.5		0.33	0.43	0.47	
Orange (citrus)	Oil	14	0.5		0.33	4.8	0.47	
Apple	Juice	< 0.57 < 0.87 0.39 0.40 MEDIAN 0.48	0.7		0.17	0.082	0.55	
	Sauce	0.78 < 0.87 0.65 0.13 MEDIAN 0.72	0.7		0.17	0.12		
	Pomace, dried	6.8 4.5 6.0 6.8 6.4 1.9 (wet) [calc 4.8 dry] MEDIAN 6.2	0.7	5	0.17	1.1	0.55	
Cherry	Preserve (canned)	0.46 0.48 0.58 0.46 MEDIAN 0.47	3		1.6	0.75	2.1	

RAC	Processed Commodity	Processing Factor[a]	RAC mrl	Processed Commodity mrl	RAC STMR	Processed Commodity STMR-P	RAC HR	Processed Commodity HR-P
Grapes	Raisin	1.5 3.1 2.6 MEDIAN 2.6	2	4	0.41	1.1	1.3	3.4
	Juice	0.66	2		0.41	0.27	1.3	
	Jelly	0.27	2		0.41	0.11	1.3	
	Pomace	1.7 1.8 1.9 1.9 MEDIAN 1.8	2	4	0.41	0.74		
	Wine	0.68 0.76 0.44 0.38 MEDIAN 0.56	2		0.41	0.23	1.3	
Plums	Dried plums (“prunes”)	2.2	3	5	1.6	3.5	2.1	4.6
Tomatoes	Juice	0.63 0.58 0.48 0.67 0.91 MEDIAN 0.63	1		0.43	0.27	1.1	
	Preserve (canned)	0.72 0.46 0.39 0.71 1.1 MEDIAN 0.58	1		0.43	0.25	1.1	
	Puree	1.2 0.92 0.58 0.71 3.4 MEDIAN 0.92	1		0.43	0.40	1.1	
	Paste	7.4	1		0.43	3.2	1.1	
	Dried	12	1		0.43	5	1.1	
French Climbing Bean	Cooked bean	0.39 0.30 0.54 0.82 MEDIAN 0.46						

RAC	Processed Commodity	Processing Factor[a]	RAC mrl	Processed Commodity mrl	RAC STMR	Processed Commodity STMR-P	RAC HR	Processed Commodity HR-P
Potato	Chips (crisps, not frits)	1.2	0.8		0.12	0.14	0.46	
	Flakes	3.5	0.8		0.12	0.42	0.46	
	Tuber, peeled and cooked	1.3	0.8					
	Peel	0.95	0.8		0.12	0.11	0.46	0.44
Hops	Beer	< 0.034 < 0.030 < 0.014 < 0.013 MEDIAN 0.022	15	N/A	5.2	0.11		

[a] Each value represents a separate study. The factor is the ratio of the total residue in the processed item divided by the total residue in the RAC. The total residue is the parent spirotetramat plus four metabolites, calculated as spirotetramat.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle and dairy cattle are provided below. The calculations were made according to the animal diets from Canada-USA, EU, and Australia in the *Table of OECD Feedstuffs Derived from Field Crop* (Annex 6 of the 2006 JMPR Report).

A poultry feeding study was not provided. However, there are no poultry feed items resulting from the RACs for which the 2008 Meeting made maximum residue level recommendations, and the results of the poultry metabolism (for which the dosing phase was 14 days) could be used to estimate the poultry dietary burden if relevant new RAC commodity MRLs were to occur in the future.

Potential cattle feed items include: almond hulls, apple pomace, citrus pulp, grape pomace, potato culls and pulp and waste and cabbage heads.

Animal dietary burden, spirotetramat total residue, ppm of dry matter diet				
		US-Canada	EU	Australia
Beef cattle	max	1.86	2.91[a]	1.71
	mean	1.04	0.89	1.57[b]
Dairy cattle	max	1.02	2.41[a]	1.53
	mean	0.66	0.42	1.53[b]

[a] Highest maximum beef or dairy cattle dietary burden suitable for maximum residue level estimates for mammalian meat and milk. Values rounded up to 3 ppm.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat and milk. Values rounded up to 2 ppm.

Animal commodity maximum residue levels

The Meeting received a report on a feeding study with lactating dairy cows. Ten lactating Holstein dairy cows (*Bos taurus*; three cows/treatment group and one control cow) were dosed orally, *via* capsule, for 29 consecutive days with spirotetramat at target dose rates (based on feed dry weight) of either 0 ppm day (control), 3.0 ppm /day, 9.0 ppm/day, or 30 ppm /day. Analytes determined in milk and tissues were: spirotetramat, spirotetramat enol and spirotetramat enol glucuronide (enol-GA). The demonstrated limit of quantitation (LOQ) was 0.005 mg/kg for each analyte in milk matrices and was 0.010 mg/kg for each analyte in the tissue matrices. The limits of detection (LOD) for each

compound were in the range of 0.002–0.005 mg/kg for tissues and 0.0007–0.001 mg/kg for milk matrices.

At the 3 ppm feeding level, each analyte was below the LOD in all tissues except kidney. For kidney, spirotetramat enol was quantified at 0.019–0.024 mg/kg, average 0.021 mg/kg.

At the 9 ppm feeding level, all analytes except spirotetramat enol were absent at the LOD in all tissues. Spirotetramat enol was measured at 0.013 mg/kg in the fat of one of three animals, average 0.008 mg/kg. The metabolite was absent in muscle, but was found at levels of 0.049–0.10 mg/kg in kidney, average 0.094 mg/kg, and at levels of 0.009 (< LOQ)–0.014 mg/kg in liver, average 0.094 mg/kg.

At the 30 ppm feeding level, all analytes were absent in milk at the LOQ (0.005 mg/kg) except for spirotetramat enol at 0.005 mg/kg in one of three cows. Residues of spirotetramat and spirotetramat enol GA were below the LOD in all milk samples, except in one milk sample at 0.0008 mg/kg. Residues of parent equivalents did not concentrate in samples of skim milk or milk fat separated mechanically from whole milk.

At the 30 ppm feeding level, spirotetramat enol was quantifiable in fat (< 0.005–0.032 mg/kg), muscle (0.0043–0.014 mg/kg), kidney (0.17–0.41 mg/kg), and liver (0.025–0.038 mg/kg). Additionally, spirotetramat enol GA was quantifiable in liver (maximum 0.018 mg/kg) and kidney (maximum 0.030 mg/kg).

Dietary burden (ppm) Feeding level ppm]		Cream	Milk	Muscle		Liver		Kidney		Fat	
		Mean	Mean	Highest	Mean	Highest	Mean	Highest	Mean	Highest	Mean
mrl beef cattle	(3) [3.0]			(< 0.003) [< 0.003[3]]		(0.006) [0.006]		(0.024) [0.024]		(< 0.005) [< 0.005[3]]	
mrl, dairy cattle	(3) [3.0/30[2]]		(0.0005) [≤ 0.005[2]]	(< 0.003) [< 0.003[3]]		(0.006)) [0.006]		(0.024) [0.024]		(< 0.005) [< 0.005[3]]	
STMR beet cattle	(2) [3.0]				(< 0.0.002) [< 0.003[3]]		(0.004) [0.006]		(0.014) [0.021]		(< 0.004) [< 0.005[3]]
STMR dairy cattle	(2.) [3.0/30[2]]		(0.0004) [< 0.005[2]]		(< 0.002) [< 0.003[3]]		(< 0.004) [0.006]		(0.014) [0.021]		(< 0.004) [< 0.005[3]]

[1] Defined as spirotetramat enol and expressed as spirotetramat equivalents. The LOQs of spirotetramat and its enol are 0.005 mg/kg each in milk and 0.01 mg/kg each in the various tissues. The estimated LODs of spirotetramat are 0.005 mg/kg in fat, 0.003 mg/kg in muscle, 0.001 mg/kg in kidney, 0.002 mg/kg in liver, and 0.0007 mg/kg in milk. The estimated LODs of spirotetramat enol are 0.005 mg/kg in fat, 0.003 mg/kg in muscle, 0.003 mg/kg in kidney, 0.005 mg/kg in liver, and 0.001 mg/kg in milk.

[2] 30 ppm feeding study only for the milk samples

[3] Limit of detection.

The Meeting estimated the following STMR values: milk 0 mg/kg; muscle 0 mg/kg; edible offal (based on kidney) 0.014 mg/kg; fat 0 mg/kg.

The Meeting estimated the following HR values: milk 0 mg/kg; muscle 0 mg/kg; edible offal (based on kidney) 0.024 mg/kg; fat 0 mg/kg.

The Meeting estimated the following maximum residue levels: milk 0.005 (*) mg/kg; meat (mammalian except marine) 0.01 (*) mg/kg; edible offal 0.03 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of spirotetramat has resulted in recommendations for MRLs and STMRs for raw and processed commodities. Consumption data were available for 32 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 0.05 mg/kg bw (Annex 3).

The Meeting concluded that the long-term intake of residues of spirotetramat 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 spirotetramat 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. For the general population the IESTI varied from 0–10% of the ARfD (1.0 mg/kg bw) while for children the IESTI varied from 0–40% of the ARfD.

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

5.23 TEBUCONAZOLE (189)

RESIDUE AND ANALYTICAL ASPECTS

Tebuconazole was evaluated in 1994 for residues and toxicology, when an ADI of 0–0.03 mg/kg body weight was established, and was re-evaluated in 1997 for residues. The present Meeting received data on analytical methods, Good Agriculture Practice (GAP) and supervised residue trial data for oranges, pome fruit, plum, elderberry, mango, papaya, leek, onion, garlic, head cabbage, Brussels sprouts, broccoli, melon, watermelon, tomato, lettuce, bean, soya, carrot, artichoke, celery, barley, rice, maize, oilseed rape, coffee, and hops. Processing studies were also provided.

The definition of the residue for compliance with MRLs and for estimations of dietary intake is tebuconazole.

Methods of analysis

In addition to the analytical methods submitted to previous meetings, new methods for analysis of tebuconazole in plant materials were reported. After extraction with organic solvents and clean-up on Florisil, C-18 or silica columns, and/or gel permeation chromatography, tebuconazole was determined by gas chromatography with a NPD, ECD or MS detectors or LC-MS/MS. In some LC methods, no clean-up step was required. In general, the LOQ ranged from 0.01 to 0.05 mg/kg.

Results of supervised residue trials on crops

Residue trial data provided to this and previous Meetings have shown that residues of tebuconazole in most treated crops decrease rapidly after the day of application, after what the levels seems to plateau. Therefore, the Meeting agreed that whenever possible, similar residue population coming from different PHI will be combined for the final estimation. In some cases, residues coming from different GAP rate also gave the same residue population and the data was combined.

Orange

Data was available from fourteen trials on oranges, of which 10 trials were from Brazil (critical GAP is 2×0.018 kg ai/hL, 20 days PHI) and four from South Africa (GAP is 2×0.02 kg ai/hL, 175 days PHI).

Two Brazilian trials conducted with 3 applications at 0.015 kg ai/hL, gave residues of 1.3 (2) mg/kg. Trials conducted at shorter PHI or a higher rate gave residues ranging from < 0.1 to 2.2 mg/kg.

In two trials conducted in South Africa, complying with that countries GAP, resulted in residues of < 0.01 and 0.02 mg/kg in the fruit and < 0.01 (2) in the pulp. Two trials conducted at double rate gave residues within the same range.

The Meeting agreed that there was insufficient data available, conducted according to GAP, to estimate a maximum residue level for tebuconazole in oranges.

Pome fruits

Ten supervised residue trials with tebuconazole in apples and pears from Southern Europe were submitted. In Italy tebuconazole is approved for use on apples with a maximum of four foliar sprays at 0.225 kg ai/ha (0.0125 kg ai/hL), with a PHI of 30 days. For pears, maximum GAP is 0.30 kg ai/ha and a 15 day PHI. GAP in Spain for apples and pears is 0.15 kg ai/ha (0.01 kg ai/hL) with a 14 day PHI. In Brazil maximum GAP for apples is 0.0125 kg ai/hL with 20 day PHI.

In four trials conducted in apples in France, Greece and Italy complying with the Italian GAP, residues within the 30 day PHI were 0.13, 0.19, 0.34 and 0.47 mg/kg. In four trials conducted in pears in Italy and Portugal according to Italian GAP, residues within a 15 day PHI were: < 0.05, 0.07, 0.28 and 0.38 mg/kg. Two other Italian trials were conducted at lower rate and PHI.

Two trials conducted on apples in Brazil (GAP of 0.0125 kg ai/hL, 20 days PHI) submitted to the 1997 JMPR gave residues of < 0.1 and 0.20 mg/kg; also submitted were two trials from Italy and Spain, conducted according to GAP, giving residues of 0.12, 0.13 and 0.24 mg/kg.

The Meeting agreed that residues from the 13 trials, conducted according to GAP, in apples and pears in Brazil and Europe submitted to both Meetings gave residues in the same range and could be combined for the purpose of estimating a STMR, HR and maximum residue levels, and with which to base a recommendation for pome fruit. Residues in rank order, median underlined, were: < 0.05, 0.07, < 0.1, 0.12, 0.13 (2), <u>0.19</u>, 0.20, 0.24, 0.28, 0.34, 0.38 and 0.47 mg/kg

The Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.47 mg/kg and an STMR of 0.19 mg/kg for tebuconazole in pome fruit.

The Meeting also agreed to withdraw its previous recommendation of 0.5 mg/kg for tebuconazole in pome fruit.

Plums

GAP for plums in France is 3×0.015 kg ai/hL with a PHI of 7 days. A total of 16 trials were conducted with tebuconazole on plums in Europe from 1992 to 2005 matching the French GAP. Residues found in whole fruit, 7 days after the final application in rank order, median underlined, were: 0.03 (2), < 0.05 (4), 0.05, 0.06, 0.07 (2), 0.08 (2), 0.10 (2), 0.12 (2) mg/kg.

Six trials conducted in France and Italy, also matching the French GAP, and previously submitted to the 1997 JMPR gave residues in whole fruit of < 0.02, 0.03 (3), 0.09 and 0.11 mg/kg.

The Meeting decided to combine all the data to increase the dataset for the purposes of estimating a maximum residue level, STMR and HR and to make a recommendation for plums. Residues from the 22 trials in rank order, median underlined, were: < 0.02, 0.03 (5), < 0.05 (4), <u>0.05, 0.06</u>, 0.07 (2), 0.08 (2), 0.09, 0.10 (2), 0.11, 0.12 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an HR of 0.12 mg/kg and an STMR of 0.055 mg/kg for tebuconazole in plums.

Elderberries

Six trials were conducted in Austria according to GAP (3× 0.038 kg ai/hL. Residues within the 24 day PHI in rank order, median underlined were: 0.26, <u>0.30, 0.39</u> and 0.70 mg/kg. In two trials, samples where harvested 14 days after the last application.

The Meeting estimated a maximum residue level of 2 mg/kg, an HR of 0.73 mg/kg and an STMR of 0.345 mg/kg for tebuconazole in elderberries.

Mango

Data was available from 18 trials on mangoes in Brazil, where the GAP is 3 × 0.02 kg ai/hL with a 20 day PHI. In eight trials conducted according to GAP residues in rank order, median underlined, were: < 0.05 (3), <u>0.02</u> (2) and < 0.1 (3) mg/kg. The trials conducted at double rate gave residues at 20 days PHI from < 0.05 to 0.09 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.1 mg/kg and an STMR of 0.02 mg/kg for tebuconazole in mango.

Papaya

Tebuconazole is registered in Brazil (GAP of 6× 0.2 kg ai/ha, 7 day PHI) and Australia (GAP of 6× 0.125 kg/ha, 3 day PHI). In six trials conducted in Brazil according to GAP, residues in rank order, median underlined, were: 0.06, 0.15, 0.17, 0.19, 0.32 and 1.2 mg/kg. Residues in six trials conducted at double rate ranged from 0.18 to 2.4 mg/kg at a PHI of 7 days.

One trial conducted in Australia at GAP gave residues of 0.07 mg/kg; one trial at double rate gave a residue of < 0.01 mg/kg.

Based on the Brazilian trials, the Meeting estimated a maximum residue level of 2 mg/kg, an HR of 1.2 mg/kg and an STMR of 0.18 mg/kg for tebuconazole in papaya.

Leek

Tebuconazole is registered in Europe at 3× 0.25 or 0.30 kg ai/ha (the Netherlands) with a 14 day PHI. In 12 field trials conducted in Belgium, France and Germany in 1995/1996, complying with the Dutch GAP, residues in rank order, median underlined, were: 0.03, 0.14, 0.15 (2), 0.19 (2), 0.20, 0.22, 0.24, 0.28, 0.31 and 0.44 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.44 mg/kg and an STMR of 0.195 mg/kg for tebuconazole in leek.

Garlic

Two trials conducted in Brazil according to GAP (4× 0.20 kg ai/ha, 14 day PHI) gave residues in the garlic bulb of 0.02 (2) mg/kg; two other trials conducted at double rate gave residues of 0.03 and 0.04 mg/kg.

Two trials conducted in France according to GAP (2× 0.25 kg ai/ha, 21 day PHI) gave residues of 0.03 and 0.06 mg/kg. Three trials conducted in 1995/1995 in Europe at the same rate and submitted to the 1997 JMPR had residues of < 0.02 (2) and 0.02 mg/kg

Residues from the seven trials according to GAP submitted to both Meetings were: < 0.02 (4), 0.02, 0.03 and 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.06 mg/kg and an STMR of 0.02 mg/kg for tebuconazole in garlic.

Onions

Six trials conducted in Brazil from 1993 to 2004 within the GAP rate (0.20 or 0.25 kg ai/ha) gave residues at 14 days PHI of < 0.02 (3), 0.02, 0.03 and 0.06 mg/kg. In six other trials, conducted at higher or lower rates, residues found were in the range of < 0.02 to 0.10 mg/kg.

Tebuconazole is registered in Germany and in the United Kingdom at 2× 0.25 kg ai/ha with a 21 day PHI. Seven trials were conducted in France (no GAP provided), Germany and the UK according to GAP. In five trials, residues in the bulb were < 0.05 (5) mg/kg. In two trials the whole plant or the washed bulb was analysed (which had been incorrectly described by 1997 Meeting).

The 11 trials conducted in Brazil and Europe complying with GAP gave residues of: < 0.02 (3) 0.02, 0.03, < 0.05 (5) and 0.06 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.06 mg/kg and an STMR of 0.05 mg/kg for tebuconazole in onion.

Brassica (cole or cabbage) vegetables

Critical GAP for tebuconazole in head cabbage in Europe is 3× 0.250 kg ai/ha, 21 day PHI (Austria, Germany and the Netherlands). In the UK, a maximum of 0.56 kg ai/ha per season is recommended. From ten trials conducted in France, Germany and UK matching European critical GAP residues in rank order, median underlined, were: < 0.05 (6), 0.32 (2), 0.37 and 0.56 mg/kg. In three other trials conducted at higher rates gave residues within the same range.

Reported GAP for tebuconazole in Brussels sprouts is 3 applications of 0.25 kg ai/ha in Germany and 0.30 kg ai/ha in the Netherlands with a, PHI of 21 days. Nine trials were conducted in France, Germany, the Netherlands and the UK from 1990 to 2000. In eight trials matching the German GAP, residues were < 0.05 (2), 0.05, 0.07, 0.11, 0.12, 0.15 and 0.19 mg/kg. In one trial matching the Netherlands GAP, residues were 0.49 mg/kg.

GAP for tebuconazole for flower head brassicas in Germany is 2× 0.25 kg ai/ha with a 21 day PHI. In Spain, GAP in broccoli consists of up to 2 applications at 0.025 kg ai/hL with a 14 day PHI. Two trials conducted in broccoli in Germany in 2003 according to GAP gave residues of < 0.02 (2) mg/kg. Four trials conducted in Italy and Spain in 2001/2002 matching Spanish GAP gave residues of < 0.05, 0.06, 0.08 and 0.15 mg/kg.

The Meeting agreed that the residue populations found in the trials in head cabbage and Brussels sprouts, conducted according to GAP, belonged to the same population and could be combined. Residues of tebuconazole in rank order, median underlined, were: (n = 19) < 0.05 (8), 0.05, 0.07, 0.11, 0.12, 0.15, 0.19, 0.32(2), 0.37, 0.49 and 0.56 mg/kg. Based on this data set, the Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.56 mg/kg and an STMR of 0.05 mg/kg for tebuconazole in brassica (cole or cabbage) vegetables.

Melons

The recommended PHI for tebuconazole in melons in Brazil is 14 days with the application rate varying according to the formulation (4× 0.15 kg ai/ha, 3× 0.20 kg ai/ha or 0.25 kg ai/ha). In seven trials conducted in Brazil using 3 to 5 applications at 0.20 to 0.30 kg ai/ha residues in the fruit 14 days after the last application were: < 0.01, < 0.05 (4), 0.03 and < 0.1 mg/kg. Three trials using 5× 0.15 kg ai/ha gave residues of < 0.05 (2) and 0.1 mg/kg. Four trials conducted at higher rates or a shorter PHI gave residues within the same range. The Meeting agreed that trials conducted in Brazil according to GAP could be combined resulting in residues of tebuconazole of: < 0.01, < 0.05 (6), 0.03, < 0.1 and 0.1 mg/kg

In Italy, tebuconazole can be applied up to 4 times at 0.125 kg ai/ha (0.0125 kg ai/hL), with a PHI of 7 days. Twenty trials conducted from 1991 to 2005 in France, Italy, Greece and Spain were submitted. In ten trials conducted according to Italian GAP residues at a PHI of 7 days in the fruit were: 0.02, 0.03 (3), 0.04, 0.05 (2), 0.06, 0.07 and 0.09 mg/kg. In three trials residues found in the pulp were: < 0.02 (3) mg/kg. In 10 trials conducted at higher rates or a shorter PHI, residues in fruit and pulp were in the same range.

The 20 trials conducted in Brazil and Europe according to GAP gave residues in the fruit of < 0.01, 0.02, 0.03 (4); 0.04, < 0.05 (6), 0.05 (2), 0.06, 0.07, 0.09, < 0.1 and 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an HR of 0.02 mg/kg (in the pulp) and an STMR of 0.02 mg/kg (in the pulp) for tebuconazole in melon, except watermelon.

Watermelon

The recommended rate for tebuconazole in watermelon in Brazil is 4× 0.20 kg ai/ha with 14 day PHI. In two trials conducted according to GAP in 2004 residues in fruit were < 0.01 and 0.01mg/kg. Two additional trials conducted at double rate gave residues up to 0.02 mg/kg.

In Italy, tebuconazole can be applied up to 4 times at 0.125 kg ai/ha (0.0125 kg ai/hL), with a PHI of 7 days. In three trials conducted in Italy from 1992 to 1993 according to GAP, residues in fruit were < 0.02, 0.03 and 0.04 mg/kg. Residues in pulp were < 0.02 (3) mg/kg. In one trial conducted at a lower rate the residue found was 0.05 mg/kg.

The Meeting agreed residues from the five trials conducted in Brazil and Italy that complied with GAP could be combined giving residues of: < 0.01, 0.01, < 0.02, 0.03 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an HR of 0.02 mg/kg (in the pulp) and an STMR of 0.02 mg/kg (in the pulp) for tebuconazole in watermelon.

Sweet corn

Seven trials were conducted in Brazil, where the GAP for sweet corn is 3× 0.20 kg ai/ha with a 15 day PHI. In four trials conducted according to GAP, residues found were: < 0.1 mg/kg (4). Four trials at double rate gave the same results.

The Meeting agreed that the trials conducted at higher GAP supports a conclusion that it is unlikely that residues in the sweet corn, from trials conducted at GAP, will exceed 0.1 mg/kg. Hence, the Meeting estimates a maximum residue level, an HR and an STMR of 0.1 mg/kg for tebuconazole in sweet corn (corn-on-the-cob).

Tomato

In Brazil tebuconazole is approved for use on tomatoes with an application rate of 4×0.25 kg ai/ha (0.025 kg ai/hL) and a PHI of 7 days. Five trials were conducted according to this GAP, resulted in residues of tebuconazole of: < 0.05 (2), 0.05, 0.06 and 0.10 mg/kg. Five other trials conducted at a lower rate gave residues in the same range.

In Italy, GAP consists of 4×0.125 kg ai/ha (0.0125 kg ai/hL) and in Spain 0.025 kg ai/hL. In both countries the PHI is 3 days. The previous Spanish GAP, which supported the current Codex MRL, had a PHI of 7 days.

Six trials conducted in Spain complying with Spanish GAP, gave residues of 0.03, 0.09, 0.13, 0.15, 0.23 and 0.28 mg/kg. In six indoor or field trials conducted in Spain and Greece at the same rate but a 7 day PHI gave residues of: 0.10, 0.13, 0.24, 0.33, 0.45 and 0.46 mg/kg.

In Poland, the GAP is 4×0.3 kg ai/ha (0.020 kg ai/hL) with a 7 day PHI. Five indoor trials conducted in Belgium, Germany and the Netherlands at 3×0.4 to 0.5 kg ai/ha (0.025 kg ai/hL) gave residues 7 days after the final application of 0.12 to 0.43 mg/kg. These trials did not match the GAP in northern Europe (Poland).

Three trials conducted according to the current Spanish GAP submitted to the 1994 JMPR gave residues of 0.04, 0.19 and 0.28 mg/kg. Two trials conducted according to GAP in South Africa (5×0.019 kg ai/hL, 7 days PHI) submitted to the 1994 JMPR gave residues of 0.02 and 0.04 mg/kg.

Sixteen trials were conducted in Mexico and USA using 6×0.23 to 0.30 kg ai/ha, giving residues of 7 days after the last application that ranged from 0.05 to 0.97 mg/kg. There is no GAP for tebuconazole in tomato in these countries.

The Meeting agreed that the trials conducted according to GAP in Brazil, South Africa and Spain belonged to different data populations and could not be combined.

The Meeting agreed that the data complying with the Spanish GAP submitted to the 1994 and the present Meeting could be used for estimating a maximum residue level, STMR and HR. The Meeting also agreed that residues from European trials conducted at 7 days PHI did not significantly differ from residues from the 3 day PHI and could be combined. Residue of tebuconazole in tomatoes in rank order, median underlined, were: (n = 15) is 0.03, 0.04, 0.09, 0.10, 0.13 (2), 0.15, 0.19, 0.23, 0.24, 0.28 (2), 0.33, 0.45 and 0.46 mg/kg

The Meeting estimated a maximum residue level of 1 mg/kg, an HR of 0.46 mg/kg and an STMR of 0.15 mg/kg for tebuconazole in tomato

The Meeting agreed to withdraw its previous recommendation of a maximum residue level of 0.2 mg/kg for tebuconazole in tomato.

Lettuce, Head

Data was available from eight supervised trials conducted in head lettuce in France, Greece, Italy, Portugal and Spain in 1998–1999 complying with the Spanish GAP (0.025 kg ai/hL with a 7 day PHI), residues within 7 days of the final treatment were: 0.18, 0.23, 0.44, 0.65, 1.3, 1.4, 2.3 and 3.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, an HR of 3.2 mg/kg and an STMR of 0.98 mg/kg for tebuconazole in head lettuce.

Beans

In Spain tebuconazole is registered for use on beans at 3× 0.025 kg ai/hL with a 3 day PHI. Eight indoor trials were conducted in French beans in France, Germany and Spain complying with Spanish GAP, giving residues in beans (with pods) of: 0.12, 0.25, 0.41, 0.43, 0.54, 0.55, 0.58 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, an HR of 1.2 mg/kg and an STMR of 0.49 mg/kg for tebuconazole in common bean (pods and/or immature seeds).

Soya bean, dry

In Brazil, GAP for tebuconazole in soya beans is a maximum of 3 applications at 0.15 kg ai/ha with a PHI of 30 days. In eight trials conducted complying with this GAP, residues were: 0.02, 0.03 (3), < 0.05 (3) and < 0.10 mg/kg. In six trials conducted at double rate residues up to 0.10 mg/kg were found.

In the USA, GAP is for 3 applications at 0.126 kg ai/ha and a 21 day PHI. In 20 trials conducted in the USA in 2003 according to the GAP rate, residues within the 21 day PHI were: < 0.01 (3), 0.01 (6), 0.02 (5), 0.03, 0.04 (2), 0.05 and 0.06 (2) mg/kg.

The Meeting agreed to combine the data from Brazil and the USA to increase the database for the purposes of estimating a maximum residue level, STMR and highest residue. Twenty eight trials conducted according to the GAP of Brazil and the USA gave residues of: < 0.01 (3), 0.01 (6), 0.02 (6), 0.03 (4), 0.04 (2), < 0.05 (3), 0.05, 0.06 (2) and < 0.10, mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.02 mg/kg for tebuconazole in soya bean (dry).

Carrot

The GAP for tebuconazole in Brazil for carrots is 4 applications at 0.20 kg ai/ha with a 14 day PHI. In five trials complying with GAP, residues found were: < 0.1 (3), 0.17 and 0.19 mg/kg. Seven additional trials conducted at higher than GAP rates gave residues ranging from < 0.10 to 0.27 mg/kg.

In Europe (Austria, German, Belgium, Ireland and the UK), tebuconazole can be applied up to 3 times at 0.25 kg ai/ha with a PHI of 21 days. In eight trials conducted in France, Germany and the UK complying with the European GAP, residues found were: 0.09, 0.10, 0.11 (2), 0.13, 0.18, 0.19 and 0.22 mg/kg.

The 13 Trials conducted according to GAP in Brazil and Europe residues found in rank order, median underlined, were: 0.07, 0.09, < 0.1 (3), 0.11 (2), 0.13, 0.17, 0.18, 0.19 (2) and 0.22 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an HR of 0.22 mg/kg and an STMR of 0.11 mg/kg for tebuconazole in carrot.

Artichoke

Tebuconazole is registered for use on artichoke in Italy (GAP 4 applications at 0.125 kg ai/ha (0.0125 kg ai/hL) and a 7 day PHI). Data was available from six trials performed in Italy and Spain, from, 1991 to 2002, that complied with Italian GAP, residues found were: < 0.05, 0.12 (2), 0.17, 0.29 and 0.32 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an HR of 0.32 mg/kg and an STMR of 0.15 mg/kg for tebuconazole in artichoke.

Celery

The use of tebuconazole in/on (stalk, bleached) celery is registered in France at 3 applications at 0.25 kg ai/ha with a PHI of 21 days. Three trials were conducted in France 2000–2001 that complied with French GAP, giving residues of 0.11, 0.19 and 0.21 mg/kg;

The Meeting agreed that there were insufficient trials conducted according to GAP to estimate a maximum residue level for tebuconazole in celery.

Barley

Tebuconazole is registered in a number of European countries, e.g., Germany (GAP 2 applications at 0.31 kg ai/ha with a PHI of 35 days), in Denmark (GAP 0.25 kg ai/ha, PHI 42 days) and France (28 days PHI). Residues from 19 trials conducted in Europe at 0.25–0.38 kg ai/ha and a PHI of 28 to 35 days were: < 0.05 (8), 0.06 (3), 0.08, 0.10, 0.13, 0.21, 0.38, 0.85, 0.93 and 0.96 mg/kg. Eighteen trials conducted at the same rate range but with a harvest interval of from 36 to 50 days resulted in residues of: < 0.05 (9), 0.06, 0.07 (3), 0.08 (2), 0.10, 0.65 and 1.1 mg/kg. The Meeting agreed that the residues from the thirty seven trials conducted in Europe could be combined resulting residues of: < 0.05 (17), 0.06 (4), 0.07 (3), 0.08 (3), 0.10 (2), 0.13, 0.21, 0.38, 0.65, 0.85, 0.93, 0.96 and 1.1 mg/kg. In three trials conducted at double rate, residues were within the same range.

The Meeting estimated a maximum residue level of 2 mg/kg and ad STMR of 0.06 mg/kg for tebuconazole in barley.

The Meeting withdraws its previous recommendation of 0.2 mg/kg for tebuconazole in barely, which had been based on a seed treatment.

Rice

Two trials were conducted with tebuconazole in rice in Brazil according to GAP (2 applications at 0.15 kg ai/ha) with residues at 35 days PHI of 0.01 and 0.02 mg/kg. In two trials conducted at double rate gave residues of 0.03 mg/kg.

In Spain, the compound is registered to be used at 0.25 kg ai/ha with a 35 day PHI. In eight trials conducted in Italy and Spain, complying with Spanish GAP, residues found in rank order, median underlined, were: 0.11, 0.12, 0.24, 0.26, 0.29, 0.33, 0.53 and 0.97 mg/kg.

The Meeting agreed that the trials conducted in Brazil and in Europe belonged to different populations and could not be combined. Hence the estimations were made based on trials conducted according to the more critical GAP of Spain

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.275 mg/kg for tebuconazole in rice.

Maize

Eight trials were conducted in Brazil, where the GAP for maize is 3 applications at 0.20 kg ai/ha with a 15 day PHI. In four trials conducted according to GAP, residues were 0.01, 0.02 and < 0.1 (2) mg/kg. Four trials at the double rate gave similar results.

The Meeting agreed that the trials conducted at higher GAP supported a conclusion that residues in harvested maize from trials conducted at GAP were unlikely would exceed 0.1 mg/kg. The Meeting estimated a maximum residue level and an STMR of 0.1 mg/kg for tebuconazole in maize.

Peanut

The GAP for tebuconazole in the USA in peanuts is 4 applications at 0.23 kg ai/ha with a 14 day PHI. No new trials were submitted to the present Meeting. The current Codex MRL of 0.05 mg/kg was estimated in 1994, based on trials conducted in the USA using 7 applications at GAP rate and in South Africa according to GAP (0.02, 0.04 and < 0.05 (4) mg/kg). Trials conducted at double GAP rate in South Africa (PHI of 42 days) resulted in no detectable residues (< 0.05 mg/kg), which indicated that residues in peanut kernels would be ≤ 0.04 mg/kg.

In 1997, thirteen new trials conducted in USA using 7 applications at the GAP rate were submitted and considered, giving residues of < 0.01 (4), 0.01, 0.03 (3), < 0.05 (4) and 0.08 mg/kg..

The current Meeting considered the residue data from trials according to GAP submitted to both the 1994 and 1997 Meetings, grouped as < 0.01 (4), 0.01, 0.02, <u>0.03</u> (3), 0.04, < 0.05 (8) and 0.08 mg/kg (n = 19). The Meeting agreed that a MRL of 0.05 mg/kg might not cover all the residue situations when trials are conducted according to GAP.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.03 mg/kg for tebuconazole in peanut kernels.

The Meeting withdraws its previous recommendation of 0.05 mg/kg for tebuconazole in peanut kernel.

Rape seed

In Germany, tebuconazole is registered for 2 applications at 0.375 kg ai/ha with a 56 day PHI. In Denmark, the rate is 2× 0.25 kg ai/ha with no PHI specified, i.e., last application no later than BBCH 69.

In twenty five trials conducted from 2000 to 2007 in Belgium, France, Germany, Netherlands and the UK using 2 applications at 0.20–0.375 kg ai/ha, according to GAP in Germany or Denmark, residues found were: 0.02 (2), 0.03 (2), 0.04 (2), < 0.05 (2), 0.06, 0.07, <u>0.08</u> (2), 0.09, 0.11 (3), 0.12 (4), 0.13, 0.16, 0.17, 0.19 and 0.28 mg/kg. Six trials conducted at a lower rate gave residues of up to 0.15 mg/kg.

One trial conducted in France according to German GAP submitted to the 1994 JMPR gave residues of < 0.05 mg/kg.

Considering the 26 trials submitted to the current Meeting and to the 1994 JMPR, the residues found in rank order, median underlined, were: 0.02 (2), 0.03 (2), 0.04 (2), < 0.05 (3), 0.06, 0.07, <u>0.08</u> (2), 0.09, 0.11 (3), 0.12 (4), 0.13, 0.16, 0.17, 0.19 and 0.28 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a highest residue of 0.28 mg/kg and an STMR of 0.09 mg/kg for tebuconazole in rape seed.

The Meeting agreed to withdraw its previous recommendation of 0.05 mg/kg for tebuconazole in rape seed.

Coffee

Tebuconazole can be used in coffee in Brazil at 3 applications at 0.25 kg ai/ha with a 30 day PHI. In five trials from Brazil conducted from 1990 to 2004 complying with GAP residues found were: 0.02 (2) and < 0.10 (3) mg/kg. Eleven trials conducted at a higher GAP gave residues that ranged from < 0.01 to 0.07 mg/kg.

Four trials conducted in Guatemala (no GAP) using 3 applications at 0.25 kg ai/ha, gave residues of: < 0.01 to 0.03 mg/kg 30 days after the last application.

The Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.1 mg/kg for tebuconazole in coffee. This estimation is supported by the trials conducted in Brazil at double GAP rate.

Hops

In the Czech Republic, tebuconazole can be applied twice at 0.56 kg ai/ha (0.02 kg ai/hL) with a 21 day PHI. In eight trials conducted in Germany complying with this GAP, residues in the cone, kiln dried, were: 5.8, 6.0, 6.3, 8.3, 11, 12, 18 and 21 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg, an HR of 21 mg/kg and an STMR of 9.65 mg/kg for tebuconazole in hops.

Animal feed commodities

Straw and/or fodder

In 36 barley trials conducted in France, Germany, Greece, Italy, Portugal, Spain and the UK using 2 applications at 0.19–0.38 kg ai/ha, complying with GAP rate in German and Denmark, residues in straw 27 to 50 days after the last application (PHI for grain) were: 0.14, 0.29, 0.38, 0.45, 0.49, 0.50, 0.71, 0.72, 0.77, 0.80, 0.86, 0.88, 1.3, 1.4, 1.7 (3), 2.0, 2.2 (2), 2.4, 2.5, 2.8 (2), 3.1, 3.3, 3.8, 3.9, 4.3, 4.9, 5.6, 5.8, 6.7, 7.9, 13, and 17 mg/kg. When the STMR and the highest residues are corrected for dry matter content (88%, according to the OECD feed table), the values derived are 2.4 and 19 mg/kg, respectively

The Meeting estimated a maximum residue level of 30 mg/kg, a highest residue of 19 mg/kg and an STMR of 2.4 mg/kg for tebuconazole in barley straw and fodder (dry).

The Meeting withdraws its previous recommendation of 10 mg/kg for barley straw and fodder (dry).

No soya bean trials were conducted where fodder samples were harvested at the grain PHI.

Four rice trials conducted in Spain and Italy according to GAP rate gave residues in straw, 33 or 35 days after the last application (grain PHI), of 1.1 (2), 1.6, and 1.7 mg/kg.

The Meeting agreed that there were insufficient trials conducted according to GAP to estimate a maximum residue level for tebuconazole in soya bean fodder or rice straw and fodder, dry.

Forage

Forage samples, described as forage, green material or rest of the plant were harvested in a number of trials at different PHIs. Whenever data was available, either the 7 days PHI residue value or any later harvest date that gave higher residues was chosen to represent the level of residues to which animals could be exposed. In cases where such data was not available, the highest value from any PHI available (up to the grain PHI) was taken, including those from a 0 day PHI.

The residues in barley forage from trials conducted according to GAP rate in Europe in rank order were (n = 39): 0.29, 0.35, 0.37, 0.78, 1.0, 1.2 (2), 1.4 (2), 2.0, 2.3, 2.8, 3.2, 3.4, 3.8, 4.3 (2), 4.7, 5.2, 5.8, 6.0, 6.1, 6.2, 6.4, 6.5, 6.7, 7.4, 7.6, 8.6, 8.9, 9.0, 9.2, 9.5, 9.6, 10, 12, 14 (2) and 18 mg/kg.

Available PHI for rape forage were 0 or 14 days; residues in rape forage were (n = 25): 2.5 (3), 2.6, 2.7, 3.1, 3.6, 3.7, 3.8, 3.9, 4.0, 4.2 (2), 4.3, 4.6, 4.8, 4.9, 5.1, 5.2, 5.7, 6.3, 7.2, 7.5 and 11 mg/kg.

Residues in rice forage from seven trials conducted at GAP rate at 0 or 7 day PHI were: 1.7, 1.8, 4.5, 5.3, 5.5, 6.2 and 8.3 mg/kg.

In 20 soya bean trials conducted in USA according to GAP rate, residues in forage at 0 or 7 day PHI were: 2.1, 3.6, 4.8, 4.9, 5.0, 5.7 (2), 7.7, 8.5 (2), 8.6, 9.1, 12, 13 (2), 14 (3), 15 and 18 mg/kg.

The Meeting noted that the barley, rape and rice forage residue data represent similar populations and could be combined as follows: (n = 91) 0.29, 0.35, 0.37, 0.78, 1.0, 1.2 (2), 1.4 (2), 1.7, 1.8, 2.0, 2.1, 2.3, 2.5 (3), 2.6, 2.7 (2), 2.8, 3.1, 3.2, 3.4, 3.6 (2), 3.7, 3.8 (2), 3.9, 4.0, 4.2 (2), 4.3 (3), 4.5, 4.6, 4.7, 4.8 (2), 4.9 (2), 5.0, 5.1, 5.2 (2), 5.3, 5.5, 5.7 (3), 5.8, 6.0, 6.1, 6.2 (2), 6.3, 6.4, 6.5, 6.7, 7.2, 7.4, 7.5, 7.6, 7.7, 8.3, 8.5 (2), 8.6 (2), 8.9, 9.0, 9.1, 9.2, 9.5, 9.6, 10, 11, 12 (2), 13 (2), 14 (5), 15 and 18 (2) mg/kg.

The Meeting estimated an STMR of 5.2 mg/kg and a highest residue of 18 mg/kg for tebuconazole in the forages of barley, rape, rice and soya bean.

Fate of residues during processing

In two processing studies conducted in Germany, treated oranges, with residues ranging from 0.20 to 0.27 mg/kg, were processed to pulp, juice and marmalade. No residues were found in the pulp (< 0.05 mg/kg), with a mean PF=< 0.22. Residues concentrated in the peel (mean PF=4), and decreased in juice (mean PF=< 0.2) and marmalade (mean PF=0.4).

Two apple processing studies were conducted in the USA (1990/2004). Treated samples contained < 0.01 and 0.03 mg/kg. Residues concentrated in wet and dry pomace, with PF of 3.3 and > 5, respectively. Washing and drying the fruit did not alter residue concentration. The PF for sauce and juice was < 0.33 and for juice concentrate 0.33. In one study submitted to the 1994 JMPR, residues in treated apple were 0.37 mg/kg. It increased slightly in washed fruit (PF=1.1) and considerably in dry pomace (PF=18). The processing factor in sauce and apple dried was 0.5 and in juice, 0.14.

Based on the estimated PFs and an STMR of 0.19 mg/kg for pome fruits, the Meeting estimated an STMR-P of 0.08 mg/kg for apple sauce, 0.08 mg/kg for apple juice (mean PF of 0.42). The Meeting also estimated an STMR-P of 0.63 mg/kg for wet apple pomace (PF=3.3) and of 2.2 mg/kg for dry apple pomace (mean PF=11.5).

One processing study was conducted in plums in the USA (2001). Residues in treated plums ranged from 0.17 to 0.19 mg/kg, concentrated in prunes with a mean PF of 1.2. In one processing study submitted to the 1997 JMPR, washed and plum preserve had a PF of 0.7, residues remained unchanged in jam and increased in prunes with a PF of 4.7.

Based on an STMR of 0.06 mg/kg, an HR of 0.12 mg/kg estimated for plums and a mean PF of 3, the Meeting estimate a maximum residue level of 0.5 mg/kg (based on a highest residue of 0.36 mg/kg) and an STMR-P of 0.18 mg/kg for prunes.

Three studies were conducted in Europe and one in the USA to determine the fate of tebuconazole residues in treated tomato (0.12 to 1.2 mg/kg) after processing. Residues were reduced in all steps, with a mean PF of 0.95 after washing; 0.25 after peeling, 0.55 for tomato juice, 0.3 in tomato preserve; 0.33 in tomato puree and 0.87 in tomato paste.

Based on the estimated PFs and an STMR of 0.19 mg/kg estimated for tomato, the Meeting estimated an STMR-P of 0.10 mg/kg for tebuconazole in tomato juice, 0.057 mg/kg in preserve, 0.06 mg/kg in purée, 0.16 mg/kg in tomato paste and 0.054 mg/kg in peeled tomato. The Meeting also estimated an HR-P of 0.115 mg/kg for peeled tomato based on an HR of 0.46 mg/kg on tomato.

In two studies conducted in Germany (2003), beans (with pods) treated in a green house with residues of 0.43 and 0.55 mg/kg were processed. Mean PFs in washed beans and cooked beans were 0.28 and 0.2, respectively. Based on an STMR of 0.48 mg/kg in the raw commodity, the Meeting estimated an STMR-P of 0.096 mg/kg for beans (with pods), cooked.

In one processing study conducted in treated soya bean in 2004, residues in the seed (0.14 mg/kg) concentrated in aspired grain fractions and hulls, with PF of 276 and 1.1, respectively. The PF was 0.2 in soya bean meal, 0.3 in protein isolate, 0.2 in defatted flour, 0.4 in full fat flour and 0.07 in refined oil.

Based on an STMR of 0.02 mg/kg in soya bean, dry, and the estimated PFs, the Meeting estimated an STMR-P of 5.5 mg/kg for aspired soya bean grain fractions, 0.022 mg/kg for soya bean hulls, 0.004 mg/kg for soya bean meal, and 0.001 mg/kg in refined oil.

In two studies conducted in barley, treated samples containing 0.65 and 0.93 mg/kg were processed into beer at a pilot plant in Germany (2002). Residues concentrated in pearl barley rub-off (mean PF=2.5) and did not change in malt sprouts. Mean PF was 0.51 in brewer's malt, 0.45 in brewer's grain, 0.30 in hops draft, 0.19 in brewer's yeast and < 0.025 in beer. Based on an estimated STMR of 0.05 mg/kg in barley, the Meeting estimated an STMR-P of 0.001 mg/kg in beer.

In two studies conducted in France (2002), treated rape seed samples containing 0.12 mg/kg were processed to oil. Residue levels did not changed in solvent-extracted oil, crude oil and extracted press cake meal, but reduced in screw-pressed oil (PF=0.1), pomace (PF=0.85) and refined oil (PF=0.8). Based on the PFs and on an STMR of 0.08 mg/kg estimated for rape seed, the Meeting estimated an STMR-P of 0.08 mg/kg for rape seed oil, crude and 0.064 mg/kg for rape seed oil, edible.

In a processing study conducted in Guatemala (1999), residues of tebuconazole in treated coffee beans (dried) were 0.04 mg/kg. PF for roasted coffee and instant coffee were 2 and 0.8 mg/kg, respectively.

Based on an STMR of 0.1 mg/kg in coffee and the estimated PFs, the Meeting estimated an STMR-P of 0.2 mg/kg for roasted coffee and of 0.08 mg/kg for instant coffee. Based on a highest residue of 0.1 mg/kg, the Meeting also recommends a maximum residue level of 0.5 mg/kg for roasted coffee.

In one study conducted in Germany (2001), treated kiln-dried hops (8.3 mg/kg) were processed to beer, with a PF of 0.01 mg/kg. Spent hops and brewer's yeast had PF of 0.01 and 0.02, respectively.

Based on an STMR of 9.65 mg/kg in hops, the estimated PF and applying a dilution factor of 10 (hops in beer, 2002 JMPR) the Meeting estimated an STMR-P of 0.009 mg/kg for beer (coming from hops).

Farm animal dietary burden

The Meeting estimated the dietary burden of tebuconazole 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 or highest residue levels estimated at the present Meeting and the current MRLs for some feed items. Dietary burden calculations are provided in Annex 6.

		Animal dietary burden, tebuconazole, ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	27.5	24.1	60[a]
	mean	14.67	7.5	17.3[c]
Dairy cattle	max	33.1	23.7	47.6[b]
	mean	15.9	7.5	26.3[d]
Poultry - broiler	max	0.12	0.08	0.19
	mean	0.11	0.06	0.19
Poultry - layer	max	0.12	7.2[e]	0.19
	mean	0.12	3.9[f]	0.19

[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 and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs.

The tebuconazole dietary burdens for animal commodity MRL and STMR estimation (residue levels in animal feeds expressed on dry weight) reached a maximum of 60 ppm for cattle and 7.2 ppm for poultry.

Farm animal feeding studies

Two dairy cattle feeding studies were submitted to the 1994 JMPR. The animals were fed for 28 days at 25/75/250 ppm or 30/90/300 ppm. No residues were detected in kidney (< 0.05 or < 0.1 mg/kg) or milk (< 0.01 or < 0.05 mg/kg) at any dose in both studies. Meat was only analysed from the higher dose groups, with no residues detected (< 0.05 or < 0.1 mg/kg). Residues in liver were < 0.05, 0.06, 0.07 mg/kg at 25 ppm and 0.06, 0.07 and 0.12 mg/kg at 75 ppm. From the second study, residues were < 0.1 (3) mg/kg at 30 mg/kg and 0.1 and 0.2 (2) mg/kg at 90 ppm.

Two poultry studies were also submitted, with laying hens fed at 2, 6 and 20 ppm tebuconazole for 28 days. Tissues and eggs were analysed for tebuconazole and residues were only found in liver at the highest dose in both studies.

Animal commodity maximum residue levels

The animal feeding studies have shown that, with the exception of cattle liver, no residues are expected in commodities following the feeding of animals at the expected dietary burden.

The Meeting estimated a maximum residue level of 0.05* mg/kg for tebuconazole in meat (from mammalian other than marine mammals), poultry meat, poultry edible offal and eggs and of 0.01* mg/kg in milks.

The Meeting also estimated an STMR of 0 in meat (from mammalian other than marine mammals), poultry meat, poultry edible offal, eggs and milks, an HR of 0 mg/kg in meat (from mammalian other than marine mammals), poultry meat and eggs, and 0.05 mg/kg in poultry edible offal.

Estimations for mammalian edible offal will be done based on the residues found in cattle liver at the two lower doses in the second study (interpolation). The Meeting estimated a maximum residue level of 0.5 mg/kg, and an HR and STMR of 0.2 mg/kg.

The Meeting withdraws its previous recommendations for tebuconazole in cattle meat, milk and edible offal and chicken eggs, meat and edible offal at the LOQ (0.05 mg/kg or 0.01 mg/kg for milk).

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for tebuconazole is 0–0.03 mg/kg bw. The International Estimated Daily Intakes (IEDI) for tebuconazole was estimated for the 13 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the current and the 1997 JMPR and MRLs recommended by the 1994 JMPR. The results are shown in Annex 3. The IEDI ranged from 1 to 9% of the maximum ADI. The Meeting concluded that the long-term intake of residues of tebuconazole from uses that have been considered by the JMPR were unlikely to present a public health concern.

Short-term intake

The International Estimated Short-term Intake (IESTI) for tebuconazole was calculated for the plant commodities for which STMRs, HRs and MRLs were estimated by the current and previous Meetings and for which consumption data were available. The results are shown in Annex 4. The IESTI ranged from 0 to 31.4 µg/kg bw for the general population and from 0 to 65.6 µg/kg bw for children. An ARfD for tebuconazole has not yet been considered by the Meeting; therefore, the risk assessment for this compound could not be finalized.

