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Pesticide residues in food 2009

Joint FAO/WHO Meeting on Pesticide Residues

REPORT 2009

World Health Organization

Food and Agriculture Organization of the United Nations

Pesticide residues in food 2009

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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
Geneva, Switzerland, 16–25 September 2009

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

LIST OF PARTICIPANTS

2009 JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

GENEVA, 16–25 SEPTEMBER 2009

FAO Members

Dr Ursula Banasiak, Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany

Professor Eloisa Dutra Caldas, University of Brasilia, College of Health Sciences, Pharmaceutical Sciences Department, Campus Universitário Darci Ribeiro, 70919-970 Brasília/DF, Brazil

Mr Stephen Funk, Health Effects Division (7509P), United States Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington DC 20460, USA

Mr Denis J. Hamilton, Principal Scientific Officer Biosecurity, Department of Primary Industries and Fisheries, PO Box 46, Brisbane, QLD 4001, Australia

Mr David Lunn, Senior Programme Manager (Residues–Plants), Export Standards Group, New Zealand Food Safety Authority, PO Box 2835, Wellington, New Zealand *(FAO Rapporteur)*

Dr Dougal MacLachlan, Australian Quarantine and Inspection Service, Australian Government Department of Agriculture, Fisheries and Forestry, GPO Box 858, Canberra, ACT 2601, Australia

Dr Bernadette Ossendorp, Centre for Substances and Integrated Risk Assessment, National Institute of Public Health and the Environment (RIVM), Antonie van Leeuwenhoeklaan 9, PO Box 1, 3720 BA Bilthoven, Netherlands *(FAO Chairman)*

Dr Yukiko Yamada, Deputy Director-General, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries, 1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8950, Japan

WHO Members

Professor Alan R. Boobis, Experimental Medicine & Toxicology, Division of Investigative Science, Faculty of Medicine, Imperial College London, Hammersmith Campus, Ducane Road, London W12 0NN, England

Dr Vicki L. Dellarco, Office of Pesticide Programs (7501P), United States Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460, USA (WHO Rapporteur)

Dr Helen Hakansson, Institute of Environmental Medicine, Karolinska Institutet, Unit of Environmental Health Risk Assessment, Box 210, Nobelsväg 13, S-171 77 Stockholm, Sweden

Professor Angelo Moretto, Department of Environmental and Occupational Health, University of Milan, International Centre for Pesticides and Health Risk Prevention, Luigi Sacco Hospital, Via Stephenson 94, 20157 Milan, Italy (WHO Chairman)

Dr Roland Solecki, Chemical Safety Division, Steering of Procedures and Overall Assessment, Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany

Dr Maria Tasheva, Consultant, National Service for Plant Protection, Ministry of Agriculture and Food, 17 Hristo Botev Bul. 1040 Sofia, Bulgaria

Secretariat

Dr habil. Árpád Ambrus, Hungarian Food Safety Office, Gyali ut 2-6, 1097 Budapest, Hungary (FAO Temporary Adviser)

Mr Kevin Bodnaruk, 26/12 Phillip Mall, West Pymble, NSW 2073, Australia (FAO Editor)

Dr Katie Calp, Pest Management Regulatory Agency, Health Canada, 2720 Riverside Drive, AL 6605E Ottawa, Canada (WHO Temporary Adviser)

Ms Gracia Brisco, Food Standards Officer, Joint FAO/WHO Food Standards Programme, Nutrition and Consumer Protection Division, Food and Agriculture Organization of the United Nations, Viale delle terme di Caracalla, 00153 Rome, Italy (Codex Secretariat)

Dr Ian Dewhurst, Chemicals Regulation Directorate, Mallard House, King's Pool, 3 Peasholme Green, York YO1 7PX, England (WHO Temporary Adviser)

Dr William Donovan, United States Environmental Protection Agency, MC 7509C, Washington, DC 20460, USA (FAO Temporary Adviser)

Mr Makoto Irie, Plant Product Safety Division, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries, 1-2-1 Kasumigaseki, Chiyoda-ku, Tokyo 100-8950, Japan (FAO Temporary Adviser)

Dr Debabrata Kanungo, Additional DG, Directorate General of Health Services, Ministry of Health and Family Welfare, West, Block No. 1, R.K. Puram, New Delhi, India (WHO Temporary Adviser)

Dr Katerina Mastovska, Eastern Regional Research Center (ERRC), Agricultural Research Service (ARS), United States Department of Agriculture, 600 E. Mermaid Lane, Wyndmoor, PA 19038, USA (FAO Temporary Adviser)

Dr Jeronimas Maskeliunas, Food Standards Officer, Joint FAO/WHO Food Standards Programme, Nutrition and Consumer Protection Division, Food and Agriculture Organization of the United Nations, Viale delle terme di Caracalla, 00153 Rome, Italy (Codex Secretariat)

Dr Heidi Mattock, 21 bis rue du Mont Ouest, 38230 Tignieu-Jameyzieu, France (WHO Editor)

Dr Douglas B. McGregor, Toxicity Evaluation Consultants, 38 Shore Road, Aberdour KY3 0TU, Scotland (WHO Temporary Adviser)

Dr Rudolf Pfeil, Toxicology of Pesticides and Biocides, Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany (WHO Temporary Adviser)

Dr Xiongwu Qiao, Shanxi Academy of Agricultural Sciences, 2 Changfeng Street, Taiyuan, Shanxi 030006, China (FAO Temporary Adviser)

Ms Jeannie Richards, 15 bis rue Georges Musy, 71100 Saint Remy, France (FAO Temprary Advisor)

Dr Prakashchandra V. Shah, United States Environmental Protection Agency, Mail Stop: 7505P, 1200 Pennsylvania Avenue NW, Washington DC 20460, USA (WHO Temporary Adviser)

Mr Christian Sieke, Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany (FAO Temporary Adviser)

Dr Angelika Tritscher, Food Safety and Zoonoses (FOS), International Programme on Chemical Safety, World Health Organization, 1211 Geneva 27, Switzerland (WHO Joint Secretary)

Ms Trijntje van der Velde, National Institute of Public Health and the Environment (RIVM), Antonie van Leeuwenhoeklaan 9, PO Box 1, 3720 BA Bilthoven, Netherlands (FAO Temporary Adviser)

Dr Gerrit Wolterink, Centre for Substances & Integrated Risk Assessment, National Institute of Public Health and the Environment (RIVM), Antonie van Leeuwenhoeklaan 9, PO Box 1, 3720 BA Bilthoven, Netherlands (WHO Temporary Adviser)

Ms Yong Zhen Yang, Plant Protection Service (AGPP), Food and Agriculture Organization of the United Nations (FAO), Viale delle Terme di Caracalla, 00153 Rome, Italy (FAO Joint Secretary)

Dr Midori Yoshida, Section Chief, Division of Pathology, Biological Safety Research Center, National Institute of Health Sciences, Ministry of Health, Labor and Welfare, 1-18-1 Kamiyoga, Setagaya-ku, Tokyo 158-8501, Japan (WHO Temporary Adviser)

Dr Jürg Zarn, Swiss Federal Office of Public Health, Nutritional and Toxicological Risks Section, Stauffacherstrasse 101, CH-8004 Zurich, Switzerland (WHO Temporary Adviser)

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
$BMDL_{10}$	benchmark-dose lower 95% confidence level
BROD	benzyloxyresorufin *O*-de-ethylase
bw	body weight
CAR	constitutive androstane receptor
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
CXL	Codex MRL
DT_{50}	time taken for 50% of the concentration to dissipate
EC_{50}	the concentration of agonist that elicits a response that is 50% of the possible maximum
EROD	ethoxyresorufin *O*-deethylase
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-FPD	gas chromatography with flame photometric detection
GGT	gamma-glutamyltransferase
GEMS/Food	Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme

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
MLE	maximum likelihood estimation
MRL	maximum residue limit
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NOAEL	no-observed-adverse-effect level
NTE	neuropathy target esterase
OECD	Organization for Economic Co-operation and Development
PPARα	peroxisome proliferator-induced receptor alpha
PHI	pre-harvest interval
ppm	parts per million
PROD	pentylresorufin *O*-dealkylase
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
UCL	upper confidence limit
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 2009 JOINT FAO/WHO MEETING OF EXPERTS

1. INTRODUCTION

A Joint FAO/WHO Meeting on Pesticide Residues (JMPR) was held at the headquarters of the World Health Organization (WHO), Geneva, Switzerland, from 16 to 25 September 2009. The Meeting brought together the Food and Agriculture Organization (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group.

The meeting was opened by Dr Bruce Aylward, Director, WHO, on behalf of the Directors-General of WHO and FAO.

Dr Aylward acknowledged the impressive and successful work performed by this programme for over 45 years, and the important role played by the Meeting in the establishment of international food safety standards, thereby contributing to the improvement of public health. The provision of independent scientific advice as a basis for public-health decision-making lies at the core of work carried out by WHO and the experts participating in the Meeting are thus contributing directly to the goals of the organization. The process of furnishing independent scientific advice and a rapid coordinated response to incidents involving food safety is of increasing importance in the current global environment. The new International Health Regulations (IHR) will play an important role in facilitating this process. Previously concerning only some communicable diseases, the IHR have been expanded to include events of non-communicable origin. Reorganization has taken place at WHO to reflect this change and the formation of the new cluster on Health Security and the Environment (HSE) will allow closer collaboration in this area. In closing, Dr Aylward noted the challenging tasks to be accomplished by the present Meeting and gratefully acknowledged the invaluable contribution made by the participating experts, including the tremendous efforts put into preparation of 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), maximum residue levels (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 25 pesticides, including three new compounds and eight compounds that were re-evaluated within the Code Committee on Pesticide Residues (CCPR) periodic review programme for toxicity or residues, or both. The Meeting established ADIs and ARfDs, estimated MRLs and recommended them for use by the Codex Committee on Pesticide Residues (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 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.

1.1 DECLARATION OF INTERESTS

The Secretariat informed the Committee that all experts participating in the 2009 JMPR had completed declaration-of-interest forms, and that no conflicts had been identified. Professor Alan Boobis and Dr Douglas McGregor had undertaken minor consultancies, but these were not related to compounds on the agenda. Experts were then asked to inform the meeting of any new potential interests that had arisen since submitting the forms and no interests were declared.