5.24 TRIAZOLE FUNGICIDE METABOLITES

TOXICOLOGY

1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole pyruvic acid and triazole lactic acid are the common metabolites derived from triazole-containing fungicides that act by inhibiting sterol synthesis. The levels of triazole pyruvic acid and triazole lactic acid found in metabolism studies are low, and no toxicological data on these compounds were available, therefore, they were not considered by the present Meeting. 1,2,4-Triazole, triazole alanine and triazole acetic acid are the commonly used names for IUPAC nomenclatures 1*H*-1,2,4-triazole (CAS No. 288-88-01), 1,2,4-triazolyl-3-alanine (CAS No. 10109-05-4), and 1*H*-1,2,4-triazol-l-ylacetic acid (CAS No. 28711-29-7),respectively. These three metabolites commonly occur as plant or soil metabolites and are collectively known as the "triazole derivative metabolites". Triazole alanine and triazole acetic acid residues are primarily associated with plant commodities, while 1,2,4-triazole is mainly associated with animal commodities, lesser amounts of this compound being found in plant commodities. 1,2,4-Triazole is found in studies of the metabolism of triazole fungicides in rats, where it may constitute approximately 1% to 65% of the dose, depending on the parent compound administered.

Triazole alanine was first evaluated by the JMPR in 1989. The Meeting concluded from the available data at that time that residues of triazole alanine arising from the use of triazole fungicides do not present a toxicological hazard. The Meeting has not previously evaluated 1,2,4-triazole and triazole acetic acid. These compounds were reviewed by the present Meeting at the request of CCPR and following recommendations made by the JMPR in 2007 (general consideration 2.3). A group of manufacturers of these pesticides have formed a taskforce known as the "Triazole Derivative Metabolite Group" (TDMG) and made a joint submission of toxicological data to the JMPR. All pivotal studies with triazole alanine and triazole acetic acid were certified as complying with GLP, unless otherwise stated in the toxicological monograph.

The toxicological database for 1,2,4-triazole was sufficient for the evaluation of this compound, while the toxicological databases for triazole alanine and triazole acetic acid were more limited. The Meeting concluded that adequate studies were available to establish an ADI for 1,2,4-triazole and a group ADI for triazole alanine and triazole acetic acid. This decision was based on the following considerations:

— The chemical structures of triazole alanine and triazole acetic acid are closely related and the two substances have similar physicochemical characteristics.

— Both triazole alanine and triazole acetic acid have the 1,2,4-triazole active (protonated) nitrogen bonded to carbon, which significantly reduces the toxicity of triazole alanine and triazole acetic acid.

— The available toxicological data suggest that triazole alanine and triazole acetic acid are less toxic than 1,2,4-triazole.

— Triazole alanine and triazole acetic acid have similar toxicokinetic profiles in that they are rapidly eliminated, primarily in the urine and mostly as the parent compound.

The Meeting recommended that the ADI and ARfD values established for these triazole metabolites may be used in risk assessment on a case-by-case basis, depending on the residue and toxicity profile of the parent compound. The Meeting also noted that these values may also be useful in a combined risk assessment, depending on the exposure situation, including whether exposure to these metabolites comes from more than one source of the parent conazoles.

1,2,4-TRIAZOLE

Biochemical aspects

In rats treated orally, radiolabelled 1,2,4-triazole was rapidly and completely absorbed and excreted mostly unchanged and mainly in the urine (80–94%) in first 24 h, irrespective of dose or route of administration. Approximately 0.1% of the administered dose was recovered within 30 h in expired air after oral and intravenous administration. Approximately 3 to 5% of the administered dose was recovered in faeces in 48 h. Approximately 2% of the administered dose was recovered in the gastrointestinal tract at 48 h. In bile-duct-fistulated rats, approximately 12% of the dose was recovered in the bile at 24 h after intravenous or in traduodenal application.

Toxicological data

1,2,4-Triazole is of moderate toxicity when administered orally. The LD_{50} in rats treated orally was 1648 mg/kg bw. The LD_{50} in rats treated dermally was 3129 mg/kg bw. 1,2,4-Triazole appears to be more toxic dermally in rabbits than in rats. The dermal LD_{50} in rabbits was > 200 and < 2000 mg/kg bw. It is slightly irritating to the skin and severely irritating to the eyes of rabbits. It is not a skin sensitizer as determined by Magnusson & Kligman (maximization) test in guinea-pigs. The following clinical signs were observed after oral dosing: sedation, breathing difficulties, reduction in general well-being, hunched posture (at higher doses). These signs appeared within 1 h of administration and were observed for a maximum of 13 days after administration. Similar clinical signs were observed in rats treated dermally.

In short-term studies in mice and rats, neurotoxicity was seen in number of studies. In a 28-day toxicity study in mice, the only treatment-related effects were slight testicular degeneration accompanied by apoptotic bodies at 2000 ppm, equal to 356 mg/kg bw per day (the LOAEL). No effects were observed in females at doses up to and including 2000 ppm, equal to 479 mg/kg bw per day. The NOAEL in mice was 500 ppm, equal to 90 mg/kg bw per day.

In a 90-day study of toxicity in mice, decreased body weights, tremors (observed from day 30), decreased body weight, and loss of cerebellar Purkinje cells were observed in males and females at 6000 ppm, equal to 988 mg/kg bw per day. At 6000 ppm (the highest dose), 9 out of 11 males showing tremors also had Purkinje cell loss, while in females at this highest dose one out of three mice with tremors had Purkinje cell loss. Decreased testicular weights and histopathological findings in testes similar to the 28-day study were observed in males at 3000 and 6000 ppm. The NOAEL was 1000 ppm, equal to 161 mg/kg bw per day, on the basis of tremors, decreased brain weights, decreased testicular weights and histopathological changes in the testes seen in males at the LOAEL of 3000 ppm, equal to 487 mg/kg bw per day.

In a 90-day dietary study of toxicity in rats, retarded body-weight development, transient effects on the central nervous system, lower erythrocyte parameters (microcytic hypochromic erythrocytes, in males only) and hepatocellular fat accumulation (males only) were observed at 2500 ppm, equivalent to 212.3 mg/kg bw per day. The NOAEL was 500 ppm, equivalent to 37.9 mg/kg bw per day. In a combined short-term study of toxicity and neurotoxicity in rats, FOB effects were observed at 3000 ppm and 1000/4000 (equal to 183 and 210 mg/kg per day, respectively) and with increased incidence and severity at week 8. Males were more severely affected than females. Other effects observed were ungroomed appearance, red nasal and lachrymal stain, yellow urine stain, muscle fasciculations, tremors, gait incoordination, decreased activity in the open field, decreased rearing, uncoordinated righting reflex and increased foot splay. A decrease in motor and locomotor activity was also observed in males at 3000 ppm during week 4 only. Decreases in absolute brain weights and degenerative lesions were seen in the cerebellum, the lumbar dorsal root ganglion and other peripheral nerves at 3000 ppm and at 1000/4000 ppm. The brain lesions were

limited to the anterior, dorsal cerebellum and were coded overall as an increased incidence of cellular degeneration and necrosis. Findings were characterized by extensive loss of Purkinje cells, variable white-matter degeneration and gliosis. Subtle atrophy of the molecular layer, primarily at the cerebellar surface, or loss of granule cells was occasionally present. The NOAEL was 500 ppm, equal to 33 mg/kg bw per day, on the basis of decreased body weight and body-weight gain, tremor and incoordination, decreased absolute brain weight, and increased incidence of neuropathology findings in the peripheral and central nervous system at the LOAEL of 3000 ppm, equal to 183 mg/kg bw per day.

1,2,4-Triazole gave negative results in a battery of assays for genotoxicity, including the Ames test in vitro, an assay for forward mutation, and a test for chromosomal aberration.

The Meeting concluded that 1,2,4-triazole is unlikely to be genotoxic.

No studies of carcinogenicity were submitted. However, the Meeting considered that 1,2,4-triazole is unlikely to be carcinogenic at anticipated levels of exposure since it does not bioaccumulate in the body, it is non-mutagenic, and because of the absence of pre-neoplastic changes with 1,2,4-triazole at high doses.

In a two-generation study of reproductive toxicity in rats, decreased body weights were observed in F_1 males at 250 ppm, equal to 16 mg/kg bw per day, the lowest dose tested. These changes in body weight were minor and were seen only in males and in only one generation and were not seen in short-term studies in rats given at doses. At 3000 ppm, parental animals (F_0) had statistically significantly reduced terminal body weights, and decreased absolute brain weights associated with mild to moderate degeneration/necrosis in the cerebellum. No F_1 offspring at the highest dose survived the lactation period. No offspring toxicity was observed at doses up to 500 ppm, equal to 30.9 mg/kg bw per day. The NOAEL for reproductive toxicity with 1,2,4-triazole was 250 ppm, equal to 16 mg/kg bw per day, on the basis of an increase in abnormal sperm in F_0 and F_1 males seen at the LOAEL of 500 ppm.

In two studies of developmental toxicity in rats, there was maternal toxicity (retarded weight gain) at 100 mg/kg bw per day or higher, developmental toxicity (decreased body weights, lower fetal and placental weights, and a higher incidence of minor skeletal deviations) at 100 mg/kg bw per day or higher, and an increased incidence of malformations (hydronephrosis, cleft palate, long-bone dysplasia, diaphragmatic hernia) at 200 mg/kg bw per day. The NOAEL for maternal toxicity and for developmental toxicity in rats was 30 mg/kg bw per day. In a study in rabbits, however, lower body-weight gain and clinical signs of systemic toxicity such as excess salivation, hyperpnoea and ptosis were evident at 45 mg/kg bw per day. Five out of 25 dams at this dose were sacrificed in a moribund condition. Developmental effects included lower body weights of fetuses at 45 mg/kg bw per day, and there were a few alterations in the urogenital system, which occurred in several fetuses. The NOAEL for maternal toxicity and for developmental toxicity was 30 mg/kg bw per day in rabbits.

The Meeting concluded that 1,2,4-triazole is teratogenic in rats and rabbits at maternally toxic doses.

No study of acute neurotoxicity was submitted. Clinical signs of neurotoxicity were observed in studies of acute toxicity in which very high doses were given dermally or orally. Neurotoxic effects observed in a short-term study of combined toxicity/neurotoxicity are described above.

The Meeting concluded that 1,2,4-triazole is neurotoxic.

The Meeting concluded that the existing database on 1,2,4-triazole was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI of 0–0.2 mg/kg bw based on a NOAEL of 250 ppm, equal to 16 mg/kg per day, on the basis of testicular effects (sperm abnormalities, sperm counts) seen at

500 ppm, equal to 30.9 mg/kg bw per day, and using a safety factor of 100. At 250 ppm, reduced body weights and body-weight gains were observed in F_1 males; however, the Meeting noted that the reductions in body weight observed at 250 ppm were marginal (< 6%) and were seen only in one sex and in only one generation and were not seen in short-term studies with similar doses. The Meeting therefore concluded that it was not necessary to use an additional safety factor. This ADI is protective for neurotoxic effects seen at 3000 ppm, 183 mg/kg bw per day, in a short-term study of toxicity/neurotoxicity in rats in which the NOAEL was 500 ppm, equal to 33 mg/kg bw per day. The Meeting considered that it was not necessary to add an additional safety factor to allow for the lack of studies of carcinogenicity because 1,2,4-triazole is unlikely to be carcinogenic at anticipated levels of exposure since it does not bioaccumulate in the body, it is non-mutagenic, and because of the absence of pre-neoplastic changes at high doses.

The Meeting established an ARfD of 0.3 mg/kg bw based on a NOAEL of 30 mg/kg bw per day, identified on the basis of alterations of the urogenital system that occurred in several fetuses at the LOAEL of 45 mg/kg bw per day and clinical signs of neurotoxicity in the dams in a study of developmental toxicity in rabbits, and using a safety factor of 100.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	90-day study of toxicity[a]	Toxicity	1000 ppm, equal to 161 mg/kg bw per day	3000 ppm, equal to 487 mg/kg bw per day
Rat	90-day study of toxicity[a]	Toxicity	500 ppm, equal to 33 mg/kg bw per day	3000 ppm, equal to 183 mg/kg bw per day
	Multigeneration study of reproductive toxicity[a]	Parental toxicity	250 ppm, equal to 16.0 mg/kg bw per day[d]	500 ppm, equal to 31 mg/kg bw per day[c]
		Offspring toxicity	500 ppm, equal to 31 mg/kg bw per day[c]	—
	Developmental toxicity[b]	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[b]	Maternal toxicity	30 mg/kg bw per day	45 mg/kg bw per day[c]
		Embryo and fetal toxicity	30 mg/kg bw per day	45 mg/kg bw per day[c]

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

[d] Marginal effects on body weight, only seen in F_1 males.

Estimate of acceptable daily intake for humans

0–0.2 mg/kg bw per day

Estimate of acute reference dose

0.3 mg/kg bw

Information that would be useful for continued evaluation of the compound

Results from epidemiological and other such observational studies of human exposures

Critical end-points for setting guidance values for exposure to 1,2,4-triazole

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid and nearly complete absorption
Distribution	Widely distributed in tissues
Potential for accumulation	Low, no evidence of significant accumulation
Rate and extent of excretion	Approximately 80–94% of the administered dose excreted in urine in first 24 h
Metabolism in animals	No significant metabolism
Toxicologically significant compounds (animals, plants and environment)	1,2,4-triazole
Acute toxicity	
Rat, LD_{50}, oral	1650 mg/kg bw
Rat, LD_{50}, dermal	3129 mg/kg bw
Rat, LC_{50}, inhalation	No adequate data
Rabbit, dermal irritation	Slight irritation
Rabbit, ocular irritation	Severe irritation
Guinea-pig, dermal sensitization	Not a sensitizer (Magnusson & Kligman test)
Short-term studies of toxicity	
Target/critical effect	Nervous system, brain
Lowest relevant oral NOAEL	500 ppm, equal to 33 mg/kg bw per day (90-day study in rats)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	Unlikely to be genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	No data
Lowest relevant NOAEL	No data

Carcinogenicity	Unlikely to be carcinogenic
Reproductive toxicity	
Reproduction target/critical effect	Sperm abnormalities, decreases in body weights
Lowest relevant reproductive NOAEL	250 ppm, equal to 16 mg/kg bw per day
Developmental target/critical effect	Urogenital alterations in rabbits
Lowest relevant developmental NOAEL	30 mg/kg bw per day (rats and rabbits)
Neurotoxicity/delayed neurotoxicity	
Neurotoxicity	Evidence of clinical signs of neurotoxicity and cerebellum lesions
Mechanistic data	
	No studies were submitted
Medical data	
	No data

Summary

	Value	*Study*	*Safety factor*
ADI	0–0.2 mg/kg bw per day	Rat, two-generation studies of reproductive toxicity	100
ARfD	0.3 mg/kg bw	Rabbit, study of developmental toxicity	100

TRIAZOLE ALANINE AND TRIAZOLE ACETIC ACID

Biochemical aspects

In rats given a single dose of radiolabelled triazole alanine (up to 994 mg/kg bw) by gavage, almost all the administered dose was absorbed on the basis of urinary excretion (69–98%). Approximately, 3–18% of the administered dose was recovered in the faeces after 7 days. Less than 0.5% of the administered dose was recovered in the expired air. No significant bioaccumulation of triazole alanine was observed. Approximately 8–30% of the excreted dose in the urine and < 1% of the dose in faeces was identified as *N*-acetyl-D,L-triazole alanine, the remainder was parent compound.

In rats given a single dose of radiolabelled triazole acetic acid by gavage, almost all the administered dose (96–112%) was absorbed on the basis of urinary excretion. Triazole acetic acid was rapidly absorbed and excreted mainly via the urine (87–104% after 7 days). Approximately 1.2–7.4% of the administered dose was recovered in the faeces after 7 days. Total radioactivity in tissues after 7 days ranged from 0.8% to 3.1% of the administered dose. Only the parent compound was found in the urine.

Toxicological data

Triazole alanine is of low acute toxicity when administered orally. The oral LD_{50} in mice and rats was > 5000 mg/kg bw. No treatment-related clinical signs or mortalities were observed in these studies.

Triazole acetic acid is of low acute toxicity when administered orally. The oral LD_{50} in rats was > 5000 mg/kg bw. A slight to moderate increase in the incidence of dyspnoea, exophthalmos, ruffled fur, and hunched posture were observed after dosing and subsided within 10 days.

For triazole alanine, no target organ or any treatment-related toxicity was observed in short-term studies in rats and dogs, except for reduced body-weight gains observed in 90-day studies of toxicity in rats and dogs (females only). No long-term studies were submitted.

For triazole acetic acid, no target organ or any treatment-related toxicity was observed in a short-term study in rats. No long-term studies were submitted.

No treatment-related toxicity was observed in a 14-day study in rats given drinking-water containing triazole alanine at concentrations up to 10 000 ppm, equal to 1491 mg/kg bw per day. Haematological and clinical chemistry parameters were not measured in this study. No treatment-related effects were seen in the 28-day study of oral toxicity in which rats were given triazole alanine at doses of up to 400 mg/kg bw per day by oral gavage. In this study, haematological, clinical chemistry and histopathological analyses were incomplete.

In a 90-day dietary study of toxicity in rats fed triazole alanine, decreased body weight gains was observed at the highest dose of 20 000 ppm, equal to 1510 mg/kg bw per day. Small decreases in concentrations of leukocytes, triglycerides and bilirubin were observed, but were considered to be of no toxicological significance since the changes were small and may have been secondary to the decreased body weights. The NOAEL was 5000 ppm, equal to 370 mg/kg bw per day.

In a 90-day dietary study of toxicity in dogs fed triazole alanine, decreased body-weight gain and food consumption was observed in females at the highest dose of 20 000 ppm, equal to 902 mg/kg bw per day. The NOAEL was 8000 ppm, equal to 322 mg/kg bw per day.

No treatment-related toxicity was observed in a 14-day study in rats given diets containing triazole acetic acid at doses of up to 8000 ppm, equal to 703.5 mg/kg bw per day.

Triazole alanine gave negative results in a adequate battery of tests for genotoxicity in vivo and in vitro.

Triazole acetic acid gave negative results in an Ames test in vitro, and in assays for mutation or cytogenotoxicity in mammalian cells.

The Meeting concluded that triazole alanine and triazole acetic acid are unlikely to be genotoxic.

No studies of carcinogenicity were available; however, triazole alanine and triazole acetic acid are unlikely to be carcinogenic at anticipated levels of exposure since they do not bioaccumulate in the body, are non-mutagenic, are not chemically reactive, and no specific target-organ toxicity was identified in the available toxicological studies with doses of up to 1510 mg/kg bw per day.

In a non-guideline, one-generation study of reproductive toxicity in rats given triazole alanine, no systemic toxicity was seen in parental animals at doses of up to 10 000 ppm, equivalent to 1000 mg/kg bw per day. In this study, a statistically significantly increase in pre-coital interval and slight reductions in neonatal weights of males and females were observed at 10 000 ppm. The NOAEL for reproductive and developmental toxicity was 2500 ppm, equal to 250 mg/kg bw per day. In a two-generation study of reproductive toxicity in rats, no systemic toxicity was observed in the parental animals at doses of up to and including 10 000 ppm. No reproductive toxicity was observed at doses of up to and including 10 000 ppm, equal to 929 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 2000 ppm, equal to 192 mg/kg bw per day, on the basis of reduced mean litter weights seen at the LOAEL of 10 000 ppm, equal to 929 mg/kg bw per day. In a study of developmental toxicity in rats given triazole alanine, no systemic toxicity was observed with triazole alanine at doses of up to and including 1000 mg/kg bw per day given by oral gavage. Increased incidences of skeletal findings were seen in the offspring at the intermediate and highest doses. These skeletal findings included unossified odontoid processes at 300 and 1000 mg/kg bw per

day, with partially ossified transverse processes of the seventh cervical vertebra (bilateral), unossified fifth sternebra, and partially ossified thirteenth thoracic centrum observed only at 1000 mg/kg bw per day. The NOAEL for developmental toxicity was 100 mg/kg bw per day.

The Meeting concluded that triazole alanine was not teratogenic. Triazole acetic is unlikely to be teratogenic on the basis of its structural and toxicological similarity with triazole alanine.

No studies of neurotoxicity with triazole alanine were submitted. However, there was no evidence that exposure to triazole alanine results in neurotoxicity in the short-term studies in rats and dogs, the study of developmental toxicity in rats, or studies of reproductive toxicity in rats.

No studies of neurotoxicity with triazole acetic acid were submitted. In a study of acute lethality, a slight to moderate increase in the incidence of dyspnoea, exophthalmos, ruffled fur, and curved body position were observed after dosing, and subsided within 10 days. These clinical signs were considered to be non-specific and attributable to bolus dosing with a very high dose (5000 mg/kg bw) by gavage rather than specific neurotoxicity.

The Meeting concluded that triazole alanine and triazole acetic acid are unlikely to be neurotoxic on the basis of the available data.

The Meeting concluded that the existing database on triazole alanine was adequate to characterize the potential hazards to fetuses, infants and children. This conclusion was also applicable to triazole acetic acid for the reasons described above.

Toxicological evaluation

The Meeting established a group ADI for triazole alanine and triazole acetic acid (alone or in combination) of 0–1.0 mg/kg bw based on a NOAEL of 100 mg/kg bw per day for developmental toxicity in a study of developmental toxicity in rats given triazole alanine, on the basis of delayed ossification seen in rats at the LOAEL 300 mg/kg bw per day, and using a safety factor of 100. The Meeting concluded that it was not necessary to use an additional safety factor for the lack of studies of carcinogenicity because the compounds are unlikely to be carcinogenic at anticipated levels of exposure, do not bioaccumulate in the body, are non-mutagenic, are not chemically reactive, and no specific target-organ toxicity was identified in the available toxicological studies with doses of up to 1510 mg/kg bw per day.

The Meeting concluded that it was unnecessary to establish an ARfD for triazole alanine and triazole acetic acid because no toxicity could be attributed to a single exposure in the available database, including a study of developmental toxicity in rats.

A toxicological monograph for triazole alanine and triazole acetic acid was prepared.

Levels relevant to risk assessment

Based on data for triazole alanine

Species	Study	Effect	NOAEL	LOAEL
Rat	Multigeneration study of reproductive toxicity[a]	Parental toxicity	10 000 ppm, equal to 929 mg/kg bw per day[c]	—
		Offspring toxicity	2000 ppm equal to 192 mg/kg bw per day	10 000 ppm, equal to 929 mg/kg bw per day[c]
	Developmental toxicity[b]	Maternal toxicity	1000 mg/kg bw per day[c]	—

		Embryo and fetal toxicity	100 mg/kg bw per day	300 mg/kg bw per day
Dog	90-day study of toxicity[b,]	Toxicity	8000 ppm, equal to 345 mg/kg bw per day	20 000 ppm, equal to 850 mg/kg bw per day[c]

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

Group ADI for triazole alanine and triazole acetic acid: 0–1 mg/kg bw per day

Estimate of acute reference dose

Unnecessary

Information that would be useful for continued evaluation of the compound

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

Critical end-points for setting guidance values for exposure to triazole alanine

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid and nearly complete absorption
Distribution	Widely distributed in tissues
Potential for accumulation	Low, no evidence of significant accumulation
Rate and extent of excretion	Approximately 96–99% of the administered dose excreted in urine in first 24 h
Metabolism in animals	Limited, about 8–19% excreted as *N*-acetyl triazole alanine in the urine. No metabolism of triazole acetic acid.
Toxicologically significant compounds (animals, plants and environment)	Triazole alanine; triazole acetic acid
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw for triazole alanine and triazole acetic acid
Rat, LD_{50}, dermal	No data
Rat, LC_{50}, inhalation	No data
Rabbit, dermal irritation	No data
Rabbit, ocular irritation	No data
Dermal sensitization	No data

S*hort-term studies of toxicity*	
Target/critical effect	Decreased body-weight gain
Lowest relevant oral NOAEL	5000 ppm, equal to 370 mg/kg bw per day (90-day study in rats)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEL	No data
Genotoxicity	
	Unlikely to be genotoxic (triazole alanine and triazole acetic acid)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	No data
Lowest relevant NOAEL	No data
Carcinogenicity	Unlikely to be carcinogenic (triazole alanine and triazole acetic acid)
Reproductive toxicity	
Reproduction target/critical effect	No toxicologically relevant effects
Lowest relevant reproductive NOAEL	10 000 ppm, equal to 929 mg/kg bw per day (rats; highest dose tested)
Developmental target/critical effect	Delayed ossifications
Lowest relevant developmental NOAEL	100 mg/kg bw per day (rats)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity	No indication of neurotoxicity from other studies
Mechanistic data	
	No data
Medical data	
	No data

Summary

	Value	*Study*	*Safety factor*
ADI	0–1 mg/kg bw per day	Rat, study of developmental toxicity (rats)	100
ARfD	Unnecessary	—	—

6. RECOMMENDATIONS

GENERAL CONSIDERATIONS

Comments on a pilot process for JMPR to recommend maximum residue levels prior to national government registration

The present Meeting acknowledged the importance of retrospective analyses of toxicity databases for pesticides and recommended that the WHO Core Assessment Group on Pesticide Residues of the JMPR or a working group established by the WHO Joint Secretariat of the JMPR could serve a valuable role in the review of these analyses that are conducted by national/supranational bodies. The JMPR would provide an independent international opinion on the scientific robustness and transparency of these analyses, make suggestions on how they may be improved, and provide comment on the implications of the results. If multiple analyses by different countries have been or will be conducted, the JMPR could also make recommendations on how to harmonize the approach and interpretation of the results. Retrospective analyses may be submitted to the JMPR/WHO Joint Secretariat for consideration by national authorities or other organizations or by the OECD Working Group on Pesticides. The analyses would need to be made available to the WHO Core Assessment Group at least 6 months before the JMPR annual meeting normally held in September and such analyses would need to be well documented (i.e., not anonymized, if possible).

The Meeting also recommended that the JMPR take on a pilot process and thus asked the JMPR/WHO Joint Secretariat to liaise with the OECD Working Group on Pesticides to identify a suitable retrospective analysis.

Comments on OECD Draft Guidance Document for Derivation of an Acute Reference Dose

The Meeting recommended that the OECD guidance document should address only oral exposure. The issues associated with setting ARVs for inhalation and dermal exposure, including route-to-route extrapolation methods, should be moved to a separate guidance document or to an annex attached to the current document.

The Meeting also noted that the provision of more guidance on issues relating to assessment of acute risk would improve both the WHO and the OECD guidance on setting of acute reference doses (ARfDs).

The global assessment of chlorantraniliprole (particularly the accompanying reporting table with the reviewer comments) was helpful for the preparation of the JMPR monograph on this pesticide.

In summary, some suggestions are listed below that might make the global assessment more useful for the JMPR:

- Decrease the level of methodological detail provided.
- Reduce the level of reporting of inconsequential findings.
- Continue to give details of comments and responses by participants.
- If possible, separate critical discussion points from minor issues in the reporting table.

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

Triazole derivative metabolites

The Meeting recommended that the ADI and ARfD values established for these triazole metabolites may be used in risk assessment on a case-by-case basis, depending on the residue and toxicity profile of the parent compound. The Meeting also noted that these values may also be useful in a combined risk assessment, depending on the exposure situation, including whether exposure to these metabolites comes from more than one source of the parent conazoles.

7. FUTURE WORK

The items listed below should be considered by the Meeting in 2010 and 2011. The compounds listed include those recommended as priorities by the CCPR at its 41st 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/ag/AGP/AGPP/Pesticid/

http://www.who.int/ipcs/food/en/

2010 JMPR

Toxicological evaluations		Residue evaluations	
New compounds			
Clopyralid		Clopyralid	
Clothianidin		Clothianidin	
Cyproconazole		Cyproconazole	
Dicamba		Dicamba	
Emamectin benzoate		Emamectin benzoate	
Etoxazole		Etoxazole	
Flubendiamide		Flubendiamide	
Meptyldinocap		Meptyldinocap	
Thiamethoxam		Thiamethoxam	
Periodic re-evaluations			
Vinclozolin (159)		Vinclozolin (159)	
Dithianon (028)	2011R	Azinphos-methyl (002)	2007T
Fenbutatin oxide (109)	2011R	Chlorothalonil (081)	2009T
		Cadusafos (174)	2009T
		Bifenthrin (178)	2009T
		Cycloxydim (179)	2009T
Evaluations			
		Fenpyroximate (193) – re-evaluate data for grapes following JMPR recommended new ARfD.	
		Difenoconazole (224) – review of alternative GAP (banana – higher MRL; additional MRLs (green beans and passion fruit)	

Triazophos (143) – residue evaluation in edible portion (soya bean – immature seeds); cereals including. Rice

Endosulfan (032) – Tea green/black

2011 JMPR

Toxicological evaluations	**Residue evaluations**	
New Compounds		
Periodic re-evaluations		
Diquat (031)	Diquat (031)	
Etofenprox (184)	Etofenprox (184)	
Dichlorvos (025)	Dithianon (028)	2010T
Fenpropathrin (185)	Fenbutatin oxide (109)	2010T

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 2008 MEETING

The following extracts of the results of the annual Joint FAO/WHO Meeting on Pesticide Residues (JMPR) are provided to make them accessible to interested parties at an early date.

The Meeting evaluated 28 pesticides, of which 6 were new compounds, and 5 were re-evaluated within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting established acceptable daily intakes (ADIs) and acute reference doses (ARfDs).

The Meeting estimated maximum residue levels, which it recommended for use as maximum residue limits (MRLs) by the CCPR. It also estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimation of the dietary intake of residues of the pesticides reviewed. Application of HR levels is explained in the report of the 1999 Meeting (section 2.4). The allocations and estimates are shown in the table.

Pesticides for which the estimated dietary intakes might, on the basis of the available information, exceed their ADIs are marked with footnotes, as explained in detail in the report of the 1999 Meeting (section 2.2). Footnotes are also applied to specific commodities when the available information indicated that the ARfD of a pesticide might be exceeded when the commodity was consumed. It should be noted that these distinctions apply only to new compounds and those re-evaluated within the CCPR periodic review programme.

The table includes the Codex reference numbers of the compounds and the Codex classification numbers (CCNs) of the commodities, to facilitate reference to the Codex maximum limits for pesticide residues (*Codex Alimentarius,* Vol. 2B) and other documents and working documents of the Codex Alimentarius Commission. Both compounds and commodities are listed in alphabetical order.

Apart from the abbreviations indicated above, the following qualifications are used in the Table.

* (following name of pesticide)	New compound
** (following name of pesticide)	Compound reviewed within CCPR periodic review programme
* (following recommended MRL)	At or about the limit of quantification
HR-P	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the HR in the raw commodity by the processing factor
Po	The recommendation accommodates post-harvest treatment of the commodity.
PoP (following recommendation for processed foods (classes D and E in the Codex classification)	The recommendation accommodates post-harvest treatment of the primary food commodity.
STMR-P	An STMR for a processed commodity calculated by applying the concentration or reduction factor for the process to the STMR calculated for the raw agricultural commodity.
W (in place of a recommended MRL)	The previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

Established ADI and ARfD values and recommended MRL, STMR and HR values

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
Azoxystrobin (229)*	AB 0660	Almond hulls	7		2.1	
ADI: 0–0.2 mg/kg bw	VS 0620	Artichoke, globe	5	–	1.8	
ARfD: unnecessary	VS 0621	Asparagus	0.01*	-	0.01	
	FI 0327	Banana	2	-	0.03 [a)]	
	GC 0640	Barley grain	0.5	-	0.08	
		Barley malt			0.01	
		Barley spent grain			0.01	
		Beer			0.002	
	FB 0018	Berries and other small fruits, except cranberry, grapes, and strawberry	5	-	1.0	
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassica	5	-	1.2	
	VA 0035	Bulb vegetables	10	-	2.2	
	VS 0624	Celery	5	-	0.43	
	FC 0001	Citrus fruit	15	-	4.9	
	SO 0691	Cotton seed	0.7	-	0.01	
	FB 0265	Cranberry	0.5	-	0.23	
	DF 0269	Dried grapes (= currants, raisins and sultanas)			0.24	
	DH 0170	Dried herbs, except dry hops	300	-	152	
	MO 0105	Edible offal (mammalian)	0.07	-	0.01	
	PE 0112	Eggs	0.01*	-	0	
	VC 0045	Fruiting vegetables, Cucurbits	1	-	0.17 (0.02[b])	
	VO 0050	Fruiting vegetables, other than Cucurbits, except Mushrooms and Sweet corn	3	-	0.35	
	FB 0269	Grapes	2	-	0.53	
	JF 0269	Grape juice			0.19	
		Grape must			0.28	
	HH 0092	Herbs	70	-	23	
	DH 1100	Hops, dry	30	-	11	
	VP 0060	Legume vegetables	3	-	1.0	
	VL 0482	Lettuce, Head	3	-	0.28	
	VL 0483	Lettuce, Leaf	3	-	0.28	
	CF 1255	Maize flour			0.01	
	GC 0645	Maize grain	0.02	-	0.01	
		Maize grits			0.003	
	CF 0645	Maize meal			0.01	
	AS 0654	Maize, fodder	40 dw		5.0 dw	
	OR 0645	Maize oil, edible	0.1	-	0.06	
		Maize starch			0.001	
	FI 0345	Mango	0.7		0.05 [a)]	
	MM 0095	Meat from mammals (other than marine mammals)	0.05 (fat)		0.01	
	FM 0183	Milk fats	0.03	-	0.03	
	ML 0106	Milks	0.01	-	0.01	
	GC 0647	Oat grain	0.5	-	0.08	
	JF 0004	Orange juice			0.39	
		Orange oil, cold-pressed			24	
	FI 0350	Papaya	0.3	-	0.02 [a)]	
	SO 0697	Peanut	0.2	-	0.01	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
	AL 1270	Peanut fodder	30		5.1	
	OR 0697	Peanut oil, edible			0.03	
	HS 0444	Peppers, chili (dried)	30	-	3.5	
	TN 0675	Pistachios	1	-	0.44	
	FI 0354	Plantain	2	-	0.03 [a)]	
	PM 0110	Poultry meat	0.01*	-	0	
	PO 0111	Poultry, Edible offal of	0.01*	-	0	
	DF 0014	Prunes			0.14	
	GC 0649	Rice	5	-	0.68	
	CF 0649	Rice bran, processed			0.82	
	CM 1205	Rice, polished			0.06	
	VR 0075	Root and tuber vegetables	1	-	0.23	
	GC 0650	Rye	0.2	-	0.01	
	OR 0541	Soya bean oil, refined			0.05	
	VD 0541	Soya bean (dry)	0.5	-	0.06	
	AL 0541	Soya bean fodder (dry)	100 dw		36 dw	
	FS 0012	Stone fruits	2	-	0.74	
	FB 0275	Strawberry	10	-	1.3	
	AS 0081	Straw and fodder (dry) of cereal grains, except maize	15 dw		1.7 dw	
	OR 0702	Sunflower seed oil, edible			0.01	
	SO 0702	Sunflower seed	0.5	-	0.04	
		Tomato conserve			0.05	
	JF 0448	Tomato juice			0.16	
		Tomato ketchup			0.21	
	VW 0448	Tomato paste			1.1	
		Tomato purée			0.35	
	TN 0085	Tree nuts, except pistachios	0.01	-	0.01	
	GC 0653	Triticale	0.2	-	0.01	
	CF 0654	Wheat bran, processed			0.004	
	CP 1211	White bread			0.001	
	CP 1212	Wholemeal bread			0.001	
		Wheat flour, low grade			0.003	
		Wheat flour, patent			0.003	
	CF 1212	Wheat flour, wholemeal			0.003	
	GC 0654	Wheat	0.2	-	0.01	
		Wheat shorts			0.001	
		Wine			0.36	
	VS 0469	Witloof chicory (sprouts)	0.3	-	0.05	

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: azoxystrobin.
The residue is fat soluble.
[a)] STMR and HR values in edible portion (pulp).
[b)] Melons only

Bifenazate (219)
ADI: 0–0.01 mg/kg bw
ARfD: Unnecessary

An incomplete data submission precluded the estimation of MRL or STMR values

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
Boscalid (221)	FI 0327	Banana	0.6	0.2	0.05	
ADI: 0–0.04 mg/kg bw	FI 0341	Kiwi fruit	5	-	0.073	
ARfD: Unnecessary						
Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant commodities): boscalid. *Definition of the residue (for estimation of dietary intake for animal commodities):* sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide including its conjugate, expressed as boscalid. The residue is fat soluble.						
Buprofezin (173)**	FC 0001	Citrus fruits	1	-	0.04	0.1
ADI: 0–0.009 mg/kg bw	JF 0004	Citrus juice			0.13	
ARfD: 0.5 mg/kg bw	FC 0004	Oranges, sweet and sour	W	0.5	-	-
	FI 0345	Mango	0.1	-	0.01	0.01
	VC 0424	Cucumber	0.2	-	0.035	0.1
	VO 0448	Tomato	1	1	0.24	0.52
	JF 0448	Tomato juice			0.053	-
	VW 0448	Tomato paste			0.22	-
		Tomato, peeled			0.041	0.088
	MM 0095	Meat from mammals (other than marine mammals)	0.05*	-	0	0
	MO 0105	Edible offal (Mammalian)	0.05*	-	0	0
	ML 0106	Milks	0.01*	-	0	0
		Citrus pulp, Dry	2			
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: buprofezin						
Carbaryl (008)	The Meeting concluded that there was insufficient data to support alternative GAP assessments for citrus, cherries and grapes.					
ADI: 0–0.008 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: carbaryl						
Carbofuran (096)						
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: sum of carbofuran, 3-hydroxycarbofuran and conjugated 3-hydroxycarbofuran, expressed as carbofuran.						
Chlorantraniliprole (230)*	VS 0624	Celery	7	-	2.1	
ADI: 0–2 mg/kg bw	GC 0080	Cereal grains	0.02	-	0.01	
ARfD: Unnecessary	SO 0691	Cotton seed	0.3	-	0.049	
	PE 0112	Eggs	0.01*	-	0	
	VC 0045	Fruiting vegetables, Cucurbits	0.3	-	0.065	
	VO 0050	Fruiting vegetables, other than Cucurbits (except Mushrooms and Sweet corn)	0.6	-	0.066	
	HS 0444	Peppers, chili (dried)	5	-	0.46	
	JF 0448	Tomato juice			0.0589	
		Tomato ketchup			0.0691	
		Tomato purée			0.102	
	VW 0448	Tomato paste			0.109	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
	FB 0269	Grapes	1	-	0.119	
	JF 0269	Grape juice			0.0869	
	DF 5263	Raisins			0.411	
		White wine			0.0262	
		Red wine			0.140	
	VL 0053	Leafy vegetables	20	-	7.3	
	MO 0105	Edible offal (Mammalian)	0.01*	-	0	
	ML 0106	Milks	0.01*	-	0	
	FM 0183	Milk fats	0.1	-	0.047	
	MM 0095	Meat (from mammals other than marine mammals)	0.01* (fat)	-	0 M 0 F	
	FP 0009	Pome fruits	0.4	-	0.07	
	JF 0226	Apple juice			0.0098	
		Apple purée			0.0063	
		Apple sauce			0.0189	
	PM 0110	Poultry meat	0.01* (fat)	-	0 M 0 F	
	PO 0111	Poultry, Edible offal of	0.01*	-	0	
	VR 0075	Root and tuber vegetables	0.02	-	0.01	
	FS 0012	Stone fruits	1	-	0.2	
	AS 0081	Straw and fodder (dry) of cereal grains	0.3	-	0.51	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: chlorantraniliprole The residue is fat-soluble						
Chlorpropham (201)	ML 0812	Cattle Milk	W	0.0005* F	0.0003	
ADI: 0–0.05 mg/kg bw	ML 0106	Milks	0.01*	-	0.00195	0.0085
ARfD: 0.5 mg/kg bw	FM 0183	Milk fats	0.02	-	0.00195	0.011
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: Chlorpropham The residue is fat-soluble						
Cyhalothrin (146)** (includes lambda-cyhalothrin)	AB 0660	Almond hulls	2		0.42	
	JF 0226	Apple, juice			0.008	-
Group ADI: 0–0.02 mg/kg bw	FS 0240	Apricots	0.5	-	0.1	0.33
Group ARfD: 0.02 mg/kg bw	VS 0621	Asparagus	0.02	-	0.01	0.01
	GC 0640	Barley	0.5	-	0.02	-
	FB 0018	Berries and other small fruits	0.2	-	0.02	0.09
	VA 0035	Bulb vegetables	0.2	-	0.05	0.11
	VB 0041	Cabbages, Head	0.3	0.2	0.08	0.17
	FS 0013	Cherries	0.3	-	0.125	0.18
	FC 0001	Citrus fruits	0.2	-	0.01	0.01
	OC 0691	Cotton seed, crude oil	W	0.02*	0.005	-
	OR 0691	Cotton seed, refined oil	W	0.02*	0.001	-
	SO 0691	Cotton seeds	W	0.02*	0.01	
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	0.3	-	0.06	0.27
	VB 0042	Flowerhead brassica	0.5	-	0.215	0.3
	VC 0045	Fruiting vegetables, Cucurbits	0.05	-	0.01	0.02
	VO 0050	Fruiting vegetables, other	0.3	-	0.03	0.18

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
		than Cucurbits except Mushrooms				
	JF 0269	Grape, juice			0.01	-
	MO 0098	Kidney of cattle, goats, pigs and sheep	0.2	-	0.03	0.09
	VP 0060	Legume vegetables	0.2	-	0.02	0.11
	MO 0099	Liver of cattle, goats, pigs and sheep	0.05	-	0.008	0.02
	GC 0645	Maize	0.02	-	0.01	
	FI 0345	Mango	0.2	-	0.03	0.07
	MM 0095	Meat (from mammals other than marine mammals)	3 (fat)	-	0.04 (muscle) 1 (fat)	0.1 (muscle) 2.2 (fat)
	ML 0106	Milks	0.2	-	0.08	-
	FS 0245	Nectarine	0.5	-	0.1	0.33
	GC 0647	Oats	0.05	-	0.01	
	SO 0088	Oilseeds	0.2	-	0.01	-
	OR 0305	Olive oil, refined			0.077	-
	OR 0305	Olive oil, virgin			0.091	-
	FT 0305	Olives	1	-	0.125	0.42
	JF 0004	Orange, juice			0.0165	-
	-	Orange, marmalade			0.05	-
	FS 0247	Peaches	0.5	-	0.1	0.33
	HS 0444	Peppers, chili (dried)	3	-	0.35	1.5
	FS 0014	Plums, except prunes	0.2	-	0.02	0.1
	FP 0009	Pome fruits	0.2	0.2	0.08	0.1
	VR 0589	Potato	W	0.02*	0	0
	VD 0070	Pulses	0.05	-	0.01	
	GC 0649	Rice	1	-	0.295	
	CM 0649	Rice bran, unprocessed			0.065	-
	CM 1205	Rice, polished			0.003	-
	VR 0075	Root and tuber vegetables	0.01*	-	0	0
	GC 0650	Rye	0.05	-	0.01	
	AS 0081	Straw and fodder (dry) of cereal grains	2 dw		0.54 dw	
	GS 0659	Sugar cane	0.05	-	0.02	0.03
	DM 0659	Sugar cane, molasses			0.001	-
	-	Sugar cane, refined sugar			0.001	-
	JF 0048	Tomato, juice			0.002	-
	VW 0448	Tomato, paste			0.007	-
	TN 0085	Tree nuts	0.01*	-	0.01	0.01
	GC 0653	Triticale	0.05	-	0.01	
	GC 0654	Wheat	0.05	-	0.01	0.03
	CF 0654	Wheat bran, unprocessed	0.1	-	0.045	-
	CF 1211	Wheat, flour			0.005	-
	-	Wine			0.01	-
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: cyhalothrin (sum of isomers) [a)] on dry matter basis						
Cypermethrins (118) **	AL 1020	Alfalfa fodder	30 acZ		11.5	20
ADI: 0–0.02 mg/kg bw	VS 0620	Artichoke, Globe	0.1 Ac	-	0.025	0.04
ARfD: 0.04 mg/kg bw	VS 0621	Asparagus	0.01* Ac	-	0.01	0.01
	GC 0640	Barley	W [1)]	0.5		
	AL 0061	Bean fodder	2 Acz	-	0.58	1.3

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
	VP 0062	Beans, Shelled	W [1)]	0.05*		
	FB 0018	Berries and other small fruits	W	0.5		
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassica	1 cAz	1	0.02	0.65
	FT 0289	Carambola	0.2 C	-	0.02	0.09
	GC 0080	Cereal grains, except rice	0.3 Acz	-	0.035	
	FS 0013	Cherries	W [1)]	1		
	HS 0444	Peppers, chili (dried)	10 C	-	3.5	4.8
	FC 0001	Citrus fruits	W	2		
	SB 0716	Coffee beans	0.05* aZ	0.05*	0	
	VP 0526	Common bean (pods and/or immature seeds)	W [1)]	0.5		
	VC 0424	Cucumber	W [1)]	0.2		
	DF 0269	Dried grapes (=Currants, Raisins and Sultanas)	0.5 cA	-	0.033	0.3
	FI 0334	Durian	1 C	-	0.135	0.47
	MO 0105	Edible offal (mammalian)	0.05* [3)]	0.05*	0.014	0.04
	VO 0440	Egg plant	0.03 A	0.2	0.01	0.02
	PE 0112	Eggs	0.01*	0.05*	0.001	0.0033
	VC 0045	Fruiting vegetables, Cucurbits	0.07 cAz	-	0.01 (0.01)[5)]	0.05 (0.01) [5)]
	FB 0269	Grapes	0.2 cA	-	0.01	0.09
	VL 0480	Kale	W [1)]	1		
	VL 0053	Leafy vegetables	0.7 cAz	-	0.07	0.52
	VA 0384	Leek	0.05 cA	0.5	0.01	0.03
	VP 0060	Legume vegetables	0.7 caZ	-	0.22	0.45
	VL 0482	Lettuce, Head	W [1)]	2		
	FI 0343	Litchi	2 C	-	0.495	0.79
	FI 0342	Longan	1 C	-	0.3	0.47
	GC 0645	Maize	W [1)]	0.05 *		
	AS 0645	Maize fodder	W [1)]	5 dry wt		
	FI 0345	Mango	0.7 C	-	0.19	0.35
	MM 0095	Meat (from mammals other than marine mammals)	2 (fat) [3)]	0.2 (fat)	0.15 fat 0.014 muscle	0.76 fat 0.04 muscle
	VC 0046	Melons, except Watermelon	W [1)]	-	0.01	0.01
	FM 0183	Milk fats	0.5	0.15		
	ML 0106	Milks	0.05	0.05 F.	0.011	
	VO 0450	Mushrooms	W	0.05*		
	FS 0245	Nectarine	W [1)]	2		
	SO 0088	Oilseed	0.1 Acz	-	0.05	
	SO 0089	Oilseed, except peanut	W [1)]	0.2		
	VO 0442	Okra	0.5 C	-	0.08	0.2
	OR 0305	Olive oil, refined	0.5 cA	-	0.41	
	OC 0305	Olive oil, virgin	0.5 cA	-	0.38	
	FT 0305	Olives	0.05* cA	-	0.05	0.05
	VA 0385	Onion, Bulb	0.01* cAz	0.1	0.01	0.01
	FI 0350	Papaya	0.5 C	-	0.135	0.23
	AL 0072	Pea hay or Pea fodder (dry)	2 Acz		0.42	1.1
	FS 0247	Peach	W [1)]	2		
	SO 0697	Peanut	W [1)]	0.05*		
	VO 0051	Peppers	W	0.5		
	VO 0444	Peppers, Chili	2 Cz	-	0.495	0.69
	VO 0445	Peppers, Sweet	0.1 aZ	-	0.05	0.07
	FS 0014	Plums (including prunes)	W [1)]	1		

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
	FP 0009	Pome fruits	0.7 aZ [4)]	2	0.205	0.56
	PM 0110	Poultry meat	0.05* (fat)	0.05*	0.002 muscle 0.008 fat	0.007 muscle 0.027 fat
	PO 0111	Poultry, Edible offal of	0.05*	-	0.002	0.007
	DF 0014	Prunes	W [1)]	-	1.9	3
	VD 0070	Pulses	0.05* aZ	-	0.05	
	GC 0649	Rice	2 aZ	-	0.57	
	VR 0075	Root and tuber vegetables	W [1)]	0.05*		
	VR 0075	Root and tuber vegetables (except sugar beet)	0.01* ACz	-	0.01	0.01
	AS 0651	Sorghum straw and fodder, dry	W [1)]			
	VD 0541	Soya bean (dry)	W [1)]	0.05*		
	VL 0502	Spinach	W [1)]	2		
	FS 0012	Stone fruits	2 aZ		0.59	0.94
	AS 0081	Straw and fodder (dry) of cereal grains	10		3.6	6.9
	FB 0275	Strawberry	0.07 A	-	0.01	0.05
	VR 0596	Sugar beet	0.1 Acz	-	0.01	
	GS 0659	Sugar cane	0.2 Z	-	0.05	0.17
	VO 0447	Sweet corn (corn-on-the-cob)	0.05* Z	0.05*	0	0
	DT 1114	Tea, Green, Black	W	20		
	VO 0448	Tomato	0.2 caZ	0.5	0.05	0.08
	OR 0172	Vegetable oils, Edible	W [2)]	0.5		
	GC 0654	Wheat	W [1)]	0.2		
	OR 0495	Rape seed oil, edible			0.06	
	JF 0448	Tomato juice			0.015	
	CM 0654	Wheat bran, unprocessed			0.084	
	CF 1211	Wheat flour			0.015	
	CF 1210	Wheat germ			0.02	
	AS 0654	Wheat straw and fodder, Dry	W	5		
		Beer			0.0011	
		Tomato canned			0.006	
		Tomato puree			0.025	
		Wine			0.001	

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: cypermethrin (sum of isomers).
The residue is fat soluble.
1) Replaced by commodity group MRL
2) Replaced by olive oil MRLs. Other vegetable oils are covered by the oilseeds MRL.
3) CCRVDF has established veterinary drug MRLs for cypermethrin and alpha-cypermethrin in cattle muscle (50 µg/kg), cattle liver (50µg/kg), cattle kidney (50 µg/kg) and cattle fat (1000 µg/kg) and the same for sheep muscle (50 µg/kg), sheep liver (50 µg/kg), sheep kidney (50 µg/kg) and sheep fat (1000 µg/kg).
4) Source of data supporting the proposed MRL: a: alpha-cypermethrin. c: cypermethrin. z: zeta-cypermethrin. Capital letters show the source of data responsible for the MRL estimate. Small letters show the sources of other data for that commodity
5) Melons only

Dimethoate (027)	VL 0482	Lettuce, Head	0.3	3	0.13	0.76
ADI: 0–0.002 mg/kg bw	VO 0445	Peppers, sweet	0.5	5	0.28	1.3
ARfD:0.02 mg/kg bw	HS 0444	Peppers, chili (dried)	3	50	2.8	13

Definition of the residue for compliance with MRLs: dimethoate
Definition of the residue for estimation of dietary intake: dimethoate and omethoate.

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
Diphenylamine (030)	ML 0812	Cattle milk	W	0.0004*	0.00015	-
ADI: 0–0.08 mg/kg bw	ML 0106	Milks	0.01*	-	0.0019	-
ARfD: unnecessary	FM 0183	Milk fats	0.01	-	0.0075	-
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: diphenylamine.						
Ethoxyquin (035)						
ADI: 0–0.005 mg/kg bw	FP 0230	Pears	3	W	5	6
ARfD: 0.5 mg/kg bw						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: ethoxyquin						
Hexythiazox (176)**						
ADI: 0–0.03 mg/kg bw						
ARfD: Unnecessary						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: hexythiazox.						
Imidacloprid (206)	AM 0660	Almond hulls	5		1.7	
ADI: 0–0.06 mg/kg bw	FB 0018	Berries and small fruits (except cranberries, grapes and strawberries)	5	-	0.89	2.8
ARfD: 0.4 mg/kg bw	SB 0716	Coffee beans	1	-	0.35	-
	MO 0095	Edible offal (Mammalian)	0.3	0.05	0.06	0.18
	PE 0112	Eggs	0.02	0.02	0.003	0.007
	ML 0106	Milks	0.1	0.02*	0.018	
	MM 0095	Meat (from mammals other than marine mammals)	0.1	0.02*	0.012 (muscle) 0.007 (fat)	0.04 (muscle) 0.02 (fat)
	VD 0072	Peas (dry)	2	-	0.62	-
	VP 0063	Peas (pods and succulent = immature seeds)	5	-	0.60	3.8
	VP 0064	Pea, shelled (succulent seeds)	2	-	0.58	1.1
	SO 0697	Peanut	1	-	0.12	0.40
	AL 1270	Peanut fodder				
	TN 0672	Pecan	W	0.05		
	FI 0355	Pomegranate	1	-	0.43	0.55
	VR 0589	Potato	W	0.5		
	PM 0110	Poultry meat	0.02	0.02	0.001 (muscle) 0.0004 (fat)	0.003 (muscle) 0.001 (fat)
	PO 0111	Poultry, edible offal of	0.05	0.02*	0.007	0.02
	VL 0494	Radish leaves (including Radish tops)	5	-	0.70	2.7
	VR 0075	Root and tuber vegetables	0.5	-	0.05	0.28
	FB 0275	Strawberry	0.5	-	0.17	0.35
	VR 0596	Sugar beet	W	0.05*		
	SO 0702	Sunflower seed	0.05*	-	0.05	
	TN 0660	Tree nuts	0.01	-	0.01	0.01
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						

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
[a] on dry matter basis						
Malathion (049)	GC 0654	Wheat	10	0.5	10	10
ADI: 0–0.3 mg/kg bw	CF 1211	Wheat flour	W	0.2	0.87	0.87
ARfD: 2 mg/kg bw	CM 0654	Wheat bran, unprocessed	25	-	25	25
	CF 1212	Wheat wholemeal			7.5	7.5
		Wheat gluten			0.012	0.012
	CP 1212	Wholemeal bread			1.2	1.2
	CP 1211	White bread			0.2	0.2
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: malathion.						
Mandipropamid (231) *	VB 0400	Broccoli	2	-	0.435	
ADI: 0–0.2 mg/kg bw	VB 0041	Cabbages, Head	3	-	0.01	
ARfD: Unnecessary	VS 0624	Celery	20	-	2.70	
	HS 0444	Peppers, chili (dried)	10	-	0.84	
	VC 0424	Cucumber	0.2	-	0.02	
	FB 0269	Grapes	2	-	0.51	
	DF 0269	Dried grapes (= Currants, Raisins, Sultanas)	5	-	1.68	
		Wine			0.366	
	JF 0269	Grape, juice			0.14	
	VL 0053	Leafy vegetables	25	-	5.65	
	VC 0046	Melons, except Watermelon	0.5	-	0.115	
	VA 0385	Onion, Bulb	0.1	-	0.01	
	VO 0051	Peppers	1	-	0.12	
	VR 0589	Potatoes	0.01*	-	0.01	
	VA 0389	Spring onion	7	-	0.48	
	VC 0431	Squash, summer	0.2	-	0.04	
	VO 0448	Tomato	0.3	-	0.06	
	JF 0448	Tomato juice			0.059	
		Tomato puree			0.068	
		Canned tomatoes			0.022	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake for plant and animal commodities): mandipropamid						
Methomyl (094)	FP 0226	Apples	0.3 [1)]	2 [2)]	0.09	0.17
ADI: 0–0.02 mg/kg bw	VB 0400	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassica	W	7 [3)]		
ARfD: 0.02 mg/kg bw	VS 0624	Celery	W	3 [1)]		
	VC 0045	Fruiting vegetables, Cucurbits	0.1 [4)]	0.1 [1)]	0.02	0.07
	FB 0269	Grapes	0.3 [1)]	7 [1)]	0.01 0.09 (for processing)	0.08 0.2 (for processing)
	VL 0482	Lettuce, Head	0.2 [1)]	-	0.01	0.07
	VL 0483	Lettuce, Leaf	0.2 [1)])	-	0.01	0.07
	VL 0053	Leafy vegetables	W	30 [3)]		
	FP 0230	Pear	0.3 [4)]	0.3 [1)]	0.09	0.18
	VO 0448	Tomato	1 [4)]	1 [2)]	0.16	0.73
	JF 0226	Apple juice			0.026	
	VW 0448	Tomato paste			0.0085	
		Wine			0.053	
	JF 0269	Grape, juice			0.0198	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
	DF 0269	Dried grapes (= Currants, Raisins, Sultanas)			0.018	0.04
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: sum of methomyl and thiodicarb expressed as methomyl 1) Resulting from data on supervised trials with methomyl 2) Resulting from data on supervised trials with thiodicarb 3) Resulting from data on supervised trials with methomyl plus thiodicarb 4) Previous MRL confirmed.						
Oxamyl (126)	The Meeting concluded that there was insufficient data to support alternative GAP assessments for citrus, cucumber, melons (except watermelon), summer squash, peppers and tomatoes.					
Profenofos (171) **	VB 0041	Cabbages, Head	W	1		
ADI: 0–0.03 mg/kg bw	SO 0691	Cotton seed	3	2	0.35	
ARfD: 1 mg/kg bw	OR 0691	Cotton seed oil, edible	W	0.05*	0.14	
	MO 0105	Edible offal (Mammalian)	0.05*	-	0	0
	PE 0112	Eggs	0.02*	0.02*	0	0
	FI 0345	Mango	0.2	-	0.06	0.07
	FI 0346	Mangosteen	10	-	2.1	3.7
	MM 0095	Meat (from mammals other than marine mammals)	0.05*	0.05*	0	0
	ML 0106	Milks	0.01*	0.01*	0	
	VO 0444	Peppers, Chili	W	5		
	HS 0444	Peppers, Chili (dried)	W	50		
	VO 0445	Peppers, Sweet	W	0.5		
	VR 0589	Potato	W	0.05*		
	PM 0110	Poultry meat	0.05*	-	0	0
	PM 0111	Poultry, Edible offal of	0.05*	-	0	0
	VO 0448	Tomato	10	2	1.3	4.7
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: profenofos						
				-		
Prothioconazole (232) *	GC 0640	Barley	0.05	-	0.01	
ADI: 0 - 0.05mg/kg bw	OS 0640	Barley straw	2	-	0.30	
ARfD: 0.8 mg/kg bw (woman of child bearing age)	MO 0032	Edible offal (Mammalian)	0.2	-	0.05	0.1
ARfD not necessary (general population)	MM 0095	Meat (from mammals other than marine mammals)	0.01	-	0.01	0.01
	MF 0100	Mammalian fats (except milk fats)	0.01	-	0.01	0.01
	ML 0106	Milks	0.004*	-	0.004	
Prothioconazole - Desthio	GC 0647	Oat	0.05	-	0.01	
ADI: 0–0.01 mg/kg bw	OS 0647	Oat straw	2	-	0.3	
ARfD: 0.01 mg/kg bw	OS 0697	Peanut	0.02*		0.01	
(woman of child bearing age)	SO 4703	Rape seed	0.05	-	0.01	
ARfD: 1 mg/kg bw	GC 0650	Rye	0.05	-	0.01	
(general population)	OS 0650	Rye straw	2	-	0.30	
	GC 0653	Triticale	0.05	-	0.01	
	OS 0653	Triticale straw	2		0.30	
	GC 0654	Wheat	0.05	-	0.01	
	CM 0081	Wheat bran			0.024	
	CF 1211	Wheat flour	0.05	-	0.004	
	CF 1210	Wheat germ			0.02	

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
	OS 0654	Wheat straw	2		0.30	
Definition of the residue (for compliance with MRL and estimation of dietary intake) for plant commodities: prothioconazole-desthio, Definition of the residue (for compliance with MRL) for animal commodities: prothioconazole-desthio. *Definition of the residue (for the estimation of dietary intake) for animal commodities:* the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio.						
Spinetoram (233) *	MO 0105	Edible offal (Mammalian)	0.01*	-	0.00625	
ADI: 0–0.05 mg/kg bw	VL 0482	Lettuce, Head	10	-	0.0895	
ARfD: Unnecessary	VL 0483	Lettuce, Leaf	10		0.0895	
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)	-	0.00625 (muscle) 0.042 (fat)	
	FM 0183	Milk fats	0.1	-	0.12	
	ML 0106	Milks	0.01*	-	0.00925	
	FC 0004	Oranges, sweet, sour	0.07	-	0.0435	
	JF 0004	Orange juice			0.003	
	FP 0009	Pome fruits	0.05	-	0.025	
	JF 0226	Apple juice			0.011	
		Apple puree or sauce			0.012	
	VR 0596	Sugar beet	0.01*	-	0.02	
	VO 0448	Tomato	0.06	-	0.02	
	TN 0085	Tree nuts	0.01	-	0.02	
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.						
Spinosad (203) ADI: 0–0.02 mg/kg bw ARfD: Unnecessary	An incomplete data submission precluded the estimation of MRL or STMR values					
Spirotetramat (234)*	AB 0660	Almond hulls	10		4.9	
ADI: 0–0.5 mg/kg bw	VB 0041	Cabbages, Head	2	-	0.23	0.92
ARfD: 1.0 mg/kg/bw	VS 0624	Celery	4	-	0.58	2.6
	FS 0012	Stone Fruit	3	-	1.6	2.1
	FC 0001	Citrus fruit	0.5	-	0.33	0.47
	VC 0011	Fruiting Vegetables, Cucurbits	0.2	-	0.057	0.18
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	4	-	1.1	3.4
	MO 0105	Edible offal (Mammalian)	0.03	-	0.014	0.024
	VB 0042	Flowerhead Brassica	1	-	0.50	0.87
	VO 0050	Fruiting vegetables, other than Cucurbits (except sweet corn, mushrooms and chili pepper)	1	-	0.43	1.1
	FB 0269	Grapes	2	-	0.41	1.3
	AB 0269	Grape pomace (dry)	4		0.74	
	DH 1100	Hops (dry)	15	-	5.2	
	VL 0053	Leafy vegetables	7	-	3.7	5.5
	MM 0095	Meat (from mammals other	0.01*	-	0 muscle	0 muscle

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
		than marine mammals)			0 fat	0 fat
	ML 0106	Milks	0.005*	-	0	0
	VO 0444	Pepper, chili (non-bell)	2	-	0.95	1.5
	HS 0444	Peppers, Chili (Dry)	15	-	6.6	11
	FP 0009	Pome fruits	0.7	-	0.17	0.55
	VR 0589	Potato	0.8	-	0.12	0.46
	DF 0014	Prunes (dried plums)	5	-	3.5	4.6
	TN 0022	Tree nuts	0.5	-	0.084	0.29
	JF 0226	Apple juice			0.082	
		Beer hops			0.11	
	JF 0269	Grape juice			0.27	
		Grape wine			0.23	
		Grape jelly			0.11	
	JF 0004	Orange juice			0.18	
		Tomato, dried			5.0	
	JF 0448	Tomato juice			0.27	
	VW 0448	Tomato paste			3.2	
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.						
Tebuconazole (189) ADI: 0–0.03 mg/kg bw	DF 0226	Apple dried			0.19	
	JF 0226	Apple juice			0.08	
		Apple sauce			0.08	
	VS 0620	Artichoke, globe	0.5	-	0.15	0.32
	GC 0640	Barley	2	0.2	0.06	
	AS 0640	Barley straw and fodder, dry	30	10		
		Beer			0.001	
	VB 0400	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassica	1	-	0.07	0.56
	VP 0526	Common bean (pods and/or immature seeds)	2	-	0.49	1.2
		Common bean (pods and/or immature seeds) cooked			0.096	
	VR 0577	Carrot	0.5	-	0.11	0.22
	MO 0812	Cattle, Edible offal of	W	0.05*		
	MM 0812	Cattle meat	W	0.05*		
	ML 0812	Cattle milk	W	0.05*		
	PE 0840	Chicken eggs	W	0.05*		
	PO 0840	Chicken, Edible offal	W	0.05*		
	PM 0840	Chicken meat	W	0.05*		
	SB 0716	Coffee beans	0.1	-	0.1	
	SM 0716	Coffee beans, roasted	0.5	-	0.2	
		Coffee instant			0.08	
	MO 0105	Edible offal (Mammalian)	0.5	-	0.2	0.2
	PE 0112	Eggs	0.05*	-	0	0
	FB 0267	Elderberries	2	-	0.345	0.70
	VA 0381	Garlic	0.1	-	0.02	0.06

Pesticide (Codex reference number)	**CCN**	**Commodity**	**Recommended MRL** mg/kg		**STMR or STMR-P** mg/kg	**HR or HR-P** mg/kg
			New	Previous		
	DH 1100	Hops, dry	30	-	9.65	
		Beer, from hops			0.009	
	VA 0384	Leek	1	-	0.195	0.44
	VL 0482	Lettuce, Head	5	-	0.98	3.2
	GC 0645	Maize	0.1	-	0.1	
	FI 0345	Mango	0.1	-	0.02	0.1
	MM 0095	Meat (from mammals other than marine mammals)	0.05*	-	0	0
	VC 0106	Melons, except Watermelon	0.2	-	0.02	0.02
	ML 0106	Milks	0.01*	-	0	0
	VA 0385	Onion, Bulb	0.1	-	0.05	0.06
	FI 0350	Papaya	2	-	0.18	1.2
	SO 0697	Peanut	0.1	0.05	0.04	
	FS 0014	Plums, excluding prunes	0.2	-	0.055	0.12
	FP 0009	Pome fruits	1	0.5	0.19	0.47
	PM 0110	Poultry meat	0.05*	-	0	0
	PO 0111	Poultry, Edible offal of	0.05*	-	0	0.05
	DF 0014	Prunes	0.5	-	0.18	
	SO 0495	Rape seed	0.5	0.05	0.09	
	OR 0495	Rape seed oil, edible			0.064	
	GC 0649	Rice	2	-	0.275	
	VD 0541	Soya bean (dry)	0.1	-	0.02	
	OR 0541	Soya bean oil, refined			0.001	
	VO 0447	Sweet corn (on-the-cob)	0.1	-	0.1	0.1
	VO 0448	Tomato	0.5	0.2	0.19	0.46
	JF 0448	Tomato juice			0.1	
		Tomato preserve			0.057	
	VW 0448	Tomato paste			0.16	
		Tomato purée			0.06	
		Tomato peeled			0.05	0.115
	VC 0432	Watermelon	0.1	-	0.02	0.02
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: tebuconazole						
Metabolites of triazoles 1, 2, 4- Triazole ADI: 0–0.2 mg/kg bw ARfD: 0.3 mg/kg bw Triazole alanine and Triazole acetic acid Group ADI: 0–1 mg/kg bw Group ARfD: Unnecessary						

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)
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)
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)
Benalaxyl (155)	1986 (R), 1987 (T), 1988 (R), 1992 (R), 1993 (R), 2005 (T)
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)
BHC (technical-grade)	1965 (T), 1968 (T,R), 1973 (T,R) (see also Lindane)
Bifenazate (219)	2006 (T, R)
Bifenthrin (178)	1992 (T,R), 1995 (R), 1996 (R), 1997 (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)
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)
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)
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)
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)
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)
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)
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)
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)
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)
Cyfluthrin (157)	1986 (R), 1987 (T and corr. to 1986 report), 1989 (R), 1990 (R), 1992 (R), 2006 (T), 2007 (R)
Cyhalothrin (146)	1984 (T,R), 1986 (R), 1988 (R), 2007 (T), 2008 (R)
Cyhexatin (067)	1970 (T,R), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T), 1978 (T,R), 1980 (T), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1988 (T), 1989 (T), 1991 (T,R), 1992 (R), 1994 (T), 2005 (T,R)
Cypermethrin (118)	1979 (T,R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R)
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)
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)
Dicloran (083)	2003 (R)
Dichlorfluanid (082)	1969 (T,R), 1974 (T,R), 1977 (T,R), 1979 (T,R), 1981 (R),1982 (R), 1983 (T,R), 1985 (R)
1,2-Dichloroethane (024)	1965 (T,R), 1967 (R), 1971 (R), 1979 (R), 1985 (R)
Dichlorvos (025)	1965 (T,R), 1966 (T,R), 1967 (T,R), 1969 (R), 1970 (T,R), 1974 (R), 1977 (T), 1993 (T,R)
Dicloran (083)	1974 (T,R), 1977 (T,R), 1998 (T,R)
Dicofol (026)	1968 (T,R), 1970 (R), 1974 (R), 1992 (T,R),

	1994 (R)
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)
Diflubenzuron (130)	1981 (T,R), 1983 (R), 1984 (T,R), 1985 (T,R), 1988 (R), 2001 (T), 2002 (R)
Dimethenamid- P (214)	2005 (T,R)
Dimethipin (151)	1985 (T,R), 1987 (T,R), 1988 (T,R), 1999 (T), 2001 (R), 2004 (T)
Dimethoate (027)	1965 (T), 1966 (T), 1967 (T,R), 1970 (R), 1973 (R in evaluation of formothion), 1977 (R), 1978 (R), 1983 (R) 1984 (T,R) 1986 (R), 1987 (T,R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1994 (R), 1996 (T), 1998 (R), 2003 (T,R), 2004 (corr. to 2003 report), 2006 (R), 2008 (R)
Dimethomorph	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)
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)
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)
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)
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)
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)
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)
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)
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)
Ferbam	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1996 (T,R)
Fipronil (202)	1997 (T), 2000 (T), 2001 (R)
Fipronil-desulfinyl	1997 (T)

Flucythrinate (152)	1985 (T, R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1993 (R)
Fludioxonil (211)	2004 (T,R), 2006 (R)
Flumethrin (195)	1996 (T,R)
Flusilazole (165)	1989 (T, R), 1990 (R), 1991 (R), 1993 (R), 1995 (T), 2007 (T, R)
Flutolanil (205)	2002 (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)
Glyphosate (158)	1986 (T,R), 1987 (R and corr. to 1986 report), 1988 (R), 1994 (R), 1997 (T,R), 2004 (T), 2005 (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)
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)
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)
Indoxacarb (216)	2005 (T,R), 2007 (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)
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)
Mecarbam (124)	1980 (T,R), 1983 (T,R), 1985 (T,R), 1986 (T,R), 1987 (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)
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)

Omethoate (055)	1971 (T,R), 1975 (T,R), 1978 (T,R), 1979 (T), 1981 (T,R), 1984 (R), 1985 (T), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1998 (R)
Organomercury compounds	1965 (T), 1966 (T,R), 1967 (T,R)
Oxamyl (126)	1980 (T,R), 1983 (R), 1984 (T), 1985 (T,R), 1986 (R), 2002 (T,R)
Oxydemeton-methyl (166)	1965 (T, as demeton-*S*-methyl sulfoxide), 1967 (T), 1968 (R), 1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (corr. to 1992 report), 2002 (T), 2004 (R)
Oxythioquinox	See Chinomethionat
Paclobutrazol (161)	1988 (T,R), 1989 (R)
Paraquat (057)	1970 (T,R), 1972 (T,R), 1976 (T,R), 1978 (R), 1981 (R), 1982 (T), 1985 (T), 1986 (T), 2003 (T), 2004 (R)
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)
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)
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)
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)
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)
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)
Propylenethiourea (PTU, 150)	1993 (T,R), 1994 (R), 1999 (T)
Prothioconazole (232)	2008 (T, R)
Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (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)
Spinetoram (233)	2008 (T, R)
Spinosad (203)	2001 (T, R, 2004 (R)
Spirotetramat (234)	2008 (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)
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)
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)
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)
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)

ANNEX 3: INTERNATIONAL ESTIMATED DAILY INTAKES OF PESTICIDE RESIDUES

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
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
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	Cabbages, 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
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	-
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	15.7	76.9	96.7	473.9	55.3	270.9	25.3	123.9	23.4	114.9	16.2	79.5
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 boysenberry & 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	152	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
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
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

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
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
HH 0720	Herbs	23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
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
-	Lettuce (head, leaf)	0.28	0.1	0.0	21.5	6.0	2.3	0.6	0.2	0.1	5.5	1.5	18.0	5.0
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
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 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
VR0075	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

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
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, zucchini)	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 peeled)	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	0.91	0.5	0.5	1.3	1.2	3.5	3.2	1.0	0.9	3.8	3.5	4.5	4.1
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
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
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
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)=			282.2		953.7		508.1		398.6		423.6		274.2
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			2.4%		7.9%		4.2%		3.3%		3.5%		2.3%
	Rounded %ADI=			2%		8%		4%		3%		4%		2%

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
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
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	Cabbages, 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
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	-
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	4.9	16.9	83.0	155.0	759.5	8.6	42.1	42.5	208.3	220.5	1080.3	28.9	141.5	30.1	147.3
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 boysenberry & 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	152	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
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

Annex 3

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day 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
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
HH 0720	Herbs	23	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
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
-	Lettuce (head, leaf)	0.28	2.4	0.7	7.0	2.0	0.2	0.1	0.6	0.2	2.0	0.6	2.4	0.7	18.2	5.1
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
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 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
VR0075	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

AZOXYSTROBIN (229) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
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, zucchini)	0.17	2.4	0.4	1.5	0.3	0.0	0.0	0.0	0.0	3.8	0.6	2.2	0.4	2.5	0.4
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.74	6.7	5.0	4.3	3.2	1.4	1.0	0.1	0.1	4.9	3.6	4.9	3.6	17.7	13.1
FB 0275	Strawberry	1.3	0.0	0.0	1.8	2.3	0.1	0.1	0.0	0.0	0.3	0.4	6.2	8.1	5.9	7.7
VR 0596	Sugar beet	0.08	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	1.1
SO 0702	Sunflower seed (excl oil)	0.04	0.1	0.0	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.8	0.1
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 peeled)	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	0.91	0.1	0.1	2.1	1.9	0.6	0.5	0.4	0.4	0.6	0.5	1.4	1.3	1.2	1.1
TN 0085	Tree nuts	0.01	16.3	0.2	15.7	0.2	9.7	0.1	1.9	0.0	19.1	0.2	29.0	0.3	5.6	0.1
GC 0653	Triticale (incl flour)	0.01	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
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)=			286.7		911.0		201.4		404.4		1278.4		408.5		443.2
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			11000		12000		12000		12000		12000		11000		12000
	%ADI=			2.6%		7.6%		1.7%		3.4%		10.7%		3.7%		3.7%
	Rounded %ADI=			3%		8%		2%		3%		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	diet correction factor	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)	0.04	0.7	15.7	0.4	86.5	2.4	52.6	1.5	24.2	0.7	16.2	0.5	12.0	0.3
-	Citrus juice NES	0.13	1	0.0	0.0	1.7	0.2	0.1	0.0	0.0	0.0	1.1	0.1	0.3	0.0
VC 0424	Cucumber	0.035	1	0.3	0.0	12.7	0.4	5.9	0.2	11.5	0.4	6.1	0.2	7.1	0.2
JF 0203	Grapefruit juice	0.13	1	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	1	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	1	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	0.7	6.3	0.0	1.0	0.0	4.6	0.0	0.2	0.0	0.7	0.0	0.3	0.0
JF 0004	Orange juice	0.13	1	0.0	0.0	2.1	0.3	4.4	0.6	1.4	0.2	16.2	2.1	22.6	2.9
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.24	1	1.3	0.3	178.4	42.8	102.8	24.7	53.4	12.8	1.6	0.4	0.0	0.0
JF 0448	Tomato juice	0.053	1	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	1	0.5	0.1	1.3	0.3	3.5	0.8	1.0	0.2	3.8	0.8	4.5	1.0
-d	Tomato, peeled	0.041	1	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.2	3.2	0.1
	Total intake (µg/person)=				1.2		46.8		27.9		14.5		5.0		5.7
	Body weight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				540		540		540		540		540		540
	%ADI=				0.2%		8.7%		5.2%		2.7%		0.9%		1.1%
	Rounded %ADI=				0%		9%		5%		3%		1%		1%

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	diet correction factor	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	0.7	15.1	0.4	153.9	4.3	3.4	0.1	41.7	1.2	218.9	6.1	23.1	0.6	18.0	0.5
-	Citrus juice NES	0.13	1	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
VC 0424	Cucumber	0.035	1	7.9	0.3	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.2	5.3	0.2
JF 0203	Grapefruit juice	0.13	1	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	1	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	1	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	0.7	12.7	0.1	26.2	0.2	6.1	0.0	12.7	0.1	9.2	0.1	8.0	0.1	1.9	0.0
JF 0004	Orange juice	0.13	1	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
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.24	1	22.8	5.5	4.1	1.0	12.3	3.0	1.8	0.4	32.8	7.9	0.4	0.1	27.3	6.6
JF 0448	Tomato juice	0.053	1	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	1	0.1	0.0	2.1	0.5	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.3
-d	Tomato, peeled	0.041	1	0.2	0.0	14.5	0.6	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	0.0
	Total intake (µg/person)=				6.4		6.8		4.0		2.2		14.5		2.6		18.0
	Body weight per region (kg bw) =				55		60		60		60		60		55		60
	ADI (µg/person)=				495		540		540		540		540		495		540
	%ADI=				1.3%		1.3%		0.7%		0.4%		2.7%		0.5%		3.3%
	Rounded %ADI=				1%		1%		1%		0%		3%		1%		3%

Annex 3

CARBOFURAN (096) International Estimated Daily Intake (IEDI) ADI = 0 - 0.001 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	0.1	38.8	3.9	17.4	1.7	16.0	1.6	6.6	0.7	21.5	2.2	33.8	3.4
SM 0716	Coffee beans, roasted	0.005	0.4	0.0	6.0	0.0	0.5	0.0	0.6	0.0	9.4	0.0	16.4	0.1
VC 0424	Cucumber	0.05	0.3	0.0	12.7	0.6	5.9	0.3	11.5	0.6	6.1	0.3	7.1	0.4
MO 0097	Edible offal of cattle, pigs & sheep	0.05	3.2	0.2	13.3	0.7	3.5	0.2	11.0	0.6	11.7	0.6	7.5	0.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.05	5.5	0.3	23.3	1.2	7.7	0.4	11.0	0.6	18.0	0.9	26.3	1.3
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
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)	0.05	68.8	3.4	190.6	9.5	79.4	4.0	302.6	15.1	179.6	9.0	237.9	11.9
JF 0004	Orange juice	0.001	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.0	22.6	0.0
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.05	4.2	0.2	54.1	2.7	30.1	1.5	11.9	0.6	0.2	0.0	0.5	0.0
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
SO 0495	Rape seed (excl oil)	0.05	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
GC 0649	Rice (incl husked, excl polished)	0.025	46.3	1.2	0.3	0.0	3.4	0.1	9.1	0.2	4.3	0.1	0.6	0.0
VC 0431	Squash, summer (= courgette, zucchini)	0.05	0.0	0.0	8.3	0.4	11.4	0.6	7.3	0.4	3.2	0.2	0.3	0.0
GS 0659	Sugar cane	0.1	30.9	3.1	43.1	4.3	51.3	5.1	0.1	0.0	5.5	0.6	0.0	0.0
SO 0702	Sunflower seed (excl oil)	0.1	0.0	0.0	13.1	1.3	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
VO 0447	Sweet corn (corn-on-the-cob)	0.03	7.3	0.2	1.0	0.0	0.1	0.0	0.5	0.0	3.3	0.1	3.6	0.1
	Total intake (µg/person)=			14.6		35.8		18.8		33.3		29.2		33.1
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			60		60		60		60		60		60
	%ADI=			24.3%		59.6%		31.3%		55.5%		48.6%		55.2%
	Rounded %ADI=			20%		60%		30%		60%		50%		60%

CARBOFURAN (096) International Estimated Daily Intake (IEDI) ADI = 0 - 0.001 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	0.1	21.4	2.1	36.6	3.7	11.4	1.1	9.2	0.9	70.2	7.0	40.5	4.1	32.6	3.3
SM 0716	Coffee beans, roasted	0.005	0.0	0.0	1.3	0.0	0.1	0.0	0.0	0.0	0.8	0.0	0.3	0.0	7.0	0.0
VC 0424	Cucumber	0.05	7.9	0.4	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.3	5.3	0.3
MO 0097	Edible offal of cattle, pigs & sheep	0.05	4.0	0.2	10.4	0.5	3.5	0.2	2.7	0.1	6.4	0.3	6.2	0.3	5.4	0.3
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.05	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	0.05	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
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)	0.05	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
JF 0004	Orange juice	0.001	0.2	0.0	1.0	0.0	3.5	0.0	0.0	0.0	1.3	0.0	6.4	0.0	56.8	0.1
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.05	7.0	0.4	117.1	5.9	2.0	0.1	2.4	0.1	200.7	10.0	0.5	0.0	0.2	0.0
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.05	52.7	2.6	57.1	2.9	50.1	2.5	4.3	0.2	54.7	2.7	41.0	2.1	168.0	8.4
SO 0495	Rape seed (excl oil)	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	0.0	0.0
GC 0649	Rice (incl husked, excl polished)	0.025	1.4	0.0	1.0	0.0	2.3	0.1	29.6	0.7	92.0	2.3	9.2	0.2	0.4	0.0
VC 0431	Squash, summer (= courgette, zucchini)	0.05	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
GS 0659	Sugar cane	0.1	26.2	2.6	1.5	0.2	33.8	3.4	5.5	0.6	18.6	1.9	3.0	0.3	20.2	2.0
SO 0702	Sunflower seed (excl oil)	0.1	0.1	0.0	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	1.8	0.2
VO 0447	Sweet corn (corn-on-the-cob)	0.03	0.2	0.0	2.4	0.1	2.2	0.1	3.3	0.1	1.7	0.1	2.8	0.1	11.2	0.3
	Total intake (µg/person)=			14.7		23.9		13.1		9.4		39.1		13.5		37.5
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			55		60		60		60		60		55		60
	%ADI=			26.7%		39.9%		21.8%		15.6%		65.1%		24.5%		62.5%
	Rounded %ADI=			30%		40%		20%		20%		70%		20%		60%

Annex 3

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day	Intake = daily intake: µg/person									
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VS 0624	Celery	2.1	0.0	0.0	0.9	1.9	0.0	0.0	2.0	4.2	1.5	3.2	0.0	0.0
GC 0080	Cereal grains	0.01	356.9	3.6	713.9	7.1	763.0	7.6	504.5	5.0	365.2	3.7	328.7	3.3
OR 0691	Cotton seed oil, edible	0.0122	0.9	0.0	4.9	0.1	1.7	0.0	6.6	0.1	0.0	0.0	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
VO 0440	Egg plant	0.06	1.7	0.1	17.5	1.2	12.3	0.8	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
VC 0045	Fruiting vegetables, Cucurbits	0.065	26.6	1.7	107.5	7.0	95.9	6.2	82.2	5.3	25.4	1.7	23.2	1.5
FB 0269	Grape (incl dried, juice, wine)	0.119	3.7	0.4	128.5	15.3	27.1	3.2	33.1	3.9	107.5	12.8	44.0	5.2
VL 0053	Leafy vegetables	7.3	5.8	42.3	45.6	332.9	10.9	79.6	26.8	195.6	18.7	136.5	38.9	284.0
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
VO 0442	Okra	0.066	3.9	0.3	1.0	0.1	5.3	0.3	0.1	0.0	0.0	0.0	0.0	0.0
VO 0051	Peppers	0.066	1.4	0.1	29.9	2.0	13.0	0.9	6.3	0.4	6.2	0.4	4.0	0.3
FP 0009	Pome fruit (incl apple juice)	0.07	0.5	0.0	84.1	5.9	21.9	1.5	45.2	3.2	61.7	4.3	46.2	3.2
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
VR0075	Root and tuber vegetables	0.01	528.2	5.3	352.8	3.5	78.5	0.8	270.3	2.7	324.1	3.2	261.3	2.6
FS 0012	Stone fruit	0.2	0.7	0.1	44.7	8.9	14.1	2.8	26.9	5.4	27.7	5.5	10.0	2.0
VO 0448	Tomato (incl juice, paste, peeled)	0.066	11.8	0.8	185.0	12.2	118.0	7.8	60.7	4.0	31.6	2.1	40.9	2.7
	Total intake (µg/person)=			54.8		398.0		111.6		230.0		173.4		304.8
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			120 000		120 000		120 000		120 000		120 000		120 000
	%ADI=			0.0%		0.3%		0.1%		0.2%		0.1%		0.3%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

CHLORANTRANILIPROLE (230) International Estimated Daily Intake (IEDI) ADI = 0 - 2 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 0624	Celery	2.1	0.0	0.0	0.3	0.6	0.0	0.0	0.0	0.0	1.0	2.1	0.0	0.0	4.2	8.8
GC 0080	Cereal grains	0.01	617.0	6.2	487.1	4.9	389.4	3.9	385.7	3.9	440.2	4.4	567.7	5.7	409.9	4.1
OR 0691	Cotton seed oil, edible	0.0122	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
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0440	Egg plant	0.066	20.1	1.3	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
VC 0045	Fruiting vegetables, Cucurbits	0.065	69.7	4.5	25.9	1.7	14.9	1.0	18.0	1.2	18.7	1.2	39.1	2.5	44.2	2.9
FB 0269	Grape (incl dried, juice, wine)	0.119	2.6	0.3	4.8	0.6	11.7	1.4	0.3	0.0	6.8	0.8	10.9	1.3	58.8	7.0
VL 0053	Leafy vegetables	7.3	40.8	297.8	12.0	87.6	12.5	91.3	9.5	69.4	5.4	39.4	50.0	365.0	39.9	291.3
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
VO 0442	Okra	0.066	4.1	0.3	1.0	0.1	7.0	0.5	15.9	1.0	1.1	0.1	3.9	0.3	0.2	0.0
VO 0051	Peppers	0.066	8.7	0.6	22.4	1.5	8.4	0.6	9.4	0.6	3.3	0.2	5.3	0.3	8.9	0.6
FP 0009	Pome fruit (incl apple juice)	0.07	20.9	1.5	12.3	0.9	3.4	0.2	0.1	0.0	11.7	0.8	24.9	1.7	45.4	3.2
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, Edible offal of	0	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
VR0075	Root and tuber vegetables	0.01	139.1	1.4	109.8	1.1	409.6	4.1	444.6	4.4	145.3	1.5	127.0	1.3	225.6	2.3
FS 0012	Stone fruit	0.2	7.0	1.4	4.9	1.0	1.4	0.3	0.1	0.0	5.5	1.1	5.5	1.1	19.4	3.9
VO 0448	Tomato (incl juice, paste, peeled)	0.066	23.5	1.6	31.7	2.1	15.0	1.0	16.2	1.1	35.6	2.3	9.9	0.7	103.0	6.8
	Total intake (µg/person)=			316.8		101.9		104.2		82.1		54.0		380.4		330.8
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
				110 00		120 00		120 00		120 00		120 00		110 00		120 00
	ADI (µg/person)=			0		0		0		0		0		0		0
	%ADI=			0.3%		0.1%		0.1%		0.1%		0.0%		0.3%		0.3%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

Annex 3

CYHALOTHRIN (146) (including Lambda-cyhalothrin) 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		
FS 0240	Apricot (incl dried)	0.1	0.3	0.0	6.2	0.6	3.9	0.4	3.2	0.3	2.0	0.2	0.8	0.1		
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		
GC 0640	Barley (incl pot, pearled, flour and grits, beer)	0.02	40.6	0.8	16.8	0.3	93.9	1.9	13.2	0.3	48.6	1.0	36.1	0.7		
FB 0018	Berries and other small fruits	0.02	3.8	0.1	145.8	2.9	29.1	0.6	41.0	0.8	118.3	2.4	53.0	1.1		
VA 0035	Bulb vegetables	0.05	8.5	0.4	60.3	3.0	37.7	1.9	37.2	1.9	31.8	1.6	16.7	0.8		
VB 0041	Cabbages, Head	0.08	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-		
MO 1280	Cattle kidney	0.03	0.4	0.0	4.4	0.1	0.0	0.0	0.9	0.0	0.0	0.0	0.6	0.0		
MO 1281	Cattle liver	0.008	0.4	0.0	4.4	0.0	1.7	0.0	0.9	0.0	1.0	0.0	0.6	0.0		
FS 0013	Cherries	0.125	0.0	0.0	6.8	0.9	0.9	0.1	6.2	0.8	3.6	0.5	0.4	0.1		
FC 0001	Citrus fruit (incl 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		
VO 0440	Egg plant	0.03	1.7	0.1	17.5	0.5	12.3	0.4	1.7	0.1	0.8	0.0	0.4	0.0		
VB 0042	Flowerhead brassicas	0.215	0.2	0.0	11.1	2.4	3.6	0.8	0.4	0.1	7.7	1.7	4.1	0.9		
VC 0045	Fruiting vegetables, Cucurbits	0.01	26.6	0.3	107.5	1.1	95.9	1.0	82.2	0.8	25.4	0.3	23.2	0.2		
VP 0060	Legume vegetables	0.02	6.1	0.1	23.0	0.5	18.0	0.4	12.8	0.3	26.9	0.5	5.3	0.1		
GC 0645	Maize (incl flour, incl germ, 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		
MF 0100	Mammalian fats (except milk fats)	1	0.8	0.8	10.0	10.0	0.9	0.9	6.6	6.6	11.8	11.8	3.7	3.7		
FI 0345	Mango (incl juice, pulp)	0.03	6.3	0.2	1.0	0.0	4.6	0.1	0.2	0.0	0.7	0.0	0.3	0.0		
MM 0095	Meat from mammals other than marine mammals: 20% as fat	1	5.5	5.5	23.3	23.3	7.7	7.7	11.0	11.0	18.0	18.0	26.3	26.3		
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.04	22.2	0.9	93.2	3.7	30.8	1.2	44.1	1.8	72.2	2.9	105.0	4.2		
ML 0106	Milks (excl processed products)	0.08	68.8	5.5	190.6	15.2	79.4	6.4	302.6	24.2	179.6	14.4	237.9	19.0		
FS 0245	Nectarine	0.1	0.0	0.0	0.5	0.1	3.3	0.3	1.8	0.2	2.8	0.3	1.6	0.2		
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		
SO 0088	Oilseed	0.01	22.3	0.2	65.2	0.7	35.4	0.4	52.0	0.5	62.1	0.6	39.4	0.4		
VO 0442	Okra	0.03	3.9	0.1	1.0	0.0	5.3	0.2	0.1	0.0	0.0	0.0	0.0	0.0		
FT 0305	Olive (table olives, only)	0.125	0.0	0.0	4.8	0.6	0.8	0.1	0.4	0.1	1.0	0.1	0.8	0.1		
OR 0305	Olive oil, refined	0.077	0.0	0.0	14.3	1.1	3.9	0.3	0.0	0.0	1.5	0.1	0.8	0.1		
OR 5330	Olive oil, residue oil	0.091	0.1	0.0	2.3	0.2	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0		
FS 0247	Peach	0.1	0.2	0.0	24.8	2.5	3.3	0.3	1.8	0.2	5.4	0.5	1.6	0.2		

CYHALOTHRIN (146) (including Lambda-cyhalothrin) 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		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VO 0051	Peppers	0.03	1.4	0.0	29.9	0.9	13.0	0.4	6.3	0.2	6.2	0.2	4.0	0.1
FS 0014	Plum (incl dried)	0.02	0.1	0.0	5.9	0.1	2.5	0.1	7.3	0.1	6.9	0.1	2.6	0.1
FP 0009	Pome fruit (incl apple juice)	0.08	0.5	0.0	84.1	6.7	21.9	1.8	45.2	3.6	61.7	4.9	46.2	3.7
GC 0656	Popcorn	0.01	0.1	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
VD 0070	Pulses	0.01	54.5	0.5	62.9	0.6	51.4	0.5	36.8	0.4	49.4	0.5	47.9	0.5
GC 0649	Rice (husked + polished)	0.295	91.0	26.8	31.6	9.3	94.6	27.9	33.2	9.8	12.7	3.7	12.7	3.7
CM 1206	Rice bran, unprocessed	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR0075	Root and tuber vegetables	0	528.2	0.0	352.8	0.0	78.5	0.0	270.3	0.0	324.1	0.0	261.3	0.0
GC 0650	Rye (incl flour)	0.01	0.1	0.0	3.7	0.0	0.3	0.0	24.3	0.2	25.8	0.3	45.8	0.5
MO 1288	Sheep kidney	0.03	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1289	Sheep liver	0.008	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GS 0659	Sugar cane	0.02	30.9	0.6	43.1	0.9	51.3	1.0	0.1	0.0	5.5	0.1	0.0	0.0
DM 0659	Sugar cane molasses	0.001	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VO 1275	Sweet corn kernels (incl corn on the cob + frozen + preserved)	0.03	14.7	0.4	2.0	0.1	0.2	0.0	1.2	0.0	6.5	0.2	7.2	0.2
VO 0448	Tomato (excl juice, paste, peeled)	0.03	1.3	0.0	178.4	5.4	102.8	3.1	53.4	1.6	1.6	0.0	0.0	0.0
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
-d	Tomato paste	0.007	0.5	0.0	1.3	0.0	3.5	0.0	1.0	0.0	3.8	0.0	4.5	0.0
TN 0085	Tree nuts	0.01	4.2	0.0	21.5	0.2	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.0
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
GC 0654	Wheat (incl bulgur wholemeal, flour)	0.01	88.4	0.9	396.3	4.0	426.5	4.3	390.2	3.9	236.3	2.4	216.0	2.2
CM 0654	Wheat bran, unprocessed	0.045	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
	Total intake (µg/person)=			45.6		101.7		66.3		70.5		70.4		69.1
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			3.8%		8.5%		5.5%		5.9%		5.9%		5.8%
	Rounded %ADI=			4%		8%		6%		6%		6%		6%

Annex 3

CYHALOTHRIN (146) (including Lambda-cyhalothrin) 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
FS 0240	Apricot (incl dried)	0.1	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
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
GC 0640	Barley (incl pot, pearled, flour and grits, beer)	0.02	5.9	0.1	20.5	0.4	5.9	0.1	2.5	0.1	20.2	0.4	16.8	0.3	43.8	0.9
FB 0018	Berries and other small fruits	0.02	2.8	0.1	6.6	0.1	11.8	0.2	0.3	0.0	8.6	0.2	17.1	0.3	69.4	1.4
VA 0035	Bulb vegetables	0.05	31.6	1.6	29.6	1.5	9.7	0.5	19.6	1.0	25.7	1.3	47.2	2.4	33.1	1.7
VB 0041	Cabbages, Head	0.08	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1280	Cattle kidney	0.03	0.0	0.0	0.9	0.0	0.4	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.0	0.0
MO 1281	Cattle liver	0.008	0.0	0.0	0.9	0.0	0.4	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.4	0.0
FS 0013	Cherries	0.125	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	2.5	0.3
FC 0001	Citrus fruit (incl 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
VO 0440	Egg plant	0.03	20.1	0.6	0.1	0.0	0.6	0.0	6.3	0.2	0.5	0.0	6.3	0.2	0.7	0.0
VB 0042	Flowerhead brassicas	0.215	9.6	2.1	7.9	1.7	0.6	0.1	0.2	0.0	0.9	0.2	1.1	0.2	8.0	1.7
VC 0045	Fruiting vegetables, Cucurbits	0.01	69.7	0.7	25.9	0.3	14.9	0.1	18.0	0.2	18.7	0.2	39.1	0.4	44.2	0.4
VP 0060	Legume vegetables	0.02	19.6	0.4	6.2	0.1	6.9	0.1	6.0	0.1	1.7	0.0	29.5	0.6	26.3	0.5
GC 0645	Maize (incl flour, incl germ, 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
MF 0100	Mammalian fats (except milk fats)	1	2.2	2.2	18.6	18.6	0.5	0.5	0.8	0.8	5.7	5.7	4.5	4.5	18.2	18.2
FI 0345	Mango (incl juice, pulp)	0.03	12.7	0.4	26.2	0.8	6.1	0.2	12.7	0.4	9.2	0.3	8.0	0.2	1.9	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	1	11.0	11.0	17.9	17.9	6.1	6.1	5.7	5.7	16.4	16.4	12.2	12.2	31.7	31.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.04	43.8	1.8	71.5	2.9	24.5	1.0	22.9	0.9	65.7	2.6	48.9	2.0	126.6	5.1
ML 0106	Milks (excl processed products)	0.08	66.0	5.3	121.1	9.7	81.6	6.5	102.4	8.2	207.7	16.6	57.0	4.6	287.9	23.0
FS 0245	Nectarine	0.1	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	0.1
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
SO 0088	Oilseed	0.01	26.2	0.3	19.8	0.2	24.9	0.2	39.9	0.4	7.4	0.1	62.7	0.6	29.9	0.3
VO 0442	Okra	0.03	4.1	0.1	1.0	0.0	7.0	0.2	15.9	0.5	1.1	0.0	3.9	0.1	0.2	0.0
FT 0305	Olive (table olives, only)	0.125	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	0.077	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0	1.6	0.1
OR 5330	Olive oil, residue oil	0.091	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
FS 0247	Peach	0.1	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	1.0
VO 0051	Peppers	0.03	8.7	0.3	22.4	0.7	8.4	0.3	9.4	0.3	3.3	0.1	5.3	0.2	8.9	0.3

Annex 3

CYHALOTHRIN (146) (including Lambda-cyhalothrin) 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
FS 0014	Plum (incl dried)	0.02	3.3	0.1	1.4	0.0	0.1	0.0	0.0	0.0	0.6	0.0	1.5	0.0	2.2	0.0
FP 0009	Pome fruit (incl apple juice)	0.08	20.9	1.7	12.3	1.0	3.4	0.3	0.1	0.0	11.7	0.9	24.9	2.0	45.4	3.6
GC 0656	Popcorn	0.01	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0
VD 0070	Pulses	0.01	41.9	0.4	91.8	0.9	35.9	0.4	45.2	0.5	160.0	1.6	59.5	0.6	140.1	1.4
GC 0649	Rice (husked + polished)	0.295	376.9	111.2	64.3	19.0	38.0	11.2	74.3	21.9	238.4	70.3	381.3	112.5	34.6	10.2
CM 1206	Rice bran, unprocessed	0.065	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VR0075	Root and tuber vegetables	0	139.1	0.0	109.8	0.0	409.6	0.0	444.6	0.0	145.3	0.0	127.0	0.0	225.6	0.0
GC 0650	Rye (incl flour)	0.01	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
MO 1288	Sheep kidney	0.03	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 1289	Sheep liver	0.008	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GS 0659	Sugar cane	0.02	26.2	0.5	1.5	0.0	33.8	0.7	5.5	0.1	18.6	0.4	3.0	0.1	20.2	0.4
DM 0659	Sugar cane molasses	0.001	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VO 1275	Sweet corn kernels (incl corn on the cob + frozen + preserved)	0.03	0.4	0.0	4.9	0.1	4.5	0.1	3.3	0.1	1.7	0.1	5.6	0.2	18.1	0.5
VO 0448	Tomato (excl juice, paste, peeled)	0.03	22.8	0.7	4.1	0.1	12.3	0.4	1.8	0.1	32.8	1.0	0.4	0.0	27.3	0.8
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
-d	Tomato paste	0.007	0.1	0.0	2.1	0.0	0.6	0.0	0.4	0.0	0.6	0.0	1.4	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
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
GC 0654	Wheat (incl bulgur wholemeal, flour)	0.01	172.9	1.7	79.0	0.8	68.1	0.7	41.9	0.4	114.1	1.1	103.4	1.0	234.2	2.3
CM 0654	Wheat bran, unprocessed	0.045	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
	Total intake (µg/person)=			144.2		82.0		32.9		42.8		122		147.0		108.9
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			13.1%		6.8%		2.7%		3.6%		10.2%		13.4%		9.1%
	Rounded %ADI=			10%		7%		3%		4%		10%		10%		9%

Annex 3

CYPERMETHRIN (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
VS 0620	Artichoke globe	0.023	0.0	0.0	10.0	0.2	2.1	0.0	0.1	0.0	0.8	0.0	0.1	0.0
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
VB 0400	Broccoli	0.02	0.0	0.0	0.7	0.0	1.2	0.0	0.1	0.0	4.2	0.1	4.0	0.1
VB 0402	Brussels sprouts	0.02	0.0	0.0	0.1	0.0	2.8	0.1	5.5	0.1	1.5	0.0	1.9	0.0
VB 0041	Cabbages, Head	0.02	1.2	0.0	14.4	0.3	2.7	0.1	16.4	0.3	15.4	0.3	18.5	0.4
FT 0289	Carambola	0.02	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0404	Cauliflower	0.02	0.1	0.0	5.2	0.1	1.2	0.0	0.1	0.0	1.7	0.0	0.1	0.0
GC 0080	Cereal grains	0.035	356.9	12.5	713.9	25.0	763.0	26.7	504.5	17.7	365.2	12.8	328.7	11.5
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
MO 0105	Edible offal (mammalian)	0.014	3.9	0.1	14.4	0.2	5.2	0.1	11.8	0.2	11.7	0.2	7.6	0.1
VO 0440	Egg plant (= aubergine)	0.01	1.7	0.0	17.5	0.2	12.3	0.1	1.7	0.0	0.8	0.0	0.4	0.0
PE 0112	Eggs	0.001	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VC 0045	Fruiting vegetables, Cucurbits	0.01	26.6	0.3	107.5	1.1	95.9	1.0	82.2	0.8	25.4	0.3	23.2	0.2
FB 0269	Grape (excl dried, incl juice, excl wine)	0.01	1.9	0.0	9.4	0.1	24.0	0.2	9.9	0.1	2.0	0.0	1.4	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.033	0.0	0.0	2.9	0.1	0.4	0.0	0.4	0.0	2.3	0.1	1.7	0.1
VL 0053	Leafy vegetables	0.07	5.8	0.4	45.6	3.2	10.9	0.8	26.8	1.9	18.7	1.3	38.9	2.7
VA 0384	Leek	0.01	0.3	0.0	5.3	0.1	0.0	0.0	0.2	0.0	4.6	0.0	1.5	0.0
VP 0060	Legume vegetables	0.22	6.1	1.3	23.0	5.1	18.0	4.0	12.8	2.8	26.9	5.9	5.3	1.2
FI 0345	Mango (incl juice, incl pulp)	0.19	6.3	1.2	1.0	0.2	4.6	0.9	0.2	0.0	0.7	0.1	0.3	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.15	5.5	0.8	23.3	3.5	7.7	1.2	11.0	1.7	18.0	2.7	26.3	3.9
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.014	22.2	0.3	93.2	1.3	30.8	0.4	44.1	0.6	72.2	1.0	105.0	1.5
ML 0106	Milks (excl processed products)	0.011	68.8	0.8	190.6	2.1	79.4	0.9	302.6	3.3	179.6	2.0	237.9	2.6
SO 0088	Oilseed	0.05	22.3	1.1	65.2	3.3	35.4	1.8	52.0	2.6	62.1	3.1	39.4	2.0
VO 0442	Okra	0.08	3.9	0.3	1.0	0.1	5.3	0.4	0.1	0.0	0.0	0.0	0.0	0.0
FT 0305	Olive (incl oil)	0.05	0.0	0.0	76.3	3.8	20.3	1.0	0.4	0.0	8.5	0.4	4.8	0.2
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
FI 0350	Papaya	0.135	5.1	0.7	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VO 0444	Peppers, Chilli	0.495	0.7	0.3	14.9	7.4	4.1	2.0	3.2	1.6	3.1	1.5	2.0	1.0
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.05	0.7	0.0	14.9	0.7	8.8	0.4	3.2	0.2	3.1	0.2	2.0	0.1