2. GENERAL CONSIDERATIONS

2.1 TRANSPARENCY IN THE MAXIMUM RESIDUE LEVEL ESTIMATION PROCESS: FURTHER CONSIDERATIONS

The Forty-first Session of the CCPR discussed transparency in the process by which maximum residue levels are estimated by the JMPR, as a response to General consideration 2.7 in the JMPR 2008 report. The Meeting in 2008 had, in addition to its usual procedure, used the North American Free Trade Agreement (NAFTA) MRL calculator to estimate maximum residue levels and had produced a summary table in which it was explained when JMPR estimates differed from estimates derived by the NAFTA calculator.

The CCPR recommended that "for the 2009 JMPR meeting the OECD statistical calculation method would be used, if available, and if not available the NAFTA calculator method would continue to be used and reported and, to the extent possible, brief explanations of derivation of the maximum residue levels would be provided when the calculator was not used".[1] The present Meeting decided that, instead of producing a summary table for these cases, it would provide additional explanation on how the value was derived for each pesticide × commodity maximum residue level recommendation.

The present Meeting noted that a MRL is the maximum residue anticipated in a commodity produced in accordance with good agricultural practice (GAP). The process of estimating a value for use as a MRL involves selection of residue trials conducted according to a critical GAP. It is generally the highest observed residue value that has the greatest influence on the estimated MRL. Small datasets (those with less than 15 data points), represent a particular challenge when undertaking an estimation. The JMPR has previously noted that 95th or 99th percentiles estimated on the basis of statistical methods are increasingly inaccurate for datasets of less than 15 points and such estimates should not be automatically used. The Meeting agreed that the estimates provided using statistical methods are generally acceptable for larger datasets. Data available to the JMPR generally have additional limitations that can compromise the use of statistical approaches, including whether the trials represent a random sample. Some of these limitations have been elaborated in previous reports of the JMPR, principally in 2008.

The JMPR employs expert judgement informed by the available tools, such as statistical approaches to estimate maximum residue levels. Additional factors are taken into account by the JMPR as part of the application of expert judgement, as discussed below.

Experience leads to an understanding of the uncertainties in the parameters involved in the estimation of maximum residue levels. From the information considered, the most appropriate value must be identified in a decision that makes the best use of all the available evidence. The initial deposit of a pesticide on a crop is the best indicator of the proper application of a pesticide when the edible part of the crop is present and well-developed at the time of application. For example, the analysis of available data on pesticides has enabled estimates to be made for the upper limits and ranges of initial deposits for many crops.[2] Various factors beyond those used in statistical calculation, such as the examples listed below, may be taken into account in the estimation of maximum residue levels.

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[1] Codex Alimentarius Commission (2009) Report of the Forty-first Session of the Codex Committee on Pesticide Residues, Beijing, China, 20–25 April 2009 (ALINORM 09/32/24), paras 30–45.

[2] Bates JAR (1990) The prediction of pesticide residues in crops by the optimum use of existing data. Pure & Applied Chemistry 62: 337–350.

Table 1 Factors to be taken into account when estimating maximum residue levels

Issue or factor	Action or comment
Accumulated data on the distribution of residues from supervised trials for residues of pesticides on a crop provide a reliable basis for the likely spread of residues within a dataset. Such data complement the limited information that can be obtained from the small datasets usually available.	The Meeting regularly considers the typical distribution of residues between trials, including initial deposits, and where limited trial data are available for a particular pesticide crop combination, adjusts the estimated maximum residue level appropriately.
Some latitude is allowed regarding how closely trials comply with GAP in selecting the dataset for maximum residue estimation (typically, a change in parameters leading to a ±25% change in residues), if the majority of trials have been conducted at the lower or higher ends of the range used to select data, this should be taken into account when recommending a maximum residue level	The Meeting makes an allowance to account for how close the majority of selected residue trials match the critical GAP.
Residues resulting from rates of application that are higher or lower than GAP, as well as studies of metabolism are taken into account in the context of the use to predict a pattern of likely residue concentrations, but are not used directly in the set of numbers that support a maximum residue level estimation or in the risk assessment.	These values may provide information on situations where no residues are expected or provide information as to whether residues scale with application rate.
Noting the effect of crop-growth stage where this aspect is particularly important. Examples of this are the herbicides haloxyfop and glyphosate, for which data selection concentrated on the growth stages that might occur before PHI rather than the time before harvest itself.	This example underlines the importance of expert judgement in selecting the suitable residue data for estimation of residue levels.
Should greater weight be given to different data within a dataset to account for differences between commercial practice and available trial conditions, e.g., varieties or cultivars grown, crops grown under protected cover versus field grown crops?	The JMPR may take into account the varieties and cultivars used in the available residue dataset. Allowances may need to be made in maximum residue level estimates, depending on the range of varieties used in the trials. For example, if no trials have been provided on small tomato varieties, a higher maximum residue level might be recommended.
Whether or not the trial data are representative of differences in cultural practices, e.g., orchard and vine crop-production techniques, planting density, hedging versus spindle versus vase in tree architecture.	The JMPR may make an allowance for unavoidable bias associated with differences in the cultural practices observed in the residue trials available.
Whether or not the trial data are representative of differences in application equipment	The JMPR may make allowance for unavoidable bias associated with differences in the application equipment used in the residue trials available
Data from trials on one crop are sometimes extrapolated to other members of a crop group or used to recommend a maximum residue level for the entire group.	The JMPR may need to make allowances for differences in crops when making recommendations based on extrapolation or for crop group MRLs
For post-harvest use of grain protectants, the application rates of the active ingredient provide a precise estimate of expected residue levels at the time of application. Additionally, the Meeting generally gives more weight to commercial-size trials than to laboratory-scale trials	The JMPR may recommend maximum residue levels at the application rate as residues higher than the amount added are not expected

Issue or factor	Action or comment
Foliar application of a non-systemic pesticide to certain crops (root and tuber, cotton, tree nuts) may result in occasional residues on the harvested commodity owing to the commodity sometimes being exposed to direct spray (e.g., open cotton bolls).	The Meeting may recognize this in estimating maximum residues.
Commercial shelling of nuts may give rise to low levels of residues in nutmeat that need to be taken into account	The Meeting may recognize this when estimating maximum residues for tree nuts.

GAP, good agricultureal practice; PHI, pre-harvest interval.

It is possible that innovation will lead to new methods (such as predictive models for residues on crops and derived commodities) that might allow improved estimation of maximum residue levels.

Conclusion

The above examples of how the JMPR uses expert judgement indicate that evaluation of residue data is a complex task that requires the consideration of factors and parameters additional to the numerical residue values. Consequently, MRL estimates cannot be based solely on automatic calculation using any currently available "statistical" methods.

2.2 THE OECD GUIDANCE DOCUMENT ON LIVESTOCK FEEDING

The Meeting was informed that the Organisation for Economic Co-operation and Development (OECD) Guidance Document on Livestock Feeding is being written and will go through the OECD approval process in 2010. Meanwhile, many essential items on livestock feeding have been included in the OECD Overview Guidance[3]. Included in the Overview is an updated version of the OECD Table on feedstuffs derived from field crops. The original version was previously adopted by the JMPR in 2007.[4] The table presents information on the consumption of various feed commodities by livestock in various regions of the world. The original version has been expanded by OECD to include several additional commodities and notably to include information on consumption by livestock in Japan.

The OECD Overview Guidance is currently intended to calculate the dietary burdens for livestock within OECD countries for the purpose of selecting appropriate doses for livestock feeding studies. However, the feedtables may also be used to construct livestock dietary burdens for the purpose of interpreting the results of feeding studies. The consumption information is combined with estimates of residues on the feed items (STMR or MRL values, as appropriate) to arrive at estimates of the total dietary burden of beef cattle, dairy cattle, sheep, pigs, and poultry for the pesticide under consideration. These values are then compared to the results of feeding studies to arrive at estimates of the levels of pesticides in milk, eggs, meat, fat, and edible offal. Results for cattle and poultry will be extrapolated to all relevant livestock.

The new method for calculating livestock dietary burden used by the NAFTA countries was noted. Commodities are classified by nutrition type (roughage, carbohydrate, protein) and maximum percentages of the total diet are set for each category for the various livestock. For example, the beef cattle diet is set at 15% roughage, 80% carbohydrate concentrate, and 5% protein concentrate. The aim of taking into account the animals' nutritional requirements is to arrive at a more realistic, less

[3] OECD Environment, Health and Safety Publications. Guidance Document on overview of residue chemistry studies. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. Revised February 2009, Environment Directorate, Paris.

[4] Food and Agriculture Organization (2007) General consideration 2.10: OECD livestock feed tables. In: Pesticide residues in food – 2007, FAO Plant Production and Protection Paper 191.

extreme diet. This reflects the situation in Canada and the United States of America (USA), but may not be applicable to other regions. OECD guidance continues to recommend the calculation of livestock dietary burden for regions other than Canada and the USA in a manner similar to that used by JMPR.

The Meeting considered that the NAFTA procedure was not applicable at the international level. This procedure relies upon intensive feeding, such as exists in very controlled situations in feed lots, and does not represent the situation in other parts of the world. The JMPR procedure maximizes livestock dietary-intake burdens of the pesticide by taking into account the feed items from different Codex classes (forage, grain, byproducts, etc.) and emphasizes the use of diverse feed items with maximum pesticide residues. This calculation is performed for every region for which there is information on livestock burden is available, the intention being to arrive at estimates that are inclusive of livestock burdens worldwide.

The JMPR procedure, as detailed in the FAO Manual[5], will be continued. The present Meeting agreed to use the latest available version of the OECD feed table and to include it in the FAO Manual, Second Edition. The revised table will be used by the Meeting in 2010. The Meeting also decided that some modification to the OECD feed table would be needed for the version placed in the FAO Manual. The OECD had grouped feed items into four broad categories: forages; roots and tubers; cereal grains/crop seeds; byproducts of processing. The category "forages" as used by OECD includes virtually all plant commodities other than grains and roots and tubers (forage, fodder, silage, hay, straw, leaves and tops, and grasses), and thus encompasses a much wider selection of commodities than the narrower Codex definition.