Annex 3

CYPERMETHRIN (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
DF 0014	Plum, dried (prunes)	1.9	0.0	0.0	0.2	0.4	0.0	0.0	0.1	0.2	0.5	1.0	0.6	1.1
FP 0009	Pome fruit (incl apple juice)	0.205	0.5	0.1	84.1	17.2	21.9	4.5	45.2	9.3	61.7	12.6	46.2	9.5
PM 0110	Poultry meat: 10% as fat	0.008	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	0.002	6.4	0.0	52.7	0.1	28.7	0.1	21.6	0.0	54.9	0.1	24.6	0.0
PO 0111	Poultry, Edible offal of	0.002	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	0.05	54.5	2.7	62.9	3.1	51.4	2.6	36.8	1.8	49.4	2.5	47.9	2.4
GC 0649	Rice (incl husked, incl polished)	0.57	91.0	51.9	31.6	18.0	94.6	53.9	33.2	18.9	12.7	7.2	12.7	7.2
VR0075	Root and tuber vegetables	0.01	528.2	5.3	352.8	3.5	78.5	0.8	270.3	2.7	324.1	3.2	261.3	2.6
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.59	0.7	0.4	44.1	26.0	14.1	8.3	26.6	15.7	26.3	15.5	8.3	4.9
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
GS 0659	Sugar cane	0.05	30.9	1.5	43.1	2.2	51.3	2.6	0.1	0.0	5.5	0.3	0.0	0.0
VO 0447	Sweet corn (corn-on-the-cob)	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, incl paste, excl peeled)	0.05	5.2	0.3	183.9	9.2	116.9	5.8	57.6	2.9	16.9	0.8	17.9	0.9
JF 0448	Tomato juice	0.015	5.2	0.1	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.1	15.2	0.2
-d	Tomato, peeled	0.006	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.0	3.2	0.0
CM 0654	Wheat bran, unprocessed	0.084	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.015	63.4	1.0	296.3	4.4	327.5	4.9	300.0	4.5	181.6	2.7	166.2	2.5
-	Wine	0.001	1.3	0.0	76.8	0.1	1.1	0.0	15.4	0.0	68.8	0.1	25.6	0.0
	Total intake (µg/person)=			83.7		143.5		126.1		90.5		79.2		60.3
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			7.0%		12.0%		10.5%		7.5%		6.6%		5.0%
	Rounded %ADI=			7%		10%		10%		8%		7%		5%

Annex 3

CYPERMETHRIN (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		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VS 0620	Artichoke globe	0.023	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
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
VB 0400	Broccoli	0.02	3.2	0.1	7.8	0.2	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.0	6.6	0.1
VB 0402	Brussels sprouts	0.02	3.4	0.1	0.4	0.0	0.0	0.0	0.0	0.0	0.5	0.0	7.9	0.2	0.3	0.0
VB 0041	Cabbages, Head	0.02	10.0	0.2	1.0	0.0	7.2	0.1	1.0	0.0	1.4	0.0	23.9	0.5	17.0	0.3
FT 0289	Carambola	0.02	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0404	Cauliflower	0.02	3.2	0.1	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.0	0.4	0.0	1.4	0.0
GC 0080	Cereal grains	0.035	617.0	21.6	487.1	17.0	389.4	13.6	385.7	13.5	440.2	15.4	567.7	19.9	409.9	14.3
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
MO 0105	Edible offal (mammalian)	0.014	4.8	0.1	10.7	0.1	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
VO 0440	Egg plant (= aubergine)	0.01	20.1	0.2	0.1	0.0	0.6	0.0	6.3	0.1	0.5	0.0	6.3	0.1	0.7	0.0
PE 0112	Eggs	0.001	22.1	0.0	71.5	0.1	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.1
VC 0045	Fruiting vegetables, Cucurbits	0.01	69.7	0.7	25.9	0.3	14.9	0.1	18.0	0.2	18.7	0.2	39.1	0.4	44.2	0.4
FB 0269	Grape (excl dried, incl juice, excl wine)	0.01	1.2	0.0	2.7	0.0	1.4	0.0	0.2	0.0	0.8	0.0	4.3	0.0	5.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.033	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	0.1
VL 0053	Leafy vegetables	0.07	40.8	2.9	12.0	0.8	12.5	0.9	9.5	0.7	5.4	0.4	50.0	3.5	39.9	2.8
VA 0384	Leek	0.01	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
VP 0060	Legume vegetables	0.22	19.6	4.3	6.2	1.4	6.9	1.5	6.0	1.3	1.7	0.4	29.5	6.5	26.3	5.8
FI 0345	Mango (incl juice, incl pulp)	0.19	12.7	2.4	26.2	5.0	6.1	1.2	12.7	2.4	9.2	1.7	8.0	1.5	1.9	0.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.15	11.0	1.6	17.9	2.7	6.1	0.9	5.7	0.9	16.4	2.5	12.2	1.8	31.7	4.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.014	43.8	0.6	71.5	1.0	24.5	0.3	22.9	0.3	65.7	0.9	48.9	0.7	126.6	1.8
ML 0106	Milks (excl processed products)	0.011	66.0	0.7	121.1	1.3	81.6	0.9	102.4	1.1	207.7	2.3	57.0	0.6	287.9	3.2
SO 0088	Oilseed	0.05	26.2	1.3	19.8	1.0	24.9	1.2	39.9	2.0	7.4	0.4	62.7	3.1	29.9	1.5
VO 0442	Okra	0.08	4.1	0.3	1.0	0.1	7.0	0.6	15.9	1.3	1.1	0.1	3.9	0.3	0.2	0.0
FT 0305	Olive (incl oil)	0.05	0.0	0.0	0.6	0.0	0.0	0.0	0.0	0.0	2.1	0.1	1.5	0.1	9.0	0.5
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
FI 0350	Papaya	0.135	1.3	0.2	11.5	1.6	1.6	0.2	13.7	1.8	14.5	2.0	1.0	0.1	0.6	0.1
VO 0444	Peppers, Chilli	0.495	8.7	4.3	13.0	6.4	4.2	2.1	4.7	2.3	1.7	0.8	2.6	1.3	4.4	2.2

CYPERMETHRIN (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	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.05	0.0	0.0	9.4	0.5	4.2	0.2	4.7	0.2	1.7	0.1	2.6	0.1	4.4	0.2
DF 0014	Plum, dried (prunes)	1.9	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 (incl apple juice)	0.205	20.9	4.3	12.3	2.5	3.4	0.7	0.1	0.0	11.7	2.4	24.9	5.1	45.4	9.3
PM 0110	Poultry meat: 10% as fat	0.008	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	0.002	15.8	0.0	118.2	0.2	22.6	0.0	4.2	0.0	131.3	0.3	24.9	0.0	103.6	0.2
PO 0111	Poultry, Edible offal of	0.002	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	0.05	41.9	2.1	91.8	4.6	35.9	1.8	45.2	2.3	160.0	8.0	59.5	3.0	140.1	7.0
GC 0649	Rice (incl husked, incl polished)	0.57	376.9	214.8	64.3	36.7	38.0	21.7	74.3	42.4	238.4	135.9	381.3	217.3	34.6	19.7
VR0075	Root and tuber vegetables	0.01	139.1	1.4	109.8	1.1	409.6	4.1	444.6	4.4	145.3	1.5	127.0	1.3	225.6	2.3
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.59	6.7	4.0	4.3	2.5	1.4	0.8	0.1	0.1	4.9	2.9	4.9	2.9	17.7	10.4
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
GS 0659	Sugar cane	0.05	26.2	1.3	1.5	0.1	33.8	1.7	5.5	0.3	18.6	0.9	3.0	0.2	20.2	1.0
VO 0447	Sweet corn (corn-on-the-cob)	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, incl paste, excl peeled)	0.05	23.3	1.2	12.6	0.6	14.6	0.7	7.2	0.4	35.2	1.8	5.9	0.3	45.0	2.3
JF 0448	Tomato juice	0.015	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	0.7
-d	Tomato, peeled	0.006	0.2	0.0	14.5	0.1	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	0.0
CM 0654	Wheat bran, unprocessed	0.084	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.015	133.0	2.0	60.1	0.9	52.4	0.8	32.2	0.5	87.7	1.3	79.6	1.2	180.1	2.7
-	Wine	0.001	1.0	0.0	0.9	0.0	6.8	0.0	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.0
	Total intake (µg/person)=			273.2		90.0		56.5		78.8		183.3		273.3		96.5
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			24.8%		7.5%		4.7%		6.6%		15.3%		24.8%		8.0%
	Rounded %ADI=			20%		7%		5%		7%		20%		20%		8%

Annex 3

DIMETHOATE (027) 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
VS 0620	Artichoke globe	0.1	0.0	0.0	10.0	1.0	2.1	0.2	0.1	0.0	0.8	0.1	0.1	0.0
VS 0621	Asparagus	0.22	0.0	0.0	1.1	0.2	0.6	0.1	0.2	0.0	1.2	0.3	0.1	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.405	40.6	16.4	16.8	6.8	93.9	38.0	13.2	5.3	48.6	19.7	36.1	14.6
VB 0402	Brussels sprouts	0.35	0.0	0.0	0.1	0.0	2.8	1.0	5.5	1.9	1.5	0.5	1.9	0.7
VB 0403	Cabbage, Savoy 1/	0.77	1.2	0.9	14.4	11.1	2.7	2.1	16.4	12.6	15.4	11.9	18.5	14.2
VB 0404	Cauliflower	0.025	0.1	0.0	5.2	0.1	1.2	0.0	0.1	0.0	1.7	0.0	0.1	0.0
VS 0624	Celery	0.2	0.0	0.0	0.9	0.2	0.0	0.0	2.0	0.4	1.5	0.3	0.0	0.0
FS 0013	Cherries	1.425	0.0	0.0	6.8	9.7	0.9	1.3	6.2	8.8	3.6	5.1	0.4	0.6
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.27	15.7	4.2	96.7	26.1	55.3	14.9	25.3	6.8	23.4	6.3	16.2	4.4
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
VL 0482	Lettuce, head	0.13	0.1	0.0	12.3	1.6	1.3	0.2	0.1	0.0	0.1	0.0	0.0	0.0
FI 0345	Mango (incl juice, incl pulp)	0.36	6.3	2.3	1.0	0.4	4.6	1.7	0.2	0.1	0.7	0.3	0.3	0.1
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 0107	Milk of cattle, goats & sheep (excl processed products)	0	52.7	0.0	189.5	0.0	65.7	0.0	295.6	0.0	179.6	0.0	237.9	0.0
FT 0305	Olive (table olives, only)	2.24	0.0	0.0	4.8	10.8	0.8	1.8	0.4	0.9	1.0	2.2	0.8	1.8
OR 0305	Olive oil, refined	0.059	0.0	0.0	14.3	0.8	3.9	0.2	0.0	0.0	1.5	0.1	0.8	0.0
JF 0004	Orange juice	0.49	0.0	0.0	2.1	1.0	4.4	2.2	1.4	0.7	16.2	7.9	22.6	11.1
FP 0230	Pear	0.57	0.1	0.1	22.3	12.7	2.8	1.6	4.8	2.7	10.7	6.1	6.8	3.9
VP 0063	Peas (green pods and/or immature seeds)	0.265	0.1	0.0	2.9	0.8	6.0	1.6	0.6	0.2	9.7	2.6	5.2	1.4
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.28	0.7	0.2	14.9	4.2	8.8	2.5	3.2	0.9	3.1	0.9	2.0	0.6
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.11	19.1	2.1	160.8	17.7	61.2	6.7	243.6	26.8	230.1	25.3	204.7	22.5
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, Edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
PF 0111	Poultry, fats	0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
MO 0822	Sheep, edible offal of	0	0.4	0.0	1.3	0.0	1.7	0.0	1.0	0.0	0.7	0.0	0.4	0.0
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
VR 0506	Turnip, garden	1.1	0.0	0.0	0.1	0.1	0.8	0.9	2.0	2.2	0.6	0.7	14.0	15.4
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.021	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
-d	Wheat bulgur wholemeal	0.027	5.5	0.1	10.2	0.3	0.7	0.0	0.2	0.0	0.1	0.0	0.0	0.0
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

Annex 3

DIMETHOATE (027) 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
	Total intake (µg/person)=			27.3		114.2		81.5		74.7		93.5		93.6
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			120		120		120		120		120		120
	%ADI=			22.8%		95.2%		67.9%		62.2%		77.9%		78.0 %
	Rounded %ADI=			20%		100%		70%		60%		80%		80%

Note 1: Because no consumption data are available for Savoy cabbage, the STMR of Savoy cabbage was applied to head cabbage (VB 0041) consumption.

DIMETHOATE (027) 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
VS 0620	Artichoke globe	0.1	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.1
VS 0621	Asparagus	0.22	3.7	0.8	0.3	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.5	0.1	1.1	0.2
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.405	5.9	2.4	20.5	8.3	5.9	2.4	2.5	1.0	20.2	8.2	16.8	6.8	43.8	17.7
VB 0402	Brussels sprouts	0.35	3.4	1.2	0.4	0.1	0.0	0.0	0.0	0.0	0.5	0.2	7.9	2.8	0.3	0.1
VB 0403	Cabbage, Savoy 1/	0.77	10.0	7.7	1.0	0.8	7.2	5.5	1.0	0.8	1.4	1.1	23.9	18.4	17.0	13.1
VB 0404	Cauliflower	0.025	3.2	0.1	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.0	0.4	0.0	1.4	0.0
VS 0624	Celery	0.2	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
FS 0013	Cherries	1.425	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.4	2.5	3.6
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, excl orange juice, incl grapefruit juice, incl NES juice)	0.27	16.9	4.6	155.0	41.9	8.6	2.3	42.5	11.5	220.5	59.5	28.9	7.8	30.1	8.1
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
VL 0482	Lettuce, head	0.13	2.4	0.3	7.0	0.9	0.2	0.0	0.6	0.1	2.0	0.3	2.4	0.3	15.7	2.0
FI 0345	Mango (incl juice, incl pulp)	0.36	12.7	4.6	26.2	9.4	6.1	2.2	12.7	4.6	9.2	3.3	8.0	2.9	1.9	0.7
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 0107	Milk of cattle, goats & sheep (excl processed products)	0	48.0	0.0	121.1	0.0	80.8	0.0	94.7	0.0	207.7	0.0	56.1	0.0	287.9	0.0
FT 0305	Olive (table olives, only)	2.24	0.0	0.0	0.1	0.2	0.0	0.0	0.0	0.0	0.6	1.3	0.0	0.0	1.0	2.2

Annex 3

DIMETHOATE (027) 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
OR 0305	Olive oil, refined	0.059	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0	1.6	0.1
JF 0004	Orange juice	0.49	0.2	0.1	1.0	0.5	3.5	1.7	0.0	0.0	1.3	0.6	6.4	3.1	56.8	27.8
FP 0230	Pear	0.57	6.4	3.6	1.9	1.1	1.2	0.7	0.0	0.0	1.8	1.0	6.9	3.9	7.8	4.4
VP 0063	Peas (green pods and/or immature seeds)	0.265	3.9	1.0	1.6	0.4	0.4	0.1	0.0	0.0	0.9	0.2	1.0	0.3	8.6	2.3
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.28	0.0	0.0	9.4	2.6	4.2	1.2	4.7	1.3	1.7	0.5	2.6	0.7	4.4	1.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.11	52.7	5.8	57.1	6.3	50.1	5.5	4.3	0.5	54.7	6.0	41.0	4.5	168.0	18.5
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, Edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
PF 0111	Poultry, fats	0	0.1	0.0	8.2	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.0
MO 0822	Sheep, edible offal of	0	0.3	0.0	0.3	0.0	0.6	0.0	0.8	0.0	0.2	0.0	0.0	0.0	0.4	0.0
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
VR 0506	Turnip, garden	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.1	0.0	0.0	0.4	0.4
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.021	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
-d	Wheat bulgur wholemeal	0.027	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.014	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
	Total intake (µg/person)=			34.1		73.6		22.5		20.2		84.9		53.2		107.7
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			110		120		120		120		120		110		120
				31.0		61.3				16.8		70.7		48.4		
	%ADI=			%		%		18.7%		%		%		%		89.7%
	Rounded %ADI=			30%		60%		20%		20%		70%		50%		90%

Note 1: Because no consumption data are available for Savoy cabbage, the STMR of Savoy cabbage was applied to head cabbage (VB 0041) consumption.

ETHOXYQUIN (035) International Estimated Daily Intake (IEDI) ADI = 0 - 0.005 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
FP 0230	Pear	5	0.1	0.5	22.3	111.5	2.8	14.0	4.8	24.0	10.7	53.5	6.8	34.0
	Total intake (µg/person)=			0.5		111.5		14.0		24.0		53.5		34.0
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			300		300		300		300		300		300
	%ADI=			0.2%		37.2%		4.7%		8.0%		17.8%		11.3%
	Rounded %ADI=			0%		40%		5%		8%		20%		10%

ETHOXYQUIN (035) International Estimated Daily Intake (IEDI) ADI = 0 - 0.005 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 0230	Pear	5	6.4	32.0	1.9	9.5	1.2	6.0	0.0	0.0	1.8	9.0	6.9	34.5	7.8	39.0
	Total intake (µg/person)=			32.0		9.5		6.0		0.0		9.0		34.5		39.0
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			275		300		300		300		300		275		300
	%ADI=			11.6%		3.2%		2.0%		0.0%		3.0%		12.5%		13.0%
	Rounded %ADI=			10%		3%		2%		0%		3%		10%		10%

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											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
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	Cabbages, 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
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 0278	Currants, black	0.89	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.0	1.6	1.4	1.0	0.9
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 0279	Currants, red, white	0.89	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.0	1.6	1.4	1.0	0.9
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

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											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
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
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
VL 0482	Lettuce, head	0.9	0.1	0.1	12.3	11.1	1.3	1.2	0.1	0.1	0.1	0.1	0.0	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: 20% as fat	0.007	5.5	0.0	23.3	0.2	7.7	0.1	11.0	0.1	18.0	0.1	26.3	0.2
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.012	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
ML 0106	Milks (excl processed products)	0.018	68.8	1.2	190.6	3.4	79.4	1.4	302.6	5.4	179.6	3.2	237.9	4.3
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
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
VD 0072	Peas (dry) (= field pea + cowpea)	0.62	6.8	4.2	1.3	0.8	1.0	0.6	2.3	1.4	4.6	2.9	3.4	2.1
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
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
VR0075	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, zucchini)	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

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											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VO 0447	Sweet corn (corn-on-the-cob)	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 peeled)	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)=			57.2		170.0		92.6		86.0		108.9		78.7
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3600		3600		3600		3600		3600		3600
	%ADI=			1.6%		4.7%		2.6%		2.4%		3.0%		2.2%
	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	Cabbages, 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

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
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
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 0278	Currants, black	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 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 0279	Currants, red, 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
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
VL 0482	Lettuce, head	0.9	2.4	2.2	7.0	6.3	0.2	0.2	0.6	0.5	2.0	1.8	2.4	2.2	15.7	14.1
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
ML 0106	Milks (excl processed products)	0.018	66.0	1.2	121.1	2.2	81.6	1.5	102.4	1.8	207.7	3.7	57.0	1.0	287.9	5.2
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

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
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
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
VD 0072	Peas (dry) (= field pea + cowpea)	0.62	1.8	1.1	2.2	1.4	3.2	2.0	26.7	16.6	1.5	0.9	1.8	1.1	1.8	1.1
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
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
VR0075	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, zucchini)	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 (corn-on-the-cob)	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 peeled)	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)=			68.8		70.4		52.9		71.7		63.1		64.3		106.0
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			3300		3600		3600		3600		3600		3300		3600
	%ADI=			2.1%		2.0%		1.5%		2.0%		1.8%		1.9%		2.9%
	Rounded %ADI=			2%		2%		1%		2%		2%		2%		3%

	MALATHION (049)	International Estimated Daily Intake (IEDI)						ADI = 0 - 0.3 mg/kg bw					
		STMR or	Diets: g/person/day										
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FP 0226	Apple (incl juice)	0.11	0.3	0.0	60.5	6.7	18.5	2.0	39.9	4.4	50.8	5.6	39.4	4.3
VS 0621	Asparagus	0.305	0.0	0.0	1.1	0.3	0.6	0.2	0.2	0.1	1.2	0.4	0.1	0.0
VD 0071	Beans (dry)	0.36	15.8	5.7	6.1	2.2	1.7	0.6	6.3	2.3	1.8	0.6	5.0	1.8
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.31	1.0	0.3	17.4	5.4	7.5	2.3	0.9	0.3	16.4	5.1	0.1	0.0
FB 0020	Blueberries	2.27	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.5	0.3	0.7	0.8	1.8
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.02	15.7	0.3	100.5	2.0	63.2	1.3	27.8	0.6	52.6	1.1	56.9	1.1
OR 0691	Cotton seed oil, edible	3.06	0.9	2.8	4.9	15.0	1.7	5.2	6.6	20.2	0.0	0.0	0.3	0.9
VC 0424	Cucumber	0.02	0.3	0.0	12.7	0.3	5.9	0.1	11.5	0.2	6.1	0.1	7.1	0.1
FB 0269	Grape (incl dried, incl juice, incl wine)	0.16	3.7	0.6	128.5	20.6	27.1	4.3	33.1	5.3	107.5	17.2	44.0	7.0
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
VL 0485	Mustard greens	0.07	0.3	0.0	0.3	0.0	0.0	0.0	5.5	0.4	0.0	0.0	1.9	0.1
-	Onion, dry	0.23	4.3	1.0	45.6	10.5	27.4	6.3	30.2	6.9	22.1	5.1	12.2	2.8
VO 0051	Peppers	0.01	1.4	0.0	29.9	0.3	13.0	0.1	6.3	0.1	6.2	0.1	4.0	0.0
VL 0502	Spinach	0.35	0.0	0.0	5.0	1.8	1.1	0.4	0.1	0.0	2.6	0.9	0.1	0.0
VA 0389	Spring onion	0.52	0.3	0.2	1.0	0.5	1.4	0.7	0.3	0.2	0.3	0.2	0.6	0.3
FB 0275	Strawberry	0.25	0.0	0.0	5.0	1.3	2.0	0.5	1.7	0.4	5.2	1.3	4.1	1.0
VO 0447	Sweet corn (corn-on-the-cob)	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, incl paste, incl peeled)	0.25	5.3	1.3	184.4	46.1	117.5	29.4	58.1	14.5	23.0	5.7	21.9	5.5
JF 0448	Tomato juice	0	5.2	0.0	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.0	15.2	0.0
VR 0506	Turnip, garden	0.05	0.0	0.0	0.1	0.0	0.8	0.0	2.0	0.1	0.6	0.0	14.0	0.7
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	10	6.0	59.8	11.1	111.1	0.8	7.5	0.2	2.0	0.2	2.2	0.0	0.0
CM 0654	Wheat bran, unprocessed	25	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.87	63.4	54.5	296.3	254.8	327.5	281.7	300.0	258.0	181.6	156.2	166.2	142.9
CP 1211	White bread	0.2	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.2
CP 1212	Wholemeal bread	1.2	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.1	0.1	1.0	1.2
	Total intake (µg/person)=			127.4		480.4		344.0		316.8		202.9		172.2
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			18000		18000		18000		18000		18000		18000
	%ADI=			0.7%		2.7%		1.9%		1.8%		1.1%		1.0%
	Rounded %ADI=			1%		3%		2%		2%		1%		1%

Annex 3

MALATHION (049) International Estimated Daily Intake (IEDI) ADI = 0 - 0.3 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
FP 0226	Apple (incl juice)	0.11	14.4	1.6	10.1	1.1	2.2	0.2	0.0	0.0	9.8	1.1	17.9	2.0	36.3	4.0
VS 0621	Asparagus	0.305	3.7	1.1	0.3	0.1	0.2	0.1	0.0	0.0	0.0	0.0	0.5	0.2	1.1	0.3
VD 0071	Beans (dry)	0.36	3.4	1.2	25.5	9.2	7.8	2.8	2.1	0.8	44.7	16.1	5.5	2.0	7.3	2.6
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.31	2.6	0.8	2.6	0.8	1.0	0.3	0.5	0.2	0.6	0.2	2.8	0.9	9.8	3.0
FB 0020	Blueberries	2.27	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	3.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.02	17.3	0.3	156.8	3.1	14.9	0.3	42.5	0.9	222.8	4.5	40.4	0.8	132.3	2.6
OR 0691	Cotton seed oil, edible	3.06	1.0	3.1	0.7	2.1	1.0	3.1	1.4	4.3	1.5	4.6	5.5	16.8	1.2	3.7
VC 0424	Cucumber	0.02	7.9	0.2	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.1	5.3	0.1
FB 0269	Grape (incl dried, incl juice, incl wine)	0.16	2.6	0.4	4.8	0.8	11.7	1.9	0.3	0.0	6.8	1.1	10.9	1.7	58.8	9.4
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
VL 0485	Mustard greens	0.07	3.4	0.2	0.4	0.0	2.4	0.2	0.3	0.0	0.5	0.0	7.9	0.6	0.3	0.0
-	Onion, dry	0.23	16.8	3.9	8.6	2.0	6.9	1.6	12.1	2.8	18.6	4.3	23.8	5.5	28.4	6.5
VO 0051	Peppers	0.01	8.7	0.1	22.4	0.2	8.4	0.1	9.4	0.1	3.3	0.0	5.3	0.1	8.9	0.1
VL 0502	Spinach	0.35	9.4	3.3	0.4	0.1	0.0	0.0	0.0	0.0	0.2	0.1	4.3	1.5	2.0	0.7
VA 0389	Spring onion	0.52	0.1	0.1	4.8	2.5	0.1	0.1	1.0	0.5	1.0	0.5	2.7	1.4	0.6	0.3
FB 0275	Strawberry	0.25	0.0	0.0	1.8	0.5	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.6	5.9	1.5
VO 0447	Sweet corn (corn-on-the-cob)	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, incl paste, incl peeled)	0.25	23.5	5.9	30.7	7.7	14.9	3.7	7.2	1.8	35.6	8.9	6.9	1.7	46.5	11.6
JF 0448	Tomato juice	0	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	0.0
VR 0506	Turnip, garden	0.05	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.1	0.0	0.0	0.4	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	10	0.0	0.0	0.9	8.7	0.0	0.0	0.0	0.4	0.1	0.9	0.0	0.0	0.1	0.7
CM 0654	Wheat bran, unprocessed	25	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.87	133.0	114.4	60.1	51.7	52.4	45.1	32.2	27.7	87.7	75.4	79.6	68.5	180.1	154.9
CP 1211	White bread	0.2	0.0	0.0	2.2	0.4	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CP 1212	Wholemeal bread	1.2	0.0	0.0	2.2	2.6	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Total intake (µg/person)=			136.9		96.7		62.0		40.0		118.4		105.8		206.1
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			16500		18000		18000		18000		18000		16500		18000
	%ADI=			0.8%		0.5%		0.3%		0.2%		0.7%		0.6%		1.1%
	Rounded %ADI=			1%		1%		0%		0%		1%		1%		1%

MANDIPROPAMID (231) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VB 0400	Broccoli	0.435	0.0	0.0	0.7	0.3	1.2	0.5	0.1	0.0	4.2	1.8	4.0	1.7
VB 0041	Cabbages, 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
VS 0624	Celery	2.7	0.0	0.0	0.9	2.4	0.0	0.0	2.0	5.4	1.5	4.1	0.0	0.0
VC 0424	Cucumber	0.02	0.3	0.0	12.7	0.3	5.9	0.1	11.5	0.2	6.1	0.1	7.1	0.1
FB 0269	Grape (excl dried, excl juice, excl wine)	0.51	1.9	1.0	9.2	4.7	23.8	12.1	9.8	5.0	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.14	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.2	1.0	0.1
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
VL 0053	Leafy vegetables	5.65	5.8	32.8	45.6	257.6	10.9	61.6	26.8	151.4	18.7	105.7	38.9	219.8
VC 0046	Melons, except watermelon	0.115	3.6	0.4	26.7	3.1	22.6	2.6	11.5	1.3	5.6	0.6	2.0	0.2
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1
-	Onion, green (= shallot, Welsh, spring onion, others)	0.48	1.2	0.6	3.9	1.9	5.6	2.7	1.1	0.5	1.1	0.5	2.4	1.2
VO 0051	Peppers	0.12	1.4	0.2	29.9	3.6	13.0	1.6	6.3	0.8	6.2	0.7	4.0	0.5
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
VC 0431	Squash, summer (= courgette, zucchini)	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 0448	Tomato (excl juice, excl paste, excl peeled)	0.06	1.3	0.1	178.4	10.7	102.8	6.2	53.4	3.2	1.6	0.1	0.0	0.0
JF 0448	Tomato juice	0.059	5.2	0.3	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.4	15.2	0.9
-	Wine	0.366	1.3	0.5	76.8	28.1	1.1	0.4	15.4	5.6	68.8	25.2	25.6	9.4
	Total intake (µg/person)=			36.0		320.1		89.9		177.5		146.1		239.1
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			12000		12000		12000		12000		12000		12000
	%ADI=			0.3%		2.7%		0.7%		1.5%		1.2%		2.0%
	Rounded %ADI=			0%		3%		1%		1%		1%		2%

Annex 3

MANDIPROPAMID (231) International Estimated Daily Intake (IEDI) ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VB 0400	Broccoli	0.435	3.2	1.4	7.8	3.4	0.0	0.0	0.0	0.0	0.3	0.1	0.4	0.2	6.6	2.9
VB 0041	Cabbages, 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
VS 0624	Celery	2.7	0.0	0.0	0.3	0.8	0.0	0.0	0.0	0.0	1.0	2.7	0.0	0.0	4.2	11.3
VC 0424	Cucumber	0.02	7.9	0.2	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.1	5.3	0.1
FB 0269	Grape (excl dried, excl juice, excl wine)	0.51	1.2	0.6	2.6	1.3	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.9	0.0	0.0
JF 0269	Grape juice	0.14	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.1	3.6	0.5
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
VL 0053	Leafy vegetables	5.65	40.8	230.5	12.0	67.8	12.5	70.6	9.5	53.7	5.4	30.5	50.0	282.5	39.9	225.4
VC 0046	Melons, except watermelon	0.115	7.5	0.9	6.1	0.7	0.7	0.1	1.4	0.2	2.5	0.3	6.9	0.8	12.4	1.4
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2	28.4	0.3
-	Onion, green (= shallot, Welsh, spring onion, others)	0.48	0.6	0.3	19.3	9.3	0.4	0.2	3.9	1.9	4.2	2.0	10.7	5.1	1.7	0.8
VO 0051	Peppers	0.12	8.7	1.0	22.4	2.7	8.4	1.0	9.4	1.1	3.3	0.4	5.3	0.6	8.9	1.1
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
VC 0431	Squash, summer (= courgette, zucchini)	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 0448	Tomato (excl juice, excl paste, excl peeled)	0.06	22.8	1.4	4.1	0.2	12.3	0.7	1.8	0.1	32.8	2.0	0.4	0.0	27.3	1.6
JF 0448	Tomato juice	0.059	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.4	0.0	0.0	2.4	0.1	45.2	2.7
-	Wine	0.366	1.0	0.4	0.9	0.3	6.8	2.5	0.1	0.0	3.4	1.2	3.6	1.3	31.0	11.3
	Total intake (µg/person)=			237.5		87.7		76.3		57.7		40.7		294.4		265.8
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100 0		1200 0		1200 0		12000		12000		1100 0		1200 0
	%ADI=			2.2%		0.7%		0.6%		0.5%		0.3%		2.7%		2.2%
	Rounded %ADI=			2%		1%		1%		0%		0%		3%		2%

METHOMYL (094) 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
FP 0226	Apple (excl juice)	0.09	0.3	0.0	56.3	5.1	18.4	1.7	38.3	3.4	40.6	3.7	28.3	2.5
JF 0226	Apple juice	0.026	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.0	6.8	0.2	7.4	0.2
VS 0621	Asparagus	0.33	0.0	0.0	1.1	0.4	0.6	0.2	0.2	0.1	1.2	0.4	0.1	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.14	40.6	5.7	16.8	2.4	93.9	13.1	13.2	1.8	48.6	6.8	36.1	5.1
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
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.005	1.0	0.0	17.4	0.1	7.5	0.0	0.9	0.0	16.4	0.1	0.1	0.0
VD 0523	Broad bean (dry)	0.02	7.3	0.1	2.1	0.0	6.9	0.1	0.0	0.0	0.4	0.0	0.1	0.0
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.034	15.7	0.5	86.5	2.9	52.6	1.8	24.2	0.8	16.2	0.6	12.0	0.4
-	Citrus juice NES	0.004	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
VD 0526	Common bean (dry)	0.02	2.0	0.0	4.5	0.1	0.2	0.0	0.7	0.0	0.2	0.0	5.0	0.1
VP 0526	Common bean (green pods and/or immature seeds)	0.055	0.5	0.0	4.7	0.3	4.1	0.2	0.0	0.0	13.1	0.7	0.0	0.0
OR 0691	Cotton seed oil, edible	0.006	0.9	0.0	4.9	0.0	1.7	0.0	6.6	0.0	0.0	0.0	0.3	0.0
VC 0045	Fruiting vegetables, Cucurbits	0.02	26.6	0.5	107.5	2.2	95.9	1.9	82.2	1.6	25.4	0.5	23.2	0.5
FB 0269	Grape (excl dried, excl juice, excl wine)	0.01	1.9	0.0	9.2	0.1	23.8	0.2	9.8	0.1	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.0198	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)	0.018	0.0	0.0	2.9	0.1	0.4	0.0	0.4	0.0	2.3	0.0	1.7	0.0
JF 0203	Grapefruit juice	0.004	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.0	0.2	0.0
-d	Lemon juice	0.004	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
-	Lettuce (head, leaf)	0.01	0.1	0.0	21.5	0.2	2.3	0.0	0.2	0.0	5.5	0.1	18.0	0.2
VD 0534	Lima bean (dry)	0.02	0.0	0.0	0.2	0.0	0.2	0.0	0.7	0.0	0.0	0.0	0.0	0.0
GC 0645	Maize (incl flour, excl oil, incl beer)	0.02	82.7	1.7	1.4	0.0	51.4	1.0	31.8	0.6	0.2	0.0	0.2	0.0
OR 0645	Maize oil, edible	0.004	0.1	0.0	4.0	0.0	2.3	0.0	0.5	0.0	0.9	0.0	0.2	0.0
-	Mandarin + mandarin-like hybrid juice	0.004	0.0	0.0	1.4	0.0	0.9	0.0	0.4	0.0	0.7	0.0	0.9	0.0
FS 0245	Nectarine	0.05	0.0	0.0	0.5	0.0	3.3	0.2	1.8	0.1	2.8	0.1	1.6	0.1
GC 0647	Oats (incl rolled)	0.02	1.4	0.0	0.6	0.0	0.2	0.0	4.2	0.1	5.7	0.1	8.9	0.2
-	Onion, dry	0.068	4.3	0.3	45.6	3.1	27.4	1.9	30.2	2.1	22.1	1.5	12.2	0.8
JF 0004	Orange juice	0.004	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.1	22.6	0.1
FS 0247	Peach	0.05	0.2	0.0	24.8	1.2	3.3	0.2	1.8	0.1	5.4	0.3	1.6	0.1
FP 0230	Pear	0.09	0.1	0.0	22.3	2.0	2.8	0.3	4.8	0.4	10.7	1.0	6.8	0.6

Annex 3

METHOMYL (094) 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
VP 0063	Peas (green pods and/or immature seeds)	0.46	0.1	0.0	2.9	1.3	6.0	2.8	0.6	0.3	9.7	4.5	5.2	2.4
VO 0051	Peppers	0.1	1.4	0.1	29.9	3.0	13.0	1.3	6.3	0.6	6.2	0.6	4.0	0.4
FS 0014	Plum (incl dried)	0.08	0.1	0.0	5.9	0.5	2.5	0.2	7.3	0.6	6.9	0.6	2.6	0.2
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
OR 0541	Soya bean oil, refined	0.04	1.6	0.1	6.5	0.3	6.0	0.2	4.0	0.2	6.3	0.3	7.0	0.3
VO 0448	Tomato (incl juice, excl paste, incl peeled)	0.0085	9.8	0.1	179.8	1.5	104.0	0.9	56.7	0.5	16.4	0.1	22.9	0.2
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.14	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	0.27	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
CF 1210	Wheat germ	0.13	0.0	0.0	1.3	0.2	0.0	0.0	1.3	0.2	0.9	0.1	1.2	0.2
-	Wine	0.0531	1.3	0.1	76.8	4.1	1.1	0.1	15.4	0.8	68.8	3.7	25.6	1.4
	Total intake (µg/person)=			9.9		32.1		29.4		15.6		26.5		16.5
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			0.8%		2.7%		2.4%		1.3%		2.2%		1.4%
	Rounded %ADI=			1%		3%		2%		1%		2%		1%

METHOMYL (094) 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
FP 0226	Apple (excl juice)	0.09	14.3	1.3	9.4	0.8	2.1	0.2	0.0	0.0	8.8	0.8	16.6	1.5	27.8	2.5
JF 0226	Apple juice	0.026	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
VS 0621	Asparagus	0.33	3.7	1.2	0.3	0.1	0.2	0.1	0.0	0.0	0.0	0.0	0.5	0.2	1.1	0.4
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.14	5.9	0.8	20.5	2.9	5.9	0.8	2.5	0.4	20.2	2.8	16.8	2.4	43.8	6.1
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
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.005	2.6	0.0	2.6	0.0	1.0	0.0	0.5	0.0	0.6	0.0	2.8	0.0	9.8	0.0

METHOMYL (094) 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
VD 0523	Broad bean (dry)	0.02	0.8	0.0	1.2	0.0	0.0	0.0	2.8	0.1	0.3	0.0	0.1	0.0	5.3	0.1
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.034	15.1	0.5	153.9	5.2	3.4	0.1	41.7	1.4	218.9	7.4	23.1	0.8	18.0	0.6
-	Citrus juice NES	0.004	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
VD 0526	Common bean (dry)	0.02	0.4	0.0	14.8	0.3	1.0	0.0	0.3	0.0	44.7	0.9	0.6	0.0	0.9	0.0
VP 0526	Common bean (green pods and/or immature seeds)	0.055	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
OR 0691	Cotton seed oil, edible	0.006	1.0	0.0	0.7	0.0	1.0	0.0	1.4	0.0	1.5	0.0	5.5	0.0	1.2	0.0
VC 0045	Fruiting vegetables, Cucurbits	0.02	69.7	1.4	25.9	0.5	14.9	0.3	18.0	0.4	18.7	0.4	39.1	0.8	44.2	0.9
FB 0269	Grape (excl dried, excl juice, excl wine)	0.01	1.2	0.0	2.6	0.0	0.0	0.0	0.2	0.0	0.0	0.0	3.7	0.0	0.0	0.0
JF 0269	Grape juice	0.0198	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)	0.018	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
JF 0203	Grapefruit juice	0.004	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
-d	Lemon juice	0.004	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
-	Lettuce (head, leaf)	0.01	2.4	0.0	7.0	0.1	0.2	0.0	0.6	0.0	2.0	0.0	2.4	0.0	18.2	0.2
VD 0534	Lima bean (dry)	0.02	0.4	0.0	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0	0.1	0.0
GC 0645	Maize (incl flour, excl oil, incl beer)	0.02	35.2	0.7	298.6	6.0	248.1	5.0	57.4	1.1	63.1	1.3	0.0	0.0	19.4	0.4
OR 0645	Maize oil, edible	0.004	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
-	Mandarin + mandarin-like hybrid juice	0.004	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
FS 0245	Nectarine	0.05	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
GC 0647	Oats (incl rolled)	0.02	0.2	0.0	2.0	0.0	0.8	0.0	0.0	0.0	3.5	0.1	0.7	0.0	7.6	0.2
-	Onion, dry	0.068	16.8	1.1	8.6	0.6	6.9	0.5	12.1	0.8	18.6	1.3	23.8	1.6	28.4	1.9
JF 0004	Orange juice	0.004	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
FS 0247	Peach	0.05	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	0.5
FP 0230	Pear	0.09	6.4	0.6	1.9	0.2	1.2	0.1	0.0	0.0	1.8	0.2	6.9	0.6	7.8	0.7
VP 0063	Peas (green pods and/or immature seeds)	0.46	3.9	1.8	1.6	0.7	0.4	0.2	0.0	0.0	0.9	0.4	1.0	0.5	8.6	4.0
VO 0051	Peppers	0.1	8.7	0.9	22.4	2.2	8.4	0.8	9.4	0.9	3.3	0.3	5.3	0.5	8.9	0.9
FS 0014	Plum (incl dried)	0.08	3.3	0.3	1.4	0.1	0.1	0.0	0.0	0.0	0.6	0.0	1.5	0.1	2.2	0.2
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
OR 0541	Soya bean oil, refined	0.04	4.3	0.2	10.6	0.4	2.0	0.1	1.4	0.1	19.5	0.8	9.2	0.4	22.0	0.9
VO 0448	Tomato (incl juice, excl paste, incl peeled)	0.0085	23.1	0.2	23.3	0.2	12.6	0.1	14.6	0.1	33.2	0.3	4.3	0.0	98.2	0.8
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.14	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	Wheat bran, unprocessed	0.27	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

Annex 3

METHOMYL (094) 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
0654																
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
CF 1210	Wheat germ	0.13	0.1	0.0	48.1	6.3	1.8	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.1
-	Wine	0.0531	1.0	0.1	0.9	0.0	6.8	0.4	0.1	0.0	3.4	0.2	3.6	0.2	31.0	1.6
	Total intake (µg/person)=			11.8		27.9		9.3		5.5		18.5		10.4		24.7
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			1.1%		2.3%		0.8%		0.5%		1.5%		0.9%		2.1%
	Rounded %ADI=			1%		2%		1%		0%		2%		1%		2%

PROFENOFOS (171) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	diet correction factor	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
FI 0345	Mango (incl juice, incl pulp)	0.06	1	6.3	0.4	1.0	0.1	4.6	0.3	0.2	0.0	0.7	0.0	0.3	0.0
-	Assorted (sub)tropical fruits NES (excl passion fruit)*	2.1	1	5.2	10.9	6.5	13.7	1.2	2.5	0.0	0.0	16.8	35.3	0.0	0.0
VO 0448	Tomato (incl juice, incl paste, incl peeled)	1.3	1	11.8	15.3	185.0	240.5	118.0	153.4	60.7	78.9	31.6	41.1	40.9	53.2
OR 0691	Cotton seed oil, edible	0.14	1	0.9	0.1	4.9	0.7	1.7	0.2	6.6	0.9	0.0	0.0	0.3	0.0
MM 0095	Meat from mammals other than marine mammals	0	1	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
MF 0100	Mammalian fats (except milk fats)	0	1	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MO 0105	Edible offal (mammalian)	0	1	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	1	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PF 0111	Poultry, fats	0	1	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	1	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	1	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	1	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
	* Mangosteen														
	Total intake (µg/person)=				26.8		254.9		156.4		79.8		76.4		53.2
	Body weight per region (kg bw) =				60		60		60		60		60		60
	ADI (µg/person)=				1800		1800		1800		1800		1800		1800
	%ADI=				1.5%		14.2%		8.7%		4.4%		4.2%		3.0%
	Rounded %ADI=				1%		10%		9%		4%		4%		3%

Annex 3

PROFENOFOS (171) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	diet correction factor	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
FI 0345	Mango (incl juice, incl pulp)	0.06	1	12.7	0.8	26.2	1.6	6.1	0.4	12.7	0.8	9.2	0.6	8.0	0.5	1.9	0.1
-	Assorted (sub)tropical fruits NES (excl passion fruit)*	2.1	1	5.7	12.0	4.7	9.9	2.4	5.0	1.1	2.3	13.1	27.5	47.2	99.1	0.7	1.5
VO 0448	Tomato (incl juice, incl paste, incl peeled)	1.3	1	23.5	30.6	31.7	41.2	15.0	19.5	16.2	21.1	35.6	46.3	9.9	12.9	103.0	133.9
OR 0691	Cotton seed oil, edible	0.14	1	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
MM 0095	Meat from mammals other than marine mammals	0	1	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
MF 0100	Mammalian fats (except milk fats)	0	1	2.2	0.0	18.6	0.0	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.0
MO 0105	Edible offal (mammalian)	0	1	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	1	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
PF 0111	Poultry, fats	0	1	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
PO 0111	Poultry, Edible offal of	0	1	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	1	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	1	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
	* Mangosteen																
	Total intake (µg/person)=				43.4		52.8		25.0		24.3		74.6		113.2		135.7
	Body weight per region (kg bw) =				55		60		60		60		60		55		60
	ADI (µg/person)=				1650		1800		1800		1800		1800		1650		1800
	%ADI=				2.6%		2.9%		1.4%		1.4%		4.1%		6.9%		7.5%
	Rounded %ADI=				3%		3%		1%		1%		4%		7%		8%

PROTHIOCONAZOLE (232) 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
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.01	40.6	0.4	16.8	0.2	93.9	0.9	13.2	0.1	48.6	0.5	36.1	0.4
CM 0081	Bran, unprocessed of cereal grain (except buckwheat, canihua, quinoa)	0.024	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 0105	Edible offal (mammalian)	0.05	3.9	0.2	14.4	0.7	5.2	0.3	11.8	0.6	11.7	0.6	7.6	0.4
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	0.01	27.7	0.3	116.5	1.2	38.5	0.4	55.1	0.6	90.2	0.9	131.3	1.3
ML 0106	Milks (excl processed products)	0.004	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)	0.01	1.4	0.0	0.6	0.0	0.2	0.0	4.2	0.0	5.7	0.1	8.9	0.1
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
SO 0495	Rape seed (incl oil)	0.01	0.9	0.0	1.8	0.0	2.5	0.0	1.9	0.0	35.7	0.4	26.1	0.3
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 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
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
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	0.02	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)=			1.2		5.5		3.3		4.1		4.3		4.5
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			0.2%		0.9%		0.6%		0.7%		0.7%		0.8%
	Rounded %ADI=			0%		1%		1%		1%		1%		1%

Annex 3

PROTHIOCONAZOLE (232) 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													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.01	5.9	0.1	20.5	0.2	5.9	0.1	2.5	0.0	20.2	0.2	16.8	0.2	43.8	0.4
CM 0081	Bran, unprocessed of cereal grain (except buckwheat, canihua, quinoa)	0.024	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
MO 0105	Edible offal (mammalian)	0.05	4.8	0.2	10.7	0.5	4.0	0.2	4.0	0.2	6.5	0.3	6.6	0.3	5.6	0.3
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	0.01	54.8	0.5	89.4	0.9	30.6	0.3	28.6	0.3	82.1	0.8	61.1	0.6	158.3	1.6
ML 0106	Milks (excl processed products)	0.004	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)	0.01	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
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
SO 0495	Rape seed (incl oil)	0.01	9.9	0.1	5.9	0.1	0.3	0.0	1.0	0.0	0.0	0.0	15.5	0.2	9.9	0.1
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 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
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
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	0.02	0.1	0.0	48.1	1.0	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
	Total intake (µg/person)=			1.9		3.6		1.2		1.3		2.6		1.8		4.6
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			0.3%		0.6%		0.2%		0.2%		0.4%		0.3%		0.8%
	Rounded %ADI=			0%		1%		0%		0%		0%		0%		1%

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											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.0435	4.2	0.2	54.1	2.4	30.1	1.4	11.9	0.5	0.2	0.0	0.5	0.0
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
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
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
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
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 (incl juice, incl paste, incl peeled)	0.02	11.8	0.2	185.0	3.7	118.0	2.4	60.7	1.2	31.6	0.6	40.9	0.8
VL 0482	Lettuce, head	0.895	0.1	0.1	12.3	11.0	1.3	1.2	0.1	0.1	0.1	0.1	0.0	0.0
VL 0483	Lettuce, leaf	0.895	0.0	0.0	9.2	8.2	1.0	0.9	0.1	0.1	5.4	4.8	18.0	16.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.046	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	0.00625	22.2	0.1	93.2	0.6	30.8	0.2	44.1	0.3	72.2	0.5	105.0	0.7
MO 0105	Edible offal (mammalian)	0.00625	3.9	0.0	14.4	0.1	5.2	0.0	11.8	0.1	11.7	0.1	7.6	0.0
ML 0106	Milks (excl processed products)	0.00925	68.8	0.6	190.6	1.8	79.4	0.7	302.6	2.8	179.6	1.7	237.9	2.2
	Total intake (µg/person)=			1.8		43.2		8.9		6.8		10.3		22.3
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			0.1%		1.4%		0.3%		0.2%		0.3%		0.7%
	Rounded %ADI=			0%		1%		0%		0%		0%		1%

Annex 3

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		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.0435	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
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
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
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
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
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 (incl juice, incl paste, incl peeled)	0.02	23.5	0.5	31.7	0.6	15.0	0.3	16.2	0.3	35.6	0.7	9.9	0.2	103.0	2.1
VL 0482	Lettuce, head	0.895	2.4	2.1	7.0	6.3	0.2	0.2	0.6	0.5	2.0	1.8	2.4	2.1	15.7	14.1
VL 0483	Lettuce, leaf	0.895	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	2.2
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.046	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	0.00625	43.8	0.3	71.5	0.4	24.5	0.2	22.9	0.1	65.7	0.4	48.9	0.3	126.6	0.8
MO 0105	Edible offal (mammalian)	0.00625	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
ML 0106	Milks (excl processed products)	0.00925	66.0	0.6	121.1	1.1	81.6	0.8	102.4	0.9	207.7	1.9	57.0	0.5	287.9	2.7
	Total intake (µg/person)=			7.3		21.5		2.2		2.9		17.1		7.1		38.9
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			0.3%		0.7%		0.1%		0.1%		0.6%		0.3%		1.3%
	Rounded %ADI=			0%		1%		0%		0%		1%		0%		1%

SPIROTETRAMAT (234) 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											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
JF 0226	Apple juice	0.082	0.0	0.0	2.8	0.2	0.1	0.0	1.1	0.1	6.8	0.6	7.4	0.6
VB 0041	Cabbages, Head	0.23	1.2	0.4	14.4	4.9	2.7	0.9	16.4	5.6	15.4	5.2	18.5	6.3
VS 0624	Celery	0.58	0.0	0.0	0.9	0.6	0.0	0.0	2.0	1.4	1.5	1.1	0.0	0.0
FS 0013	Cherries	1.6	0.0	0.0	6.8	10.9	0.9	1.4	6.2	9.9	3.6	5.8	0.4	0.6
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.33	15.7	5.2	100.5	33.2	63.2	20.9	27.8	9.2	52.6	17.4	56.9	18.8
MO 0105	Edible offal (mammalian)	0.014	3.9	0.1	14.4	0.2	5.2	0.1	11.8	0.2	11.7	0.2	7.6	0.1
VB 0042	Flowerhead brassicas	0.50	0.2	0.1	11.1	5.3	3.6	1.7	0.4	0.2	7.7	3.7	4.1	2.0
VO 0050	Fruiting vegetables other than cucurbits	0.43	33.5	14.4	236.9	101.9	148.9	64.0	70.2	30.2	50.4	21.7	53.9	23.2
VC 0045	Fruiting vegetables, Cucurbits	0.057	26.6	1.5	107.5	6.1	95.9	5.5	82.2	4.7	25.4	1.4	23.2	1.3
FB 0269	Grape (excl dried, excl juice, excl wine)	0.41	1.9	0.8	9.2	3.7	23.8	9.5	9.8	3.9	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.27	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.4	1.0	0.3
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	2.9	3.2	0.4	0.4	0.4	0.4	2.3	2.5	1.7	1.9
DH 1100	Hops, dry	5.2	0.1	0.6	0.1	0.6	0.1	0.6	0.1	0.6	0.3	1.7	0.1	0.6
-d	Lettuce and similar (incl witloof chicory sprouts)	3.7	0.2	0.2	23.8	28.6	3.6	4.3	0.6	0.7	11.9	14.3	18.0	21.6
MF 0100	Mammalian fats (except milk fats)	0	0.8	0.0	10.0	0.0	0.9	0.0	6.6	0.0	11.8	0.0	3.7	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	5.5	0.0	23.3	0.1	7.7	0.0	11.0	0.0	18.0	0.1	26.3	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.2	30.8	0.1	44.1	0.1	72.2	0.1	105.0	0.2
ML 0106	Milks (excl processed products)	0	68.8	0.3	190.6	0.8	79.4	0.3	302.6	1.2	179.6	0.7	237.9	1.0
VL 0485	Mustard greens	3.7	0.3	0.8	0.3	0.8	0.0	0.0	5.5	13.8	0.0	0.0	1.9	4.8
FS 0245	Nectarine	1.6	0.0	0.0	0.5	0.4	3.3	2.5	1.8	1.4	2.8	2.1	1.6	1.2
FS 0247	Peach	1.6	0.2	0.2	24.8	18.8	3.3	2.5	1.8	1.4	5.4	4.1	1.6	1.2
VO 0444	Peppers, Chilli	0.95	0.7	0.7	14.9	14.5	4.1	4.0	3.2	3.1	3.1	3.0	2.0	1.9
FS 0014	Plum (excl dried)	1.6	0.1	0.0	5.3	1.9	2.5	0.9	7.0	2.5	5.5	2.0	0.9	0.3
DF 0014	Plum, dried (prunes)	3.5	0.0	0.0	0.2	0.2	0.0	0.0	0.1	0.1	0.5	0.5	0.6	0.6
FP 0009	Pome fruit (excl apple juice)	0.17	0.5	0.1	79.9	12.8	21.8	3.5	43.6	7.0	51.5	8.2	35.1	5.6
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.12	19.1	2.3	160.8	19.3	61.2	7.3	243.6	29.2	230.1	27.6	204.7	24.6
VL 0502	Spinach	3.7	0.0	0.0	5.0	8.0	1.1	1.8	0.1	0.2	2.6	4.2	0.1	0.2

Annex 3

SPIROTETRAMAT (234) 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											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
JF 0448	Tomato juice	0.27	5.2	1.4	0.5	0.1	0.4	0.1	2.1	0.6	6.9	1.9	15.2	4.1
-d	Tomato paste	3.2	0.5	1.6	1.3	4.2	3.5	11.2	1.0	3.2	3.8	12.2	4.5	14.4
TN 0085	Tree nuts	0.084	4.2	0.4	21.5	1.8	3.9	0.3	3.0	0.3	5.5	0.5	10.2	0.9
-	Wine	0.23	1.3	0.3	76.8	19.2	1.1	0.3	15.4	3.9	68.8	17.2	25.6	6.4
	Total intake (µg/person)=			31.2		302.4		144.2		134.9		160.2		144.5
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			3000		3000		3000		3000		3000		3000
	%ADI=			1.0%		10.1%		4.8%		4.5%		5.3%		4.8%
	Rounded %ADI=			1%		10%		5%		4%		5%		5%

SPIROTETRAMAT (234) 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	0.082	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.5
VB 0041	Cabbages, Head	0.23	10.0	3.4	1.0	0.3	7.2	2.4	1.0	0.3	1.4	0.5	23.9	8.1	17.0	5.8
VS 0624	Celery	0.58	0.0	0.0	0.3	0.2	0.0	0.0	0.0	0.0	1.0	0.7	0.0	0.0	4.2	3.0
FS 0013	Cherries	1.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.5	2.5	4.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.33	17.3	5.7	156.8	51.7	14.9	4.9	42.5	14.0	222.8	73.5	40.4	13.3	132.3	43.7
MO 0105	Edible offal (mammalian)	0.014	4.8	0.1	10.7	0.1	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
VB 0042	Flowerhead brassicas	0.5	9.6	4.6	7.9	3.8	0.6	0.3	0.2	0.1	0.9	0.4	1.1	0.5	8.0	3.8
VO 0050	Fruiting vegetables other than cucurbits	0.43	57.2	24.6	60.1	25.8	35.5	15.3	51.1	22.0	42.2	18.1	31.5	13.5	134.8	58.0
VC 0045	Fruiting vegetables, Cucurbits	0.057	69.7	4.0	25.9	1.5	14.9	0.8	18.0	1.0	18.7	1.1	39.1	2.2	44.2	2.5
FB 0269	Grape (excl dried, excl juice, excl wine)	0.41	1.2	0.5	2.6	1.0	0.0	0.0	0.2	0.1	0.0	0.0	3.7	1.5	0.0	0.0
JF 0269	Grape juice	0.27	0.0	0.0	0.1	0.0	1.0	0.3	0.0	0.0	0.6	0.2	0.4	0.1	3.6	1.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.1	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.4	2.6	2.9
DH 1100	Hops, dry	5.2	0.0	0.0	0.1	0.6	0.1	0.6	0.1	0.6	0.1	0.6	0.1	0.6	0.6	3.3
-d	Lettuce and similar (incl witloof chicory	3.7	7.1	8.5	7.0	8.4	0.6	0.7	1.9	2.3	2.0	2.4	7.1	8.5	30.6	36.7

SPIROTETRAMAT (234) 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
	sprouts)															
MF 0100	Mammalian fats (except milk fats)	0	2.2	0.0	18.6	0.1	0.5	0.0	0.8	0.0	5.7	0.0	4.5	0.0	18.2	0.1
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0	11.0	0.0	17.9	0.1	6.1	0.0	5.7	0.0	16.4	0.1	12.2	0.0	31.7	0.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.1	71.5	0.1	24.5	0.0	22.9	0.0	65.7	0.1	48.9	0.1	126.6	0.3
ML 0106	Milks (excl processed products)	0	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
VL 0485	Mustard greens	3.7	3.4	8.5	0.4	1.0	2.4	6.0	0.3	0.8	0.5	1.3	7.9	19.8	0.3	0.8
FS 0245	Nectarine	1.6	1.7	1.3	1.7	1.3	0.0	0.0	0.0	0.0	1.0	0.8	1.7	1.3	1.4	1.1
FS 0247	Peach	1.6	1.7	1.3	1.7	1.3	1.1	0.8	0.1	0.1	1.0	0.8	1.7	1.3	10.2	7.8
VO 0444	Peppers, Chilli	0.95	8.7	8.4	13.0	12.6	4.2	4.1	4.7	4.6	1.7	1.6	2.6	2.5	4.4	4.3
FS 0014	Plum (excl dried)	1.6	3.0	1.1	0.8	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.3	0.5	0.2
DF 0014	Plum, dried (prunes)	3.5	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
FP 0009	Pome fruit (excl apple juice)	0.17	20.8	3.3	11.6	1.8	3.3	0.5	0.1	0.0	10.7	1.7	23.6	3.8	36.9	5.9
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.12	52.7	6.3	57.1	6.9	50.1	6.0	4.3	0.5	54.7	6.6	41.0	4.9	168.0	20.2
VL 0502	Spinach	3.7	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
JF 0448	Tomato juice	0.27	0.0	0.0	0.8	0.2	0.1	0.0	7.2	1.9	0.0	0.0	2.4	0.6	45.2	12.2
-d	Tomato paste	3.2	0.1	0.3	2.1	6.7	0.6	1.9	0.4	1.3	0.6	1.9	1.4	4.5	1.2	3.8
TN 0085	Tree nuts	0.084	16.3	1.4	15.7	1.3	9.7	0.8	1.9	0.2	19.1	1.6	29.0	2.4	5.6	0.5
-	Wine	0.23	1.0	0.3	0.9	0.2	6.8	1.7	0.1	0.0	3.4	0.9	3.6	0.9	31.0	7.8
	Total intake (µg/person)=			99.1		129.1		47.9		50.2		116.6		99.3		234.9
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2750		3000		3000		3000		3000		2750		3000
	%ADI=			3.6%		4.3%		1.6%		1.7%		3.9%		3.6%		7.8%
	Rounded %ADI=			4%		4%		2%		2%		4%		4%		8%

Annex 3

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 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	0.08	0.0	0.0	2.8	0.2	0.1	0.0	1.1	0.1	6.8	0.5	7.4	0.6
DF 0226	Apple, dried	0.19	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0620	Artichoke globe	0.15	0.0	0.0	10.0	1.5	2.1	0.3	0.1	0.0	0.8	0.1	0.1	0.0
FI 0327	Banana 1/	0.01	38.8	0.4	17.4	0.2	16.0	0.2	6.6	0.1	21.5	0.2	33.8	0.3
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.06	40.6	2.4	16.8	1.0	93.9	5.6	13.2	0.8	48.6	2.9	36.1	2.2
VP 0526	Common bean (pods and/or immature seeds)	0.49	0.0	0.0	2.7	1.3	4.5	2.2	0.2	0.1	0.4	0.2	0.0	0.0
VB 0400	Broccoli	0.07	0.0	0.0	0.7	0.0	1.2	0.1	0.1	0.0	4.2	0.3	4.0	0.3
VB 0401	Broccoli, Chinese	0.07	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0402	Brussels sprouts	0.07	0.0	0.0	0.1	0.0	2.8	0.2	5.5	0.4	1.5	0.1	1.9	0.1
VB 0041	Cabbages, Head	0.07	1.2	0.1	14.4	1.0	2.7	0.2	16.4	1.1	15.4	1.1	18.5	1.3
VR 0577	Carrot	0.11	0.6	0.1	15.1	1.7	8.1	0.9	13.9	1.5	27.1	3.0	28.4	3.1
VB 0404	Cauliflower	0.07	0.1	0.0	5.2	0.4	1.2	0.1	0.1	0.0	1.7	0.1	0.1	0.0
FS 0013	Cherries 1/	0.76	0.0	0.0	6.8	5.2	0.9	0.7	6.2	4.7	3.6	2.7	0.4	0.3
SB 0716	Coffee beans (excl green, excl extracts, excl roasted)	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
SM 0716	Coffee beans, roasted	0.2	0.4	0.1	6.0	1.2	0.5	0.1	0.6	0.1	9.4	1.9	16.4	3.3
VC 0424	Cucumber 1/	0.035	0.3	0.0	12.7	0.4	5.9	0.2	11.5	0.4	6.1	0.2	7.1	0.2
MO 0105	Edible offal (mammalian)	0.2	3.9	0.8	14.4	2.9	5.2	1.0	11.8	2.4	11.7	2.3	7.6	1.5
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0267	Elderberries	0.345	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VA 0381	Garlic	0.02	0.4	0.0	3.9	0.1	3.8	0.1	3.7	0.1	1.0	0.0	0.6	0.0
FB 0269	Grape (excl dried, excl juice, excl wine) 2/	2	1.9	3.8	9.2	18.5	23.8	47.6	9.8	19.6	0.0	0.0	0.0	-0.1
JF 0269	Grape juice 3/	0.42	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.6	1.0	0.4
DF 0269	Grape, dried (= currants, raisins and sultanas) 3/	3	0.0	0.0	2.9	8.7	0.4	1.2	0.4	1.2	2.3	6.9	1.7	5.1
DH 1100	Hops, dry	9.65	0.1	1.0	0.1	1.0	0.1	1.0	0.1	1.0	0.3	2.9	0.1	1.0
VB 0405	Kohlrabi	0.07	0.3	0.0	0.1	0.0	0.0	0.0	5.5	0.4	12.3	0.9	1.9	0.1
VA 0384	Leek	0.195	0.3	0.1	5.3	1.0	0.0	0.0	0.2	0.0	4.6	0.9	1.5	0.3
VL 0482	Lettuce, head	0.98	0.1	0.1	12.3	12.1	1.3	1.3	0.1	0.1	0.1	0.1	0.0	0.0
GC 0645	Maize (excl flour, excl oil, excl beer)	0.1	0.0	0.0	1.4	0.1	51.4	5.1	11.9	1.2	0.2	0.0	0.2	0.0
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
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
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	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 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 0647	Oats (excl rolled) 1/	0	0.1	0.0	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)	0.05	5.5	0.3	49.5	2.5	33.0	1.7	31.3	1.6	23.2	1.2	14.6	0.7
FI 0350	Papaya	0.18	5.1	0.9	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
FS 0247	Peach 1/	0.21	0.2	0.0	24.8	5.2	3.3	0.7	1.8	0.4	5.4	1.1	1.6	0.3
SO 0697	Peanut, shelled (excl oil)	0.04	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 0445	Peppers, sweet (incl. pim(i)ento) 1/	0.14	0.7	0.1	14.9	2.1	8.8	1.2	3.2	0.4	3.1	0.4	2.0	0.3
FS 0014	Plum (excl dried)	0.055	0.1	0.0	5.3	0.3	2.5	0.1	7.0	0.4	5.5	0.3	0.9	0.0
DF 0014	Plum, dried (prunes)	0.18	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.5	0.1	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.19	0.5	0.1	79.9	15.2	21.8	4.1	43.6	8.3	51.5	9.8	35.1	6.7
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)	0.09	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	0.064	0.3	0.0	0.7	0.0	1.0	0.1	0.7	0.0	13.7	0.9	10.0	0.6
GC 0649	Rice (excl husked, excl polished)	0.275	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0
GC 0650	Rye (excl flour) 3/	0.05	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VD 0541	Soya bean (dry, excl oil)	0.02	0.9	0.0	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.001	1.6	0.0	6.5	0.0	6.0	0.0	4.0	0.0	6.3	0.0	7.0	0.0
VC 0431	Squash, summer (= courgette, zucchini) 2/	0.02	0.0	0.0	8.3	0.2	11.4	0.2	7.3	0.1	3.2	0.1	0.3	0.0
VO 0447	Sweet corn (corn-on-the-cob)	0.1	7.3	0.7	1.0	0.1	0.1	0.0	0.5	0.1	3.3	0.3	3.6	0.4
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.19	1.3	0.3	178.4	33.9	102.8	19.5	53.4	10.1	1.6	0.3	0.0	0.0
JF 0448	Tomato juice	0.10	5.2	0.5	0.5	0.0	0.4	0.0	2.1	0.2	6.9	0.7	15.2	1.5
-d	Tomato paste	0.16	0.5	0.1	1.3	0.2	3.5	0.6	1.0	0.2	3.8	0.6	4.5	0.7
-d	Tomato, peeled	0.05	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.2	3.2	0.1
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) 2/	0.05	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
-	Wine 3/	0.5	1.3	0.7	76.8	38.4	1.1	0.6	15.4	7.7	68.8	34.4	25.6	12.8
	Total intake (µg/person)=			12.9		158		98.5		65.6		78.7		44.6
	Body weight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			0.7%		8.8%		5.4%		3.6%		4.4%		2.5%
	Rounded %ADI=			1%		9%		5%		4%		4%		2%

1/ STMR from the 1997 JMPR; 2/ Codex MRL recommended at the 1994 JMPR; 3/ PF from the 1997 JMPR applied to grape MRL

Annex 3

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 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	0.08	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.5
DF 0226	Apple, dried	0.19	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VS 0620	Artichoke globe	0.15	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.2
FI 0327	Banana 1/	0.01	21.4	0.2	36.6	0.4	11.4	0.1	9.2	0.1	70.2	0.7	40.5	0.4	32.6	0.3
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.06	5.9	0.4	20.5	1.2	5.9	0.4	2.5	0.2	20.2	1.2	16.8	1.0	43.8	2.6
VP 0526	Common bean (pods and/or immature seeds)	0.49	0.2	0.1	2.0	1.0	0.0	0.0	0.0	0.0	0.2	0.1	0.0	0.0	7.9	3.9
VB 0400	Broccoli	0.07	3.2	0.2	7.8	0.5	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.0	6.6	0.5
VB 0401	Broccoli, Chinese	0.07	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0402	Brussels sprouts	0.07	3.4	0.2	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	Cabbages, Head	0.07	10.0	0.7	1.0	0.1	7.2	0.5	1.0	0.1	1.4	0.1	23.9	1.7	17.0	1.2
VR 0577	Carrot	0.11	5.4	0.6	7.9	0.9	2.5	0.3	3.5	0.4	4.1	0.5	8.6	0.9	19.4	2.1
VB 0404	Cauliflower	0.07	3.2	0.2	0.1	0.0	0.3	0.0	0.1	0.0	0.6	0.0	0.4	0.0	1.4	0.1
FS 0013	Cherries 1/	0.76	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	1.9
SB 0716	Coffee beans (excl green, excl extracts, excl roasted)	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	0.0	0.0
SM 0716	Coffee beans, roasted	0.2	0.0	0.0	1.3	0.3	0.1	0.0	0.0	0.0	0.8	0.2	0.3	0.1	7.0	1.4
VC 0424	Cucumber 1/	0.035	7.9	0.3	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.2	5.3	0.2
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
MO 0105	Edible offal (mammalian)	0.2	4.8	1.0	10.7	2.1	4.0	0.8	4.0	0.8	6.5	1.3	6.6	1.3	5.6	1.1
FB 0267	Elderberries	0.345	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VB 0042	Flowerhead brassicas	0.07	9.6	0.5	7.9	0.4	0.6	0.0	0.2	0.0	0.9	0.0	1.1	0.1	8.0	0.4
VA 0381	Garlic	0.02	6.4	0.1	1.2	0.0	0.1	0.0	0.3	0.0	1.9	0.0	5.0	0.1	2.5	0.1
FB 0269	Grape (excl dried, excl juice, excl wine) 3/	2	1.2	2.4	2.6	5.2	0.0	0.0	0.2	0.3	0.0	0.0	3.7	7.4	0.0	-0.1
JF 0269	Grape juice4/	0.42	0.0	0.0	0.1	0.0	1.0	0.4	0.0	0.0	0.6	0.3	0.4	0.2	3.6	1.5
DF 0269	Grape, dried (= currants, raisins and sultanas) 4/	3	0.0	0.0	0.2	0.6	0.2	0.6	0.0	0.0	0.3	0.9	0.4	1.2	2.6	7.8
DH 1100	Hops, dry	9.65	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	5.8
VB 0405	Kohlrabi	0.07	3.4	0.2	0.0	0.0	0.0	0.0	0.3	0.0	0.5	0.0	7.9	0.6	0.7	0.0
VA 0384	Leek	0.195	0.8	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.1	0.0
VL 0482	Lettuce, head	0.98	2.4	2.4	7.0	6.9	0.2	0.2	0.6	0.6	2.0	2.0	2.4	2.4	15.7	15.4
GC 0645	Maize (excl flour, excl oil, excl beer)	0.1	0.6	0.1	0.0	0.0	0.1	0.0	0.0	0.0	7.7	0.8	0.0	0.0	19.4	1.9
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
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
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	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

TEBUCONAZOLE (189) International Estimated Daily Intake (IEDI) ADI = 0 - 0.03 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 0647	Oats (excl rolled) 1/	0	0.0	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.5	0.0	0.0	0.0
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
FI 0350	Papaya	0.18	1.3	0.2	11.5	2.1	1.6	0.3	13.7	2.5	14.5	2.6	1.0	0.2	0.6	0.1
FS 0247	Peach 1/	0.21	1.7	0.4	1.7	0.4	1.1	0.2	0.1	0.0	1.0	0.2	1.7	0.4	10.2	2.1
SO 0697	Peanut, shelled (excl oil)	0.04	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.1	0.2	0.0	0.7	0.0	6.0	0.2
VO 0444	Peppers, Chilli	1.4	8.7	12.2	13.0	18.2	4.2	5.9	4.7	6.6	1.7	2.4	2.6	3.6	4.4	6.2
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.14	0.0	0.0	9.4	1.3	4.2	0.6	4.7	0.7	1.7	0.2	2.6	0.4	4.4	0.6
FS 0014	Plum (excl dried)	0.055	3.0	0.2	0.8	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.1	0.5	0.0
DF 0014	Plum, dried (prunes)	0.18	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.2	0.0	0.6	0.1
FP 0009	Pome fruit (excl apple juice)	0.19	20.8	3.9	11.6	2.2	3.3	0.6	0.1	0.0	10.7	2.0	23.6	4.5	36.9	7.0
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
SO 0495	Rape seed (excl oil)	0.09	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	0.064	3.8	0.2	2.3	0.1	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.4	3.8	0.2
GC 0649	Rice (excl husked, excl polished)	0.275	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0
GC 0650	Rye (excl flour) 3/	0.05	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.9	0.0	0.0	0.0
VD 0541	Soya bean (dry, excl oil)	0.02	1.8	0.0	0.0	0.0	0.0	0.0	3.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0
OR 0541	Soya bean oil, refined	0.001	4.3	0.0	10.6	0.0	2.0	0.0	1.4	0.0	19.5	0.0	9.2	0.0	22.0	0.0
VC 0431	Squash, summer (= courgette, zucchini) 3/	0.02	2.4	0.0	1.5	0.0	0.0	0.0	0.0	0.0	3.8	0.1	2.2	0.0	2.5	0.1
VO 0447	Sweet corn (corn-on-the-cob)	0.1	0.2	0.0	2.4	0.2	2.2	0.2	3.3	0.3	1.7	0.2	2.8	0.3	11.2	1.1
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.19	22.8	4.3	4.1	0.8	12.3	2.3	1.8	0.4	32.8	6.2	0.4	0.1	27.3	5.2
JF 0448	Tomato juice	0.10	0.0	0.0	0.8	0.1	0.1	0.0	7.2	0.7	0.0	0.0	2.4	0.2	45.2	4.5
-d	Tomato paste	0.16	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
-d	Tomato, peeled	0.05	0.2	0.0	14.5	0.7	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	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)	0.05	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
-	Wine 4/	0.5	1.0	0.5	0.9	0.5	6.8	3.4	0.1	0.1	3.4	1.7	3.6	1.8	31.0	15.5
	Total intake (µg/person)=			21.0		31.3		12.6		9.6		24.0		30.0		87.5
	Body weight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			1.3%		1.7%		0.7%		0.5%		1.4%		1.8%		4.9%
	Rounded %ADI=			1%		2%		1%		1%		1%		2%		5%

1/ STMR from the 1997 JMPR; 2/ residue from the contribution of hops in the beer composition; 3/Codex MRL recommended at the 1994 JMPR; 4/ PF from the 1997 JMPR applied to grape MRL

ANNEX 4: INTERNATIONAL ESTIMATES OF SHORT-TERM DIETARY INTAKES OF PESTICIDE RESIDUES

BUPROFEZIN (173) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

Maximum %ARfD: 1%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0204	Lemon	-	0.1	FRA	52.2	111	173	SWE	92	3	2a	0.56	0%
VC 0424	Cucumber	-	0.1	FRA	52.2	348	410	BEL	385	3	2b	2.00	0%
FC 0203	Grapefruit	-	0.1	JPN	52.6	947	400	JPN	400	3	2a	3.32	1%
JF 0203	Grapefruit juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Lemon juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
FC 0206	Mandarin	-	0.1	FRA	52.2	639	168	USA	124	3	2a	1.70	0%
-	Mandarin + mandarin-like hybrid juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
FI 0345	Mango	-	0.01	AUS	67.0	567	339	SWE	234	3	2a	0.15	0%
JF 0004	Orange juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.1	FRA	52.2	1044	200	JPN	200	3	2a	2.77	1%
VO 0448	Tomato	-	0.52	FRA	52.2	387	150	JPN	150	3	2a	6.84	1%
JF 0448	Tomato juice	0.053	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	0.22	-	-	-	ND	-	-	ND	ND	ND	ND	-
-	Tomatoes peeled	-	0.088	-	-	ND	-	-	ND	ND	ND	ND	-

BUPROFEZIN (173) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS** Acute RfD= 0.5 mg/kg bw (500 µg/kg bw) Maximum %ARfD: 3%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0204	Lemon	-	0.1	JPN	15.9	88	173	SWE	92	3	2b	1.67	0%
VC 0424	Cucumber	-	0.1	NLD	17.0	162	410	BEL	385	3	2b	2.86	1%
FC 0203	Grapefruit	-	0.1	FRA	18.9	405	400	JPN	400	3	2a	6.38	1%
JF 0203	Grapefruit juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Lemon juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
FC 0206	Mandarin	-	0.1	JPN	15.9	353	168	USA	124	3	2a	3.79	1%
-	Mandarin + mandarin-like hybrid juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
FI 0345	Mango	-	0.01	Thai	17.1	191	339	SWE	234	3	2b	0.34	0%
JF 0004	Orange juice	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.1	UNK	14.5	495	200	JPN	200	3	2a	6.17	1%
VO 0448	Tomato	-	0.52	FRA	18.9	215	150	JPN	150	3	2a	14.18	3%
JF 0448	Tomato juice	0.053	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	0.22	-	-	-	ND	-	-	ND	ND	ND	ND	-
-	Tomatoes peeled	-	0.088	-	-	ND	-	-	ND	ND	ND	ND	-

CARABARYL (008) International estimate of short term intake (IESTI) for **GENERAL POPULATION** ARfD= 0.2 mg/kg bw (200 µg/kg bw) Maximum %ARfD: 20%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% ARfD rounded
FC 0203	Grapefruit	-	1.16	JPN	52.6	947	400	JPN	400	3	2a	38.52	20%
FC 0204	Lemon	-	1.16	FRA	52.2	111	100	FRA	64	3	2a	5.32	3%
FC 0206	Mandarin	-	1.16	FRA	52.2	639	168	USA	124	3	2a	19.72	10%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	1.16	FRA	52.2	1044	229	UNK	160	3	2a	30.32	20%

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CARBARYL (008) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS** ARfD= 0.2 mg/kg bw (200 µg/kg bw) Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% ARfD rounded
FC 0203	Grapefruit	-	1.16	FRA	18.9	405	400	JPN	400	3	2a	73.96	40%
FC 0204	Lemon	-	1.16	JPN	15.9	88	173	SWE	92	3	2b	19.35	10%
FC 0206	Mandarin	-	1.16	JPN	15.9	353	70	JPN	70	3	2a	35.99	20%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	1.16	UNK	14.5	495	200	JPN	200	3	2a	71.60	40%

CARBOFURAN (96) International estimate of short term intake (IESTI) for **GENERAL POPULATION** Acute RfD= 0.001 mg/kg bw (1 µg/kg bw) Maximum %ARfD: 510%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0327	Banana	-	0.1	FRA	52.2	714	708	USA	481	3	2a	3.21	320%
MF 0812	Cattle fat	-	0.05	USA	65.0	60	-	-	ND	ND	1	0.05	5%
SB 0716	Coffee beans	0.005	-	FRA	52.2	117	-	-	ND	ND	3	0.01	1%
VC 0424	Cucumber	-	0.29	FRA	52.2	348	301	USA	286	3	2a	5.11	510%
MO 0096	Edible offal of cattle, goats, horses, pigs & sheep	-	0.05	FRA	52.2	327	-	-	ND	ND	1	0.31	30%
MF 0814	Goat fat	-	0.05	USA	65.0	18	-	-	ND	ND	1	0.01	1%
MF 0816	Horse fat	-	0.05	-	-	ND	-	-	ND	ND	1	ND	-
GC 0645	Maize	0	-	FRA	52.2	212	-	-	ND	ND	3	0.00	0%
FC 0206	Mandarin	-	0.05	FRA	52.2	639	168	USA	124	3	2a	0.85	90%
MM 0096	Meat of cattle, goats, horses, pigs & sheep	-	0.05	AUS	67.0	520	-	-	ND	ND	1	0.39	40%
VC 0046	Melons, except watermelon, stated as cantaloupe, VC 4199	-	0.13	USA	65.0	606	552	USA	276	3	2a	2.32	230%
ML 0106	Milks	0.05	-	USA	65.0	2466	-	-	ND	ND	3	1.90	190%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.05	FRA	52.2	1044	251	SWE	178	3	2a	1.34	130%
MF 0818	Pig fat	-	0.05	AUS	67.0	144	-	-	ND	ND	1	0.11	10%

Annex 4

CARBOFURAN (96) International estimate of short term intake (IESTI) for **GENERAL POPULATION** Acute RfD= 0.001 mg/kg bw (1 µg/kg bw) Maximum %ARfD: 510%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VR 0589	Potato	-	0.11	FRA	52.2	639	122	USA	99	3	2a	1.76	180%
SO 0495	Rape seed	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
CM 0649	Rice, husked	0.025	-	JPN	52.6	319	-	-	ND	ND	3	0.15	20%
MF 0822	Sheep fat	-	0.05	USA	65.0	54	-	-	ND	ND	1	0.04	4%
VC 0431	Squash, summer (= courgette)	-	0.26	FRA	52.2	351	196	USA	186	3	2a	3.60	360%
GS 0659	Sugar cane	-	0.06	Thai	53.5	366	-	-	ND	ND	ND	ND	-
SO 0702	Sunflower seed	0.1	-	USA	65.0	193	-	-	ND	ND	3	0.30	30%
VO 0447	Sweet corn (corn-on-the-cob)	-	0.08	Thai	53.5	383	200	JPN	200	3	2a	1.17	120%

CARBOFURAN (96) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS** Acute RfD= 0.001 mg/kg bw (1 µg/kg bw) Maximum %ARfD: 830%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0327	Banana	-	0.1	FRA	18.9	477	708	USA	481	3	2b	7.57	760%
MF 0812	Cattle fat	-	0.05	USA	15.0	27	-	-	ND	ND	1	0.09	9%
SB 0716	Coffee beans	0.005	-	FRA	18.9	70	-	-	ND	ND	3	0.02	2%
VC 0424	Cucumber	-	0.29	NLD	17.0	162	301	USA	286	3	2b	8.29	830%
MO 0096	Edible offal of cattle, goats, horses, pigs & sheep	-	0.05	FRA	18.9	86	-	-	ND	ND	1	0.23	20%
MF 0814	Goat fat	-	0.05	USA	15.0	3	-	-	ND	ND	1	0.01	1%
MF 0816	Horse fat	-	0.05	-	-	ND	-	-	ND	ND	1	ND	-
GC 0645	Maize	0	-	FRA	18.9	117	-	-	ND	ND	3	0.00	0%
FC 0206	Mandarin	-	0.05	JPN	15.9	353	168	USA	124	3	2a	1.89	190%
MM 0096	Meat of cattle, goats, horses, pigs & sheep	-	0.05	AUS	19.0	261	-	-	ND	ND	1	0.69	70%
VC 0046	Melons, except watermelon, stated as cantaloupe, VC 4199	-	0.13	USA	15.0	270	552	USA	276	3	2b	7.01	700%
ML 0106	Milks	0.05	-	USA	15.0	1286	-	-	ND	ND	3	4.29	430%

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CARBOFURAN (96) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS** Acute RfD= 0.001 mg/kg bw (1 µg/kg bw) Maximum %ARfD: 830%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.05	UNK	14.5	495	251	SWE	178	3	2a	2.94	290%
MF 0818	Pig fat	-	0.05	FRA	18.9	65	-	-	ND	ND	1	0.17	20%
VR 0589	Potato	-	0.11	SAF	14.2	300	122	USA	99	3	2a	3.85	390%
SO 0495	Rape seed	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
CM 0649	Rice, husked	0.025	-	FRA	18.9	121	-	-	ND	ND	3	0.16	20%
MF 0822	Sheep fat	-	0.05	USA	15.0	28	-	-	ND	ND	1	0.09	9%
VC 0431	Squash, summer (= courgette)	-	0.26	AUS	19.0	219	196	USA	186	3	2a	8.09	810%
GS 0659	Sugar cane	-	0.06	Thai	17.1	181	-	-	ND	ND	ND	ND	-
SO 0702	Sunflower seed	0.1	-	USA	15.0	24	-	-	ND	ND	3	0.16	20%
VO 0447	Sweet corn (corn-on-the-cob)	-	0.08	Thai	17.1	197	200	JPN	200	3	2b	2.76	280%

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for
GENERAL POPULATION

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 70%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0226	Apple	-	0.08	USA	65.0	1348	138	USA	127	3	2a	1.97	10%
JF 0226	Apple juice	0.008	-	-	-	ND	-	-	ND	ND	3	ND	-
FS 0240	Apricot	-	0.33	FRA	52.2	369	35	USA	34	3	2a	2.75	10%
VS 0621	Asparagus	-	0.01	NLD	63.0	398	25	FRA	13	3	2a	0.07	0%
GC 0640	Barley	0.02	-	NLD	63.0	378	-	-	ND	ND	3	0.12	1%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.11	FRA	52.2	261	-	-	ND	ND	1	0.55	3%
VP 0062	Beans, shelled (immature seeds)	-	0.11	FRA	52.2	400	-	-	ND	ND	1	0.84	4%
FB 0018	Berries and other small fruits	-	0.09	AUS	67.0	750	-	-	ND	ND	1	1.01	5%
FB 0264	Blackberries	-	0.09	AUS	67.0	138	-	-	ND	ND	1	0.19	1%
FB 0020	Blueberries	-	0.09	AUS	67.0	158	-	-	ND	ND	1	0.21	1%
CM 0081	Bran, unprocessed of cereal grain (except buckwheat, canihua, quinoa)	0.045	-	AUS	67.0	37	-	-	ND	ND	3	0.02	0%
CP 0179	Bread & other cooked cereal products	0.01	-	JPN	52.6	378	-	-	ND	ND	3	0.07	0%
VD 0523	Broad bean (dry)	0.01	-	AUS	67.0	139	-	-	ND	ND	3	0.02	0%
VP 0522	Broad bean (green pods & immature seeds)	-	0.11	-	-	ND	-	-	ND	ND	1	ND	-
VP 0523	Broad bean, shelled (immature seeds)	-	0.11	NLD	63.0	387	-	-	ND	ND	1	0.68	3%
VB 0400	Broccoli	-	0.3	FRA	52.2	537	608	USA	474	3	2a	8.54	40%
VB 0041	Cabbages, Head	-	0.67	SAF	55.7	362	1650	BEL	1403	3	2b	13.07	70%
MF 0812	Cattle fat	-	2.2	USA	65.0	60	-	-	ND	ND	1	2.05	10%
VB 0404	Cauliflower (head)	-	0.3	UNK	70.1	579	575	USA	224	3	2a	4.40	20%
VC 0423	Chayote	-	0.02	AUS	67.0	196	-	-	ND	ND	1	0.06	0%
FS 0013	Cherries	-	0.18	FRA	52.2	360	5	JPN	5	1	1	1.24	6%
VD 0524	Chick-pea (dry)	0.01	-	USA	65.0	205	-	-	ND	ND	3	0.03	0%
VP 0526	Common bean (green pods and/or immature seeds)	-	0.11	NLD	63.0	431	-	-	ND	ND	1	0.75	4%
SO 0691	Cotton seed	0.01	-	USA	65.0	3	-	-	ND	ND	3	0.00	0%
OR 0691	Cotton seed oil, edible	0.001	-	USA	65.0	9	-	-	ND	ND	3	0.00	0%
VD 0527	Cowpea (dry)	0.01	-	USA	65.0	205	-	-	ND	ND	3	0.03	0%
VD 0527	Cowpea (dry), stated as black-eyed pea VD 4467	0.01	-	NLD	63.0	28	-	-	ND	ND	3	0.00	0%

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 70%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FB 0265	Cranberries	-	0.09	USA	65.0	229	-	-	ND	ND	1	0.32	2%
VC 0424	Cucumber	-	0.02	FRA	52.2	348	400	FRA	360	3	2b	0.40	2%
FB 0021	Currants, red, black, white	-	0.09	FRA	52.2	163	-	-	ND	ND	1	0.28	1%
FB 0266	Dewberries, incl boysen- & loganberry	-	0.09	AUS	67.0	152	-	-	ND	ND	1	0.20	1%
VO 0440	Egg plant	-	0.18	AUS	67.0	487	548	USA	444	3	2a	3.69	20%
FB 0267	Elderberries	-	0.09	NLD	63.0	21	-	-	ND	ND	1	0.03	0%
VA 0380	Fennel, bulb	-	0.11	FRA	52.2	401	234	USA	218	3	2a	1.76	9%
VD 0561	Field pea (dry)	0.01	-	FRA	52.2	356	-	-	ND	ND	3	0.07	0%
VD 0561	Field pea (dry), stated as pea (dry), VD 4511	0.01	-	NLD	63.0	252	-	-	ND	ND	3	0.04	0%
VP 0528	Garden pea (green pods & immature seeds)	-	0.11	USA	65.0	244	-	-	ND	ND	1	0.41	2%
VP 0529	Garden pea, shelled (immature seeds)	-	0.11	NLD	63.0	301	-	-	ND	ND	1	0.52	3%
VA 0381	Garlic	-	0.11	Thai	52.2	33	-	-	ND	ND	1	0.07	0%
VC 0425	Gherkin	-	0.02	NLD	63.0	96	15	FRA	15	1	1	0.03	0%
FB 0268	Gooseberries	-	0.09	-	-	ND	-	-	ND	ND	1	ND	-
FB 0269	Grape (excl wine)	-	0.09	AUS	67.0	513	125	FRA	118	3	1	0.69	3%
JF 0269	Grape juice	0.01	-	FRA	52.2	696	-	-	ND	ND	3	0.13	1%
FC 0203	Grapefruit	-	0.01	JPN	52.6	947	400	JPN	400	3	2a	0.33	2%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.27	USA	65.0	70	-	-	ND	ND	1	0.29	1%
MO 0098	Kidney of cattle, goats, pigs and sheep	-	0.09	USA	65.0	788	-	-	ND	ND	1	1.09	5%
VA 0384	Leek	-	0.11	FRA	52.2	177	100	FRA	50	3	2a	0.58	3%
FC 0204	Lemon	-	0.01	FRA	52.2	111	100	FRA	64	3	2a	0.05	0%
VD 0533	Lentil (dry)	0.01	-	FRA	52.2	614	-	-	ND	ND	3	0.12	1%
VP 0534	Lima bean (green pods & immature seeds)	-	0.11	USA	65.0	241	-	-	ND	ND	1	0.41	2%
FC 0205	Lime	-	0.01	AUS	67.0	590	67	USA	56	3	2a	0.10	1%
SO 0693	Linseed	0.01	-	NLD	63.0	21	-	-	ND	ND	3	0.00	0%
MO 0099	Liver of cattle, goats, pigs and sheep	-	0.02	USA	65.0	380	-	-	ND	ND	1	0.12	1%
VC 0427	Loofah, angled (= angled gourd)	-	0.02	Thai	53.5	215	-	-	ND	ND	1	0.08	0%
FP 0228	Loquat	-	0.08	AUS	67.0	64	-	-	ND	ND	ND	ND	-
GC 0645	Maize	0.01	-	FRA	52.2	212	-	-	ND	ND	3	0.04	0%
FC 0206	Mandarin	-	0.01	FRA	52.2	639	100	FRA	72	3	2a	0.15	1%

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 70%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0345	Mango	-	0.07	AUS	67.0	567	339	SWE	234	3	2a	1.08	5%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	2.2	AUS	67.0	104	-	-	ND	ND	1	3.42	20%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.1	AUS	67.0	417	-	-	ND	ND	1	0.62	3%
VC 0046	Melons, except watermelon	-	0.02	FRA	52.2	1044	700	FRA	420	3	2a	0.72	4%
ML 0106	Milks	0.08	-	USA	65.0	2466	-	-	ND	ND	3	3.04	20%
VD 0536	Mung bean (dry)	0.01	-	Thai	53.5	80	-	-	ND	ND	3	0.02	0%
SO 0090	Mustard seed, stated as mustard seed SO 0485	0.01	-	AUS	67.0	21	-	-	ND	ND	3	0.00	0%
FS 0245	Nectarine	-	0.33	FRA	52.2	604	136	USA	125	3	2a	5.40	30%
GC 0647	Oats	0.01	-	USA	65.0	175	-	-	ND	ND	3	0.03	0%
VO 0442	Okra	-	0.18	USA	65.0	235	10	JPN	10	1	1	0.65	3%
FT 0305	Olive	-	0.42	FRA	52.2	116	-	-	ND	ND	1	0.93	5%
OR 0305	Olive oil, refined	0.077	-	FRA	52.2	48	-	-	ND	ND	3	0.07	0%
-	Olive oil, residue oil	0.091	-	-	-	ND	-	-	ND	ND	3	ND	-
VA 0385	Onion, Bulb	-	0.11	NLD	63.0	172	110	USA	100	3	2a	0.65	3%
VA 0387	Onion, Welsh	-	0.11	JPN	52.6	99	100	JPN	100	3	2b	0.62	3%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.01	FRA	52.2	1044	190	FRA	137	3	2a	0.25	1%
OR 1240	Palm kernel oil, edible	0.01	-	FRA	52.2	10	-	-	ND	ND	3	0.00	0%
OR 0696	Palm oil, edible	0.01	-	NLD	63.0	7	-	-	ND	ND	3	0.00	0%
FS 0247	Peach	-	0.33	SAF	55.7	685	98	USA	85	3	2a	5.07	30%
OR 0697	Peanut oil, edible	0.01	-	AUS	67.0	54	-	-	ND	ND	3	0.01	0%
SO 0697	Peanut, shelled	0.01	-	FRA	52.2	135	-	-	ND	ND	3	0.03	0%
SO 0703	Peanut, whole in shell	-	0.15	SAF	55.7	144	-	-	ND	ND	1	0.39	2%
FP 0230	Pear	-	0.08	FRA	52.2	568	166	USA	151	3	2a	1.33	7%
VD 0072	Peas (dry)	0.01	-	FRA	52.2	356	-	-	ND	ND	3	0.07	0%
VP 0063	Peas (green pods & immature seeds)	-	0.11	JPN	52.6	63	-	-	ND	ND	1	0.13	1%
VP 0064	Peas, shelled (immature seeds)	-	0.11	FRA	52.2	435	-	-	ND	ND	1	0.92	5%
VO 0444	Peppers, Chilli	-	0.18	USA	65.0	90	45	USA	43	3	2a	0.49	2%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.18	FRA	52.2	90	172	UNK	160	3	2b	0.93	5%
VD 0537	Pigeon pea	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 70%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FS 0014	Plum (incl dried)	-	0.1	Thai	53.5	480	66	USA	62	3	2a	1.13	6%
GC 0656	Popcorn	0.01	-	JPN	52.6	175	-	-	ND	ND	3	0.03	0%
SO 0698	Poppy seed	0.01	-	AUS	67.0	9	-	-	ND	ND	3	0.00	0%
FP 0231	Quince	-	0.08	AUS	67.0	175	92	USA	56	3	2a	0.34	2%
OR 0495	Rape seed oil, edible	0.01	-	AUS	67.0	65	-	-	ND	ND	3	0.01	0%
FB 0272	Raspberries, red, black	-	0.09	FRA	52.2	251	-	-	ND	ND	1	0.43	2%
CM 1206	Rice bran, unprocessed	0.065	-	AUS	67.0	50	-	-	ND	ND	3	0.05	0%
CM 0649	Rice, husked	0.295	-	JPN	52.6	319	-	-	ND	ND	3	1.79	9%
CM 1205	Rice, polished	0.003	-	Thai	53.5	412	-	-	ND	ND	3	0.02	0%
VR 0075	Root and tuber vegetables	-	0	-	-	ND	-	-	ND	ND	ND	ND	-
FB 0273	Rose hips	-	0.09	NLD	63.0	25	-	-	ND	ND	1	0.04	0%
GC 0650	Rye	0.01	-	FRA	52.2	161	-	-	ND	ND	3	0.03	0%
OR 0699	Safflower seed oil, edible	0.01	-	AUS	67.0	19	-	-	ND	ND	3	0.00	0%
SO 0700	Sesame seed	0.01	-	Thai	53.5	24	-	-	ND	ND	3	0.00	0%
OR 0700	Sesame seed oil, edible	0.01	-	AUS	67.0	19	-	-	ND	ND	3	0.00	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.01	Thai	53.5	554	210	FRA	126	3	2a	0.15	1%
VA 0388	Shallot	-	0.11	AUS	67.0	71	-	-	ND	ND	1	0.12	1%
VC 0430	Snake gourd	-	0.02	Thai	53.5	215	-	-	ND	ND	1	0.08	0%
VD 0541	Soya bean (dry)	0.01	-	JPN	52.6	159	-	-	ND	ND	3	0.03	0%
VP 0541	Soya bean (immature seeds)	-	0.11	Thai	53.5	129	-	-	ND	ND	1	0.27	1%
OR 0541	Soya bean oil, refined	0.01	-	USA	65.0	98	-	-	ND	ND	3	0.02	0%
VA 0389	Spring onion	-	0.11	Thai	53.5	71	-	-	ND	ND	1	0.15	1%
VC 0431	Squash, summer (= courgette)	-	0.02	FRA	52.2	351	300	FRA	270	3	2a	0.34	2%
FB 0275	Strawberry	-	0.09	FRA	52.2	531	14	FRA	13	1	1	0.92	5%
GS 0659	Sugar cane	0.03	-	Thai	53.5	366	-	-	ND	ND	3	0.21	1%
DM 0659	Sugar cane molasses	0.001	-	AUS	67.0	214	-	-	ND	ND	3	0.00	0%
SO 0702	Sunflower seed	0.01	-	USA	65.0	193	-	-	ND	ND	3	0.03	0%
OR 0702	Sunflower seed oil, edible	0.01	-	FRA	52.2	54	-	-	ND	ND	3	0.01	0%
VO 0447	Sweet corn (corn-on-the-cob)	-	0.18	Thai	53.5	383	215	UNK	125	3	2a	2.13	10%
VO 0448	Tomato	-	0.18	FRA	52.2	387	105	FRA	102	3	2a	2.04	10%

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 70%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
JF 0448	Tomato juice	0.002	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	0.007	-	-	-	ND	-	-	ND	ND	ND	ND	-
TN 0085	Tree nuts	-	0.01	JPN	52.6	107	-	-	ND	ND	1	0.00	0%
FB 0019	Vaccinium berries (incl. Bearberry)	-	0.09	-	-	ND	-	-	ND	ND	1	ND	-
VC 0432	Watermelon	-	0.02	USA	65.0	1939	4518	USA	2078	3	2b	1.79	9%
GC 0654	Wheat	0.01	-	FRA	52.2	703	-	-	ND	ND	3	0.13	1%
CM 0654	Wheat bran, unprocessed	0.045	-	USA	65.0	80	-	-	ND	ND	3	0.06	0%
-	Wine	0.01	-	FRA	52.2	1006	-	-	ND	ND	3	0.19	1%
VC 0433	Winter squash (= pumpkin), stated as pumpkin, VC 0429	-	0.02	SAF	55.7	1003	1000	JPN	1000	3	2a	1.08	5%
VP 0544	Yard-long beans (green pods & immature seeds)	-	0.11	Thai	53.5	139	-	-	ND	ND	1	0.28	1%

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 160%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0204	Lemon	-	0.01	JPN	15.9	88	100	FRA	64	3	2a	0.14	1%
FP 0226	Apple	-	0.08	USA	15.0	679	138	USA	127	3	2a	4.97	20%
JF 0226	Apple juice	0.008	-	-	-	ND	-	-	ND	ND	3	ND	-
FS 0240	Apricot	-	0.33	AUS	19.0	414	35	USA	34	3	2a	8.36	40%
VS 0621	Asparagus	-	0.01	USA	15.0	178	25	FRA	13	3	2a	0.14	1%
GC 0640	Barley	0.02	-	AUS	19.0	14	-	-	ND	ND	3	0.01	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.11	FRA	18.9	215	-	-	ND	ND	1	1.25	6%
VP 0062	Beans, shelled (immature seeds)	-	0.11	FRA	18.9	220	-	-	ND	ND	1	1.28	6%
FB 0018	Berries and other small fruits	-	0.09	AUS	19.0	221	-	-	ND	ND	1	1.05	5%
FB 0264	Blackberries	-	0.09	FRA	18.9	50	-	-	ND	ND	1	0.24	1%
FB 0020	Blueberries	-	0.09	USA	15.0	21	-	-	ND	ND	1	0.13	1%
CM 0081	Bran, unprocessed of cereal grain (except buckwheat, canihua, quinoa)	0.045	-	AUS	19.0	13	-	-	ND	ND	3	0.03	0%
CP 0179	Bread & other cooked cereal products	0.01	-	JPN	15.9	227	-	-	ND	ND	3	0.14	1%
VD 0523	Broad bean (dry)	0.01	-	AUS	19.0	32	-	-	ND	ND	3	0.02	0%
VP 0522	Broad bean (green pods & immature seeds)	-	0.11	-	-	ND	-	-	ND	ND	1	ND	-
VP 0523	Broad bean, shelled (immature seeds)	-	0.11	-	-	ND	-	-	ND	ND	1	ND	-
VB 0400	Broccoli	-	0.3	FRA	18.9	254	608	USA	474	3	2b	12.11	60%
VB 0041	Cabbages, Head	-	0.67	SAF	14.2	220	1650	BEL	1403	3	2b	31.16	160%
MF 0812	Cattle fat	-	2.2	USA	15.0	27	-	-	ND	ND	1	3.96	20%
VB 0404	Cauliflower (head)	-	0.3	NLD	17.0	209	575	USA	224	3	2b	11.08	60%
VC 0423	Chayote	-	0.02	AUS	19.0	105	-	-	ND	ND	1	0.11	1%
FS 0013	Cherries	-	0.18	AUS	19.0	250	5	JPN	5	1	1	2.37	10%
VD 0524	Chick-pea (dry)	0.01	-	USA	15.0	34	-	-	ND	ND	3	0.02	0%
VP 0526	Common bean (green pods and/or immature seeds)	-	0.11	NLD	17.0	184	-	-	ND	ND	1	1.19	6%
SO 0691	Cotton seed	0.01	-	USA	15.0	1	-	-	ND	ND	3	0.00	0%
OR 0691	Cotton seed oil, edible	0.001	-	USA	15.0	6	-	-	ND	ND	3	0.00	0%
VD 0527	Cowpea (dry)	0.01	-	USA	15.0	43	-	-	ND	ND	3	0.03	0%