The feed table will be modified to indicate the Codex crop group of each commodity (see Figure 1). This is important because in performing the calculation of livestock dietary burden, the total burden for the group is considered as well as the burden from each individual commodity. For example, if residues occurred in clover, alfalfa fodder, and bean fodder (the group of legume animal feeds), they should be considered in sequence, beginning with the calculated highest residue in the dry-weight feed. The detailed procedure is described in the FAO Manual.

In 2005, the JMPR expressed the opinion that fresh forages for animals were not an item of international trade requiring Codex MRLs and decided not to recommend further forage MRLs (Annex 5, reference *104*).[6] The Meeting stated that data on forage residues would continue to be evaluated and used in the estimation of farm-animal dietary burden. There may be situations in which fresh forages should be evaluated as being consumed only locally. i.e., being added to livestock dietary burden only in regions where relevant GAP produces residues in the fresh forage.

5 Food and Agriculture Organization. 2002. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed.

6 Food and Agriculture Organization (2005) General consideration 2.1: JMPR recommendations for animal forage. In: Pesticide residues in food – 2005. FAO Plant Production and Protection Paper, 183:32.

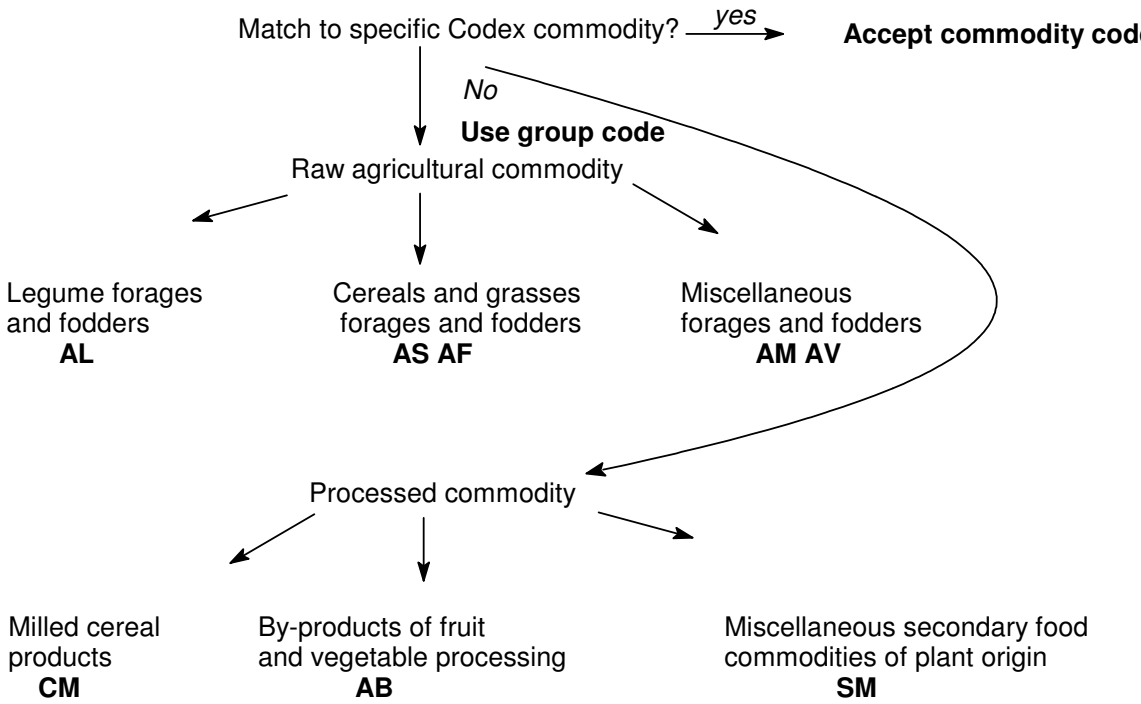

Figure 1 Determination of Codex commodity codes for the OECD category "forages"

2.3 GUIDANCE FOR DATA SUBMISSION FOR ESTIMATION OF RESIDUE LEVELS IN/ON SPICES

In response to the request of the CCPR at its Thirty-fourth Session, the 2002 JMPR considered the options for estimating maximum residue levels for spices based on monitoring data (Annex 5, reference 95, section 2.7) and provided guidance on the format for reporting such data. As the CCPR at its Thirty-fifth Session had decided to elaborate MRLs based on monitoring data (Annex 5, reference *95*, section 2.7), the 2003 JMPR gave further consideration to possible options for estimating maximum residue levels where sufficient monitoring data were not available and prepared guidelines for conducting selective surveys to generate pesticide residue data reflecting the field and post-harvest application of pesticides (Annex 5, reference *95*, section 2.5).

The 2004 JMPR considered the nature of monitoring results and defined the basic principles for the evaluation of monitoring data to estimate maximum residue levels (Annex 5, reference *95*, section 2.6). The Meeting at that time recommended maximum residue levels that encompass at least 95% of the residues with 95% probability (in 95% of cases). To satisfy this requirement, a minimum of 59 residue datapoints for each spice commodity × pesticide residue combination is required.

The Meeting at that time further recommended that monitoring results should not be used for estimating maximum residue levels that reflect post-harvest use, which results in much higher residue values than foliar application or exposure to spray drift.

The present Meeting noted that the guidance given by the JMPR in previous reports might have been misinterpreted and, as a consequence, the residue data submitted were insufficient for evaluation.

In order to assist collection and submission of the appropriate information, the Meeting re-emphasized that:

- The minimum number of datapoints required for each pesticide × spice commodity combination is 59;
- Where residue data are available for several spice commodities belonging to one group of spices, the JMPR will evaluate the residue data and if the residue distributions can be considered similar, then the JMPR may recommend a MRL for the commodity group;
- The JMPR cannot make any recommendations for pesticide classes such as organophosphates, carbamates, pyrethroids. If it is claimed, for instance, that no organophosphorous compounds were detected in 20 samples of a spice commodity, then it must be specified which compounds have been looked for and what were the respective LOQ and recovery values. The method performance parameters indicated must be supported with appropriate data on method validation.

In addition, the supporting information should be provided as specified in the JMPR reports on actual agricultural, storage and processing practice, the need for post-harvest protection, etc.

Comprehensive information on data requirements is also available in the second edition of the FAO Manual (section 3.6).

2.4 UPDATE OF THE FAO MANUAL ON THE SUBMISSION AND EVALUATION OF DATA ON PESTICIDE RESIDUES FOR THE ESTIMATION OF MAXIMUM RESIDUE LEVELS IN FOOD AND FEED

The first version of this manual, published in 1997, presented the principles applied by the JMPR. As the evaluation process is continually evolving, the first version of the manual was revised in 2002 and published as the first official edition. It incorporated additional information from the JMPR reports of 1997–2001. The last eight years have seen many changes in residue evaluations. The JMPR has elaborated some new principles, as well as revised many existing principles used for the evaluation of pesticide residues, which have been reproduced in the reports of its meetings.

The OECD Working Group on Pesticide has also elaborated several guidelines and guidance documents that are directly related to the design of supporting studies used in the evaluation of pesticide residues. The activities of the JMPR FAO Panel and the OECD Working Group were complementary, as several experts contributed to both activities. The OECD Working Group considered the principles applied by the JMPR, and the JMPR incorporated a number of the OECD guidelines in its evaluations. The 2006 JMPR (Annex 5, reference *107*, section 2.1) decided that the OECD guidelines and guidance documents would be used in the preparation of future versions of the FAO Manual with the aims of maximum harmonization and future opportunities for work share.

The present second edition of the FAO Manual describes the basic principles currently applied by the FAO Panel in the evaluation of pesticide residues for recommending maximum residue levels. Some elements of the OECD documents have been incorporated in the manual without specific attribution. These guidelines and guidance documents have been cited in the references. In cases where more detailed information relating to a specific subject was considered to be particularly useful for the reader, the reference to the relevant guideline is given.

In addition to general updating of the text, the second edition contains new information on:

- Metabolism studies;
- Requirements regarding on environmental fate;
- Performance characteristics of analytical methods;
- Planning and implementing supervised residue trials;

- Use of residue monitoring data for estimation of maximum residue levels for spices;
- Statistical evaluation of residue data;
- Calculation of burden in animals, based on expanded feed consumption tables;
- Estimation of dietary intake of residues.

In order to improve the ease with which the subject of interest can be located in the manual, the sections are numbered. The chapter number is indicated in bold type, and the appendices are referenced with Roman numbers.

The second edition of the manual will be published by FAO and will be placed on the FAO website.

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

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

3.1 BOSCALID (221)

Background

Boscalid is a systemic fungicide that was first evaluated by JMPR in 2006 for residues and toxicology as a new active substance. The Meeting established an ADI for boscalid of 0–0.04 mg/kg bw and considered that an ARfD was unnecessary. Owing to the incomplete data submission for residues in follow-up crops, the Meeting decided that a risk assessment of residues in rotational crops could not be finalised at that time. The 2008 JMPR reviewed residue data for additional uses involving banana and kiwifruit.

In response to the request of the CCPR at its Forty-first Session,[7] the present Meeting reconsidered all the available data for a finalization of the dietary risk assessment for boscalid. New data were submitted regarding the metabolism and degradation of boscalid in soil, uptake in follow-up crops and livestock feeding to the 2009 JMPR. Further studies, GAP information and supervised residue trials referred to in the present report are described in the evaluation of boscalid as a new active substance by the 2006 JMPR.

Overview on the evaluation procedure for boscalid in rotational crops as applied by JMPR

The Meeting followed the general procedure outlined under point 2.9 in the JMPR report of 2008. In the first step, field-decline studies were used to estimate the half-life of boscalid in soil under the assumption of first-order kinetics. The Meeting identified DT_{50} values of 208, 365 and 746 days as values representing the total range of possible half-lives of boscalid in soil.