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 160%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VD 0527	Cowpea (dry), stated as black-eyed pea VD 4467	0.01	-	NLD	17.0	28	-	-	ND	ND	3	0.02	0%
FB 0265	Cranberries	-	0.09	USA	15.0	102	-	-	ND	ND	1	0.61	3%
VC 0424	Cucumber	-	0.02	NLD	17.0	162	400	FRA	360	3	2b	0.57	3%
FB 0021	Currants, red, black, white	-	0.09	AUS	19.0	584	-	-	ND	ND	1	2.77	10%
FB 0266	Dewberries, incl boysen- & loganberry	-	0.09	AUS	19.0	76	-	-	ND	ND	1	0.36	2%
VO 0440	Egg plant	-	0.18	JPN	15.9	219	548	USA	444	3	2b	7.45	40%
FB 0267	Elderberries	-	0.09	NLD	17.0	9	-	-	ND	ND	1	0.05	0%
VA 0380	Fennel, bulb	-	0.11	FRA	18.9	145	234	USA	218	3	2b	2.54	10%
VD 0561	Field pea (dry)	0.01	-	USA	15.0	11	-	-	ND	ND	3	0.01	0%
VD 0561	Field pea (dry), stated as pea (dry), VD 4511	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
VP 0528	Garden pea (green pods & immature seeds)	-	0.11	USA	15.0	109	-	-	ND	ND	1	0.80	4%
VP 0529	Garden pea, shelled (immature seeds)	-	0.11	NLD	17.0	146	-	-	ND	ND	1	0.94	5%
VA 0381	Garlic	-	0.11	FRA	18.9	4	-	-	ND	ND	1	0.02	0%
VC 0425	Gherkin	-	0.02	NLD	17.0	56	15	FRA	15	1	1	0.07	0%
FB 0268	Gooseberries	-	0.09	-	-	ND	-	-	ND	ND	1	ND	-
FB 0269	Grape (excl wine)	-	0.09	AUS	19.0	342	125	FRA	118	3	1	1.62	8%
JF 0269	Grape juice	0.01	-	FRA	18.9	500	-	-	ND	ND	3	0.26	1%
FC 0203	Grapefruit	-	0.01	FRA	18.9	405	400	JPN	400	3	2a	0.64	3%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.27	USA	15.0	59	-	-	ND	ND	1	1.07	5%
MO 0098	Kidney of cattle, goats, pigs and sheep	-	0.09	USA	15.0	187	-	-	ND	ND	1	1.12	6%
VA 0384	Leek	-	0.11	FRA	18.9	125	100	FRA	50	3	2a	1.31	7%
VD 0533	Lentil (dry)	0.01	-	FRA	18.9	291	-	-	ND	ND	3	0.15	1%
VP 0534	Lima bean (green pods & immature seeds)	-	0.11	USA	15.0	117	-	-	ND	ND	1	0.86	4%
FC 0205	Lime	-	0.01	AUS	19.0	26	67	USA	56	3	2b	0.04	0%
SO 0693	Linseed	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
MO 0099	Liver of cattle, goats, pigs and sheep	-	0.02	USA	15.0	136	-	-	ND	ND	1	0.18	1%
VC 0427	Loofah, angled (= angled gourd)	-	0.02	Thai	17.1	130	-	-	ND	ND	1	0.15	1%
FP 0228	Loquat	-	0.08	-	-	ND	-	-	ND	ND	ND	ND	-
GC 0645	Maize	0.01	-	FRA	18.9	117	-	-	ND	ND	3	0.06	0%
FC 0206	Mandarin	-	0.01	JPN	15.9	353	100	FRA	72	3	2a	0.31	2%

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 160%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0345	Mango	-	0.07	Thai	17.1	191	339	SWE	234	3	2b	2.35	10%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	2.2	AUS	19.0	52	-	-	ND	ND	1	6.03	30%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.1	AUS	19.0	208	-	-	ND	ND	1	1.10	5%
VC 0046	Melons, except watermelon	-	0.02	FRA	18.9	597	700	FRA	420	3	2a	1.52	8%
ML 0106	Milks	0.08	-	USA	15.0	1286	-	-	ND	ND	3	6.86	30%
VD 0536	Mung bean (dry)	0.01	-	Thai	17.1	56	-	-	ND	ND	3	0.03	0%
SO 0090	Mustard seed, stated as mustard seed SO 0485	0.01	-	AUS	19.0	13	-	-	ND	ND	3	0.01	0%
FS 0245	Nectarine	-	0.33	AUS	19.0	302	136	USA	125	3	2a	9.59	50%
GC 0647	Oats	0.01	-	USA	15.0	62	-	-	ND	ND	3	0.04	0%
VO 0442	Okra	-	0.18	USA	15.0	203	10	JPN	10	1	1	2.43	10%
FT 0305	Olive	-	0.42	FRA	18.9	202	-	-	ND	ND	1	4.48	20%
OR 0305	Olive oil, refined	0.077	-	FRA	18.9	25	-	-	ND	ND	3	0.10	1%
-	Olive oil, residue oil	0.091	-	-	-	ND	-	-	ND	ND	3	ND	-
VA 0385	Onion, Bulb	-	0.11	NLD	17.0	86	110	USA	100	3	2b	1.66	8%
VA 0387	Onion, Welsh	-	0.11	JPN	15.9	49	100	JPN	100	3	2b	1.01	5%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.01	UNK	14.5	495	190	FRA	137	3	2a	0.53	3%
OR 1240	Palm kernel oil, edible	0.01	-	FRA	18.9	5	-	-	ND	ND	3	0.00	0%
OR 0696	Palm oil, edible	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
FS 0247	Peach	-	0.33	AUS	19.0	315	98	USA	85	3	2a	8.44	40%
OR 0697	Peanut oil, edible	0.01	-	AUS	19.0	9	-	-	ND	ND	3	0.00	0%
SO 0697	Peanut, shelled	0.01	-	USA	15.0	78	-	-	ND	ND	3	0.05	0%
SO 0703	Peanut, whole in shell	-	0.15	SAF	14.2	50	-	-	ND	ND	1	0.53	3%
FP 0230	Pear	-	0.08	UNK	14.5	279	166	USA	151	3	2a	3.21	20%
VD 0072	Peas (dry)	0.01	-	USA	15.0	86	-	-	ND	ND	3	0.06	0%
VP 0063	Peas (green pods & immature seeds)	-	0.11	JPN	15.9	48	-	-	ND	ND	1	0.33	2%
VP 0064	Peas, shelled (immature seeds)	-	0.11	UNK	14.5	174	-	-	ND	ND	1	1.32	7%
VO 0444	Peppers, Chilli	-	0.18	AUS	19.0	31	45	USA	43	3	2b	0.87	4%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.18	Thai	17.1	71	172	UNK	160	3	2b	2.25	10%
VD 0537	Pigeon pea	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 160%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FS 0014	Plum (incl dried)	-	0.1	Thai	17.1	377	66	USA	62	3	2a	2.93	10%
GC 0656	Popcorn	0.01	-	JPN	15.9	53	-	-	ND	ND	3	0.03	0%
SO 0698	Poppy seed	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
FP 0231	Quince	-	0.08	NLD	17.0	1	92	USA	56	3	2b	0.01	0%
OR 0495	Rape seed oil, edible	0.01	-	AUS	19.0	18	-	-	ND	ND	3	0.01	0%
FB 0272	Raspberries, red, black	-	0.09	FRA	18.9	157	-	-	ND	ND	1	0.75	4%
CM 1206	Rice bran, unprocessed	0.065	-	USA	15.0	3	-	-	ND	ND	3	0.01	0%
CM 0649	Rice, husked	0.295	-	FRA	18.9	121	-	-	ND	ND	3	1.89	9%
CM 1205	Rice, polished	0.003	-	JPN	15.9	199	-	-	ND	ND	3	0.04	0%
VR 0075	Root and tuber vegetables	-	0	-	-	ND	-	-	ND	ND	ND	ND	-
FB 0273	Rose hips	-	0.09	NLD	17.0	16	-	-	ND	ND	1	0.08	0%
GC 0650	Rye	0.01	-	NLD	17.0	37	-	-	ND	ND	3	0.02	0%
OR 0699	Safflower seed oil, edible	0.01	-	FRA	18.9	1	-	-	ND	ND	3	0.00	0%
SO 0700	Sesame seed	0.01	-	Thai	17.1	20	-	-	ND	ND	3	0.01	0%
OR 0700	Sesame seed oil, edible	0.01	-	AUS	19.0	5	-	-	ND	ND	3	0.00	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.01	Thai	17.1	327	210	FRA	126	3	2a	0.34	2%
VA 0388	Shallot	-	0.11	AUS	19.0	18	-	-	ND	ND	1	0.10	1%
VC 0430	Snake gourd	-	0.02	Thai	17.1	130	-	-	ND	ND	1	0.15	1%
VD 0541	Soya bean (dry)	0.01	-	JPN	15.9	88	-	-	ND	ND	3	0.06	0%
VP 0541	Soya bean (immature seeds)	-	0.11	Thai	17.1	66	-	-	ND	ND	1	0.42	2%
OR 0541	Soya bean oil, refined	0.01	-	USA	15.0	35	-	-	ND	ND	3	0.02	0%
VA 0389	Spring onion	-	0.11	Thai	17.1	53	-	-	ND	ND	1	0.34	2%
VC 0431	Squash, summer (= courgette)	-	0.02	AUS	19.0	219	300	FRA	270	3	2b	0.69	3%
FB 0275	Strawberry	-	0.09	FRA	18.9	354	14	FRA	13	1	1	1.68	8%
GS 0659	Sugar cane	0.03	-	Thai	17.1	181	-	-	ND	ND	3	0.32	2%
DM 0659	Sugar cane molasses	0.001	-	AUS	19.0	168	-	-	ND	ND	3	0.01	0%
SO 0702	Sunflower seed	0.01	-	USA	15.0	24	-	-	ND	ND	3	0.02	0%
OR 0702	Sunflower seed oil, edible	0.01	-	FRA	18.9	27	-	-	ND	ND	3	0.01	0%
VO 0447	Sweet corn (corn-on-the-cob)	-	0.18	Thai	17.1	197	215	UNK	125	3	2a	4.70	20%
VO 0448	Tomato	-	0.18	FRA	18.9	215	105	FRA	102	3	2a	3.99	20%

Annex 4

CYHALOTHRIN (146) (including Lambda-cyhalothrin)

International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 160%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
JF 0448	Tomato juice	0.002	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	0.007	-	-	-	ND	-	-	ND	ND	ND	ND	-
TN 0085	Tree nuts	-	0.01	AUS	19.0	28	-	-	ND	ND	1	0.00	0%
FB 0019	Vaccinium berries (incl. Bearberry)	-	0.09	-	-	ND	-	-	ND	ND	1	ND	-
VC 0432	Watermelon	-	0.02	AUS	19.0	1473	4518	USA	2078	3	2b	4.65	20%
GC 0654	Wheat	0.01	-	FRA	18.9	384	-	-	ND	ND	3	0.20	1%
CM 0654	Wheat bran, unprocessed	0.045	-	USA	15.0	30	-	-	ND	ND	3	0.09	0%
-	Wine	0.01	-	FRA	18.9	89	-	-	ND	ND	3	0.05	0%
VC 0433	Winter squash (= pumpkin), stated as pumpkin, VC 0429	-	0.02	SAF	14.2	224	1000	JPN	1000	3	2b	0.95	5%
VP 0544	Yard-long beans (green pods & immature seeds)	-	0.11	Thai	17.1	79	-	-	ND	ND	1	0.51	3%

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)
Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight,g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0226	Apple	-	0.56	USA	65.0	1348	138	USA	127	3	2a	13.80	30%
VS 0620	Artichoke globe	-	0.04	FRA	62.3	534	230	FRA	99	3	2a	0.47	1%
VS 0621	Asparagus	-	0.01	NLD	63.0	398	25	FRA	13	3	2a	0.07	0%
GC 0640	Barley	0.035	-	NLD	63.0	378	-	-	ND	ND	3	0.21	1%
-	Barley beer	0.001	-	-	-	ND	-	-	ND	ND	3	ND	-
VD 0071	Beans (dry)	0.05	-	FRA	62.3	255	-	-	ND	ND	3	0.21	1%
VP 0062	Beans, shelled (immature seeds)	-	0.45	FRA	62.3	312	-	-			1	2.25	6%
VB 0400	Broccoli	-	0.65	USA	65.0	376	310	BEL	186	3	2a	7.48	20%
VB 0402	Brussels sprouts	-	0.65	NLD	63.0	394	10	UNK	7	1	1	4.06	10%
VB 0041	Cabbages, Head	-	0.65	SAF	55.7	362	771	UNK	540	3	2b	12.68	30%
FT 0289	Carambola (= star fruit)	-	0.09	Thai	53.5	388	-	-	ND	ND	ND	ND	-
VR 0577	Carrot	-	0.01	NLD	63.0	335	100	FRA	89	3	2a	0.08	0%
VB 0404	Cauliflower (head)	-	0.65	UNK	70.1	579	1000	BEL	640	3	2b	16.11	40%
FS 0013	Cherries	-	0.94	FRA	62.3	375	5	FRA	4	1	1	5.66	10%
SB 0716	Coffee beans	0	-	NLD	63.0	66	-	-	ND	ND	3	0.00	0%
VP 0526	Common bean (green pods and/or immature seeds)	-	0.45	NLD	63.0	431	-	-			1	3.08	8%
SO 0691	Cotton seed	0.05	-	USA	65.0	3	-	-	ND	ND	3	0.00	0%
VC 0424	Cucumber	-	0.05	NLD	63.0	313	400	FRA	360	3	2b	0.75	2%
FI 0334	Durian	-	0.47	Thai	53.5	471	3000	Thai	930	3	2b	12.41	30%
MO 0105	Edible offal (mammalian)	-	0.04	FRA	62.3	277	-	-	ND	ND	1	0.18	0%
VO 0440	Egg plant	-	0.02	AUS	67.0	487	80	JPN	80	3	2a	0.19	0%
PE 0112	Eggs	-	0.0033	Thai	53.5	195	-	-	ND	ND	1	0.01	0%
VL 0476	Endive	-	0.52	NLD	63.0	404	-	-	ND	ND	ND	ND	-
VD 0561	Field pea (dry), stated as pea (dry), VD 4511	0.05	-	NLD	63.0	252	-	-	ND	ND	3	0.20	1%
FB 0269	Grape (excl wine)	-	0.09	AUS	67.0	513	150	JPN	150	3	2a	1.09	3%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.3	FRA	62.3	135	-	-	ND	ND	1	0.65	2%
VA 0384	Leek	-	0.03	FRA	62.3	374	100	FRA	50	3	2a	0.23	1%
VL 0482	Lettuce, head	-	0.52	USA	65.0	213	539	USA	512	3	2b	5.10	10%

Annex 4

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)
Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0343	Litchi	-	0.79	Thai	53.5	264	33	Thai	21	3	2a	4.51	10%
FI 0342	Longan	-	0.47	Thai	53.5	389	10	Thai	7	1	1	3.42	9%
GC 0645	Maize	0.035	-	FRA	62.3	260	-	-	ND	ND	3	0.15	0%
FI 0345	Mango	-	0.35	FRA	62.3	567	207	USA	139	3	2a	4.74	10%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.76	AUS	67.0	104	-	-	ND	ND	1	1.18	3%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.04	AUS	67.0	417	-	-	ND	ND	1	0.25	1%
VC 0046	Melons, except watermelon	-	0.01	USA	65.0	655	700	FRA	420	3	2a	0.23	1%
ML 0106	Milks	0.011	-	USA	65.0	2466	-	-	ND	ND	3	0.42	1%
GC 0647	Oats	0.035	-	FRA	62.3	305	-	-	ND	ND	3	0.17	0%
VO 0442	Okra	-	0.2	USA	65.0	235	10	JPN	10	1	1	0.72	2%
FT 0305	Olive	-	0.05	NLD	63.0	63	-	-	ND	ND	ND	ND	-
VA 0385	Onion, Bulb	-	0.01	FRA	62.3	306	140	FRA	126	3	2a	0.09	0%
FI 0350	Papaya	-	0.23	USA	65.0	567	304	USA	204	3	2a	3.45	9%
FS 0247	Peach	-	0.94	SAF	55.7	685	98	USA	85	3	2a	14.44	40%
FP 0230	Pear	-	0.56	USA	65.0	693	166	USA	151	3	2a	8.57	20%
VD 0072	Peas (dry)	0.05	-	FRA	62.3	445	-	-	ND	ND	3	0.36	1%
VP 0063	Peas (green pods & immature seeds)	-	0.45	JPN	52.6	63	-	-			1.00	0.54	1%
VP 0064	Peas, shelled (immature seeds)	-	0.45	UNK	70.1	437	-	-			1.00	2.80	7%
VO 0444	Peppers, Chilli	-	0.69	USA	65.0	90	45	USA	43	3	2a	1.88	5%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.07	FRA	62.3	207	40	JPN	40	3	2a	0.32	1%
FS 0014	Plum (incl dried)	-	0.94	Thai	53.5	480	66	USA	62	3	2a	10.61	30%
DF 0014	Plum, dried (prunes)	-	3	USA	65.0	303	6	FRA	5	1	1	13.98	30%
VR 0589	Potato	-	0.01	NLD	63.0	687	200	FRA	160	3	2a	0.16	0%
PM 0110	Poultry meat: 10% as fat	-	0.027	AUS	67.0	43	-	-	ND	ND	1	0.02	0%
PM 0110	Poultry meat: 90% as muscle	-	0.007	AUS	67.0	388	-	-	ND	ND	1	0.04	0%
PO 0111	Poultry, Edible offal of	-	0.007	USA	65.0	248	-	-	ND	ND	1	0.03	0%
OR 0495	Rape seed oil, edible	0.06	-	AUS	67.0	65	-	-	ND	ND	3	0.06	0%
GC 0649	Rice	0.57	-	FRA	62.3	312	-	-	ND	ND	3	2.85	7%
VD 0541	Soya bean (dry)	0.05	-	JPN	52.6	159	-	-	ND	ND	3	0.15	0%
VL 0502	Spinach (bunch)	-	0.52	NLD	63.0	820	340	USA	245	3	2a	10.81	30%

Annex 4

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)
Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FB 0275	Strawberry	-	0.05	FRA	62.3	346	14	FRA	13	1	1	0.28	1%
GS 0659	Sugar cane	-	0.17	Thai	53.5	366	-	-	ND	ND	ND	ND	-
VO 0447	Sweet corn (corn-on-the-cob)	-	0	Thai	53.5	383	215	UNK	125	3	2a	0.00	0%
VO 0448	Tomato	-	0.08	USA	65.0	391	123	USA	123	3	2a	0.78	2%
GC 0654	Wheat	0.035	-	USA	65.0	383	-	-	ND	ND	3	0.21	1%
CM 0654	Wheat bran, unprocessed	0.084	-	USA	65.0	80	-	-	ND	ND	ND	ND	-
-	Wine	0.001	-	AUS	67.0	1131	-	-	ND	ND	3	0.02	0%

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)
Maximum %ARfD: 90%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0226	Apple	-	0.56	USA	15.0	679	138	USA	127	3	2a	34.82	90%
VS 0620	Artichoke globe	-	0.04	FRA	17.8	89	230	FRA	99	3	2b	0.60	2%
VS 0621	Asparagus	-	0.01	USA	15.0	178	25	FRA	13	3	2a	0.14	0%
GC 0640	Barley	0.035	-	AUS	19.0	14	-	-	ND	ND	3	0.03	0%
-	Barley beer	0.001	-	-	-	ND	-	-	ND	ND	3	ND	-
VD 0071	Beans (dry)	0.05	-	FRA	17.8	209	-	-	ND	ND	3	0.59	1%
VP 0062	Beans, shelled (immature seeds)	-	0.45	FRA	17.8	198	-	-			1	5.00	10%
VB 0400	Broccoli	-	0.65	USA	15.0	164	310	BEL	186	3	2b	21.35	50%
VB 0402	Brussels sprouts	-	0.65	NLD	17.0	213	10	UNK	7	1	1	8.13	20%
VB 0041	Cabbages, Head	-	0.65	SAF	14.2	220	771	UNK	540	3	2b	30.23	80%
FT 0289	Carambola (= star fruit)	-	0.09	Thai	17.1	245	-	-	ND	ND	ND	ND	-
VR 0577	Carrot	-	0.01	FRA	17.8	205	100	FRA	89	3	2a	0.22	1%
VB 0404	Cauliflower (head)	-	0.65	NLD	17.0	209	1000	BEL	640	3	2b	24.00	60%
FS 0013	Cherries	-	0.94	FRA	17.8	297	5	FRA	4	1	1	15.67	40%
SB 0716	Coffee beans	0	-	NLD	17.0	19	-	-	ND	ND	3	0.00	0%

Annex 4

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)
Maximum %ARfD: 90%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VP 0526	Common bean (green pods and/or immature seeds)	-	0.45	NLD	17.0	184	-	-			1	4.87	10%
SO 0691	Cotton seed	0.05	-	USA	15.0	1	-	-	ND	ND	3	0.00	0%
VC 0424	Cucumber	-	0.05	NLD	17.0	162	400	FRA	360	3	2b	1.43	4%
FI 0334	Durian	-	0.47	Thai	17.1	289	-	-	ND	ND	ND	ND	-
MO 0105	Edible offal (mammalian)	-	0.04	FRA	17.8	203	-	-	ND	ND	1	0.46	1%
VO 0440	Egg plant	-	0.02	JPN	15.9	219	80	JPN	80	3	2a	0.48	1%
PE 0112	Eggs	-	0.0033	Thai	17.1	109	-	-	ND	ND	1	0.02	0%
VL 0476	Endive	-	0.52	NLD	17.0	212	-	-	ND	ND	ND	ND	-
VD 0561	Field pea (dry), stated as pea (dry), VD 4511	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
FB 0269	Grape (excl wine)	-	0.09	AUS	19.0	342	150	JPN	150	3	2a	3.04	8%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.3	USA	15.0	59	-	-	ND	ND	1	1.19	3%
VA 0384	Leek	-	0.03	FRA	17.8	121	100	FRA	50	3	2a	0.37	1%
VL 0482	Lettuce, head	-	0.52	Thai	17.1	117	539	USA	512	3	2b	10.65	30%
FI 0343	Litchi	-	0.79	Thai	17.1	147	-	-	ND	ND	ND	ND	-
FI 0342	Longan	-	0.47	Thai	17.1	232	-	-	ND	ND	ND	ND	-
GC 0645	Maize	0.035	-	FRA	17.8	148	-	-	ND	ND	3	0.29	1%
FI 0345	Mango	-	0.35	Thai	17.1	191	207	USA	139	3	2a	9.59	20%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.76	AUS	19.0	52	-	-	ND	ND	1	2.08	5%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.04	AUS	19.0	208	-	-	ND	ND	1	0.44	1%
VC 0046	Melons, except watermelon	-	0.01	AUS	19.0	413	700	FRA	420	3	2b	0.65	2%
ML 0106	Milks	0.011	-	USA	15.0	1286	-	-	ND	ND	3	0.94	2%
GC 0647	Oats	0.035	-	USA	15.0	62	-	-	ND	ND	3	0.15	0%
VO 0442	Okra	-	0.2	USA	15.0	203	10	JPN	10	1	1	2.70	7%
FT 0305	Olive	-	0.05	FRA	17.8	49	-	-	ND	ND	ND	ND	-
VA 0385	Onion, Bulb	-	0.01	FRA	17.8	127	140	FRA	126	3	2a	0.21	1%
FI 0350	Papaya	-	0.23	USA	15.0	240	304	USA	204	3	2a	9.93	20%
FS 0247	Peach	-	0.94	AUS	19.0	315	98	USA	85	3	2a	24.05	60%
FP 0230	Pear	-	0.56	UNK	14.5	279	166	USA	151	3	2a	22.44	60%

Annex 4

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)
Maximum %ARfD: 90%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VD 0072	Peas (dry)	0.05	-	FRA	17.8	107	-	-	ND	ND	3	0.30	1%
VP 0063	Peas (green pods & immature seeds)	-	0.45	JPN	15.9	48	-	-			1	1.35	3%
VP 0064	Peas, shelled (immature seeds)	-	0.45	UNK	14.5	174	-	-			1	5.40	10%
VO 0444	Peppers, Chilli	-	0.69	AUS	19.0	31	45	USA	43	3	2b	3.32	8%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.07	Thai	17.1	71	40	JPN	40	3	2a	0.62	2%
FS 0014	Plum (incl dried)	-	0.94	Thai	17.1	377	66	USA	62	3	2a	27.54	70%
DF 0014	Plum, dried (prunes)	-	3	AUS	19.0	170	6	FRA	5	1	1	26.85	70%
VR 0589	Potato	-	0.01	SAF	14.2	300	200	FRA	160	3	2a	0.44	1%
PM 0110	Poultry meat: 10% as fat	-	0.027	AUS	19.0	22	-	-	ND	ND	1	0.03	0%
PM 0110	Poultry meat: 90% as muscle	-	0.007	AUS	19.0	201	-	-	ND	ND	1	0.07	0%
PO 0111	Poultry, Edible offal of	-	0.007	USA	15.0	37	-	-	ND	ND	1	0.02	0%
OR 0495	Rape seed oil, edible	0.06	-	AUS	19.0	18	-	-	ND	ND	3	0.06	0%
GC 0649	Rice	0.57	-	FRA	17.8	223	-	-	ND	ND	3	7.13	20%
VD 0541	Soya bean (dry)	0.05	-	JPN	15.9	88	-	-	ND	ND	3	0.28	1%
VL 0502	Spinach (bunch)	-	0.52	SAF	14.2	420	340	USA	245	3	2a	33.32	80%
FB 0275	Strawberry	-	0.05	AUS	19.0	176	14	FRA	13	1	1	0.46	1%
GS 0659	Sugar cane	-	0.17	Thai	17.1	181	-	-	ND	ND	ND	ND	-
VO 0447	Sweet corn (corn-on-the-cob)	-	0	Thai	17.1	197	215	UNK	125	3	2a	0.00	0%
VO 0448	Tomato	-	0.08	USA	15.0	159	123	USA	123	3	2a	2.16	5%
GC 0654	Wheat	0.035	-	USA	15.0	151	-	-	ND	ND	3	0.35	1%
CM 0654	Wheat bran, unprocessed	0.084	-	USA	15.0	30	-	-	ND	ND	ND	ND	-
-	Wine	0.001	-	AUS	19.0	4	-	-	ND	ND	3	0.00	0%

Annex 4

DIMETHOATE (027) International estimate of short term intake (IESTI) for GENERAL POPULATION — Acute RfD =0.02 mg/kg bw (20 µg/kg bw) — Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet						Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
				Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g				
VL 0482	Lettuce, head	-	0.76	USA	65.0	213	558	UNK	413	3	2b	7.46	40%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	1.3	FRA	52.2	90	172	UNK	160	3	2b	6.75	30%

DIMETHOATE (027) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS** — Acute RfD =0.02 mg/kg bw (20 µg/kg bw) — Maximum %ARfD: 80%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet						Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
				Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g				
VL 0482	Lettuce, head	-	0.76	Thai	17.1	117	558	UNK	413	3	2b	15.57	80%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	1.3	Thai	17.1	71	172	UNK	160	3	2b	16.22	80%

ETHOXYQUIN (035) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)
Maximum %ARfD: 20%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0230	Pear	-	6	FRA	52.2	568	166	USA	151	3	2a	100.01	20%

ETHOXYQUIN (035) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)
Maximum %ARfD: 50%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0230	Pear	-	6	UNK	14.5	279	166	USA	151	3	2a	240.46	50%

Annex 4

IMIDACLOPRID (206) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.4 mg/kg bw (400 µg/kg bw)
Maximum %ARfD: 10%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion. g/person	Unit weight Unit weight. g	Country	Unit weight. edible portion. g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
TN 0085	Tree nuts	-	0.01	JPN	52.6	107	-	-	ND	ND	1	0.02	0%
TN 0660	Almonds	-	0.01	JPN	52.6	74	-	-	ND	ND	1	0.01	0%
VR 0574	Beetroot	-	0.28	NLD	63.0	414	62	USA	43	3	2a	2.23	1%
FB 0264	Blackberries	-	2.8	AUS	67.0	138	-	-	ND	ND	1	5.77	1%
FB 0020	Blueberries	-	2.8	AUS	67.0	158	-	-	ND	ND	1	6.61	2%
FB 4079	Boysenberry	-	2.8	AUS	67.0	21	-	-	ND	ND	1	0.90	0%
VR 0577	Carrot	-	0.28	NLD	63.0	335	61	USA	50	3	2a	1.93	0%
TN 0295	Cashew nut	-	0.01	Thai	53.5	200	-	-	ND	ND	1	0.04	0%
VR 0463	Cassava	-	0.28	Thai	53.5	161	-	-	ND	ND	1	0.84	0%
VR 0578	Celeriac	-	0.28	FRA	62.3	374	156	USA	134	3	2a	2.89	1%
TN 0664	Chestnuts	-	0.01	AUS	67.0	400	-	-	ND	ND	1	0.06	0%
FB 0265	Cranberries	-	2.8	USA	65.0	229	-	-	ND	ND	1	9.88	2%
FB 0278	Currant, black	-	2.8	UNK	70.1	1036	-	-	ND	ND	1	41.38	10%
FB 0279	Currant, red, white	-	2.8	FRA	62.3	153	-	-	ND	ND	1	6.89	2%
FB 0021	Currants, red, black, white	-	2.8	FRA	62.3	153	-	-	ND	ND	1	6.89	2%
FB 0266	Dewberries, incl boysen- & loganberry	-	2.8	AUS	67.0	152	-	-	ND	ND	1	6.36	2%
MO 0105	Edible offal (mammalian)	-	0.18	FRA	62.3	277	-	-	ND	ND	1	0.80	0%
PE 0112	Eggs	-	0.007	Thai	53.5	195	-	-	ND	ND	1	0.03	0%
FB 0267	Elderberries	-	2.8	NLD	63.0	21	-	-	ND	ND	1	0.95	0%
VP 0528	Garden pea (green pods & immature seeds)	-	3.8	USA	65.0	244	-	-	ND	ND	1	14.29	4%
VP 0529	Garden pea, shelled (immature seeds)	-	1.1	NLD	63.0	301	-	-	ND	ND	1	5.25	1%
FB 0268	Gooseberries	-	2.8	FRA	62.3	153	-	-	ND	ND	1	6.89	2%
TN 0666	Hazelnut	-	0.01	AUS	67.0	70	-	-	ND	ND	1	0.01	0%
VR 0585	Jerusalem artichoke	-	0.28	AUS	67.0	10	150	USA	104	3	2b	0.13	0%
TN 0669	Macadamia nut	-	0.01	USA	65.0	107	-	-	ND	ND	1	0.02	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.02	AUS	67.0	104	-	-	ND	ND	1	0.03	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.04	AUS	67.0	417	-	-	ND	ND	1	0.25	0%

Annex 4

IMIDACLOPRID (206) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.4 mg/kg bw (400 µg/kg bw)
Maximum %ARfD: 10%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion. g/person	Unit weight Unit weight. g	Country	Unit weight. edible portion. g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
ML 0106	Milks	0.018	-	USA	65.0	2466	-	-	ND	ND	3	0.68	0%
VR 0588	Parsnip	-	0.28	UNK	70.1	202	133	USA	113	3	2a	1.71	0%
SO 0697	Peanut, shelled	-	0.40	FRA	62.3	161	-	-	ND	ND	1	1.04	0%
VD 0072	Peas (dry)	0.62	-	FRA	62.3	445	-	-	ND	ND	3	4.43	1%
VP 0063	Peas (green pods & immature seeds)	-	3.8	JPN	52.6	63	-	-	ND	ND	1	4.52	1%
VP 0064	Peas, shelled (immature seeds)	-	1.1	UNK	70.1	437	-	-	ND	ND	1	6.85	2%
TN 0672	Pecan	-	0.01	AUS	67.0	23	-	-	ND	ND	1	0.00	0%
TN 0673	Pine nut	-	0.01	AUS	67.0	47	-	-	ND	ND	1	0.01	0%
TN 0675	Pistachio nut	-	0.01	AUS	67.0	300	-	-	ND	ND	1	0.04	0%
VR 0589	Potato	-	0.28	NLD	63.0	687	122	USA	99	3	2a	3.93	1%
PM 0110	Poultry meat: 10% as fat	-	0.001	AUS	67.0	43	-	-	ND	ND	1	0.00	0%
PM 0110	Poultry meat: 90% as muscle	-	0.003	AUS	67.0	388	-	-	ND	ND	1	0.02	0%
PO 0111	Poultry, Edible offal of	-	0.02	USA	65.0	248	-	-	ND	ND	1	0.08	0%
VR 0494	Radish	-	0.28	FRA	62.3	204	8	UNK	7	1	1	0.92	0%
VR 0591	Radish, Japanese	-	0.28	JPN	52.6	267	1000	JPN	1000	3	2b	4.26	1%
FB 0272	Raspberries, red, black	-	2.8	FRA	62.3	324	-	-	ND	ND	1	14.56	4%
FB 0273	Rose hips	-	2.8	NLD	63.0	25	-	-	ND	ND	1	1.12	0%
VR 0498	Salsify	-	0.28	UNK	70.1	334	-	-	ND	ND	1	1.33	0%
FB 0275	Strawberry	-	0.35	FRA	62.3	346	13	UNK	12	1	1	1.94	0%
SO 0702	Sunflower seed	0.05	-	USA	65.0	193	-	-	ND	ND	3	0.15	0%
VR 0497	Swede	-	0.28	FRA	62.3	204	-	-	ND	ND	1	0.92	0%
VR 0508	Sweet potato	-	0.28	USA	65.0	536	130	USA	105	3	2a	3.21	1%
VR 0506	Turnip, garden	-	0.28	USA	65.0	235	122	USA	105	3	2a	1.91	0%
TN 0678	Walnut	-	0.01	FRA	62.3	136	-	-	ND	ND	1	0.02	0%

Annex 4

IMIDACLOPRID (206) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.4 mg/kg bw (400 µg/kg bw)
Maximum %ARfD: 50%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion. g/person	Unit weight Unit weight. g	Country	Unit weight. edible portion. g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
TN 0085	Tree nuts	-	0.01	AUS	19.0	28	-	-	ND	ND	1	0.01	0%
TN 0660	Almonds	-	0.01	FRA	17.8	31	-	-	ND	ND	1	0.02	0%
VR 0574	Beetroot	-	0.28	FRA	17.8	223	62	USA	43	3	2a	4.87	1%
FB 0264	Blackberries	-	2.8	FRA	17.8	48	-	-	ND	ND	1	7.48	2%
FB 0020	Blueberries	-	2.8	FRA	17.8	138	-	-	ND	ND	1	21.76	5%
FB 4079	Boysenberry	-	2.8	USA	15.0	2	-	-	ND	ND	1	0.34	0%
VR 0577	Carrot	-	0.28	FRA	17.8	205	61	USA	50	3	2a	4.79	1%
TN 0295	Cashew nut	-	0.01	Thai	17.1	99	-	-	ND	ND	1	0.06	0%
VR 0463	Cassava	-	0.28	Thai	17.1	113	-	-	ND	ND	1	1.86	0%
VR 0578	Celeriac	-	0.28	FRA	17.8	108	156	USA	134	3	2b	5.08	1%
TN 0664	Chestnuts	-	0.01	Thai	17.1	122	-	-	ND	ND	1	0.07	0%
FB 0265	Cranberries	-	2.8	USA	15.0	102	-	-	ND	ND	1	18.98	5%
FB 0278	Currant, black (note 1)	-	2.8	UNK	14.5	1054	-	-	ND	ND	1	203.53	50%
FB 0279	Currant, red, white	-	2.8	-	-	ND	-	-	ND	ND	1	ND	-
FB 0021	Currants, red, black, white	-	2.8	AUS	19.0	584	-	-	ND	ND	1	86.10	20%
FB 0266	Dewberries, incl boysen- & loganberry	-	2.8	AUS	19.0	76	-	-	ND	ND	1	11.20	3%
MO 0105	Edible offal (mammalian)	-	0.18	FRA	17.8	203	-	-	ND	ND	1	2.05	1%
PE 0112	Eggs	-	0.007	Thai	17.1	109	-	-	ND	ND	1	0.04	0%
FB 0267	Elderberries	-	2.8	NLD	17.0	9	-	-	ND	ND	1	1.46	0%
VP 0528	Garden pea (green pods & immature seeds)	-	3.8	USA	15.0	109	-	-	ND	ND	1	27.70	7%
VP 0529	Garden pea, shelled (immature seeds)	-	1.1	NLD	17.0	146	-	-	ND	ND	1	9.45	2%
FB 0268	Gooseberries	-	2.8	-	-	ND	-	-	ND	ND	1	ND	-
TN 0666	Hazelnut	-	0.01	NLD	17.0	11	-	-	ND	ND	1	0.01	0%
VR 0585	Jerusalem artichoke	-	0.28	-	-	ND	150	USA	104	3	ND	ND	-
TN 0669	Macadamia nut	-	0.01	-	-	ND	-	-	ND	ND	1	ND	-
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.02	AUS	19.0	52	-	-	ND	ND	1	0.05	0%

Annex 4

IMIDACLOPRID (206) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.4 mg/kg bw (400 µg/kg bw)
Maximum %ARfD: 50%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion. g/person	Unit weight Unit weight. g	Country	Unit weight. edible portion. g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.04	AUS	19.0	208	-	-	ND	ND	1	0.44	0%
ML 0106	Milks	0.018	-	USA	15.0	1286	-	-	ND	ND	3	1.54	0%
VR 0588	Parsnip	-	0.28	UNK	14.5	227	133	USA	113	3	2a	8.75	2%
SO 0697	Peanut, shelled	-	0.40	USA	15.0	78	-	-	ND	ND	1	2.07	1%
VD 0072	Peas (dry)	0.62	-	FRA	17.8	107	-	-	ND	ND	3	3.72	1%
VP 0063	Peas (green pods & immature seeds)	-	3.8	JPN	15.9	48	-	-	ND	ND	1	11.40	3%
VP 0064	Peas, shelled (immature seeds)	-	1.1	UNK	14.5	174	-	-	ND	ND	1	13.20	3%
TN 0672	Pecan	-	0.01	AUS	19.0	22	-	-	ND	ND	1	0.01	0%
TN 0673	Pine nut	-	0.01	AUS	19.0	18	-	-	ND	ND	1	0.01	0%
TN 0675	Pistachio nut	-	0.01	AUS	19.0	63	-	-	ND	ND	1	0.03	0%
VR 0589	Potato	-	0.28	SAF	14.2	300	122	USA	99	3	2a	9.81	2%
PM 0110	Poultry meat: 10% as fat	-	0.001	AUS	19.0	22	-	-	ND	ND	1	0.00	0%
PM 0110	Poultry meat: 90% as muscle	-	0.003	AUS	19.0	201	-	-	ND	ND	1	0.03	0%
PO 0111	Poultry, Edible offal of	-	0.02	USA	15.0	37	-	-	ND	ND	1	0.05	0%
VR 0494	Radish	-	0.28	FRA	17.8	122	8	UNK	7	1	1	1.91	0%
VR 0591	Radish, Japanese	-	0.28	JPN	15.9	132	1000	JPN	1000	3	2b	7.00	2%
FB 0272	Raspberries, red, black	-	2.8	FRA	17.8	76	-	-	ND	ND	1	11.98	3%
FB 0273	Rose hips	-	2.8	NLD	17.0	16	-	-	ND	ND	1	2.58	1%
VR 0498	Salsify	-	0.28	UNK	14.5	125	-	-	ND	ND	1	2.41	1%
FB 0275	Strawberry	-	0.35	AUS	19.0	176	13	UNK	12	1	1	3.25	1%
SO 0702	Sunflower seed	0.05	-	USA	15.0	24	-	-	ND	ND	3	0.08	0%
VR 0497	Swede	-	0.28	FRA	17.8	122	-	-	ND	ND	1	1.91	0%
VR 0508	Sweet potato	-	0.28	USA	15.0	166	130	USA	105	3	2a	7.03	2%
VR 0506	Turnip, garden	-	0.28	JPN	15.9	77	122	USA	105	3	2b	4.09	1%
TN 0678	Walnut	-	0.01	USA	15.0	6	-	-	ND	ND	1	0.00	0%

Note 1: The Meeting noticed the very high consumption for black currants of 1054 g for children in the UK with a body weight of 14.5 kg in the large portion and recommended confirmation of this figure.

Annex 4

MALATHION (049) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS** Acute RfD= 2 mg/kg bw (2000 µg/kg bw) Maximum %ARfD: 10%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
GC 0654	Wheat	-	10	FRA	18.9	384	-	-	ND	ND	1	203.30	10%
CM 0654	Wheat bran, unprocessed	-	25	USA	15.0	30	-	-	ND	ND	1	49.50	2%
CF 1211	Wheat flour	-	0.87	FRA	18.9	245	-	-	ND	ND	1	11.14	1%
CF 1212	Wheat wholemeal	-	7.5	USA	15.0	74	-	-	ND	ND	1	36.33	2%
CP 1211	White bread	-	0.2	SAF	14.2	270	-	-	ND	ND	1	3.80	0%
CP 1212	Wholemeal bread	-	1.2	SAF	14.2	240	-	-	ND	ND	1	20.28	1%

MALATHION (049) International estimate of short term intake (IESTI) for **GENERAL POPULATION** Acute RfD= 2 mg/kg bw (2000 µg/kg bw) Maximum %ARfD: 7%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
GC 0654	Wheat	-	10	FRA	52.2	703	-	-	ND	ND	1	134.60	7%
CM 0654	Wheat bran, unprocessed	-	25	USA	65.0	80	-	-	ND	ND	1	30.75	2%
CF 1211	Wheat flour	-	0.86	FRA	52.2	479	-	-	ND	ND	1	7.89	0%
CF 1212	Wheat wholemeal	-	7.4	USA	65.0	155	-	-	ND	ND	1	17.69	1%
CP 1211	White bread	-	0.2	FRA	52.2	474	-	-	ND	ND	1	1.82	0%
CP 1212	Wholemeal bread	-	1.2	SAF	55.7	395	-	-	ND	ND	1	8.52	0%

METHOMYL (094) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 50%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit wt, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0226	Apple	-	0.17	USA	65.0	1348	110	FRA	100	3	2a	4.05	20%
VS 0621	Asparagus	-	1.1	NLD	63.0	398	25	FRA	13	3	2a	7.39	40%
GC 0640	Barley	0.14	-	NLD	63.0	378	-	-	ND	ND	3	0.84	4%
VD 0071	Beans (dry)	0.023	-	FRA	52.2	360	-	-	ND	ND	3	0.16	1%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.68	FRA	52.2	261	-	-	ND	ND	1	3.40	20%
VD 0523	Broad bean (dry)	0.023	-	AUS	67.0	139	-	-	ND	ND	3	0.05	0%
VD 0526	Common bean (dry)	0.023	-	FRA	52.2	360	-	-	ND	ND	3	0.16	1%
VD 0526	Common bean (dry), stated as kidney bean VD 4503	0.023	-	Thai	53.5	82	-	-	ND	ND	3	0.04	0%
VP 0526	Common bean (green pods and immature seeds) stated as French bean, VP 4415	-	0.68	NLD	63.0	360	-	-	ND	ND	1	3.89	20%
VP 0526	Common bean (green pods and/or immature seeds)	-	0.68	NLD	63.0	431	-	-	ND	ND	1	4.65	20%
VP 0526	Common bean (green pods and/or immature seeds) stated as haricot bean, VP 4427	-	0.68	AUS	67.0	67	-	-	ND	ND	1	0.68	3%
SO 0691	Cotton seed	0.1	-	USA	65.0	3	-	-	ND	ND	3	0.01	0%
OR 0691	Cotton seed oil, edible	0.006	-	USA	65.0	9	-	-	ND	ND	3	0.00	0%
VC 0424	Cucumber	-	0.07	FRA	52.2	348	400	FRA	360	3	2b	1.40	7%
VC 0425	Gherkin	-	0.07	NLD	63.0	96	15	FRA	15	1	1	0.11	1%
FB 0269	Grape (excl wine)	-	0.08	AUS	67.0	513	456	SWE	438	3	2a	1.66	8%
JF 0269	Grape juice	0.0198	-	FRA	52.2	696	-	-	ND	ND	3	0.26	1%
FC 0203	Grapefruit	-	0.18	JPN	52.6	947	400	JPN	400	3	2a	5.98	30%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.04	USA	65.0	70	-	-	ND	ND	1	0.04	0%
FC 0204	Lemon	-	0.18	FRA	52.2	111	173	SWE	92	3	2a	1.02	5%
VL 0482	Lettuce, head	-	0.07	USA	65.0	213	450	BEL	360	3	2b	0.69	3%
VL 0483	Lettuce, leaf	-	0.07	NLD	63.0	152	160	BEL	144	3	2a	0.49	2%
VD 0534	Lima bean (dry)	0.023	-	USA	65.0	202	-	-	ND	ND	3	0.07	0%
VP 0534	Lima bean (green pods & immature seeds)	-	0.68	USA	65.0	241	-	-	ND	ND	1	2.52	10%
FC 0205	Lime	-	0.18	AUS	67.0	590	67	USA	56	3	2a	1.89	9%
GC 0645	Maize	0.02	-	FRA	52.2	212	-	-	ND	ND	3	0.08	0%
OR 0645	Maize oil, edible	0.004	-	NLD	63.0	56	-	-	ND	ND	3	0.00	0%

Annex 4

METHOMYL (094) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)
Maximum %ARfD: 50%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit wt, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0206	Mandarin	-	0.18	FRA	52.2	639	168	USA	124	3	2a	3.06	20%
VC 0046	Melons, except watermelon	-	0.07	FRA	52.2	1044	1000	USA	630	3	2a	3.09	20%
FS 0245	Nectarine	-	0.1	FRA	52.2	604	136	USA	125	3	2a	1.64	8%
GC 0647	Oats	0.02	-	USA	65.0	175	-	-	ND	ND	3	0.05	0%
VA 0385	Onion, Bulb	-	0.14	NLD	63.0	172	200	JPN	200	3	2b	1.15	6%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.18	FRA	52.2	1044	205	BEL	139	3	2a	4.56	20%
FS 0247	Peach	-	0.1	SAF	55.7	685	150	JPN	150	3	2a	1.77	9%
FP 0230	Pear	-	0.18	FRA	52.2	568	170	BEL	162	3	2a	3.07	20%
VP 0063	Peas (green pods & immature seeds)	-	4	JPN	52.6	63	-	-	ND	ND	1	4.76	20%
VO 0444	Peppers, Chilli	-	0.44	USA	65.0	90	45	USA	43	3	2a	1.20	6%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.44	FRA	52.2	90	185	BEL	148	3	2b	2.28	10%
FS 0014	Plum (incl dried)	-	0.51	Thai	53.5	480	59	BEL	55	3	2a	5.63	30%
VR 0589	Potato	-	0	FRA	52.2	639	122	USA	99	3	2a	0.00	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.18	Thai	53.5	554	210	FRA	126	3	2a	2.71	10%
VD 0541	Soya bean (dry)	0.023	-	JPN	52.6	159	-	-	ND	ND	3	0.07	0%
OR 0541	Soya bean oil, refined	0.04	-	USA	65.0	98	-	-	ND	ND	3	0.06	0%
VC 0431	Squash, summer (= courgette)	-	0.07	FRA	52.2	351	300	FRA	270	3	2a	1.20	6%
VO 0448	Tomato	-	0.73	FRA	52.2	387	150	BEL	143	3	2a	9.39	50%
VC 0432	Watermelon	-	0.07	USA	65.0	1939	4518	USA	2078	3	2b	6.26	30%
GC 0654	Wheat	0.14	-	FRA	52.2	703	-	-	ND	ND	3	1.88	9%
CM 0654	Wheat bran, unprocessed	0.27	-	USA	65.0	80	-	-	ND	ND	3	0.33	2%
CF 1211	Wheat flour	0.003	-	FRA	52.2	479	-	-	ND	ND	3	0.03	0%
CF 1210	Wheat germ	0.13	-	FRA	52.2	174	-	-	ND	ND	3	0.43	2%
-	Wine	0.053	-	FRA	52.2	1006	-	-	ND	ND	3	1.02	5%
VC 0433	Winter squash (= pumpkin), stated as pumpkin, VC 0429	-	0.07	SAF	55.7	1003	1000	JPN	1000	3	2a	3.77	20%
VP 0544	Yard-long beans (green pods & immature seeds)	-	0.68	Thai	53.5	139	-	-	ND	ND	1	1.76	9%

Annex 4

METHOMYL (094) International estimate of short term intake (IESTI) for Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

CHILDREN UP TO 6 YEARS Maximum %ARfD: 100%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit wt, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FP 0226	Apple	-	0.17	USA	15.0	679	162	SWE	149	3	2a	11.07	60%
VS 0621	Asparagus	-	1.1	USA	15.0	178	25	FRA	13	3	2a	14.90	70%
GC 0640	Barley	0.14	-	AUS	19.0	14	-	-	ND	ND	3	0.10	1%
VD 0071	Beans (dry)	0.023	-	AUS	19.0	222	-	-	ND	ND	3	0.27	1%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.68	FRA	18.9	215	-	-	ND	ND	1	7.75	40%
VD 0523	Broad bean (dry)	0.023	-	AUS	19.0	32	-	-	ND	ND	3	0.04	0%
VD 0526	Common bean (dry)	0.023	-	FRA	18.9	145	-	-	ND	ND	3	0.18	1%
VD 0526	Common bean (dry), stated as kidney bean VD 4503	0.023	-	Thai	17.1	45	-	-	ND	ND	3	0.06	0%
VP 0526	Common bean (green pods and immature seeds) stated as French bean, VP 4415	-	0.68	NLD	17.0	253	-	-	ND	ND	1	10.12	50%
VP 0526	Common bean (green pods and/or immature seeds)	-	0.68	NLD	17.0	184	-	-	ND	ND	1	7.36	40%
VP 0526	Common bean (green pods and/or immature seeds) stated as haricot bean, VP 4427	-	0.68	AUS	19.0	42	-	-	ND	ND	1	1.50	8%
SO 0691	Cotton seed	0.1	-	USA	15.0	1	-	-	ND	ND	3	0.01	0%
OR 0691	Cotton seed oil, edible	0.006	-	USA	15.0	6	-	-	ND	ND	3	0.00	0%
VC 0424	Cucumber	-	0.07	NLD	17.0	162	400	FRA	360	3	2b	2.00	10%
VC 0425	Gherkin	-	0.07	NLD	17.0	56	59	UKN	55	3	2a	0.69	3%
FB 0269	Grape (incl wine)	-	0.08	JPN	15.9	388	456	SWE	438	3	2b	5.85	30%
JF 0269	Grape juice	0.0198	-	FRA	18.9	500	-	-	ND	ND	3	0.52	3%
FC 0203	Grapefruit	-	0.18	FRA	18.9	405	400	JPN	400	3	2a	11.48	60%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.04	USA	15.0	59	-	-	ND	ND	1	0.16	1%
FC 0204	Lemon	-	0.18	JPN	15.9	88	173	SWE	92	3	2b	3.00	20%
VL 0482	Lettuce, head	-	0.07	Thai	17.1	117	450	BEL	360	3	2b	1.43	7%
VL 0483	Lettuce, leaf	-	0.07	NLD	17.0	102	160	BEL	144	3	2b	1.26	6%
VD 0534	Lima bean (dry)	0.023	-	USA	15.0	74	-	-	ND	ND	3	0.11	1%
VP 0534	Lima bean (green pods & immature seeds)	-	0.68	USA	15.0	117	-	-	ND	ND	1	5.32	30%
FC 0205	Lime	-	0.18	AUS	19.0	26	67	USA	56	3	2b	0.73	4%
GC 0645	Maize	0.02	-	FRA	18.9	117	-	-	ND	ND	3	0.12	1%
OR 0645	Maize oil, edible	0.004	-	NLD	17.0	12	-	-	ND	ND	3	0.00	0%

Annex 4

METHOMYL (094) International estimate of short term intake (IESTI) for Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

CHILDREN UP TO 6 YEARS Maximum %ARfD: 100%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit wt, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0206	Mandarin	-	0.18	JPN	15.9	353	168	USA	124	3	2a	6.81	30%
VC 0046	Melons, except watermelon	-	0.07	FRA	18.9	597	700	FRA	420	3	2a	5.32	30%
FS 0245	Nectarine	-	0.1	AUS	19.0	302	110	FRA	99	3	2a	2.63	10%
GC 0647	Oats	0.02	-	USA	15.0	62	-	-	ND	ND	3	0.08	0%
VA 0385	Onion, Bulb	-	0.14	NLD	17.0	86	140	FRA	126	3	2b	2.11	10%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.18	UNK	14.5	495	200	JPN	200	3	2a	11.11	60%
FS 0247	Peach	-	0.1	AUS	19.0	315	150	JPN	150	3	2a	3.24	20%
FP 0230	Pear	-	0.18	UNK	14.5	279	170	BEL	162	3	2a	7.47	40%
VP 0063	Peas (green pods & immature seeds)	-	4	JPN	15.9	48	-	-	ND	ND	1	12.00	60%
VO 0444	Peppers, Chilli	-	0.44	AUS	19.0	31	45	USA	43	3	2b	2.12	10%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.44	Thai	17.1	71	119	USA	98	3	2b	5.49	30%
FS 0014	Plum (incl dried)	-	0.51	Thai	17.1	377	66	USA	62	3	2a	14.94	70%
VR 0589	Potato	-	0	SAF	14.2	300	122	USA	99	3	2a	0.00	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.18	Thai	17.1	327	210	FRA	126	3	2a	6.09	30%
VD 0541	Soya bean (dry)	0.023	-	JPN	15.9	88	-	-	ND	ND	3	0.13	1%
OR 0541	Soya bean oil, refined	0.04	-	USA	15.0	35	-	-	ND	ND	3	0.09	0%
VC 0431	Squash, summer (= courgette)	-	0.07	AUS	19.0	219	300	FRA	270	3	2b	2.42	10%
VO 0448	Tomato	-	0.73	FRA	18.9	215	150	BEL	143	3	2a	19.33	100%
VC 0432	Watermelon	-	0.07	AUS	19.0	1473	4518	USA	2078	3	2b	16.28	80%
GC 0654	Wheat	0.14	-	FRA	18.9	384	-	-	ND	ND	3	2.85	10%
CM 0654	Wheat bran, unprocessed	0.27	-	USA	15.0	30	-	-	ND	ND	3	0.53	3%
CF 1211	Wheat flour	0.003	-	FRA	18.9	245	-	-	ND	ND	3	0.04	0%
CF 1210	Wheat germ	0.13	-	USA	15.0	8	-	-	ND	ND	3	0.07	0%
-	Wine	0.053	-	FRA	18.9	89	-	-	ND	ND	3	0.25	1%
VC 0433	Winter squash (= pumpkin), stated as pumpkin, VC 0429	-	0.07	SAF	14.2	224	1000	JPN	1000	3	2b	3.32	20%
VP 0544	Yard-long beans (green pods & immature seeds)	-	0.68	Thai	17.1	79	-	-	ND	ND	1	3.13	20%

PROFENOFOS (171) International estimate of short term intake (IESTI) for Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

GENERAL POPULATION Maximum %ARfD: 6%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion g/kg bw/day	Large portion, g/person	Unit weight Unit weight, g	Country	% edible portion	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0345	Mango	-	0.07	AUS	67.0	8.46	567	300	BEL	68%	204	3	2a	1.02	0%
OR 0691	Cotton seed oil, edible	0.14	-	USA	65.0	0.14	9	-	-	-	ND	ND	3	0.02	0%
MO 0105	Edible offal (mammalian)	-	0	FRA	52.2	6.27	327	-	-	-	ND	ND	1	0.00	0%
PE 0112	Eggs	-	0	Thai	53.5	3.64	195	-	-	-	ND	ND	1	0.00	0%
MF 0100	Mammalian fats (except milk fats)	-	0	-	-	ND	ND	-	-	-	ND	ND	1	ND	-
FI 0346	Mangostan, stated as mangosteen FI 4137	-	3.7	Thai	53.5	5.16	276	-	-	-	ND	ND	ND	ND	-
MM 0095	Meat from mammals other than marine mammals	-	0	AUS	67.0	7.78	521	-	-	-	ND	ND	1	0.00	0%
ML 0106	Milks	0	-	USA	65.0	37.94	2466	-	-	-	ND	ND	3	0.00	0%
PM 0110	Poultry meat	-	0	AUS	67.0	6.44	431	-	-	-	ND	ND	1	0.00	0%
PO 0111	Poultry, Edible offal of	-	0	USA	65.0	3.81	248	-	-	-	ND	ND	1	0.00	0%
PF 0111	Poultry, fats	-	0	USA	65.0	0.66	43	-	-	-	ND	ND	1	0.00	0%
VO 0448	Tomato	-	4.7	FRA	52.2	7.41	387	150	JPN	100%	150	3	2a	61.84	6%

Annex 4

PROFENOFOS (171) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion g/kg bw/day	Large portion, g/person	Unit weight Unit weight, g	Country	% edible portion	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FI 0345	Mango	-	0.07	Thai	17.1	11.17	191	300	BEL	68%	204	3	2b	2.35	0%
OR 0691	Cotton seed oil, edible	0.14	-	USA	15.0	0.41	6	-	-	-	ND	ND	3	0.06	0%
MO 0105	Edible offal (mammalian)	-	0	FRA	18.9	4.57	86	-	-	-	ND	ND	1	0.00	0%
PE 0112	Eggs	-	0	Thai	17.1	6.38	109	-	-	-	ND	ND	1	0.00	0%
MF 0100	Mammalian fats (except milk fats)	-	0	-	-	ND	ND	-	-	-	ND	ND	1	ND	-
FI 0346	Mangostan, stated as mangosteen FI 4137	-	3.7	Thai	17.1	10.13	173	-	-	-	ND	ND	ND	ND	-
MM 0095	Meat from mammals other than marine mammals	-	0	AUS	19.0	13.71	261	-	-	-	ND	ND	1	0.00	0%
ML 0106	Milks	0	-	USA	15.0	85.71	1286	-	-	-	ND	ND	3	0.00	0%
PM 0110	Poultry meat	-	0	AUS	19.0	11.78	224	-	-	-	ND	ND	1	0.00	0%
PO 0111	Poultry, Edible offal of	-	0	FRA	18.9	5.26	99	-	-	-	ND	ND	1	0.00	0%
PF 0111	Poultry, fats	-	0	USA	15.0	1.05	16	-	-	-	ND	ND	1	0.00	0%
VO 0448	Tomato	-	4.7	FRA	18.9	11.40	215	150	JPN	100%	150	3	2a	128.18	10%

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for **WOMEN OF CHILD BEARING AGE**

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)
Maximum %ARfD: 2%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
SO 0495	Rape seed	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0640	Barley	0.01	-	NLD	63.0	378	-	-	ND	ND	3	0.63	1%
MO 0105	Edible offal (mammalian)		0.1	FRA	52.2	327	-	-	ND	ND	3	ND	-
MF 0100	Mammalian fats (except milk fats)		0.01	-	-	ND	-	-	ND	ND	3	ND	-
MM 0095	Meat from mammals other than marine mammals		0.01	AUS	67.0	521	-	-	ND	ND	3	0.08	-
ML 0106	Milks	0.004	-	USA	65.0	2466	-	-	ND	ND	3	0.15	2%
GC 0647	Oats	0.01	-	USA	65.0	175	-	-	ND	ND	ND	ND	-
GC 0650	Rye	0.01	-	FRA	52.2	161	-	-	ND	ND	3	0.03	0%
GC 0654	Wheat	0.01	-	FRA	52.2	703	-	-	ND	ND	ND	ND	-
CF 1211	Wheat flour	0.004	-	FRA	52.2	479	-	-	ND	ND	ND	ND	-
CF 1210	Wheat germ	0.02	-	FRA	52.2	174	-	-	ND	ND	3	0.07	1%

Annex 4

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 1 mg/kg bw

Maximum %ARfD: 0

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
SO 0495	Rape seed	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0640	Barley	0.01	-	AUS	19.0	14	-	-	ND	ND	3	0.01	0%
MO 0105	Edible offal (mammalian)		0.1	FRA	18.9	86	-	-	ND	ND	1	0.45	-
MF 0100	Mammalian fats (except milk fats)		0.01	-	-	ND	-	-	ND	ND	1	ND	-
MM 0095	Meat from mammals other than marine mammals		0.01	AUS	19.0	261	-	-	ND	ND	1	0.14	-
ML 0106	Milks	0.004	-	USA	15.0	1286	-	-	ND	ND	3	0.34	0%
GC 0647	Oats	0.01	-	USA	15.0	62	-	-	ND	ND	ND	ND	-
GC 0650	Rye	0.01	-	NLD	17.0	37	-	-	ND	ND	3	0.02	0%
GC 0654	Wheat	0.01	-	FRA	18.9	384	-	-	ND	ND	ND	ND	-
CF 1211	Wheat flour	0.004	-	FRA	18.9	245	-	-	ND	ND	ND	ND	-
CF 1210	Wheat germ	0.02	-	USA	15.0	8	-	-	ND	ND	3	0.01	0%

Annex 4

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 1 mg/kg bw

Maximum %ARfD: 0%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
SO 0495	Rape seed	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0640	Barley	0.01	-	NLD	63.0	378	-	-	ND	ND	3	0.06	0%
MO 0105	Edible offal (mammalian)		0.1	FRA	52.2	327	-	-	ND	ND	1	0.63	-
MF 0100	Mammalian fats (except milk fats)		0.01	-	-	ND	-	-	ND	ND	1	ND	-
MM 0095	Meat from mammals other than marine mammals		0.01	AUS	67.0	521	-	-	ND	ND	1	0.08	-
ML 0106	Milks	0.004	-	USA	65.0	2466	-	-	ND	ND	3	0.15	0%
GC 0647	Oats	0.01	-	USA	65.0	175	-	-	ND	ND	3.00	ND	-
GC 0650	Rye	0.01	-	FRA	52.2	161	-	-	ND	ND	3	0.03	0%
GC 0654	Wheat	0.01	-	FRA	52.2	703	-	-	ND	ND	3.00	ND	-
CF 1211	Wheat flour	0.004	-	FRA	52.2	479	-	-	ND	ND	ND	ND	-
CF 1210	Wheat germ	0.02	-	FRA	52.2	174	-	-	ND	ND	3	0.07	0%

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 1.0 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
TN 0660	Almonds	-	0.29	JPN	52.6	74	-	-	ND	ND	1	0.41	0%
FP 0226	Apple	-	0.55	USA	65.0	1348	138	USA	127	3	2a	13.56	1%
JF 0226	Apple juice	0.082		-	-	ND	-	-	ND	ND	3	ND	-
DF 0226	Apple, dried	-	0.55	AUS	67.0	10	-	-	ND	ND	ND	ND	-
FS 0240	Apricot	-	2.1	FRA	52.2	369	35	USA	34	3	2a	17.53	2%
VC 0421	Balsam pear, stated as bitter gourd, VC 4195	-	0.18	Thai	53.5	120	-	-	ND	ND	ND	ND	-
TN 0662	Brazil nut	-	0.29	NLD	63.0	23	-	-	ND	ND	1	0.10	0%
VB 0400	Broccoli	-	0.87	FRA	52.2	537	608	USA	474	3	2a	24.76	2%
VB 0401	Broccoli, Chinese	-	0.87	AUS	67.0	231	-	-	ND	ND	ND	ND	-
VB 0402	Brussels sprouts	-	0.87	FRA	52.2	351	10	UNK	7	1	1	5.86	1%
VB 0041	Cabbages, Head	-	0.92	SAF	55.7	362	908	USA	717	3	2b	17.94	2%
TN 0295	Cashew nut	-	0.29	Thai	53.5	200	-	-	ND	ND	1	1.08	0%
VB 0404	Cauliflower (head)	-	0.87	UNK	70.1	579	1500	JPN	1500	3	2b	21.56	2%
VS 0624	Celery (stalk)	-	2.6	FRA	52.2	238	40	USA	40	3	2a	15.81	2%
VS 0624	Celery (whole)	-	2.6	FRA	52.2	238	700	BEL	462	3	2b	35.49	4%
VL 0464	Chard	-	5.5	NLD	63.0	569	-	-	ND	ND	ND	ND	-
VC 0423	Chayote	-	0.18	AUS	67.0	196	-	-	ND	ND	ND	ND	-
FS 0013	Cherries	-	2.1	FRA	52.2	360	5	UNK	4	1	1	14.49	1%
FS 0013	Cherries	-	2.1	FRA	52.2	360	5	BEL	4	1	1	14.49	1%
TN 0664	Chestnuts	-	0.29	FRA	52.2	373	-	-	ND	ND	1	2.07	0%
VL 0469	Chicory leaves (head)	-	5.5	USA	65.0	40	53	USA	47	3	2b	10.23	1%
VL 0469	Chicory leaves (head)	-	5.5	USA	65.0	40	100	BEL	85	3	2b	10.23	1%
VL 0466	Chinese cabbage, type pak-choi	-	5.5	USA	65.0	377	840	USA	798	3	2b	95.70	10%
TN 0665	Coconut	-	0.29	AUS	67.0	84	-	-	ND	ND	ND	ND	-
VL 0470	Corn salad	-	5.5	FRA	52.2	84	-	-	ND	ND	ND	ND	-
VL 0510	Cos lettuce	-	5.5	JPN	52.6	144	-	-	ND	ND	ND	ND	-
VL 0472	Cress, garden	-	5.5	AUS	67.0	27	-	-	ND	ND	ND	ND	-
VC 0424	Cucumber	-	0.18	FRA	52.2	348	301	USA	286	3	2a	3.17	0%

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 1.0 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
MO 0105	Edible offal (mammalian)	-	0.024	FRA	52.2	327	-	-	ND	ND	1	0.15	0%
VO 0440	Egg plant	-	1.1	AUS	67.0	487	548	USA	444	3	2a	22.57	2%
VL 0476	Endive	-	5.5	FRA	52.2	339	-	-	ND	ND	ND	ND	-
VC 0425	Gherkin	-	0.18	NLD	63.0	96	116	USA	81	3	2a	0.74	0%
FB 0269	Grape (excl wine)	-	1.3	AUS	67.0	513	456	SWE	438	3	2a	26.94	3%
JF 0269	Grape juice	0.27	-	FRA	52.2	696	-	-	ND	ND	3	3.60	0%
FC 0203	Grapefruit	-	0.47	JPN	52.6	947	400	JPN	400	3	2a	15.61	2%
JF 0203	Grapefruit juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	3.4	USA	65.0	70	-	-	ND	ND	1	3.67	0%
TN 0666	Hazelnut	-	0.29	AUS	67.0	70	-	-	ND	ND	1	0.30	0%
VL 0480	Kale	-	5.5	NLD	63.0	337	-	-	ND	ND	ND	ND	-
VB 0405	Kohlrabi	-	0.87	NLD	63.0	283	135	USA	99	3	2a	6.63	1%
FC 0204	Lemon	-	0.47	FRA	52.2	111	108	USA	72	3	2a	2.30	0%
-	Lemon juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-
VL 0482	Lettuce, head	-	5.5	USA	65.0	213	539	USA	512	3	2b	53.96	5%
VL 0483	Lettuce, leaf	-	5.5	NLD	63.0	152	160	BEL	144	3	2a	38.40	4%
FC 0205	Lime	-	0.47	AUS	67.0	590	67	USA	56	3	2a	4.93	0%
VC 0427	Loofah, angled (= angled gourd)	-	0.18	Thai	53.5	215	-	-	ND	ND	ND	ND	-
FP 0228	Loquat	-	0.55	AUS	67.0	64	-	-	ND	ND	ND	ND	-
TN 0669	Macadamia nut	-	0.29	USA	65.0	107	-	-	ND	ND	1	0.48	0%
FC 0206	Mandarin	-	0.47	FRA	52.2	639	168	USA	124	3	2a	7.99	1%
VC 0046	Melons, except watermelon	-	0.18	FRA	52.2	1044	1000	USA	630	3	2a	7.94	1%
VC 0046	Melons, except watermelon, stated as cantaloupe, VC 4199	-	0.18	USA	65.0	606	500	JPN	500	3	2a	4.45	0%
VC 0046	Melons, except watermelon, stated as cantaloupe, VC 4199	-	0.18	USA	65.0	606	552	USA	276	3	2a	3.21	0%
VL 0485	Mustard greens	-	5.5	USA	65.0	228	-	-	ND	ND	ND	ND	-
FS 0245	Nectarine	-	2.1	FRA	52.2	604	136	USA	125	3	2a	34.39	3%
VO 0442	Okra	-	1.1	USA	65.0	235	10	JPN	10	1	1	3.98	0%
JF 0004	Orange juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 1.0 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 10%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.47	FRA	52.2	1044	131	USA	96	3	2a	11.12	1%
FS 0247	Peach	-	2.1	SAF	55.7	685	150	JPN	150	3	2a	37.14	4%
FP 0230	Pear	-	0.55	FRA	52.2	568	166	USA	151	3	2a	9.17	1%
-d	Pear, dried	-	0.55	AUS	67.0	21	-	-	ND	ND	ND	ND	-
TN 0672	Pecan	-	0.29	AUS	67.0	23	-	-	ND	ND	1	0.10	0%
VO 0444	Peppers, Chilli	-	1.5	USA	65.0	90	45	USA	43	3	2a	4.08	0%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	1.1	FRA	52.2	90	119	USA	98	3	2b	5.71	1%
TN 0673	Pine nut	-	0.29	AUS	67.0	47	-	-	ND	ND	1	0.20	0%
TN 0675	Pistachio nut	-	0.29	AUS	67.0	300	-	-	ND	ND	1	1.30	0%
FS 0014	Plum (incl dried)	-	2.1	Thai	53.5	480	66	USA	62	3	2a	23.71	2%
FC 4020	Pomelo	-	0.47	Thai	53.5	554	-	-	ND	ND	ND	ND	-
VR 0589	Potato	-	0.46	FRA	52.2	639	122	USA	99	3	2a	7.37	1%
VL 0492	Purslane	-	5.5	NLD	63.0	476	-	-	ND	ND	ND	ND	-
FP 0231	Quince	-	0.55	AUS	67.0	175	92	USA	56	3	2a	2.36	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.47	Thai	53.5	554	210	FRA	126	3	2a	7.08	1%
VC 0430	Snake gourd	-	0.18	Thai	53.5	215	-	-	ND	ND	ND	ND	-
VL 0502	Spinach (bunch)	-	5.5	NLD	63.0	820	340	USA	245	3	2a	114.30	10%
VC 0431	Squash, summer (= courgette)	-	0.18	FRA	52.2	351	196	USA	186	3	2a	2.50	0%
FC 4031	Tangelo	-	0.47	AUS	67.0	114	-	-	ND	ND	ND	ND	-
VO 0448	Tomato	-	1.1	FRA	52.2	387	123	USA	123	3	2a	13.33	1%
JF 0448	Tomato juice	0.27	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	3.2	-	-	-	ND	-	-	ND	ND	ND	ND	-
TN 0085	Tree nuts	-	0.29	JPN	52.6	107	-	-	ND	ND	1	0.59	0%
VL 0506	Turnip greens	-	5.5	USA	65.0	353	-	-	ND	ND	ND	ND	-
VL 0473	Watercress	-	5.5	AUS	67.0	86	-	-	ND	ND	ND	ND	-
VC 0432	Watermelon	-	0.18	USA	65.0	1939	4518	USA	2078	3	2b	16.11	2%
-	Wine	0.23	-	FRA	52.2	1006	-	-	ND	ND	3	4.43	0%
VC 0433	Winter squash (= pumpkin)	-	0.18	USA	65.0	729	1000	JPN	1000	3	2b	6.06	1%

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 1.000 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
TN 0660	Almonds	-	0.29	USA	15.0	13	-	-	ND	ND	1	0.26	0%
FP 0226	Apple	-	0.55	USA	15.0	679	200	JPN	200	3	2a	39.55	4%
JF 0226	Apple juice	0.082		-	-	ND	-	-	ND	ND	3	ND	-
DF 0226	Apple, dried	-	0.55	AUS	19.0	4	-	-	ND	ND	ND	ND	-
FS 0240	Apricot	-	2.1	AUS	19.0	414	35	USA	34	3	2a	53.23	5%
VC 0421	Balsam pear, stated as bitter gourd, VC 4195	-	0.18	Thai	17.1	87	-	-	ND	ND	ND	ND	-
TN 0662	Brazil nut	-	0.29	-	-	ND	-	-	ND	ND	1	ND	-
VB 0400	Broccoli	-	0.87	FRA	18.9	254	608	USA	474	3	2b	35.13	4%
VB 0401	Broccoli, Chinese	-	0.87	-	-	ND	-	-	ND	ND	ND	ND	-
VB 0402	Brussels sprouts	-	0.87	NLD	17.0	213	10	UNK	7	1	1	10.88	1%
VB 0041	Cabbages, Head	-	0.92	SAF	14.2	220	908	USA	717	3	2b	42.78	4%
TN 0295	Cashew nut	-	0.29	Thai	17.1	99	-	-	ND	ND	1	1.68	0%
VB 0404	Cauliflower (head)	-	0.87	NLD	17.0	209	575	USA	224	3	2b	32.13	3%
VS 0624	Celery (stalk)	-	2.6	FRA	18.9	157	40	USA	40	3	2a	32.66	3%
VS 0624	Celery (whole)	-	2.6	FRA	18.9	157	700	BEL	462	3	2b	64.97	6%
VL 0464	Chard	-	5.5	FRA	18.9	47	-	-	ND	ND	ND	ND	-
VC 0423	Chayote	-	0.18	AUS	19.0	105	-	-	ND	ND	ND	ND	-
FS 0013	Cherries	-	2.1	AUS	19.0	250	5	FRA	4	1	1	27.64	3%
FS 0013	Cherries	-	2.1	AUS	19.0	250	5	JPN	5	1	1	27.64	3%
TN 0664	Chestnuts	-	0.29	FRA	18.9	196	-	-	ND	ND	1	3.00	0%
VL 0469	Chicory leaves (head)	-	5.5	USA	15.0	19	53	USA	47	3	2b	20.63	2%
VL 0469	Chicory leaves (head)	-	5.5	USA	15.0	19	100	BEL	85	3	2b	20.63	2%
VL 0466	Chinese cabbage, type pak-choi	-	5.5	JPN	15.9	183	840	USA	798	3	2b	189.59	20%
TN 0665	Coconut	-	0.29	NLD	17.0	17	-	-	ND	ND	ND	ND	-
VL 0470	Corn salad	-	5.5	FRA	18.9	40	-	-	ND	ND	ND	ND	-
VL 0510	Cos lettuce	-	5.5	-	-	ND	-	-	ND	ND	ND	ND	-
VL 0472	Cress, garden	-	5.5	-	-	ND	-	-	ND	ND	ND	ND	-
VC 0424	Cucumber	-	0.18	NLD	17.0	162	301	USA	286	3	2b	5.15	1%

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 1.000 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
MO 0105	Edible offal (mammalian)	-	0.024	FRA	18.9	86	-	-	ND	ND	1	0.11	0%
VO 0440	Egg plant	-	1.1	JPN	15.9	219	548	USA	444	3	2b	45.51	5%
VL 0476	Endive	-	5.5	NLD	17.0	212	-	-	ND	ND	ND	ND	-
VC 0425	Gherkin	-	0.18	NLD	17.0	56	116	USA	81	3	2b	1.77	0%
FB 0269	Grape (excl wine)	-	1.3	AUS	19.0	342	456	SWE	438	3	2b	70.20	7%
JF 0269	Grape juice	0.27	-	FRA	18.9	500	-	-	ND	ND	3	7.15	1%
FC 0203	Grapefruit	-	0.47	FRA	18.9	405	400	JPN	400	3	2a	29.97	3%
JF 0203	Grapefruit juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	3.4	USA	15.0	59	-	-	ND	ND	1	13.43	1%
TN 0666	Hazelnut	-	0.29	FRA	18.9	27	-	-	ND	ND	1	0.42	0%
VL 0480	Kale	-	5.5	NLD	17.0	149	-	-	ND	ND	ND	ND	-
VB 0405	Kohlrabi	-	0.87	-	-	ND	135	USA	99	3	ND	ND	-
FC 0204	Lemon	-	0.47	JPN	15.9	88	108	USA	72	3	2a	6.89	1%
-	Lemon juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-
VL 0482	Lettuce, head	-	5.5	Thai	17.1	117	539	USA	512	3	2b	112.70	10%
VL 0483	Lettuce, leaf	-	5.5	NLD	17.0	102	160	BEL	144	3	2b	99.00	10%
FC 0205	Lime	-	0.47	AUS	19.0	26	67	USA	56	3	2b	1.92	0%
VC 0427	Loofah, angled (= angled gourd)	-	0.18	Thai	17.1	130	-	-	ND	ND	ND	ND	-
FP 0228	Loquat	-	0.55	-	-	ND	-	-	ND	ND	ND	ND	-
TN 0669	Macadamia nut	-	0.29	-	-	ND	-	-	ND	ND	1	ND	-
FC 0206	Mandarin	-	0.47	JPN	15.9	353	168	USA	124	3	2a	17.79	2%
VC 0046	Melons, except watermelon	-	0.18	FRA	18.9	597	1000	USA	630	3	2b	17.05	2%
VC 0046	Melons, except watermelon, stated as cantaloupe, VC 4199	-	0.18	USA	15.0	270	500	JPN	500	3	2b	9.71	1%
VC 0046	Melons, except watermelon, stated as cantaloupe, VC 4199	-	0.18	USA	15.0	270	552	USA	276	3	2b	9.71	1%
VL 0485	Mustard greens	-	5.5	USA	15.0	53	-	-	ND	ND	ND	ND	-
FS 0245	Nectarine	-	2.1	AUS	19.0	302	136	USA	125	3	2a	61.05	6%
VO 0442	Okra	-	1.1	USA	15.0	203	10	JPN	10	1	1	14.85	1%
JF 0004	Orange juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-

Annex 4

SPIROTETRAMAT (234) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 1.000 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 40%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.47	UNK	14.5	495	200	JPN	200	3	2a	29.01	3%
FS 0247	Peach	-	2.1	AUS	19.0	315	150	JPN	150	3	2a	68.03	7%
FP 0230	Pear	-	0.55	UNK	14.5	279	166	USA	151	3	2a	22.04	2%
TN 0672	Pecan	-	0.29	AUS	19.0	22	-	-	ND	ND	1	0.34	0%
VO 0051	Peppers	-	1.1	Thai	17.1	71	-	-	ND	ND	ND	ND	-
VO 0444	Peppers, Chilli	-	1.5	AUS	19.0	31	45	USA	43	3	2b	7.22	1%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	1.1	Thai	17.1	71	119	USA	98	3	2b	13.73	1%
TN 0673	Pine nut	-	0.29	AUS	19.0	18	-	-	ND	ND	1	0.27	0%
TN 0675	Pistachio nut	-	0.29	AUS	19.0	63	-	-	ND	ND	1	0.95	0%
FS 0014	Plum (incl dried)	-	2.1	Thai	17.1	377	40	JPN	40	3	2a	56.11	6%
DF 0014	Plum, dried (prunes)	-	4.6	AUS	19.0	170	6	FRA	5	1	1	41.17	4%
FC 4020	Pomelo	-	0.47	Thai	17.1	327	-	-	ND	ND	ND	ND	-
VR 0589	Potato	-	0.46	SAF	14.2	300	122	USA	99	3	2a	16.11	2%
VL 0492	Purslane	-	5.5	-	-	ND	-	-	ND	ND	ND	ND	-
FP 0231	Quince	-	0.55	NLD	17.0	1	92	USA	56	3	2b	0.10	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.47	Thai	17.1	327	210	FRA	126	3	2a	15.91	2%
VC 0430	Snake gourd	-	0.18	Thai	17.1	130	-	-	ND	ND	ND	ND	-
VL 0502	Spinach (bunch)	-	5.5	SAF	14.2	420	340	USA	245	3	2a	352.43	40%
VC 0431	Squash, summer (= courgette)	-	0.18	AUS	19.0	219	196	USA	186	3	2a	5.60	1%
-	Squashes & pumpkins & gourds	-	0.18	-	-	ND	-	-	ND	ND	ND	ND	-
VO 0448	Tomato	-	1.1	FRA	18.9	215	123	USA	123	3	2a	26.86	3%
JF 0448	Tomato juice	0.27	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	3.2	-	-	-	ND	-	-	ND	ND	ND	ND	-
TN 0085	Tree nuts	-	0.29	AUS	19.0	28	-	-	ND	ND	1	0.42	0%
VL 0506	Turnip greens	-	5.5	USA	15.0	90	-	-	ND	ND	ND	ND	-
VL 0473	Watercress	-	5.5	AUS	19.0	6	-	-	ND	ND	ND	ND	-
VC 0432	Watermelon	-	0.18	AUS	19.0	1473	4518	USA	2078	3	2b	41.85	4%
-	Wine	0.23	-	FRA	18.9	89	-	-	ND	ND	3	1.09	0%
VC 0433	Winter squash (= pumpkin)	-	0.18	USA	15.0	169	1000	JPN	1000	3	2b	6.07	1%

Annex 4

TEBUCONAZOLE (189) International estimate of short term intake (IESTI) for **GENERAL POPULATION** ARfD= not yet considered

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% ARfD rounded
FP 0226	Apple	-	0.47	USA	65.0	1348	162	SWE	149	3	2a	11.90	-
JF 0226	Apple juice	0.08	-	-	-	ND	-	-	ND	ND	3	ND	-
DF 0226	Apple, dried	0.19	-	AUS	67.0	10	-	-	ND	ND	3	0.03	-
VS 0620	Artichoke globe	-	0.32	FRA	52.2	512	350	BEL	140	3	2a	4.85	-
FI 0327	Banana 1/	-	0.05	FRA	52.2	714	1218	SWE	767	3	2b	2.05	-
GC 0640	Barley	0.06	-	NLD	63.0	378	-	-	ND	ND	3	0.36	-
VB 0400	Broccoli	-	0.56	FRA	52.2	537	310	BEL	186	3	2a	9.75	-
VB 0402	Brussels sprouts	-	0.56	FRA	52.2	351	10	UNK	7	1	1	3.77	-
VB 0041	Cabbages, Head	-	0.56	SAF	55.7	362	1650	BEL	1403	3	2b	10.92	-
VR 0577	Carrot	-	0.22	FRA	52.2	348	100	FRA	89	3	2a	2.22	-
VB 0404	Cauliflower (head)	-	0.56	UNK	70.1	579	1000	BEL	640	3	2b	13.88	-
FS 0013	Cherries 1/	-	3.1	FRA	52.2	360	5	FRA	4	1	1	21.39	-
SB 0716	Coffee beans	0.2	-	FRA	52.2	117	-	-	ND	ND	3	0.45	-
VP 0526	Common bean (green pods and/or immature seeds)	-	1.2	NLD	63.0	431	-	-	ND	ND	1	8.21	-
VC 0424	Cucumber 1/	-	0.19	FRA	52.2	348	410	BEL	385	3	2b	3.80	-
MO 0105	Edible offal (mammalian)	-	0.2	FRA	52.2	327	-	-	ND	ND	1	1.25	-
PE 0112	Eggs	-	0	Thai	53.5	195	-	-	ND	ND	1	0.00	-
FB 0267	Elderberries	-	0.73	NLD	63.0	21	-	-	ND	ND	1	0.25	-
VA 0381	Garlic	-	0.06	Thai	52.2	33	-	-	ND	ND	1	0.04	-
FB 0269	Grape (excl wine) 2/	-	2	AUS	67.0	513	125	FRA	118	3	2a	22.33	-
JF 0269	Grape juice 3/	0.42	-	FRA	52.2	696	-	-	ND	ND	3	5.60	-
DF 0269	Grapes, dried (= currants, raisins and sultanas) 3/	-	3	USA	65.0	70	-	-	ND	ND	1	3.24	-
DH 1100	Hops, dry	9.65	-	FRA	52.2	13	-	-	ND	ND	3	2.41	-
VB 0405	Kohlrabi	-	0.56	NLD	63.0	283	135	USA	99	3	1	2.51	-
VA 0384	Leek	-	0.44	FRA	52.2	177	225	BEL	169	3	2a	4.34	-
VL 0482	Lettuce, head	-	3.2	USA	65.0	213	558	UNK	413	3	2b	31.39	-
GC 0645	Maize	0.1	-	FRA	52.2	212	-	-	ND	ND	3	0.41	-
FI 0345	Mango	-	0.1	AUS	67.0	567	339	SWE	234	3	2a	1.54	-

Annex 4

TEBUCONAZOLE (189) International estimate of short term intake (IESTI) for **GENERAL POPULATION** ARfD= not yet considered

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% ARfD rounded
MM 0095	Meat from mammals other than marine mammals	-	0	AUS	67.0	521	-	-	ND	ND	1	0.00	-
VC 0046	Melons, except watermelon	-	0.02	FRA	52.2	1044	720	BEL	540	3	2a	0.81	-
ML 0106	Milks	0	-	USA	65.0	2466	-	-	ND	ND	3	0.00	-
GC 0647	Oats 1/	0	-	USA	65.0	175	-	-	ND	ND	3	0.00	-
VA 0385	Onion, Bulb	-	0.06	NLD	63.0	172	165	UNK	150	3	2a	0.45	-
FI 0350	Papaya	-	1.2	USA	65.0	567	250	JPN	250	3	2a	19.69	-
FS 0247	Peach 1/	-	0.81	SAF	55.7	685	140	BEL	126	3	2a	13.63	-
SO 0697	Peanut, shelled	0.03	-	FRA	52.2	135	-	-	ND	ND	3	0.08	-
FP 0230	Pear	-	0.47	FRA	52.2	568	187	UNK	170	3	2a	8.18	-
VO 0445	Peppers, sweet (incl. pim(i)ento) 1/	-	0.36	FRA	52.2	90	172	UNK	160	3	2b	1.87	-
FS 0014	Plum (incl dried)	-	0.12	Thai	53.5	480	59	UNK	55	3	2a	1.33	-
DF 0014	Plum, dried (prunes)	-	0.18	USA	65.0	303	6	FRA	5	1	3.00	0.84	-
PM 0110	Poultry meat	-	0	AUS	67.0	431	-	-	ND	ND	1	0.00	-
PO 0111	Poultry, Edible offal of	-	0.05	USA	65.0	248	-	-	ND	ND	1	0.19	-
FP 0231	Quince	-	0.47	AUS	67.0	175	92	USA	56	3	2a	2.01	-
OR 0495	Rape seed oil, edible	0.064	-	AUS	67.0	65	-	-	ND	ND	3	0.06	-
GC 0649	Rice	0.275	-	FRA	52.2	246	-	-	ND	ND	3	1.30	-
GC 0650	Rye 2/	0.05	-	FRA	52.2	161	-	-	ND	ND	3	0.15	-
VD 0541	Soya bean (dry)	0.02	-	JPN	52.6	159	-	-	ND	ND	3	0.06	-
VC 0431	Squash, summer (= courgette) 2/	-	0.02	FRA	52.2	351	300	FRA	270	3	2a	0.34	-
VO 0447	Sweet corn (corn-on-the-cob)	-	0.1	Thai	53.5	383	200	JPN	200	3	2a	1.46	-
VO 0448	Tomato	-	0.46	FRA	52.2	387	150	BEL	143	3	2a	5.92	-
JF 0448	Tomato juice	0.08	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	0.13	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomatoes peeled	-	0.115	-	-	ND	-	-	ND	ND	1	ND	-
VC 0432	Watermelon	-	0.02	USA	65.0	1939	4518	USA	2078	3	2b	1.79	-
GC 0654	Wheat 2/	0.05	-	FRA	52.2	703	-	-	ND	ND	3	0.67	-
-	Wine 3/	0.5	-	FRA	52.2	1006	-	-	ND	ND	3	9.64	-

1/ STMR from the 1997 JMPR; 2/ Codex MRL recommended at the 1994 JMPR; 3/ PF from the 1997 JMPR applied to grape MRL

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 EXPERT GROUPS 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.
4. Evaluation of the toxicity of pesticide residues in food. FAO Meeting Report, No. PL/1965/10/1; WHO/Food Add./27.65, 1965.
5. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/Food Add./28.65, 1965.
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ANNEX 6: LIVESTOCK DIETARY BURDEN

Livestock dietary burden tables

The livestock dietary burdens were estimated by considering the commodities listed in the tables below.

Azoxystrobin (229)

Estimated maximum dietary burden of farm animals

BEEF CATTLE	MAX											
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)			
						US-CAN	EU	AU	US-CAN	EU	AU	
Barley straw	AS	11	hr	100	11	5			0.55			
Cabbage heads and leaves	VB	2.3	hr	15	15		15			2.3		
Corn forage	AF	7.2	hr	40	18	15	20		2.7	3.6		
Corn stover	AS	25	hr	100	25	25	25		6.3	6.3		
Soya bean forage	AL	23	hr	56	41			20			8.2	
Soya bean hay	AL	62	hr	100	62	30		80	19		50	
Sugar beet leaves or tops	AV	44	hr	23	191		20			38		
Wheat forage	AF	5.4	hr	25	22	25	20		5.4	4.3		
Total						100	100	100	34	55	58	

Azoxystrobin (229)

Estimated maximum dietary burden of farm animals

DAIRY CATTLE	MAX										
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						US-CAN	EU	AU	US-CAN	EU	AU
Citrus pulp, dried	AB	9.3	STMR-P	91	10	5			0.51		
Corn forage	AF	7.2	HR	40	18	10	30		1.8	5.4	
Corn stover	AS	25	HR	100	25	15	20	40	3.8	5.0	10
Soya bean hay	AL	62	HR	100	62	30		40	19		25
Sugar beet leaves or tops	AV	44	HR	23	191		30			57	
Wheat forage	AF	5.4	HR	25	22	40	20	20	8.6	4.3	4.3
Total						100	100	100	33	72	39

Azoxystrobin (229)

Estimated maximum dietary burden of farm animals

POULTRY BROILER	MAX										
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						US-CAN	EU	AU	US-CAN	EU	AU
Barley grain	GC	0.08	STMR	88	0.09	35	70		0.03	0.06	
Peanut meal	SO	0.01	STMR-P	85	0.01			10			0.001
Rice bran	CF	0.82	STMR-P	90	0.91	25	10	20	0.23	0.09	0.18
Rice grain	GC	0.68	STMR	88	0.77	20		50	0.15		0.39
Soya bean hulls	AB	0.13	STMR-P	90	0.14	20	10	5	0.03	0.01	0.01
Soya bean seed	VD	0.06	STMR	89	0.07			15			0.01
Swede root	VR	0.45	HR	10	4.5		10			0.45	
Total						100	100	100	0.44	0.62	0.59

Azoxystrobin (229)

Estimated maximum dietary burden of farm animals

POULTRY - LAYER	MAX											
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)			
						US-CAN	EU	AU	US-CAN	EU	AU	
Barley grain	GC	0.08	STMR	88	0.09	45	40		0.04	0.04		
Cabbage heads and leaves	VB	2.3	HR	15	15		5			0.77		
Corn stover	AS	25	HR	100	25		10			2.5		
Peanut meal	SO	0.01	STMR-P	85	0.01			10			0.001	
Rice bran	CF	0.82	STMR-P	90	0.91	25	5	20	0.23	0.05	0.18	
Rice grain	GC	0.68	STMR	88	0.77	20		50	0.15		0.39	
Soya bean hay	AL	62	HR	100	62		10			6.2		
Soya bean hulls	AB	0.13	STMR-P	90	0.14	10	5	5	0.01	0.01	0.01	
Soya bean seed	VD	0.06	STMR	89	0.07			15			0.01	
Sugar beet leaves or tops	AV	44	HR	23	191		5			9.6		
Swede root	VR	0.45	HR	10	4.5		10			0.45		
Wheat forage	AF	5.4	HR	25	22		10			2.2		
Total						100	100	100	0.44	22	0.59	

Azoxystrobin (229)

Estimated STMR dietary burden of farm animals

BEEF CATTLE	STMR											
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)			
						US-CAN	EU	AU	US-CAN	EU	AU	
Barley forage	AF	1.7	STMR	30	5.7	5	10		0.28	0.57		
Cabbage heads and leaves	VB	1.2	STMR	15	8.0		20			1.6		
Citrus pulp, dried	AB	9.3	STMR-P	91	10	10	5		1.0	0.51		
Corn forage	AF	1.6	STMR	40	4.0	5			0.20			
Corn stover	AS	5	STMR	100	5.0	25	25		1.3	1.3		
Soya bean forage	AL	9.4	STMR	56	17			20			3.4	
Soya bean hay	AL	36	STMR	100	36	30		80	11		29	
Sugar beet leaves or tops	AV	16	STMR	23	70		20			14		
Wheat forage	AF	1.9	STMR	25	7.6	25	20		1.9	1.5		
Total						100	100	100	15	19	32	

Azoxystrobin (229)

Estimated STMR dietary burden of farm animals

DAIRY CATTLE	STMR											
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)			
						US-CAN	EU	AU	US-CAN	EU	AU	
Barley forage	AF	1.7	STMR	30	5.7		10			0.57		
Cabbage heads and leaves	VB	1.2	STMR	15	8.0		20			1.6		
Citrus pulp, dried	AB	9.3	STMR-P	91	10	10	20	10	1.0	2.0	1.0	
Corn forage	AF	1.6	STMR	40	4.0	5			0.20			
Corn stover	AS	5	STMR	100	5.0	15			0.75			
Grape pomace, wet	AB	1.6	STMR-P	15	11			20			2.1	
Soya bean hay	AL	36	STMR	100	36	30		40	11		14	
Sugar beet leaves or tops	AV	16	STMR	23	70		30			21		
Wheat forage	AF	1.9	STMR	25	7.6	40	20	30	3.0	1.5	2.3	
Total						100	100	100	16	27	20	

Azoxystrobin (229)

Estimated STMR dietary burden of farm animals

POULTRY - BROILER STMR

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						US-CAN	EU	AU	US-CAN	EU	AU
Peanut meal	SO	0.01	STMR-P	85	0.01			10			0.001
Rice bran	CF	0.82	STMR-P	90	0.91	25	10	20	0.23	0.09	0.18
Rice grain	GC	0.68	STMR	88	0.77	20		50	0.15		0.39
Rice grain	GC	0.08	STMR	88	0.09	35	70		0.03	0.06	
Soya bean hulls	AB	0.13	STMR-P	90	0.14	20	10	5	0.03	0.01	0.01
Soya bean seed	VD	0.06	STMR	89	0.07			15			0.01
Swede root	VR	0.23	STMR	10	2.3		10			0.23	
Total						100	100	100	0.44	0.40	0.59

Azoxystrobin (229)

Estimated STMR dietary burden of farm animals

POULTRY— LAYER STMR

Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)			Residue contribution (mg/kg)		
						US-CAN	EU	AU	US-CAN	EU	AU
Barley grain	GC	0.08	STMR	88	0.09	45	40		0.04	0.04	
Cabbage heads and leaves	VB	1.2	STMR	15	8.0		5			0.40	
Corn stover	AS	5	STMR	100	5.0		10			0.50	
Peanut meal	SO	0.01	STMR-P	85	0.01			10			0.001
Rice bran	CF	0.82	STMR-P	90	0.91	25	5	20	0.23	0.05	0.18
Rice grain	GC	0.68	STMR	88	0.77	20		50	0.15		0.39
Soya bean hay	AL	36	STMR	100	36		10			3.6	
Soya bean hulls	AB	0.13	STMR-P	90	0.14	10	5	5	0.01	0.01	0.01
Soya bean seed	VD	0.06	STMR	89	0.07			15			0.01
Sugar beet leaves or tops	AV	16	STMR	23	70		5			3.5	
Swede root	VR	0.23	STMR	10	2.3		10			0.23	
Wheat forage	AF	1.9	STMR	25	7.6		10			0.76	
Total						100	100	100	0.44	9.1	0.59

Buprofezin (173)

Estimated mean and maximum dietary burden of farm animals

BEEF CATTLE MEAN/MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Citrus, dried pulp	AB	1.2	STMR-P	91	1.319	10	5	30	0.13	0.07	0.40
Total						10	5	30	0.13	0.07	0.40

DAIRY CATTLE MEAN/MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Citrus, dried pulp	AB	1.2	STMR-P	91	1.319	10	20	30	0.13	0.26	0.40
Total						10	20	30	0.13	0.26	0.40

Buprofezin (173)
Estimated mean and maximum dietary burden of farm animals

POULTRY - BROILER — MEAN/MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Citrus, dried pulp	AB	1.2	STMR-P	91	1.319						
Total						0	0	0	0.00	0.00	0.00

POULTRY - LAYER — MEAN/MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Citrus, dried pulp	AB	1.2	STMR-P	91	1.319						
Total						0	0	0	0.00	0.00	0.00

Chlorantraniliprole (230)
Estimated maximum dietary burden of farm animals

BEEF CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Apple pomace, wet	AB	0.154	STMR-P	40	0.385	20	20		0.08	0.08	
Grape pomace, wet	AB	0.3035	STMR-P	15	2.023			20			0.40
cotton seed (for hulls)	SO	0.1029	STMR	90	0.114	20			0.02		
cotton gin trash	AM?	4.1	STMR	90	4.556	5			0.23		
barley grain		0.004	STMR	88	0.005	10	20		0.00	0.00	
wheat forage		0.083	HR	25	0.332	25	20	80	0.08	0.07	0.27
wheat hay		0.15	HR	88	0.170	20	20		0.03	0.03	
Total						100	80	100	0.45	0.18	0.67

Chlorantraniliprole (230)
Estimated maximum dietary burden of farm animals

DAIRY CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Apple pomace, wet	AB	0.154	STMR-P	40	0.385	10	10		0.04	0.04	
Grape pomace, wet	AB	0.3035	STMR-P	15	2.023			20			0.40
cotton seed	SO	0.049	STMR	88	0.056		10			0.01	
cotton seed (for meal)	SO	0.0368	STMR	89	0.041		5			0.00	
cotton seed (for hulls)	SO	0.1029	STMR	90	0.114	10		10	0.01		0.01
barley grain		0.004	STMR	88	0.005		15			0.00	
wheat forage		0.083	HR	25	0.332	40	20	60	0.13	0.07	0.20
wheat hay		0.15	HR	88	0.170	40	20	10	0.07	0.03	0.02
Total						100	80	100	0.25	0.15	0.63

Chlorantraniliprole (230)
Estimated maximum dietary burden of farm animals

POULTRY - BROILER MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Potato culls	VR	0.004	HR	20	0.020		10			0.00	
Cotton seed (for meal)	SO	0.0368	STMR	89	0.041	20	5	10	0.01	0.00	0.00
barley grain		0.004	STMR	88	0.005	75	70	15	0.00	0.00	0.00
oat grain		0.004	STMR	89	0.004						
Total						95	85	80	0.012	0.007	0.007

Chlorantraniliprole (230)
Estimated maximum dietary burden of farm animals

POULTRY - LAYER MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Potato culls	VR	0.004	HR	20	0.020		10			0.00	
Cotton seed (for meal)	SO	0.0368	STMR	89	0.041	20	5	10	0.01	0.00	0.00
barley grain		0.004	STMR	88	0.005	70	65		0.00	0.00	
wheat forage		0.083	HR	25	0.332		10			0.03	
wheat hay		0.15	HR	88	0.170		10			0.02	
wheat grain		0.004	STMR	89	0.004			55			0.00
Total						90	100	65	0.011	0.057	0.007

Chlorantraniliprole (230)
Estimated mean dietary burden of farm animals

BEEF CATTLE MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Apple pomace, wet	AB	0.154	STMR-P	40	0.385	20	20		0.08	0.08	
Grape pomace, wet	AB	0.3035	STMR-P	15	2.023			20			0.40
cotton seed (for meal)	SO	0.0368	STMR	89	0.041		5			0.00	
cotton seed (for hulls)	SO	0.1029	STMR	90	0.114	20		20	0.02		0.02
cotton gin trash	AM?	4.1	STMR	90	4.556	5			0.23		
barley grain		0.004	STMR	88	0.005	30	35		0.00	0.00	
wheat forage		0.022	STMR	25	0.088	25	20	60	0.02	0.02	0.05
wheat hay		0.045	STMR	88	0.051		20			0.01	
Total						100	100	100	0.35	0.11	0.48

Chlorantraniliprole (230)
Estimated mean dietary burden of farm animals

DAIRY CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Apple pomace, wet	AB	0.154	STMR-P	40	0.385	10	10		0.04	0.04	
Grape pomace, wet	AB	0.3035	STMR-P	15	2.023			20			0.40
Potato culls	VR	0.003	STMR	20	0.015	10		10	0.00		0.00
cotton seed	SO	0.049	STMR	88	0.056		10			0.01	
cotton seed (for hulls)	SO	0.1029	STMR	90	0.114	15		10	0.02		0.01
barley grain		0.004	STMR	88	0.005	25	40		0.00	0.00	
wheat forage		0.022	STMR	25	0.088	40	20	60	0.04	0.02	0.05
wheat hay		0.045	STMR	88	0.051		20			0.01	
Total						100	100	100	0.09	0.07	0.47

Chlorantraniliprole (230)
Estimated mean dietary burden of farm animals

POULTRY - BROILER — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Potato culls	VR	0.003	STMR	20	0.015		10			0.00	
Cotton seed (for meal)	SO	0.0368	STMR	89	0.041	20	5	10	0.01	0.00	0.00
barley grain		0.004	STMR	88	0.005	75	70	15	0.00	0.00	0.00
wheat grain		0.004	STMR	89	0.004			55			0.00
Total						95	85	80	0.012	0.007	0.007

Chlorantraniliprole (230)
Estimated mean dietary burden of farm animals

POULTRY - LAYER — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Potato culls	VR	0.003	STMR	20	0.015		10			0.00	
Cotton seed (for meal)	SO	0.0368	STMR	89	0.041	20	5	10	0.01	0.00	0.00
barley grain		0.004	STMR	88	0.005	70	65		0.00	0.00	
wheat forage		0.022	STMR	25	0.088		10			0.01	
wheat hay		0.045	STMR	88	0.051		10			0.01	
wheat grain		0.004	STMR	89	0.004			55			0.00
Total						90	100	65	0.011	0.020	0.007

Cypermethrins (118)

Estimated maximum dietary burden of livestock

BEEF CATTLE — MAX

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Alfalfa forage	AL	11	high residue	35	31.429	60	70	100	18.86	22.00	31.43
Sugar beet leaves or tops	AV	8.3	high residue	100	8.300		20			1.66	
Barley straw	AS AF	6.9	high residue	100	6.900		10			0.69	
Maize fodder	AS AF	6.9	high residue	100	6.900	25			1.73		
Rice	GC	0.57	STMR	88	0.648	15			0.10		
Total						100	100	100	20.68	24.35	31.43

Cypermethrins (118)

Estimated maximum dietary burden of livestock

DAIRY CATTLE — MAX

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Alfalfa forage	AL	11	high residue	35	31.429	40	40	60	12.57	12.57	18.86
Sugar beet leaves or tops	AV	8.3	high residue	100	8.300		30			2.49	
Maize fodder	AS AF	6.9	high residue	100	6.900	15		40	1.04		2.76
Barley straw	AS AF	6.9	high residue	100	6.900		30			2.07	
Rice	GC	0.57	STMR	88	0.648	20			0.13		
Carrot culls	VR	0.01	HR	12	0.083	10			0.01		
Beans (dry)	VD	0.05	STMR	88	0.057	15			0.01		
Total						100	100	100	13.75	17.13	21.62

As well as the commodities shown in the table for beef and dairy cattle, the following were also considered: barley forage, barley grain, bean forage, cabbage heads and leaves, grape pomace, maize, maize forage, oat straw, oats, pea hay or pea fodder, pea vines, dry peas, rice straw and fodder, soya beans , wheat, wheat forage and wheat bran.