After the estimation of half-lives, the highest plateau-level concentrations of boscalid in soil after annual application according to GAPs reported in 2006 were estimated. The calculation indicated that all uses reported globally, except those involving 4.5 kg ai/ha per year, resulted in boscalid plateau-level residues in soil equivalent to an application rate of 2.1 kg ai/ha or less.

In the next step, field rotational-crop studies on various commodities conducted at rates of 2.1 kg ai/ha per year were reviewed to estimate mean, median and highest residues expected following uptake of boscalid via plant roots. These additional residues were compared to boscalid levels found in the corresponding commodities after direct treatment according to GAPs described in the 2006 JMPR report. In case of a significant contribution of residues, arising after crop rotation, to residues following direct treatment, both pathways were taken into account simultaneously for an overall estimation of maximum residue levels as well as for STMR and highest residue values.

[7] Codex Alimentarius Commission (2009) Report of the Forty-first Session of the Codex Committee on Pesticide Residues, Beijing, China, 20–25 April 2009 (ALINORM 09/32/24), para 124.

Whenever appropriate, the Meeting decided to extrapolate its recommendations to whole commodity groups to include as many minor crops as possible that are likely to be exposed to boscalid via crop rotation as well as direct application.

Example 1: Root and tuber vegetables

Based on the use of boscalid on carrots, boscalid residues in the roots following direct treatment were: < 0.05, 0.06, 0.12, 0.17, 0.18, 0.19, 0.28, 0.34 mg/kg.

For carrot roots, residues were found with mean, median and highest residues of 0.13 mg/kg, 0.065 mg/kg and 0.37 mg/kg, respectively. The Meeting concluded that root and tuber vegetables may be influenced significantly by an additional uptake of boscalid via the roots. The Meeting decided to add the mean residue of 0.13 mg/kg found in field studies on carrots roots to the median residue of 0.175 mg/kg obtained from supervised field trials on carrot roots for an overall STMR for boscalid in carrot roots of 0.305 mg/kg. In addition, the Meeting recommended a maximum residue level of 2 mg/kg for the group of root and tuber vegetables, based on the use of boscalid on carrot roots.

Example 2: Oilseeds

Based on the use of boscalid on sunflowers, boscalid residues in the seeds following direct treatment were: < 0.05, 0.08, 0.09, 0.13, 0.16, 0.16, 0.23, 0.45 mg/kg.

In field studies on succeeding crops, the mean, median and highest residues in alfalfa, soya bean and cotton seeds were 0.05 mg/kg, 0.05 mg/kg and 0.06 mg/kg, respectively, with most of the values below the LOQ of 0.05 mg/kg. The Meeting concluded that residues in oilseeds caused by an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment. The Meeting estimated a maximum residue level and an STMR value for boscalid in oilseeds of 1 mg/kg and 0.145 mg/kg, respectively, based on sunflower seeds.

Owing to the large number of commodities that are subject to crop rotation and new studies submitted to JMPR 2009, a detailed report, a long-term dietary risk assessment and a recommendation table are presented in Annex 1 of the present report.

3.2 CARBOFURAN (096)

Background

At the Forty-first Session of the CCPR,[8] the Delegation of the European Community (EC) raised concerns regarding the ADI and ARfD for carbofuran that had been established by the JMPR in 2008, both these values being higher than those established by the EC.

Evaluation of carbofuran by the JMPR

In 2008, the Meeting established an ARfD of 0.001 mg/kg bw based on the "overall NOAEL" identified by the 2004 JMPR (Annex 5, reference *101*, p. 9) of 0.03 mg/kg bw per day identified on the basis of inhibition of brain acetylcholinesterase activity in rat pups aged 11 days. This NOAEL was supported by the BMD_{10} (benchmark dose at the 10% effect level) of 0.04 mg/kg bw and the $BMDL_{10}$ (lower 95% confidence limit for the BMD_{10}) of 0.03 mg/kg bw extrapolated by the United States EPA[9] from data on the inhibition of brain acetylcholinesterase activity in pups aged 11 days

[8] Codex Alimentarius Commission (2009) Report of the Forty-first Session of the Codex Committee on Pesticide Residues, Beijing, China, 20–25 April 2009 (ALINORM 09/32/24), para 85.

[9] US EPA (2008a) Carbofuran: HED revised risk assessment for the Notice of Intent to Cancel (NOIC). Memorandum from Drew D, Morton TG, Lowit A, & Reaves E. to Andreasen J. Dated 3 January 2008; US EPA (2008b) Carbofuran: proposed

from three studies (Tyl *et al*., 2005; Moser *et al*., 2007; and Hoberman, 2007a).[10] A safety factor of 25 was considered to be appropriate because the acute toxic effects of carbofuran are dependent on C_{max} rather than the area under the curve of concentration–time (AUC) and data indicated that the sensitivity of acetylcholinesterase activity to inhibition by carbofuran was similar in humans and laboratory animals (rats, dogs) (Annex 5, reference *113*, p.7). The ARfD was considered to be adequately protective of infants and children since it was based on the NOAEL identified in studies in pups aged 11 days.

The 2008 JMPR noted that this ARfD was lower than the 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 2008 JMPR 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.

Evaluation of carbofuran by the EC

The EC also considered the studies of acute toxicity in rats, except for the study by Moser *et al*. (2007), as key studies for establishing reference doses. However, the EC emphasized that they did not consider either the ARfD of 0.001 mg/kg bw or the ADI of 0–0.001 mg/kg bw to be sufficiently protective for neurotoxicity in children. On the basis of the information provided by the EC, the concerns raised by the EC centred on the following issues:

- In the study of Hoberman (2007a), the lowest dose of 0.03mg/kg bw was considered to be a lowest-observed-adverse effect level (LOAEL) rather than a NOAEL, since brain acetylcholinesterase activity in female pups aged 11 days was inhibited by 20% ($p < 0.01$).
- On the basis of the studies from Tyl (2005) and Hoberman (2007a), the EC calculated a BMD_{10} of 0.014–0.016 mg/kg bw. This BMD_{10} was considered to be supportive of an extra two-fold safety factor to extrapolate the LOAEL for pups (0.03 mg/kg bw) to a NOAEL (0.015 mg/kg bw).
- The EC noted that a safety factor of 100 should be maintained to derive the ADI and ARfD for carbofuran. EC considered it insufficiently proven that a lower safety factor should be applied based upon the assumption that N-methyl carbamate toxicity, which is dependent on a C_{max} rather than an AUC effect, would exhibit lower inter- or intraspecies variability.

In conclusion, the EC concluded that an ADI of 0–0.00015 mg/kg bw and an ARfD of 0.00015 mg/kg bw should be established, based on an extrapolated NOAEL of 0.015 mg/kg bw and a safety factor of 100.

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tolerance revocations. Federal Register 73(148):44863–44892.

[10] Hoberman AM (2007a) Cholinesterase depression in juvenile (day 11) and adult rats following acute oral (gavage) dose of carbofuran technical. Unpublished report No. A2006-6137 dated 31 May 2007 from Charles River Laboratories Preclinical Services, Horsham, PA, USA. Submitted to WHO by FMC Corporation, Agricultural Products Group, Philadelphia, PA, USA.

Moser VC, McDaniel KL, Phillips PM (2007) Report on cholinesterase comparative sensitivity study of carbofuran: adult and PND11. Unpublished report dated 14 November 2007 from Neurotoxicology Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, US EPA, Research Triangle Park, North Carolina 27711. Submitted to WHO by Office of Pesticide Programs, US EPA, Washington, DC, USA.

Tyl RW, Marr M, Myers CB (2005) Acute dose-response study of carbofuran technical administered by gavage to adult and postnatal day 11 male and female CD (Sprague-Dawley) rats. Unpublished report No. A2005-5981 dated 7 November 2005 from RTI International, Center for Life Sciences and Toxicology, Research Triangle Park, NC, USA. Submitted to WHO by FMC Corporation, Agricultural Products Group, Philadelphia, PA, USA.

Comments by the JMPR

After consideration of the EC concerns and after reviewing the conclusions of the 2008 JMPR, the present Meeting highlighted the following points:

- In one study (Hoberman, 2007a), inhibition of brain acetylcholinesterase activity was 20% in female pups at a dose of 0.03 mg/kg bw. In male pups, however, inhibition was only 13% and data indicated no evidence for a sex-specific difference in sensitivity to inhibition of brain acetylcholinesterase activity by carbofuran. Also, in the corresponding dose range-finding study (Hoberman, 2007b),[11] inhibition of brain acetylcholinesterase activity at a dose of 0.03 mg/kg bw was only 10% or 11% in male and female pups, respectively. Thus, based on data from both studies and for both sexes, the present Meeting considered the dose of 0.03 mg/kg bw to be an overall NOAEL for pups aged 11 days, since inhibition of brain acetylcholinesterase activity was clearly less than 20%.
- The overall NOAEL of 0.03 mg/kg bw is supported by the benchmark-dose analysis of data on brain acetylcholinesterase activity from the three studies in rat pups aged 11 days (Tyl et al., 2005; Hoberman, 2007a; Moser *et al.*, 2007). The estimated BMD_{10} for brain acetylcholinesterase activity was 0.04 mg/kg bw, while the $BMDL_{10}$ was 0.03 mg/kg bw. The Meeting considered that the BMD_{10} used by the JMPR was more reliable than that calculated by the EC as it used data from three studies (Moser *et a*l., 2007; Tyl *et al*., 2005; Hoberman, 2007a) rather than two (Tyl *et al*., 2005c; Hoberman, 2007a).
- For carbofuran, the acute toxic effects are dependent on C_{max} rather than AUC and data indicated that the sensitivity of humans and laboratory animals (rats, dogs) to inhibition of acetylcholinesterase activity was similar. Thus the Meeting considered that a safety factor of 25 was appropriate. A detailed rationale for this position is included in the report of the 2008 JMPR (Annex 5, reference *113*, p.7: Safety factors for acute C_{max}-dependent effects: specific considerations with respect to carbamates such as carbofuran).

Therefore, the Meeting reaffirmed both the ARfD of 0.001 mg/kg bw and the ADI of 0–0.001 mg/kg bw based on an overall NOAEL of 0.03 mg/kg bw for inhibition of brain acetylcholinesterase activity in rat pups aged 11 days and with a safety factor of 25. Also, the Meeting confirmed that both the ADI and the ARfD are adequately protective of infants and children.

3.3 CHLORANTRANILIPROLE (230)

Background

At the Forty-first Session of the CCPR, the Delegation of the USA raised concerns regarding the reasoning for the maximum residue levels for chlorantraniliprole in grapes and leafy vegetables (spinach) differing from estimates made using the NAFTA calculator.[12] A concern form was submitted.

The Meeting noted there were many approaches to estimating MRLs, including experience, modelling and the use of statistics to evaluate sets of numbers. Experience takes into account the crop varieties used in residue trials and their potential for residues, the number of trials, distribution of trial locations, size of trial plots, timing of spray applications, spray volumes, use of spray additives

[11] Hoberman AM (2007b) Acute oral (gavage) dose range-finding study of cholinesterase depression from carbofuran technical in juvenile (day 11) rats. Unpublished report No. A2006-6135 dated 31 May 2007 from Charles River Laboratories Preclinical Services, Horsham, PA, USA. Submitted to WHO by FMC Corporation, Agricultural Products Group, Philadelphia, PA, USA.

[12] Codex Alimentarius Commission (2009) Report of the Forty-first Session of the Codex Committee on Pesticide Residues, Beijing, China, 20–25 April 2009 (ALINORM 09/32/24), para 126.

such as adjuvants, range of half-times for residue decline and the large database of residue of data for other pesticides on the same or similar crops. These factors cannot be taken into account by the NAFTA calculator (see General consideration 2.1).

Statistical methods use well-established mathematical approaches to estimate a number. The NAFTA calculator used by the JMPR uses a decision-tree approach to estimate one of the following:

- The upper 95% confidence limit for the 95th percentile residue
- The point estimate of the 99th percentile residue
- The mean plus three-times the standard deviation.

The JMPR has previously suggested in the report of its meeting in 2008 that more than 15 datapoints are required for application of the statistical approaches described above, although the NAFTA White Paper[13] acknowledges that the accuracy of NAFTA estimates for smaller datasets diminishes as sample size decreases. The JMPR considered a combination of experience of historical data and statistical methods to arrive at the MRL recommendations.

Grapes

Data from seventeen residue trials matching GAP were available with a highest residue of 0.52 mg/kg. The estimate derived from use of the NAFTA calculator was 1.4 mg/kg; however, the Meeting noted that the data in the Q-Q plot depart from the trend line at the high end of the plot, where extrapolation to provide the NAFTA calculator derived estimate occurred. The Meeting could not conclude that the data follow a lognormal distribution. The range of estimates provided by the different options in the NAFTA calculator, before rounding, were:

- Assuming the data follow a normal distribution:
    - 95% upper confidence level for the 95th percentile 0.61 mg/kg
    - 99th percentile (point estimate) 0.59 mg/kg
- Assuming the data follow a lognormal distribution:
    - 95% upper confidence level for the 95th percentile 1.64 mg/kg
    - 99th percentile (point estimate) 1.39 mg/kg
    - Upper prediction level for the 95th percentile assuming a coefficient of variation of 1 0.77 mg/kg
- Non-parametric methods
    - Mean plus 3 times the standard deviation 0.70 mg/kg
    - EU method II 0.66 mg/kg.

The 2008 JMPR took into account experience of likely high residues at the day of the last spray and use of decline half-lives obtained from the reported residue decline trials (assuming a DT_{50} of 34 days). Noting the above and the complete range of estimates derived from the NAFTA calculator, the Meeting recommended a value of 1 mg/kg for grapes.

The Meeting confirmed its previous recommendation of 1 mg/kg for grapes.

[13] Statistical Basis of the NAFTA method for calculating pesticide maximum residue limits from field trial data. http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648026e8d0

Leafy vegetables (spinach)

The 2008 JMPR estimated a maximum residue level for leafy vegetables based on a dataset of seven residue trials for spinach with a highest observed residue of 8.9 mg/kg. The NAFTA calculator estimated 15 mg/kg. Visual inspection of the Q-Q plot in the NAFTA calculator did not enable the Meeting to conclude the data follow a log-normal distribution. The range of estimates provided by the different options in the NAFTA calculator, before rounding, were:

- Assuming the data follow a normal distribution:
    - 95% upper confidence level for the 95th percentile 13.1 mg/kg
    - 99th percentile (point estimate) 11.31 mg/kg
- Assuming the data follow a lognormal distribution:
    - 95% upper confidence level for the 95th percentile 19.98 mg/kg
    - 99th percentile (point estimate) 14.5 mg/kg
    - Upper prediction level for the 95th percentile assuming a coefficient of variation of 1 64 mg/kg
- Non-parametric methods:
    - Mean plus three-times the standard deviation 12.7 mg/kg
    - EU method II 16.6 mg/kg.

As with grapes, the 2008 JMPR took into account experience of likely high residues at the day of the last spray the decline half-lives obtained from the reported residue decline trials (DT_{50} time of 14 days). Noting the range of estimates available from use of the NAFTA calculator, the small dataset and the results based on an estimate from the day of the last spray, the 2008 JMPR estimated a maximum residue level of 20 mg/kg.

The Meeting confirmed its previous recommendation of 20 mg/kg for leafy vegetables.

The present Meeting also reiterated the statement of the 2008 JMPR that, for small datasets, the NAFTA White Paper and reviews of the performance of the calculator suggest a large uncertainty in such estimates of high percentiles. Use of other tools and experience is needed to ensure that the maximum residue level estimates are realistic.

3.4 CYFLUTHRIN (157)/BETA-CYFLUTHRIN (228) – ALTERNATIVE GAP

Cyfluthrin and beta-cyfluthrin were evaluated for toxicology by the 2006 JMPR and for residues by the 2007 JMPR under the CCPR periodic review programme, and maximum residue levels for cyfluthrin, arising from the use of either cyfluthrin or beta-cyfluthrin on a number of commodities, were recommended.

The 2007 JMPR estimated short-term intakes for children that exceeded the ARfD of 0.04 mg/kg bw for broccoli and head cabbage and noted that there were insufficient data to support an estimation of lower maximum residue levels based on alternative GAPs for these commodities.

At the Forty-first Session of the CCPR in 2009, the Committee agreed that if no data were available to support lower MRLs for broccoli and head cabbage (based on alternative GAP), the draft MRLs would be considered for withdrawal at the 2010 session.[14]

[14] Codex Alimentarius Commission (2009) Report of the Forty-first Session of the Codex Committee on Pesticide Residues, Beijing, China, 20–25 April 2009 (ALINORM 09/32/24), paras 106–107.

Information on current GAP and new supervised trials data from Indonesia were provided to the 2009 JMPR for cabbages, but no new residue data or information were available for broccoli.

Results of supervised trials on crops

Based on US GAP and residue data for cyfluthrin, the 2007 JMPR estimated a maximum residue level of 4 mg/kg, an STMR of 0.25 mg/kg and an HR of 2.1 mg/kg for cyfluthrin in cabbage (head) but estimated that the short-term intake for children was 240% of the ARfD (0.04 mg/kg bw).

Cabbages, Head – beta-cyfluthrin

Residue trials conducted in Germany matching the GAP of Sweden and Poland (10 g ai/ha; PHI of 7 days) and evaluated by the 2007 JMPR, reported residues of < 0.01, < 0.01, 0.06 and 0.08 mg/kg.

New trials with beta-cyfluthrin reported to the Meeting from Indonesia (GAP, 15 g ai/ha; PHI of 7 days) reported residues of < 0.01, 0.02 and 0.05 mg/kg.

The Meeting agreed that the data were insufficient to estimate a maximum residue level to support an alternative GAP for beta-cyfluthrin on cabbage (head).

Cabbages, Head – cyfluthrin

Residue trials with cyfluthrin conducted in Portugal and Spain, matching the GAP of Italy (25 g ai/ha; PHI of 3 days) reported residues of 0.01 and 0.09 mg/kg.

Trials conducted in Germany, matching the GAP of Belgium (maximum of 2 applications, 25 g ai/ha, PHI of 14 days) reported residues of < 0.01, 0.02 and 0.06 mg/kg.

The Meeting agreed that the data were insufficient to estimate a maximum residue level to support an alternative GAP for cyfluthrin on cabbage (head).

Alternative GAP was considered by the present Meeting, but the previous HR recommendation was confirmed because of insufficient residue data. Hence, a refinement of the international estimate of short-term dietary intake (IESTI) was not possible with the current data. The Meeting established a group ARfD for cyfluthrin and beta-cyfluthrin in 2006 on the basis of acute neurotoxicity observed in a 4-week study in rats and a safety factor of 25, and it is unlikely that it could be refined.

3.5 FENTHION (39)

Background

Fenthion is an insecticide that has been used since 1957 for the control of a wide range of insect pests on fruit, vines, olives, vegetables, cotton, tea, sugar-cane, sugar-beet, and rice. The use pattern also includes the postharvest disinfestation of fruit, the control of insect pests (e.g., mosquitoes, fleas) for public health purposes and animal houses and for the control of animal ectoparasites.

Evaluation of fenthion by the JMPR

Fenthion was first evaluated by the JMPR in 1971 and has been reviewed several times since, most recently in 1995 within the periodic review programme of the CCPR. An ADI of 0–0.007 mg/kg bw was established.

The 2000 JMPR could not evaluate studies of residues in peaches, cherries and olives, since the trials were performed in EU Member States and the related GAP in those countries was pending.

Consideration of fenthion by CCPR and by the EC

The CCPR at its Thirty-fourth Session in 2003 noted that the current Codex MRLs are mainly based on EU uses, and that fenthion was under evaluation in the EU.[15]

In 2004, the EU decided not to include fenthion in Annex I of Directive EC/ 91/414, implying that all uses of fenthion within the EU would stop. Since the current Codex MRLs are based on European use labels and European supervised field trials, CCPR considered revoking all existing Codex MRLs.