Cypermethrins (118)

Estimated maximum dietary burden of livestock

POULTRY - BROILER — MAX

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Rice grain	GC	0.57	STMR	88	0.65	20		50	0.130		0.324
Carrot culls	VR	0.01	HR	12	0.083		10			0.008	
Bean seed	VD	0.05	STMR	88	0.057	20	20	50	0.011	0.011	0.028
Barley grain	GC	0.035	STMR	88	0.040	60	70		0.024	0.028	
Total						100	100	100	0.16	0.05	0.35

Cypermethrins (118)

Estimated maximum dietary burden of livestock

POULTRY - LAYER — MAX

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Pea vines	AL	2.1	high residue	25	8.40		10			0.840	
Beet, sugar tops	AV	8.3	high residue	100	8.30		5			0.415	
Wheat straw	AS AF	6.9	high residue	100	6.90		10			0.690	
Cabbage heads leaves	VB	0.65	high residue	15	4.33		5			0.217	
Rice grain	GC	0.57	STMR	88	0.65	20		50	0.130		0.324
Carrot culls	VR	0.01	HR	12	0.083		10			0.008	
Bean seed	VD	0.05	STMR	88	0.057	20	20	50	0.011	0.011	0.028
Barley grain	GC	0.035	STMR	88	0.040	50	40		0.020	0.016	
Wheat milled, bran	CM	0.024	STMR	88	0.027	10			0.003		
Total						100	100	100	0.16	2.20	0.35

As well as the commodities shown in the table for poultry broilers and layers, the following were also considered: barley grain, barley straw, bean seed, sugar beet tops, cabbage heads and leaves, carrot culls, maize fodder, maize forage, maize grain, oat grain, oat straw, pea seed, pea straw, pea vines, rice grain, wheat forage, wheat grain, wheat bran and wheat straw.

Cypermethrins (118)

Estimated mean dietary burden of livestock

BEEF CATTLE — MEAN

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Alfalfa fodder	AL	11.5	STMR	100	11.500	60		80	6.90		9.20
Alfalfa forage	AL	3.65	STMR	35	10.429		70	20		7.30	2.09
Wheat straw and fodder, Dry	AS AF	3.6	STMR	100	3.600						
Maize fodder	AS AF	3.6	STMR	100	3.600	25	25		0.90	0.90	
Sugar beet leaves or tops	AV	1.5	STMR	100	1.500		5			0.08	
Rice	GC	0.57	STMR	88	0.648	15			0.10		
Total						100	100	100	7.90	8.28	11.29

Cypermethrins (118)

Estimated mean dietary burden of livestock

DAIRY CATTLE — MEAN

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Alfalfa fodder	AL	11.5	STMR	100	11.500	40	40	60	4.60	4.60	6.90
Sugar beet leaves or tops	AV	1.5	STMR	23	6.522		30			1.96	
Maize fodder	AS AF	3.6	STMR	100	3.600	15		40	0.54		1.44
Barley straw	AS AF	3.60	STMR	100	3.600		30			1.08	
Rice	GC	0.57	STMR	88	0.648	20			0.13		
Carrot culls	VR	0.01	STMR	12	0.083	10			0.01		
Beans (dry)	VD	0.05	STMR	88	0.057	15			0.01		
Total						100	100	100	5.29	7.64	8.34

Cypermethrins (118)

Estimated mean dietary burden of livestock

POULTRY - BROILER — MEAN

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Rice grain	GC	0.57	STMR	88	0.65	20		50	0.130		0.324
Carrot culls	VR	0.01	STMR	12	0.083		10			0.008	
Bean seed	VD	0.05	STMR	88	0.057	20	20	50	0.011	0.011	0.028
Barley grain	GC	0.035	STMR	88	0.040	55	70		0.022	0.028	
Wheat milled, bran	CM	0.024	STMR	88	0.027	5			0.001		
Total						100	100	100	0.16	0.05	0.35

Cypermethrins (118)

Estimated mean dietary burden of livestock

POULTRY - LAYER — MEAN

Commodity	Commod group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Wheat straw	AS AF	3.6	STMR	100	3.60		10			0.360	
Pea vines	AL	0.45	STMR	25	1.80		10			0.180	
Beet, sugar tops	AV	1.5	STMR	100	1.50		5			0.075	
Rice grain	GC	0.57	STMR	88	0.65	20		50	0.130		0.324
Cabbage heads leaves	VB	0.02	STMR	15	0.13		5			0.007	
Carrot culls	VR	0.01	STMR	12	0.083		10			0.008	
Bean seed	VD	0.05	STMR	100	0.050	20	20	50	0.010	0.010	0.025
Barley grain	GC	0.035	STMR	88	0.040	50	40		0.020	0.016	
Wheat milled, bran	CM	0.024	STMR	88	0.027	10			0.003		
Total						100	100	100	0.16	0.66	0.35

Imidacloprid (206)

Estimated maximum dietary burden of livestock

BEEF CATTLE — MAX

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Beet, sugar tops	AM	0.67	HR	23	2.913		20			0.58	
Oat, forage	AF	0.67	HR	30	2.233	25	20		0.56	0.45	
Peanut, hay	AL	24	HR	85	28.235	25		60	7.06		16.94
Wheat, forage	AF	0.67	HR	25	2.680			40			1.07
Wheat, straw	AS	0.45	HR	88	0.511	10			0.05		
Potato, culls	VR	0.28	HR	20	1.400	30			0.42		
Swede, roots	VR	0.28	HR	10	2.800		40			1.12	
Pea, seed	VD	0.62	STMR	90	0.689		20			0.14	
Almond, hulls	AM	1.5	STMR	90	1.667	10			0.17		
						100	100	100	8.29	2.29	18.01

Imidacloprid (206)
Estimated maximum dietary burden of livestock

DAIRY CATTLE MAX

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Beet, sugar tops	AM	0.67	HR	23	2.913		30			0.87	
Cabbage heads, leaves	VB	0.32	HR	15	2.133		20			0.43	
Oat, forage	AF	0.67	HR	30	2.233		20			0.45	
Peanut, hay	AL	24	HR	85	28.235	20		60	5.65		16.94
Wheat, forage	AF	0.67	HR	25	2.680	40		40	1.07		1.07
Carrot, culls	VR	0.28	HR	12	2.333	10			0.23		
Swede, roots	VR	0.28	HR	10	2.800		20			0.56	
Pea, seed	VD	0.62	STMR	90	0.689		10			0.07	
Almond, hulls	AM	1.5	STMR	90	1.667	10			0.17		
Wheat, milled byproducts	CM	0.175	STMR	88	0.199	20			0.04		
Total						100	100	100	7.16	2.38	18.01

Imidacloprid (206)
Estimated maximum dietary burden of livestock

POULTRY - BROILER MAX

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Swede, roots	VR	0.28	HR	10	2.800		10			0.28	
Barley, grain	GC	0.05	STMR	88	0.057			15			0.01
Corn, field, grain	GC	0.05	STMR	88	0.057	80			0.05		
Pea, seed	VD	0.62	STMR	90	0.689	20	20	5	0.14	0.14	0.03
Rye, grain	GC	0.05	STMR	88	0.057		70	50		0.04	0.03
Peanut, meal	SO	0.12	STMR	85	0.141			10			0.01
Wheat, milled byproducts	CM	0.175	STMR	88	0.199			20			0.04
Total						100	100	100	0.19	0.46	0.12

Imidacloprid (206)
Estimated maximum dietary burden of livestock

POULTRY - LAYER MAX

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Beet, sugar tops	AM	0.67	HR	23	2.913		5			0.15	
Cabbage heads, leaves	VB	0.32	HR	15	2.133		5			0.11	
Wheat, forage	AF	0.67	HR	25	2.680		10			0.27	
Wheat, straw	AS	0.45	HR	88	0.511		10			0.05	
Swede, roots	VR	0.28	HR	10	2.800		10			0.28	
Corn, field, grain	GC	0.05	STMR	88	0.057	70	40		0.04	0.02	
Pea, seed	VD	0.62	STMR	90	0.689	20	20		0.14	0.14	
Wheat, grain	GC	0.05	STMR	89	0.056			55			0.03
Peanut, meal	SO	0.12	STMR	85	0.141	10		10	0.01		0.01
Sunflower, meal	SO	0.05	STMR	92	0.054			15			0.01
Wheat, milled byproducts	CM	0.175	STMR	88	0.199			20			0.04
Total						100	100	100	0.19	1.02	0.09

Imidacloprid (206)

Estimated mean dietary burden of livestock

BEEF CATTLE MEAN

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Beet, sugar tops	AM	0.425	STMR	23	1,848		20			0.37	
Peanut, hay	AL	8,2	STMR	85	9,647	25		60	2,41		5,79
Wheat, forage	AF	0.09	STMR	25	0.360	25	20		0.09	0.07	
Potato, culls	VR	0.05	STMR	20	0.250	30			0.08		
Swede, roots	VR	0.05	STMR	10	0.500		40			0.20	
Pea, seed	VD	0.62	STMR	90	0.689		20	40		0.14	0.28
Apple pomace, wet	AB	0.11	STMR	40	0.275	20			0.06		
Total						100	100	100	2.64	0.78	6.07

Imidacloprid (206)

Estimated mean dietary burden of livestock

DAIRY CATTLE MEAN

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Beet, sugar tops	AM	0.425	STMR	23	1,848		30			0.55	
Cabbage heads, leaves	VB	0.08	STMR	15	0.533		20			0.11	
Peanut, hay	AL	8,2	STMR	85	9,647	20		60	1,93		5,79
Wheat, forage	AF	0.09	STMR	25	0.360	40			0.14		
Swede, roots	VR	0.05	STMR	10	0.500		20	10		0.10	0.05
Pea, seed	VD	0.62	STMR	90	0.689		20	20		0.14	0.14
Almond, hulls	AM	1,5	STMR	90	1,667	10		10	0.17		0.17
Apple pomace, wet	AB	0.11	STMR	40	0.275		10			0.03	
Wheat, milled byproducts	CM	0.175	STMR	88	0.199	30			0.06		
Total						100	100	100	2.30	0.93	6.14

Imidacloprid (206)

Estimated mean dietary burden of livestock

POULTRY - BROILER MEAN

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Swede, roots	VR	0.05	STMR	10	0.500		10			0.05	
Oat, grain	GC	0.05	STMR	89	0.056			15			0.01
Pea, seed	VD	0.62	STMR	90	0.689	20	20	5	0.14	0.14	0.03
Rye, grain	GC	0.05	STMR	88	0.057			50			0.03
Wheat, grain	GC	0.05	STMR	89	0.056		40			0.02	
Peanut, meal	SO	0.12	STMR	85	0.141	30	10	10	0.04	0.01	0.01
Wheat, milled byproducts	CM	0.175	STMR	88	0.199	50	20	20	0.10	0.04	0.04
Total						100	100	100	0.28	0.26	0.12

Imidacloprid (206)

Estimated mean dietary burden of livestock

POULTRY - LAYER — MEAN

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Beet, sugar tops	AM	0.425	STMR	23	1,848		5			0.09	
Cabbage heads, leaves	VB	0.08	STMR	15	0.533		5			0.03	
Swede, roots	VR	0.05	STMR	10	0.500		10			0.05	
Pea, seed	VD	0.62	STMR	90	0.689	20	20	5	0.14	0.14	0.03
Wheat, grain	GC	0.05	STMR	89	0.056		40	50		0.02	0.03
Peanut, meal	SO	0.12	STMR	85	0.141	30		10	0.04		0.01
Sunflower, meal	SO	0.05	STMR	92	0.054			15			0.01
Wheat, milled byproducts	CM	0.175	STMR	88	0.199	50	20	20	0.10	0.04	0.04
Total						100	100	100	0.28	0.37	0.12

Lambda cyhalothrin (146)

Estimated maximum dietary burden

BEEF CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Corn, field forage	AF	2.8	highest residue	40	7.000	40	80	80	2.80	5.60	5.60
Peanut, hay	AL	2.2	highest residue	85	2.588	25	0	20	0.65	0.00	0.52
Rice, hulls	CM	1.9	STMR-P	90	2.111	10	0	0	0.21	0.00	0.00
Apple, pomace wet	AB	0.65	STMR-P	40	1.625	20	20	0	0.33	0.33	0.00
Oats, straw (dry-weight)	AS	1.6	highest residue	100	1.600	5	0	0	0.08	0.00	0.00
Total						100	100	100	4.07	5.93	6.12

Lambda cyhalothrin (146)

Estimated maximum dietary burden

DAIRY CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Corn, field forage	AF	2.8	highest residue	40	7.000	50	60	80	3.50	4.20	5.60
Peanut, hay	AL	2.2	highest residue	85	2.588	20	0	20	0.52	0.00	0.52
Rice, hulls	CM	1.9	STMR-P	90	2.111	10	0	0	0.21	0.00	0.00
Apple, pomace wet	AB	0.65	STMR-P	40	1.625	10	10	0	0.16	0.16	0.00
Oats, straw (dry-weight)	AS	1.6	highest residue	100	1.600	10	20	0	0.16	0.32	0.00
Wheat, milled byproducts	CC	0.98	STMR-P	88	1.114	0	10	0	0.00	0.11	0.00
Total						100	100	100	**4.55**	**4.79**	**6.12**

Lambda cyhalothrin (146)
Estimated maximum dietary burden

POULTRY - BROILER — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Wheat, milled byproducts	CC	0.98	STMR-P	88	1.114	50	20	20	0.56	0.22	0.22
Rice, grain	GC	0.3	STMR	88	0.335	20	0	50	0.07	0.00	0.17
Rice, bran/pollard	CM	0.07	STMR-P	90	0.072	25	10	20	0.02	0.01	0.01
Barley, grain	GC	0.02	STMR	88	0.023	0	70	0	0.00	0.02	0.00
Bean seed	VD	0.01	STMR	88	0.011	5	0	10	0.00	0.00	0.00
Total						100	100	100	**0.65**	**0.25**	**0.40**

Lambda cyhalothrin (146)
Estimated maximum dietary burden

POULTRY - LAYER — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Corn, field forage	AF	2.8	highest residue	40	7.000	0	10	0	0.00	0.70	0.00
Wheat, straw (dry-weight)	AS	1.6	highest residue	100	1.600	0	10	0	0.00	0.16	0.00
Wheat, milled byproducts	CC	0.98	STMR-P	88	1.114	50	20	20	0.56	0.22	0.22
Rice, grain	GC	0.3	STMR	88	0.335	20	0	50	0.07	0.00	0.17
Rice, bran/pollard	CM	0.07	STMR-P	90	0.072	25	5	20	0.02	0.00	0.01
Barley, grain	GC	0.02	STMR	88	0.023	0	55	0	0.00	0.01	0.00
Bean seed	VD	0.01	STMR	88	0.011	5	0	10	0.00	0.00	0.00
Total						100	100	100	**0.65**	**1.09**	**0.40**

Lambda-cyhalothrin (146)
Estimated mean dietary burden

BEEF CATTLE — MEAN

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Corn, field forage	AF	1.85	STMR	40	4.625	40	80	80	1.85	3.70	3.70
Rice, hulls	CM	1.9	STMR-P	90	2.111	10	0	5	0.21	0.00	0.11
Apple, pomace wet	AB	0.65	STMR-P	40	1.625	20	20	15	0.33	0.33	0.24
Peanut, hay	AL	1.3	STMR	85	1.529	25	0	0	0.38	0.00	0.00
Wheat, milled byproducts	CC	0.98	STMR-P	88	1.114	5	0	0	0.06	0.00	0.00
Total						100	100	100	2.83	4.03	4.05

Lambda-cyhalothrin (146)
Estimated mean dietary burden

DAIRY CATTLE — MEAN

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Corn, field forage	AF	1.85	STMR	40	4.625	50	60	80	2.31	2.78	3.70
Rice, hulls	CM	1.9	STMR-P	90	2.111	10	0	10	0.21	0.00	0.21
Apple, pomace wet	AB	0.65	STMR-P	40	1.625	10	10	10	0.16	0.16	0.16
Peanut, hay	AL	1.3	STMR	85	1.529	20	0	0	0.31	0.00	0.00
Wheat, milled byproducts	CC	0.98	STMR-P	88	1.114	10	30	0	0.11	0.33	0.00
Total						100	100	100	3.1	3.27	4.07

Lambda-cyhalothrin (146)

Estimated mean dietary burden

POULTRY - BROILER — MEAN

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Wheat, milled byproducts	CC	0.98	STMR-P	88	1.114	50	20	20	0.56	0.22	0.22
Rice, grain	GC	0.3	STMR	88	0.335	20	0	50	0.07	0.00	0.17
Rice, bran/pollard	CM	0.07	STMR-P	90	0.072	25	10	20	0.02	0.01	0.01
Barley, grain	GC	0.02	STMR	88	0.023	5	70	0	0.00	0.02	0.00
Bean seed	VD	0.01	STMR	88	0.011	0	0	10	0.00	0.00	0.00
Total						100	100	100	**0.65**	**0.25**	**0.40**

Lambda-cyhalothrin (146)

Estimated mean dietary burden

POULTRY - LAYER — MEAN

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Corn, field forage	AF	1.85	STMR	40	4.625	0	10	0	0.00	0.46	0.00
Wheat, milled byproducts	CC	0.98	STMR-P	88	1.114	50	20	20	0.56	0.22	0.22
Wheat, straw (dry-weight)	AS	0.54	STMR	100	0.540	0	10	0	0.00	0.05	0.00
Rice, grain	GC	0.3	STMR	88	0.335	20	0	50	0.07	0.00	0.17
Rice, bran/pollard	CM	0.07	STMR-P	90	0.072	25	5	20	0.02	0.00	0.01
Barley, grain	GC	0.02	STMR	88	0.023	0	55	0	0.00	0.01	0.00
Bean seed	VD	0.01	STMR	88	0.011	5	0	10	0.00	0.00	0.00
Total						100	100	100	**0.65**	**0.74**	**0.40**

Mandipropamid (231)

Estimated maximum dietary burden of farm animals

BEEF CATTLE — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US–CAN	EU	AU	US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733			20			1.55
Cabbage heads, leaves	VC	5.8	high residue	15	38.667		20			7.73	
Potato culls	VR	0.01	high residue	20	0.050	30	30	10	0.02	0.02	0.01
Total						30	50	30	0.02	7.75	1.56

Mandipropamid (231)

Estimated maximum dietary burden of farm animals

DAIRY CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US–CAN	EU	AU	Residue contribution (ppm) US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733			20			1.55
Cabbage heads, leaves	VC	5.8	high residue	15	38.667		20			7.73	
Potato culls	VR	0.01	high residue	20	0.050	10	30	10	0.01	0.02	0.01
Total						10	50	30	0.01	7.75	1.56

Mandipropamid (231)

Estimated maximum dietary burden of farm animals

POULTRY – BROILER — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US–CAN	EU	AU	Residue contribution (ppm) US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733						
Cabbage heads, leaves	VC	5.8	high residue	15	38.667		5			1.93	
Potato culls	VR	0.01	high residue	20	0.050		10			0.01	
Total							15			1.94	

Mandipropamid (231)

Estimated maximum dietary burden of farm animals

POULTRY – LAYER — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US–CAN	EU	AU	Residue contribution (ppm) US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733						
Cabbage heads, leaves	VC	5.8	high residue	15	38.667		5			1.93	
Potato culls	VR	0.01	high residue	20	0.050		10			0.01	
Total							15			1.94	

Mandipropamid (231)

Estimated mean dietary burden of farm animals

BEEF CATTLE — MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US–CAN	EU	AU	Residue contribution (ppm) US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733			20			1.55
Cabbage heads, leaves	VC	3.55	STMR	15	23.667		20			4.73	
Potato culls	VR	0.01	STMR	20	0.050	30	30	10	0.02	0.02	0.01
Total						30	50	30	0.02	4.75	1.56

Mandipropamid (231)

Estimated mean dietary burden of farm animals

DAIRY CATTLE — MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733			20			1.55
Cabbage heads, leaves	VC	3.55	STMR	15	23.667		20			4.73	
Potato culls	VR	0.01	STMR	20	0.050	30	30	10	0.02	0.02	0.01
Total						30	50	30	0.02	4.75	1.56

Mandipropamid (231)

Estimated mean dietary burden of farm animals

POULTRY – BROILER — MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US–CAN	EU	AU	Residue contribution (ppm) US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733						
Cabbage heads, leaves	VC	3.55	STMR	15	23.667						
Potato culls	VR	0.01	STMR	20	0.050		10			0.01	
Total							10			0.01	

Mandipropamid (231)

Estimated mean dietary burden of farm animals

POULTRY – LAYER — MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US–CAN	EU	AU	Residue contribution (ppm) US–CAN	EU	AU
Grape pomace, wet	AB	1.16	STMR-P	15	7.733						
Cabbage heads, leaves	VC	3.55	STMR	15	23.667		5			1.18	
Potato culls	VR	0.01	STMR	20	0.050		10			0.01	
Total							15			1.19	

Profenofos (171)

Estimated maximum/mean dietary burden

BEEF CATTLE — MAX/MEAN

Commodity	Commodity group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Cotton meal	SO	0.19	STMR	89	0.213		5			0.01	
Cotton hulls	SO	0.49	STMR	90	0.544	20		20	0.11		0.11
Total						20	5	20	0.11	0.01	0.11

DAIRY CATTLE — MAX/MEAN

Commodity	Commod group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Cotton meal	SO	0.19	STMR	89	0.213		5			0.01	
Cotton hulls	SO	0.49	STMR	90	0.544	15		10	0.08		0.05
Total						15	5	10	0.08	0.01	0.05

Profenofos (171)

Estimated maximum/mean dietary burden

POULTRY - BROILER MAX/MEAN

Commodity	Commod group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Cotton meal	SO	0.19	STMR	89	0.213	20	5	10	0.04	0.01	0.02
Total						20	5	10	0.04	0.01	0.02

POULTRY - LAYER MAX/MEAN

Commodity	Commod group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Cotton meal	SO	0.19	STMR	89	0.213	20	5	10	0.04	0.01	0.02
Total						20	5	10	0.04	0.01	0.02

Prothioconazole (232)

Estimated maximum dietary burden of livestock

BEEF CATTLE MAX

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Barley, forage	AF	2.6	HR	30	8.67	30	30		2.60	2.60	
Wheat, forage	AF	2.6	HR	25	10.4			100			10.4
Barley, grain	GC	0.01	STMR	88	0.011	50	70		0.0057	0.0080	
Total						80	100	100	2.61	2.61	10.40

Prothioconazole (232)

Estimated maximum dietary burden of livestock

DAIRY CATTLE MAX

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Barley, forage	AF	2.6	HR	30	8.67		30			2.60	
Oat, forage	AF	2.6	HR	30	8.67			90			7.8
Wheat, forage	AF	2.6	HR	25	10.4	40			4.16		
Barley, grain	GC	0.01	STMR	88	0.011	45	40	10	0.0051	0.0045	0.0011
Total						85	70	100	4.17	2.61	7.80

Prothioconazole (232)

Estimated mean dietary burden of livestock

BEEF CATTLE MEAN

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Barley, forage	AF	0.96	STMR	30	3.05	30	30		0.96	0.96	
Wheat, forage	AF	0.96	STMR	25	3.66			100			3.84
Barley, grain	GC	0.01	STMR	88	0.011	50	70		0.0057	0.0080	
Total						80	100	100	0.96	0.96	3.84

Prothioconazole (232)

Estimated mean dietary burden of livestock

DAIRY CATTLE — MEAN

Commodity	Commodity group	Residue mg/kg	Basis	% Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	Diet content (%) EU	Diet content (%) AU	Residue contribution (ppm) US-CAN	Residue contribution (ppm) EU	Residue contribution (ppm) AU
Barley, forage	AF	0.96	HR	30	3.05		30			0.96	
Oat, forage	AF	0.96	HR	30	3.05			90			2.75
Wheat, forage	AF	0.96	HR	25	3.66	40			1.54		
Barley, grain	GC	0.01	STMR	88	0.011	45	40	10	0.0051	0.0045	0.0011
Total						85	70	100	1.55	0.96	2.75

Prothioconazole (232)

Estimated maximum dietary burden of livestock

POULTRY - BROILER — MAX

Commodity	Commod group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	Diet content (%) EU	Diet content (%) AU	Residue contribution (ppm) US-CAN	Residue contribution (ppm) EU	Residue contribution (ppm) AU
Barley grain	GC	0.01	STMR	88	0.011	75			0.009		
Wheat grain	GC	0.01	STMR	89	0.011	5	70	70	0.001	0.008	0.008
Total						80	70	70	0.01	0.008	0.008

Prothioconazole (232)

Estimated maximum dietary burden of livestock

POULTRY - LAYER — MAX

Commodity	Commod group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	Diet content (%) EU	Diet content (%) AU	Residue contribution (ppm) US-CAN	Residue contribution (ppm) EU	Residue contribution (ppm) AU
Wheat forage	AF	2.6	HR	25	10.4		10			1.04	
Barley grain	GC	0.01	STMR	88	0.011		90			0.01	
Triticale grain	GC	0.01	STMR	89	0.011	80			0.009		
Wheat grain	GC	0.01	STMR	89	0.011			55			0.006
Total						80	100	55	0.009	1.050	0.006

Prothioconazole (232)

Estimated mean dietary burden of livestock

POULTRY - BROILER — MEAN

Commodity	Commod group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	Diet content (%) EU	Diet content (%) AU	Residue contribution (ppm) US-CAN	Residue contribution (ppm) EU	Residue contribution (ppm) AU
Barley grain	GC	0.01	STMR	88	0.011	75			0.009		
Wheat grain	GC	0.01	STMR	89	0.011	5	70	70	0.001	0.008	0.008
Total						80	70	70	0.01	0.008	0.008

Prothioconazole (232)

Estimated mean dietary burden of livestock

POULTRY - LAYER — /MEAN

Commodity	Commod group	Residue mg/kg	Basis	%Dry matter	Residue dw mg/kg	Diet content (%) US-CAN	Diet content (%) EU	Diet content (%) AU	Residue contribution (ppm) US-CAN	Residue contribution (ppm) EU	Residue contribution (ppm) AU
Wheat forage	AF	0.915	HR	25			10			0.37	
Barley grain	GC	0.01	STMR	88	0.011		90			0.01	
Triticale grain	GC	0.01	STMR	89	0.011	80			0.009		
Wheat grain	GC	0.01	STMR	89	0.011			55			0.006
Total						80	100	55	0.009	0.376	0.006

Spinetoram (233)

Estimated maximum dietary burden of livestock

BEEF CATTLE — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Sugar beet tops	AV	0.20	Highest residue	23	0.870		20			0.174	
Apple pomace, dry	AB	0.081	STMR-P	91[a]	0.127	20	20	20	0.018	0.018	0.018
Total						20	40	20	0.018	0.192	0.018

Spinetoram (233)

Estimated maximum dietary burden of livestock

DAIRY CATTLE — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Sugar beet tops	AV	0.20	Highest residue	23	0.870		30			0.261	
Apple pomace, dry	AB	0.81	STMR-P	91[a]	0.127	10	10	10	0.0089	0.0089	0.0089
Total						10	40	10	0.0089	0.270	0.0089

Spinetoram (233)

Estimated mean dietary burden of livestock

BEEF CATTLE — MEAN

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Sugar beet tops	AV	0.135	STMR	23	0.587		20			0.117	
Apple pomace, dry	AB	0.081	STMR-P	91[a]	0.127	20	20	20	0.018	0.018	0.018
Total						20	40	20	0.018	0.135	0.018

a using the DM of dry citrus pulp.

Spinetoram (233)

Estimated mean dietary burden of livestock

DAIRY CATTLE — MEAN

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Sugar beet tops	AV	0.135	STMR	23	0.587		30			0.176	
Apple pomace, dry	AB	0.081	STMR-P	91[a]	0.127	10	10	10	0.0089	0.0089	0.0089
Total						10	40	20	0.0089	0.185	0.0089

a using the DM of dry citrus pulp.

Spirotetramat (234)

Estimated maximum dietary burden of farm animals

BEEF CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Apple pomace, dry	AB	1.1	STMR-P	100	1.100	20	20	0	0.22	0.22	
Cabbage heads	VB	0.92	HR	15	6.133	0	20	0		1.23	
Citrus pulp, dry	AB	0.43	STMR-P	91	0.484	0.1	0	0	0.00		
Grape pomace, wet	AB	0.74	STMR-P	15	4.9	0	0	20			0.98
Almond hulls	TN	4.9	STMR	90	5.444	10	0	10	0.54		0.54
Potato waste	VR	0.44	HR-P	12	3.667	30	40	5	1.10	1.47	0.18
Total						60.1	80	35	1.86	2.91	1.71

Spirotetramat (234)

Estimated maximum dietary burden of farm animals

DAIRY CATTLE — MAX

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Apple pomace, dry	AB	1.1	STMR-P	100	1.100	10	0	0	0.11		
Cabbage heads	VB	0.92	HR	15	6.133	0	20	0		1.23	
Citrus pulp, dry	AB	0.43	STMR-P	91	0.47	0	20	0		0.09	
Grape pomace, wet	AB	0.74	STMR-P	15	4.9	0	0	20			0.98
Almond hulls	TN	4.9	STMR	90	5.444	10	0	10	0.54		0.54
Potato waste	VR	0.44	HR-P	12	3.667	10	30	0	0.37	1.10	
Total						30	70	30	1.02	2.41	1.53

Spirotetramat (234)

Estimated mean dietary burden of farm animals

BEEF CATTLE — MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Apple pomace, dry	AB	1.1	STMR-P	100	1.100	20	20	0	0.22	0.22	
Cabbage heads	VB	0.23	STMR	15	1.533	0	20	0		0.31	
Citrus pulp, dry	AB	0.43	STMR-P	91	0.47	0	0	0			
Grape pomace, wet	AB	0.74	STMR-P	15	4.9	0	0	20			0.98
Almond hulls	TN	4.9	STMR	90	5.444	10	0	10	0.54		0.54
Potato waste	VR	0.11	STMR-P	12	0.917	30	40	5	0.28	0.37	0.05
Total						60	80	35	1.04	0.89	1.57

Spirotetramat (234)

Estimated mean dietary burden of farm animals

DAIRY CATTLE — MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
Apple pomace, dry	AB	1.1	STMR-P	100	1.100	10	0	0	0.11		
Cabbage heads	VB	0.23	STMR	15	1.533	0	20	0		0.31	
Citrus pulp, dry	AB	0.43	STMR-P	91	0.47	0	20	0		0.09	
Grape pomace, wet	AB	0.74	STMR-P	15	4.9	0	0	20			0.98
Almond hulls	TN	4.9	STMR	90	5.444	10	0	10	0.54		0.54
Potato waste	VR	0.11	STMR-P	12	0.917	1	3	0	0.01	0.03	
Total						21	43	30	0.66	0.42	1.53

Tebuconazole (189)
Estimated maximum dietary burden of farm animals

BEEF CATTLE* MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
barley forage	AF	18	highest residue	30	60.000	30	30		18.00	18.00	
rape forage	AF	18	highest residue	30	60.000			100			60.00
barley straw	AS	17	highest residue	89	19.101		30			5.73	
Peanut fodder	AS	30	MRL	85	35.294	25			8.82		
barley	GC	0.06	STMR	88	0.068		20			0.01	
rice	GC	0.275	STMR	88	0.313	20			0.06		
Soya bean aspired grain		5.5	STMR-P	85	6.471	5			0.32		
Apple pomace, wet	AB	0.63	STMR-P	40	1.575	20	20		0.32	0.32	
Total						100	100	100	27.21	23.74	60.00

*other commodities considered : soya bean forage, rye straw, wheat straw, rye, wheat, maize, soya bean, soya bean meal, soya bean hulls

Tebuconazole (189)
Estimated maximum dietary burden of farm animals

DAIRY CATTLE* MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
barley forage	AF	18	highest residue	30	60.000	40	30	50	24.00	18.00	30.00
barley straw	AS	17	highest residue	89	19.101		30			5.73	
Peanut fodder	AS	30	MRL	85	35.294	25		50	8.82		17.65
barley		0.06	STMR	88	0.068		30			0.02	
rice		0.275	STMR	88	0.313	20			0.06		
Maize	GC	0.1	STMR	88	0.114	5			0.01		
Apple pomace, wet	AB	0.63	STMR-P	40	1.575	10	10		0.16	0.16	
Total						100	100	100	32.89	23.75	47.65

*other commodities considered : rape forage, soya bean forage, rye straw, wheat straw, rye, wheat, maize, soya bean, soya bean meal, soya bean hulls

Tebuconazole (189)
Estimated mean dietary burden of farm animals

BEEF CATTLE* MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US-CAN	EU	AU	Residue contribution (ppm) US-CAN	EU	AU
barley forage	AF	5.2	STMR	30	17.333	30	30		5.20	5.20	
rape forage	AF	5.2	STMR	30	17.333			100			17.33
Wheat straw and fodder	AS	10	MRL	88	11.364		20			2.27	
Peanut fodder	AS	30	MRL	85	35.294	25			8.82		
barley	GC	0.06	STMR	88	0.068	20	50		0.01	0.03	
Soya bean aspired grain		5.5	STMR-P	85	6.471	5			0.32		
Apple pomace, wet	AB	0.63	STMR-P	40	1.575	20	20		0.32	0.32	
Total						100	100	100	14.36	7.51	17.33

*other commodities considered : soya bean forage, rye straw, wheat straw, rice, rye, wheat, maize, soya bean, soya bean meal, soya bean hulls

Tebuconazole (189)

Estimated mean dietary burden of farm animals

DAIRY CATTLE — MEAN

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
barley forage	AF	5.2	STMR	30	17.333	40	30	50	6.93	5.20	8.67
Wheat straw and fodder	AS	10	MRL	88	11.364		20			2.27	
Peanut fodder	AS	30	MRL	85	35.294	25		50	8.82		17.65
Maize	GC	0.1	STMR	88	0.114	35	40		0.04	0.05	
Apple pomace, wet	AB	0.63	STMR-P	40	1.575	10	10		0.16	0.16	
Total						100	100	100	15.80	7.52	26.31

*other commodities considered : rape forage, soya bean forage, rye straw, barley, rice, rye, wheat, soya bean, soya bean meal, soya bean hulls

Tebuconazole (189)

Estimated maximum dietary burden of farm animals

POULTRY - BROILER — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
barley grain		0.06	STMR	88	0.068	75	70		0.05	0.05	
rice grain		0.275	STMR	88	0.313	20		50	0.06		0.16
rye grain		0.05	MRL	88	0.057			35			0.02
corn grain		0.1	STMR	88	0.114	5	30		0.01	0.03	
soya bean		0.02	STMR	89	0.022						
wheat	GC	0.05	MRL	89	0.056			15			0.01
Total						100	70	100	0.11	0.05	0.18

*other commodities considered : soya bean

Tebuconazole (189)

Estimated maximum dietary burden of farm animals

POULTRY - LAYER — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
rape forage		18	highest residue	30	60.000		10			6.00	
wheat straw and fodder	AS	10	MRL	88	11.364		10			1.14	
barley grain		0.06	STMR	88	0.068	75	70	15	0.05	0.05	0.01
rice grain		0.275	STMR	88	0.313	20		50	0.06		0.16
rye grain		0.05	MRL	88	0.057	5		35	0.00		0.02
wheat	GC	0.05	MRL	89	0.056		10			0.01	
Total						100	80	100	0.11648	7.19	0.18636

*other commodities considered : soya bean forage, barley straw, maize, soya bean

Tebuconazole (189)

Estimated mean dietary burden of farm animals

POULTRY - BROILER — MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
barley grain		0.055	STMR	88	0.063	75	50		0.05	0.03	
rice grain		0.275	STMR	88	0.313	20		50	0.06		0.16
rye grain		0.05	MRL	88	0.057	5	50		0.00	0.03	
wheat	GC	0.05	MRL	89	0.056			50			0.03
Total						100	100	100	0.11	0.06	0.18

*other commodities considered : maize, soya bean

Tebuconazole (189)
Estimated mean dietary burden of farm animals

POULTRY - LAYER MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)			Residue contribution (ppm)		
		mg/kg		%	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
rape forage		5.2	STMR	30	17.333		10			1.73	
soya bean forage		5.2	STMR	56	9.286		10			0.93	
wheat straw and fodder	AS	10	MRL	88	11.364		10			1.14	
barley grain		0.055	STMR	88	0.063	75		15	0.05		0.01
rice grain		0.275	STMR	88	0.313	20		50	0.06		0.16
rye grain		0.05	MRL	88	0.057			35			0.02
corn grain		0.1	STMR	88	0.114	5	70		0.01	0.08	
Total						100	100	100	0.12	3.88	0.19

*other commodities considered : barley straw, soya bean and wheat

ANNEX 7: CORRECTIONS TO THE REPORT OF THE 2007 MEETING

Annex 3 and 4 entries for propiconazole, omitted from the 2007 Report, are listed below.

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

		STMR or	Diets: g/person/day											
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0.06	38.8	1.6	17.4	0.7	16.0	0.7	6.6	0.3	21.5	0.9	33.8	1.4
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.0675	40.6	2.7	16.8	1.1	93.9	6.3	13.2	0.9	48.6	3.3	36.1	2.4
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.06	3.1	0.2	12.6	0.8	2.9	0.2	1.4	0.1	10.1	0.6	18.0	1.1
FB 0265	Cranberries	0.174	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.1	0.0	0.0	0.6	0.1
MO 0105	Edible offal (mammalian)	0.6	3.9	2.3	14.4	8.6	5.2	3.1	11.8	7.1	11.7	7.0	7.6	4.6
PE 0112	Eggs	0.05	2.5	0.1	29.7	1.5	25.1	1.3	24.5	1.2	37.8	1.9	27.4	1.4
GC 0645	Maize (incl flour, incl oil, incl beer)	0.05	82.7	4.1	148.4	7.4	135.9	6.8	31.8	1.6	33.3	1.7	7.5	0.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.05	5.5	0.3	23.3	1.2	7.7	0.4	11.0	0.6	18.0	0.9	26.3	1.3
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)	0.01	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4
TN 0672	Pecan	0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
FI 0353	Pineapple (incl canned, incl juice)	0.02	3.8	0.1	6.2	0.1	0.6	0.0	0.9	0.0	7.7	0.2	8.2	0.2
GC 0656	Popcorn	0.05	0.1	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
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
SO 0495	Rape seed (incl oil)	0.06	0.9	0.1	1.8	0.1	2.5	0.2	1.9	0.1	35.7	2.1	26.1	1.6
GC 0650	Rye (incl flour)	0.06	0.1	0.0	3.7	0.2	0.3	0.0	24.3	1.5	25.8	1.5	45.8	2.7
VD 0541	Soya bean (dry, incl oil)	0.03	9.9	0.3	36.4	1.1	34.3	1.0	22.4	0.7	35.3	1.1	39.2	1.2
VR 0596	Sugar beet	0.06	0.0	0.0	40.7	2.4	0.0	0.0	0.1	0.0	6.0	0.4	0.1	0.0
GS 0659	Sugar cane	0	30.9	0.0	43.1	0.0	51.3	0.0	0.1	0.0	5.5	0.0	0.0	0.0
VO 0447	Sweet corn (corn-on-the-cob)	0.05	7.3	0.4	1.0	0.1	0.1	0.0	0.5	0.0	3.3	0.2	3.6	0.2
GC 0653	Triticale (incl flour)	0.06	0.0	0.0	115.8	6.9	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.06	88.4	5.3	396.3	23.8	426.5	25.6	390.2	23.4	236.3	14.2	216.0	13.0
	Total intake (µg/person)=			19.7		65.6		49.5		43.9		44.4		40.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			4200		4200		4200		4200		4200		4200
	%ADI=			0.5%		1.6%		1.2%		1.0%		1.1%		1.0%
	Rounded %ADI=			0%		2%		1%		1%		1%		1%

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0.06	21.4	0.9	36.6	1.5	11.4	0.5	9.2	0.4	70.2	2.9	40.5	1.7	32.6	1.4
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.0675	5.9	0.4	20.5	1.4	5.9	0.4	2.5	0.2	20.2	1.4	16.8	1.1	43.8	3.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.06	0.2	0.0	7.0	0.4	0.5	0.0	0.2	0.0	5.3	0.3	5.7	0.3	12.4	0.7
FB 0265	Cranberries	0.174	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	0.4
MO 0105	Edible offal (mammalian)	0.6	4.8	2.9	10.7	6.4	4.0	2.4	4.0	2.4	6.5	3.9	6.6	4.0	5.6	3.4
PE 0112	Eggs	0.05	22.1	1.1	71.5	3.6	16.6	0.8	5.1	0.3	17.6	0.9	35.2	1.8	57.4	2.9
GC 0645	Maize (incl flour, incl oil, incl beer)	0.05	35.2	1.8	298.6	14.9	248.1	12.4	57.4	2.9	63.1	3.2	58.6	2.9	85.5	4.3
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.05	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	0.05	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)	0.01	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
TN 0672	Pecan	0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
FI 0353	Pineapple (incl canned, incl juice)	0.02	3.9	0.1	11.7	0.2	12.6	0.3	11.1	0.2	16.6	0.3	21.4	0.4	22.6	0.5
GC 0656	Popcorn	0.05	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1
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
SO 0495	Rape seed (incl oil)	0.06	9.9	0.6	5.9	0.4	0.3	0.0	1.0	0.1	0.0	0.0	15.5	0.9	9.9	0.6
GC 0650	Rye (incl flour)	0.06	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.1	0.8	0.0
VD 0541	Soya bean (dry, incl oil)	0.03	25.9	0.8	59.4	1.8	11.2	0.3	11.0	0.3	109.3	3.3	51.5	1.5	123.2	3.7
VR 0596	Sugar beet	0.06	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	0.9
GS 0659	Sugar cane	0	26.2	0.0	1.5	0.0	33.8	0.0	5.5	0.0	18.6	0.0	3.0	0.0	20.2	0.0
VO 0447	Sweet corn (corn-on-the-cob)	0.05	0.2	0.0	2.4	0.1	2.2	0.1	3.3	0.2	1.7	0.1	2.8	0.1	11.2	0.6
GC 0653	Triticale (incl flour)	0.06	1.3	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GC 0654	Wheat (incl bulgur wholemeal, incl flour)	0.06	172.9	10.4	79.0	4.7	68.1	4.1	41.9	2.5	114.1	6.8	103.4	6.2	234.2	14.1
	Total intake (µg/person)=			23.3		47.8		25.0		12.1		36.6		26.1		52.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			3850		4200		4200		4200		4200		3850		4200
	%ADI=			0.6%		1.1%		0.6%		0.3%		0.9%		0.7%		1.3%
	Rounded %ADI=			1%		1%		1%		0%		1%		1%		1%

Annex 7

PROPICONAZOLE (160) International estimate of short term intake (IESTI) for **GENERAL POPULATION**

Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 1%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
TN 0672	Pecan	-	0.02	AUS	67.0	23	-	-	ND	ND	1	0.01	0%
FI 0327	Banana	-	0.087	SAF	55.7	613	900	FRA	612	3	2a	2.87	1%
GC 0640	Barley	0.0675	-	NLD	63.0	378	-	-	ND	ND	3	0.41	0%
SB 0716	Coffee beans	0.06	-	NLD	63.0	66	-	-	ND	ND	3	0.06	0%
FB 0265	Cranberries	-	0.39	USA	65.0	229	-	-	ND	ND	ND	ND	-
MO 0105	Edible offal (mammalian)	-	0.8	FRA	62.3	277	-	-	ND	ND	1	3.55	1%
PE 0112	Eggs	-	0.05	Thai	53.5	195	-	-	ND	ND	1	0.18	0%
GC 0645	Maize	0.05	-	FRA	62.3	260	-	-	ND	ND	3	0.21	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.05	AUS	67.0	104	-	-	ND	ND	1	0.08	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.05	AUS	67.0	417	-	-	ND	ND	1	0.31	0%
ML 0106	Milks	0.01	-	USA	65.0	2466	-	-	ND	ND	3	0.38	0%
FI 0353	Pineapple	-	0.02	JPN	52.6	371	700	FRA	420	3	2b	0.42	0%
GC 0656	Popcorn	0.05	-	JPN	52.6	175	-	-	ND	ND	ND	ND	-
PM 0110	Poultry meat: 10% as fat	-	0.05	AUS	67.0	43	-	-	ND	ND	1	0.03	0%
PM 0110	Poultry meat: 90% as muscle	-	0.05	AUS	67.0	388	-	-	ND	ND	1	0.29	0%
SO 0495	Rape seed	0.06	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0650	Rye	0.06	-	NLD	63.0	77	-	-	ND	ND	3	0.07	0%
VD 0541	Soya bean (dry)	0.03	-	JPN	52.6	159	-	-	ND	ND	3	0.09	0%
VR 0596	Sugar beet	0.06	-	-	-	ND	-	-	ND	ND	ND	ND	-
GS 0659	Sugar cane	0	-	Thai	53.5	366	-	-	ND	ND	ND	ND	-
VO 0447	Sweet corn (corn-on-the-cob)	-	0.05	Thai	53.5	383	200	JPN	200	3	2a	0.73	0%
GC 0653	Triticale	0.06	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0654	Wheat	0.06	-	USA	65.0	383	-	-	ND	ND	3	0.35	0%

PROPICONAZOLE (160) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.300 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 3%

Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Large portion diet Country	Body weight (kg)	Large portion, g/person	Unit weight Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
TN 0672	Pecan	-	0.02	AUS	19.0	22	-	-	ND	ND	1	0.02	0%
FI 0327	Banana	-	0.087	JPN	15.9	312	900	FRA	612	3	2b	5.12	2%
GC 0640	Barley	0.0675	-	AUS	19.0	14	-	-	ND	ND	3	0.05	0%
SB 0716	Coffee beans	0.06	-	NLD	17.0	19	-	-	ND	ND	3	0.07	0%
FB 0265	Cranberries	-	0.39	USA	15.0	102	-	-	ND	ND	ND	ND	-
MO 0105	Edible offal (mammalian)	-	0.8	FRA	17.8	203	-	-	ND	ND	1	9.11	3%
PE 0112	Eggs	-	0.05	Thai	17.1	109	-	-	ND	ND	1	0.32	0%
GC 0645	Maize	0.05	-	FRA	17.8	148	-	-	ND	ND	3	0.42	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.05	AUS	19.0	52	-	-	ND	ND	1	0.14	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.05	AUS	19.0	208	-	-	ND	ND	1	0.55	0%
ML 0106	Milks	0.01	-	USA	15.0	1286	-	-	ND	ND	3	0.86	0%
FI 0353	Pineapple	-	0.02	JPN	15.9	216	700	FRA	420	3	2b	0.82	0%
GC 0656	Popcorn	0.05	-	JPN	15.9	53	-	-	ND	ND	ND	ND	-
PM 0110	Poultry meat: 10% as fat	-	0.05	AUS	19.0	22	-	-	ND	ND	1	0.06	0%
PM 0110	Poultry meat: 90% as muscle	-	0.05	AUS	19.0	201	-	-	ND	ND	1	0.53	0%
SO 0495	Rape seed	0.06	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0650	Rye	0.06	-	NLD	17.0	37	-	-	ND	ND	3	0.13	0%
VD 0541	Soya bean (dry)	0.03	-	JPN	15.9	88	-	-	ND	ND	3	0.17	0%
VR 0596	Sugar beet	0.06	-	-	-	ND	-	-	ND	ND	ND	ND	-
GS 0659	Sugar cane	0	-	Thai	17.1	181	-	-	ND	ND	ND	ND	-
VO 0447	Sweet corn (corn-on-the-cob)	-	0.05	Thai	17.1	197	200	JPN	200	3	2b	1.73	1%
GC 0653	Triticale	0.06	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0654	Wheat	0.06	-	USA	15.0	151	-	-	ND	ND	3	0.60	0%

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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 9 to 18 September 2008. The FAO Panel of Experts had met in Preparatory Sessions from 4 to 8 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 (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 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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