The CCPR at its Fortieth Session in 2008 noted that GAP information for cherries, citrus fruit and olives would be provided by Australia and decided to maintain the Codex MRLs for cherries, citrus fruits, olives and olive oil, virgin, for 4 years under the periodic review programme. The Committee also decided to delete the proposed MRLs for olive oil, virgin, mandarins and orange, sweet, sour, since they were based on European uses.[16]

Comments by JMPR

The present Meeting did not receive any data to evaluate, and noted that fenthion was not scheduled for periodic re-evaluation until 2017.

3.6 METHOMYL (094)

Background

The CCPR at its Forty-first Session[17] noted the concerns expressed by the EC and Norway regarding acute dietary intake for grape and tomato, based on the ARfD established by the EC. The delegation of the EC informed the Committee that they would submit a concern form for apple.

Evaluation of methomyl by the JMPR

Methomyl is a carbamate insecticide that is registered throughout the world for foliar application on numerous agricultural crops. JMPR has evaluated the compound several times since 1978. In 1989, an ADI of 0–0.03 mg/kg bw was established and in 2001, the Meeting was requested to establish an ARfD. The Meeting at that time established an ARfD of 0.02 mg/kg bw based on the results of a study in human volunteers. The Meeting noted that this ARfD was lower than the ADI, and concluded that the ADI and ARfD should be based on the same NOAEL. The ADI was accordingly revised to 0–0.02 mg/kg bw.

Methomyl was evaluated for residues under the periodic review programme of the CCPR in 2001. Maximum residue levels for methomyl, arising from the use of either methomyl or thiodicarb, were recommended for a number of crops. 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.

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[15] Codex Alimentarius Commission (2003) Report of the Thirty-fourth Session of the Codex Committee on Pesticide Residues, The Hague, The Netherlands 13–18 May 2002 (ALINORM 03/24), paras 80–81.

[16] Codex Alimentarius Commission (2008) Report of the Fortieth Session of the Codex Committee on Pesticide Residues, Hangzhou, China, 14–19 April 2008 (ALINORM 08/31/24), paras 50–51.

[17] Codex Alimentarius Commission (2009) Report of the Forty-first Session of the Codex Committee on Pesticide Residues, Beijing, China, 20–25 April 2009 (ALINORM 09/32/24), para 78.

The CCPR at its Thirty-eighth Session[18] requested JMPR to consider using alternative GAPs to recommend lower MRLs for apples, brassica vegetables, celery, fruiting vegetables, cucurbits, grapes, leafy vegetables and pears. The 2008 JMPR was able to recommend maximum residue levels for apple, pear, cucurbits (cucumbers, courgettes and melons), grapes, lettuce and tomatoes. Most of the recommendations were based on European data. No new residue data or information was available for brassica vegetables and celery and the 2008 JMPR withdrew its previous recommendations for those commodities.

The international estimated daily intakes (IEDI) in the 13 GEMS/Food Consumption Cluster Diets, based on the STMRs estimated by the 2008 JMPR were in the range of 0% to 3% of the maximum ADI of 0.02 mg/kg bw. The IESTI varied from 0% to 50% of the ARfD (0.02 mg/kg bw) for the general population. The IESTI varied from 0% to 100% of the ARfD for children aged 6 years and younger. The highest percentages (50% of the ARfD for the general population, 100% of the ARfD for children) were found for tomatoes. The Meeting concluded that neither the long-term nor the short-term intake of residues of thiodicarb and methomyl from uses that had been considered by the JMPR was unlikely to present a public health concern.

Evaluation of methomyl by the EC

The present Meeting received the EC concern form, together with the results of the EU dietary-intake calculation. The following information was presented: "Using EC endpoints (ARfD 0.0025 mg/kg bw/day) and risk assessment methodologies (EFSA model PRIMo rev2), apples are 666% of the ARfD[19], using an HR value of 0.17 mg/kg (15 trials). It is acknowledged that a higher ARfD of 0.01 mg/kg bw/day is accepted by JMPR, based on a human volunteer study. Even using the JMPR ARfD with EC risk assessment methodologies, apples are 167% of the ARfD."

Comments by JMPR

The present Meeting noted that the ARfD established by JMPR is 0.02 mg/kg bw, not 0.01 mg/kg bw, as was incorrectly reported in the EC concern form. Furthermore, the Meeting noted that using the JMPR ARfD with the EC risk-assessment methodologies, the short-term intake (children, large portion for UK infant, 180 g/person) for apples was 83% when using a variability factor of 7, while it was 61% of the ARfD when using a variability factor of 5. The Meeting, using a variability factor of 3, calculated a short-term intake of 60% of the ARfD for children, based on a children's large portion from the USA of 680 g/person.

The Meeting confirmed that the short-term intake of residues of thiodicarb and methomyl from uses on apple is unlikely to present a public health concern.

3.7 PHORATE (112)

Phorate is a systemic organophosphate contact insecticide and acaricide that inhibits acetylcholinesterase activity. Residue and analytical aspects of phorate were evaluated by the JMPR in 1977, 1984, 1990, 1991, 1992, and 2005. The evaluation in 2005 was a periodic review. The toxicological periodic review was conducted in 2004, when an ADI of 0–0.0007 mg/kg bw and an ARfD of 0–0.003 mg/kg bw were established.

The residue definition for phorate, both for enforcement and for risk assessment for animal and plant commodities, is: the sum of the parent, its oxygen analogue, and their sulfoxides and

[18] Codex Alimentarius Commission (2006) Report of the Thirty-eighth Session of the Codex Committee on Pesticide Residues, Fortaleza, Brazil, 3– 8 April 2006 (ALINORM 06/29/24), paras 80– 81.

[19] For children.

sulfones, expressed as phorate. The analytical methodology available relies on the oxidation of all phorate-related residues to the common moiety metabolite, phoratoxon sulfone.

The 2005 JMPR noted that the acute dietary intake of potato by children aged up to 6 years amounted to 120% of the ARfD. The value of 120% represents the IESTI for potato, microwaved with peel. The CCPR in 2006 therefore decided not to advance the maximum residue level in the Codex step system. The CCPR in 2007 was informed that the manufacturers would provide additional data for processed potato in 2008 for evaluation by the 2009 JMPR.

The present Meeting received a new study of processing in potatoes to facilitate a refinement of the risk assessment.

Methods of analysis

Total phorate-related residues (oxidizable to phoratoxon sulfone) were determined by gas chromatography with flame photometric detection (GC-FPD), following method M-1620 (see 2005 JMPR). The reported LOQ was 0.049 mg/kg eq, the LOD was 0.003 mg/kg eq. Method verification recoveries at 0.049, 0.25 and 2.0 mg/kg eq were for each fortification level above 90% (n=3, RSD, < 4%).

Fate of residues in storage and during processing

The Meeting received new information on the fate of incurred residues of phorate during washing and microwave cooking of potatoes. The samples from the field studies were analysed twice, owing to the variable results of the first experiment. The reason for this was considered to be as follows. The application of phorate in this study was as an in-furrow granule. As a result, it is possible that potatoes formed directly in the furrow accumulated more phorate, both on the surface, including adhered soil, and internally, than potatoes formed outside the treated furrow. In order to get a representative field sample, the potatoes were sampled from directly in the row (in the furrow where the insecticide was applied) as well as from the sides of the row. Each collected treated sample contained randomly selected potatoes from both areas, with potentially great variability in residue content between potatoes used in each processing step. The Meeting considered this to be a plausible explanation for the variable results.

The second experiment was modified to reduce this potential variability between potatoes used in each processing step, by direct pairing of potatoes/potato parts across the unwashed versus washed and cooked samples. For the second processing set, the frozen whole potato retained samples held by the processing facility were used for processing.

Mean weight loss for the potatoes during cooking in processing experiment 2 (66%, mean of treated samples) was significantly higher than the weight loss in processing experiment 1 (15%). For microwaving, 15–20% is the commercial norm. Projected residues at 15% weight loss to correct for excess weight loss due to frozen storage of potatoes before processing were reported by the study director.

The Meeting decided that the experiment in which frozen potatoes with peel were microwaved does not reflect common practices. The Meeting could not confirm that the extensive weight loss did not result in an unusual loss of phorate residues. The Meeting decided not to use the results of the new processing study, and confirmed its previous recommendations.

Using the HR for potato (0.27 mg/kg,) the 2005 JMPR estimated highest residues for the processed commodities (HR-Ps) as listed below. Furthermore, using the STMR for potato (0.05 mg/kg), the Meeting estimated STMR-Ps for these commodities.

Table 2 Estimation of highest concentrations of phorate residues in processed potato commodities

Commodity	Processing factor (median or best estimate)	STMR-P (mg/kg)	HR-P (mg/kg)
Potatoes boiled with peel	0.13	0.0065	0.0351
Potatoes boiled without peel	0.11	0.0055	0.0287
Potatoes baked with peel	0.28	0.014	0.0756
Potatoes baked without peel	0.27	0.0135	0.0729
French fries	0.38	0.019	0.1026
Potatoes microwaved with peel	0.36	0.018	0.0972

HR-P, highest residue in a processed commodity calculated by multiplying the HR of the raw commodity by the corresponding processing factor; supervised trials median residue in a processed commodity calculated by multiplying the STMR of the raw commodity by the corresponding processing factor

The 2005 JMPR decided to use the HR-P and STMR-P for potatoes, microwaved with peel, in the calculations of dietary intake for potatoes since this represented the worst-case situation. The present Meeting noted that the dietary intake of French fries would also be critical.

DIETARY RISK ASSESSMENT

Long-term intake

Conclusion of the 2005 JMPR:

The IEDIs of phorate, based on the STMRs estimated for 18 commodities, for the five GEMS/Food regional diets were in the range of 9% to 20% of the maximum ADI (0–0.0007 mg/kg bw/d). The Meeting concluded that the long-term intake of residues of phorate resulting from uses that have been considered by the JMPR was unlikely to present a public health concern.

Short-term intake

The IESTI for phorate was calculated for potatoes, both by using the HR for potatoes, microwaved with peel, and for French fries, the latter based on new consumption data. The results of which can be found in Annex 4.

The IESTI represented 70% of the ARfD (0.003 mg/kg bw) for the general population (both for potatoes, microwaved with peel, and for French fries) and 170% and 180% of the ARfD for children, from consumption of potatoes, microwaved with peel, and French fries, respectively. The information provided to the JMPR precludes an estimate that the dietary intake of potatoes by children aged 6 years and younger would be below the ARfD.

The Meeting noted that the dietary intake estimation was already based on residues in processed potatoes, leaving little room for refinement. Furthermore, the ARfD was based on a single-dose study and it was unlikely that it could be refined.

3.8 PROCYMIDONE (136)

Background

At the Fortieth Session of the CCPR, the Delegation of the EC raised concerns regarding the ADI and ARfD for procymidone established by the JMPR in 2007, which were higher than those established by the EC.[20]

Evaluation of procymidone by the JMPR

In 2007, the Meeting established an ADI of 0–0.1 mg/kg bw for procymidone based on the overall NOAEL of 12.5 mg/kg bw per day identified on the basis of hypospadias and alterations in testes, prostate and epididymis weights in two studies of reproductive toxicity in rats and a study of developmental toxicity in rats, with a safety factor of 100. The ADI was supported by NOAELs of 14 mg/kg bw per day in a long-term study in rats and 17 mg/kg bw per day in a long-term study in mice. An ARfD of 0.1 mg/kg bw was established based on the NOAEL of 12.5 mg/kg bw per day identified on the basis of hypospadias in a study of developmental toxicity in rats, with a safety factor of 100. The 2007 JMPR concluded that the effects on organ weights seen in studies of reproductive toxicity were largely a consequence of postnatal exposure over a period of time and therefore not appropriate for the establishment of an ARfD.

Evaluation of procymidone by the EC

The concern raised by the EC, as stated on the concern form, was that procymidone and its metabolite (PCM-CH_2OH) bind to the human androgen receptor in vitro, indicating that procymidone has antiandrogenic activity in humans. Since data on toxicokinetics in humans still do not exist, it was concluded that it cannot be excluded that human exposure to procymidone would not lead to teratogenic effects. The EC also noted that procymidone is classified as "Repr. Cat. 2 R61"[21] in the EC.

The documentation submitted by the EC cited two sets of reference doses for procymidone. The first set of reference doses was agreed following an expert toxicology meeting and are the agreed values cited in the "Review Report" supporting the authorization of procymidone.[22] These values comprise an ADI of 0.025 mg/kg bw based on a NOAEL of 2.5 mg/kg bw per day from a study of reproductive toxicity in rats, with a safety factor of 100, and an ARfD of 0.035 mg/kg bw based on the NOAEL of 3.5 mg/kg bw from a study of developmental toxicity in rats, with a safety factor of 100.

The second set of reference doses was proposed in an addendum produced by the rapporteur member state (France) in 2007, which had not been discussed by EC toxicologists at any peer review meetings. The ADI of 0.0028 mg/kg bw was based on a LOAEL of 2.5 mg/kg bw per day from a study of reproductive toxicity in rats, with a safety factor of 900 (3 for moving from a LOAEL to a NOAEL; 3 for interspecies variability; 10 for intraspecies variability and 10 for severity of effect). The ARfD of 0.012 mg/kg bw based on the NOAEL of 3.5 mg/kg bw from a study of developmental toxicity in rats, with a safety factor of 300 (3 for interspecies variability; 10 for intraspecies variability and 10 for severity of effect).

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[20] Codex Alimentarius Commission (2008) Report of the Fortieth Session of the Codex Committee on Pesticide Residues, Hangzhou, China, 14–19 April 2008 (ALINORM 08/31/24), para 73.

[21] May cause harm to the unborn child. Toxic to reproduction, Category 2, i.e.,likely to be relevant to humans.

[22] European Commission (2006) Review report for the active substance procymidone. Finalized in the Standing Committee on the Food Chain and Animal Health at its meeting on 27 January 2006 in view of the inclusion of procymidone in Annex 1 of Directive 91/414/EEC. SANCO/4064/2001 rev 1, dated 19 January 2006. European Commission Health and Consumer Protection Directorate-General. Draft working document.

The available information provided by the EC gave no detailed rationale for:

- The effects seen at the LOAELs used in the first evaluation;
- Changing from a NOAEL to a LOAEL in the study of reproductive toxicity;
- The reduction of the default interspecies safety factor;
- The additional safety factor for severity.

Comments by the JMPR

In order to respond as thoroughly as possible to the concerns raised, the 2009 JMPR went to considerable lengths to obtain more detailed information on the basis for the EC concerns, as these were not clearly described or justified on the concern form or submitted documents. The Meeting requested that any future concerns submitted to JMPR are accompanied by comprehensive and transparent supporting information.

The 2007 JMPR and 2007 EC appear to have had access to the same supporting databases. The 2007 JMPR discussed the reproductive effects of procymidone in great depth (performing its own benchmark-dose calculations for some end-points) and concluded that procymidone was a reproductive toxicant and could bind to the human androgen receptor in vitro. The 2007 JMPR also considered in depth the data on the toxicity of procymidone metabolites and the data on toxicokinetics in rats, rabbits and monkeys and their relevance to human exposures.

The main differences between the evaluations made by the 2007 JMPR and the EC were the NOAELs identified, and in the 2007 EC proposals, the safety factors chosen. The present Meeting reviewed tabulated data on a number of end-points, including all those identified in additional EC documents as being the basis for identifying the NOAELs used to set the EC reference doses. These end-points included anogenital distances, testes, prostate, epididymis and seminal vesicle weights, hypospadias, undescended testes and histopathology of testes, epididymides, coagulating glands, prostate and seminal vesicles. The present Meeting also reviewed the publications describing the 2007 JMPR decisions.

The present Meeting noted that the monograph produced by the 2007 JMPR described some effects at the intermediate dietary concentration of 250 ppm (17 mg/kg bw per day), which would give a NOAEL of 3.0 mg/kg bw per day (50 ppm) identified in the first study of reproductive toxicity. However, these findings were not evident at the NOAEL of 14 mg/kg bw per day in the long-term study in rats, for the parental effects, nor at the NOAEL of 12.5 mg/kg bw per day in the subsequent study of reproductive toxicity, for the pup effects. The present Meeting confirmed that the overall NOAEL from the studies of reproductive toxicity in rats was 12.5 mg/kg bw per day based on the NOAELs that were between the LOAEL and NOAEL for the first study of reproductive toxicity. The present Meeting noted that most of the findings mentioned in EC documents were not seen below doses of 37 mg/kg bw per day.

In the study of developmental toxicity in rats, the only finding at 12.5 mg/kg bw per day was a statistically significant (but < 10%) change in anogenital distance in male fetuses removed by caesarean section. However, in the part of this study where dams were allowed to deliver naturally, there were no significant effects on anogenital distance at postnatal days 1 or 21 in the group at 12.5 mg/kg bw per day. The present Meeting confirmed that the findings at 12.5 mg/kg bw per day were not adverse and identified this dose as the NOAEL.

The EC addendum gave no explanation for the choice of the non-default safety factors for interspecies (3) and severity (10). The 2007 JMPR discussed the use of a data-derived safety factor when deriving the ARfD for procymidone, but concluded that the uncertainties were such that this was not justifiable. The 2007 JMPR considered that the findings at the LOAELs were such that no additional safety factors were needed to derive the ARfD and ADI. The present Meeting confirmed that a safety factor of 100 was appropriate for deriving both the ADI and the ARfD for procymidone.

The present Meeting reaffirmed the ADI for procymidone of 0–0.1 mg/kg bw based on the overall NOAEL of 12.5 mg/kg bw per day from two studies of reproductive toxicity in rats and an ARfD for procymidone of 0.1 mg/kg bw based on the NOAEL of 12.5 mg/kg bw per day in a study of developmental toxicity in rats, both with a safety factor of 100.

3.9 SPIROTETRAMAT (234)

Background

At the Forty-first Session of the CCPR, the Delegation of the USA expressed concern over the maximum residue level estimation of 0.5 mg/kg made by the 2008 JMPR and submitted a concern form. The USA noted that there were 11 trials in the USA and that use of the NAFTA calculator produced an estimate of 0.3 mg/kg in the USA, from the same dataset. An explanation of the derivation of the JMPR estimate was requested and a request was made to consider 0.3 mg/kg as a revised estimate.

Consideration and response

The supervised field trial data were from USA trials conducted on almonds and pecans. The results in ranked order were: 0.020 (3), 0.031, 0.048, 0.054, 0.082, 0.089, 0.094, 0.13, 0.25 mg/kg (Annex 5, reference *113*, p.333).

The HR is 0.25 mg/kg, and thus the MRL would be somewhat greater than 0.25 mg/kg. The median was 0.05 mg/kg. All values exceed the limit of quantitation.

The Meeting noted that only 11 sample values were available for combined almond and pecan field trial sample results. The value of 0.5 mg/kg was based upon the consideration of a relatively small number of trials, meaning that one or more high residue values may have been missed in the limited crop field trials conducted, and on the need to cover possible residues from nut varieties of the tree nut group that were not included in the limited trials on pecans and almonds only.

The Meeting considered the results of the NAFTA statistical calculation spreadsheet. It provided estimates in the range of 0.3–0.6 mg/kg, depending on the distribution selected. The spreadsheet selected UPL median 95th value (0.3 mg/kg). This reflects the spreadsheet decision that the distribution is log-normal, but due to the small number of datapoints a diversion from the log normal 99 estimate (0.4 mg/kg) and the log-normal 95/95 value (0.6 mg/kg) is made.

The Meeting also noted that while the JMPR used the same dataset as the USA, there are differences in the treatment of that data that could lead to different estimates from the NAFTA calculator. The USA would have 22 residue values because of the procedure of using two datapoints per trial location. This inclusion of duplicate points would no doubt result in the use of the log-normal 99 or log-normal 95/95 value. The Meeting has rejected this approach, as it believes that samples from the same plot at the same site are not independent, and uses the highest residue from each trial site.

Furthermore, the Meeting decided that statistical methods may not be appropriate for datasets of fewer than 15 values (Annex 5, reference *113*, General consideration 2.8, p. 40). Examples show the uncertainty of the estimation based on a small number of residue datapoints, and this uncertainty and likelihood of underestimating the maximum residue level is clearly explained in the Canada/US White Paper for the NAFTA calculator[23].

[23] Statistical Basis of the NAFTA method for calculating pesticide maximum residue limits from field trial data. http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648026e8d0

The Meeting considered that given the small dataset with HR of 0.25 mg/kg and the need to extrapolate pecan and almond data to all nuts, the maximum residue level should be estimated at 0.5 mg/kg. The lowest possible estimate could not be 0.3 mg/kg, as this was seen as too restrictive based on the few trial results available and the extrapolation to nut varieties with no trial data.

The Meeting confirmed its previous recommendation of 0.5 mg/kg for spirotetramat on tree nuts.

3.10 TRIADIMEFON (133) AND TRIADIMENOL (168)

Background

Triadimefon and triadimenol have been evaluated by the JMPR several times between 1978 and 2007. These compounds were re-evaluated as part of the periodic review programme of CCPR in 2007 for residues and in 2004 for toxicology. The Meeting recommended a number of maximum residue levels and established an ADI of 0–0.03 mg/kg bw and an ARfD of 0.08 mg/kg bw for both compounds. In 2008, the Fortieth Session of the CCPR, due to dietary intake concerns, requested JMPR to consider the alternative GAP approach to assess whether a lower maximum residue level recommendation for grapes was possible.

Information on current GAPs submitted to the 2009 JMPR included a company's statement that the GAP from Taiwan, China, is no longer supported.

Results of supervised residue trials on crops

For triadimefon and triadimenol, GAP information on grapes submitted to the present Meeting was similar to the GAPs on which the re-evaluation for periodic review in 2007 was based. Although the GAP from Taiwan, China, no longer supported by the company was available in 2007, the evaluation of supervised residue trial data was based on uses reported from Belarus, Croatia, Kazakhstan, Russia, South Africa, the former Yugoslav Republic of Macedonia, and the USA (triadimefon) as well as Australia, Bulgaria, Cyprus, France, Georgia, Italy, Moldavia, New Zealand, South Africa and the Ukraine (triadimenol). None of these GAPs have been revised to allow a re-evaluation in view of an alternative GAP approach.

The 2007 JMPR considered all supervised field trials available for grapes and decided to combine all residue data, since due to the high variability within the crop field trial, data could not be attributed to one specific GAP. Residue data selected in 2007 were: < 0.02(3), 0.03, < 0.04, < 0.04, 0.04(3), < 0.05(5), 0.05, 0.05, 0.06, 0.06, 0.07(4), 0.08, 0.08, 0.09(3), 0.1, 0.1, 0.11, 0.11, 0.15(4), 0.16, 0.17, 0.18, 0.21, 0.25, 0.27, 0.27, 0.28, 0.3, 0.32, 0.33, 0.36, 0.37, 0.43, 0.46, 0.54, 0.58, 0.59, 0.6, 0.6, 0.69, 0.78, 0.78, 0.8, 1.4, 1.7, 1.9 and 3.2 mg/kg (sum of triadimefon and triadimenol).

The HR of 3.2 mg/kg was based on one supervised field trial conducted with triadimefon according to the GAPs reported for Croatia and the former Yugoslav Republic of Macedonia using an application rate of 0.0025 kg ai/hL with a PHI of 35 days. This GAP represents the lowest application rate in combination with the highest PHI reported for all uses of triadimefon and triadimenol on grapes.

The second highest residue of 1.9 mg/kg found in grapes followed the use of triadimenol according to GAP reported from South Africa using 0.12 kg ai/ha (0.0075 kg ai/hL) with a PHI of 14 days.

The third highest residue of 1.7 mg/kg is based on a supervised field trial conducted with triadimefon according to the GAP reported from Belarus and Kazakhstan (0.0075 kg ai/hL; PHI, 30 days).

In view of this consideration, the 2007 JMPR concluded that an alternative GAP approach was not applicable to uses of triadimefon and triadimenol on grapes. Based on the uses of both

triadimefon and triadimenol, the Meeting confirmed its previous recommendation and estimated an STMR value of 0.15 mg/kg, an HR value of 3.2 mg/kg and a maximum residue level of 5 mg/kg for the sum of triadimefon and triadimenol in grapes.

Comment by the JMPR

The present Meeting concluded that an alternative GAP approach for the use of triadimefon and triadimenol on grapes was not possible since high residues would arise from all available GAPs, and confirmed the dietary risk assessment already presented in the re-evaluation in 2007.

The Meeting noted that the IESTI calculation for grapes at the HR level of 3.2 mg/kg, as well as the consumption of grapes at a level of 1.9 mg/kg and 1.7 mg/kg would lead to an exceedance of the ARfD.

The Meeting noted that although the ARfD is based on a study of acute neurotoxicity in rats given triadimefon and a safety factor of 25, the large dose spacing between the NOAEL and the LOAEL suggests the possibility that the ARfD may be refined (e.g., by benchmark-dose calculations).

4. DIETARY RISK ASSESSMENT

Assessment of risk from long-term dietary intake

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.[24] 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.

Bifenthrin, cadusafos, chlorothalonil and cycloxydim were evaluated for toxicology at the current Meeting under the Periodic Re-evaluation Programme and ADIs were allocated. The long-term dietary risk assessment for these compounds will be considered during the periodic review for residues at subsequent Meetings.

The outcome of the evaluations of carbofuran, chlorantraniliprole, cyfluthrin/beta-cyfluthrin, fenthion, methomyl, paraquat, phorate, prochloraz, procymidone, triadimefon/triadimenol and spirotetramat performed at this Meeting was such that the long-term dietary intake assessment were considered unnecessary.

A summary of the long-term dietary risk assessments conducted by the present meeting is shown on Table 3. 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[25].

Table 3 Summary of long-term dietary of risk assessments conducted by the 2009 JMPR

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
155	Benalaxyl	0-0.07	0-1
221	Boscalid	0-0.04	9-30
173	Buprofezin	0-0.009	1-50
090	Chlorpyrifos-methyl	0-0.01	20-140
118	Cypermethrin (includes alpha and zeta cypermethrin)	0-0.02	7-30
197	Fenbuconazole	0-0.03	0-2
235	Fluopicolide 2,6-dichlorobenzamide (M-01)	0-0.08 0-0.02	1-10 0-1
194	Haloxyfop and haloxyfop P	0-0.0007	20-80
176	Hexythiazox	0-0.03	0-2
216	Indoxacarb	0-0.01	1-30
236	Metaflumizone	0-0.1	0-1
209	Methoxyfenozide	0-0.1	0-8

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

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

CCPR code	Compound Name	ADI (mg/kg bw)	Range of IEDI, as % of maximum ADI
232	Prothioconazole[a]		
	Prothioconazole-desthio	0-0.01	0-2
237	Spirodiclofen	0-0.01	0-9
227	Zoxamide	0-0.5	0-0.3

[a] based on prothioconazole-desthio

Possible risk assessment refinement when IEDI exceeds the ADI

Chorpyrifos-methyl

The IEDI exceeded the ADI for the Cluster diets C (110% ofADI) and H (140% of ADI). The intake coming from the consumption of maize represented 42.7 and 72.8% of the total intake, respectively. The estimation of a STMR made by the Meeting considered the alternative GAP approach. A way of refining the long-term intake of chlorpyrifos-methyl is to have information on the expected residues in maize processed commodities, such as maize flour and cooked maize. The ADI for chlorpyrifos-methyl was established by the present Meeting on the basis of a NOAEL of 1 mg/kg bw/d from a 2-year study in rats and a safety factor of 100. However, two other studies had LOAELs of 3 mg/kg bw/d, therefore it is considered unlikely that the ADI could be refined.

Assessment of risk from short-term dietary intake

Available consumption data was used at the present Meeting to assess the risks associated with short term dietary intake for compounds with STMR and HR estimated 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[26] refined 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 $\leq$ 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[27]. 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 of the 2003 JMPR report. Detailed guidance on setting ARfD is described in Section 2.1 of the 2004 JMPR report[28].

On the basis of data received by the present or previous Meetings, JMPR considered the establishment of an ARfD to be unnecessary for boscalid, chlorantraniliprole, hexythiazox, metaflumizone, spirodiclofen and zoxamide. Therefore, it was not necessary to estimate the short-term intakes for these compounds.

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

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

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

Bifenthrin, cadusafos, chlorothalonil and cycloxydim were evaluated for toxicology at this Meeting under the Periodic Re-evaluation Programme and ARfDs were allocated. The short-term dietary risk assessment for these compounds will be considered during the periodic review for residues at subsequent Meetings.

The outcome of the evaluation of fenthion, methomyl, prochloraz, procymidone and spirotetramat performed at this Meeting was such that it was not necessary to undertake short-term dietary intake assessments.

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

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

Table 4 Summary of short-term dietary risk assessments conducted by the 2009 JMPR

CCPR code	Compound Name	ARfD (mg/kg bw)	Commodity	Percentage of ARfD	
				General population	Children aged ≤ 6 years
155	Benalaxyl	0.1 [a]	all	0-4 [a]	NR
173	Buprofezin	0.5	all	0-30	0-50
096	Carbofuran	0.001	Banana Mandarin Orange	80 20 30	150 40 60
090	Chorpyrifos-methyl	0.1	all	0-10	0-30
157/228	Cyfluthrin/beta-cyfluthrin**	0.04	Cabbages, Head	100	240
118	Cypermethrin (includes alpha and zeta cypermethrin)	0.04	all	0-20	0-40
194	Haloxyfop & Haloxyfop-P	0.08	all	0-10	0-10
216	Indoxacarb	0.1	Lettuce, Leaf Others	60 0-10	150 0-20
235	Fluopicolide 2,6-dichlorobenzamide (M-01)	0.6 [a] 0.6	All all	0-70[a] 0-1	NR 0-2
209	Methoxyfenozide	0.9	all	0-2	0-6
057	Paraquat	0.006	rice	0	0
142	Prochloraz	0.1	Mushrooms	7	10
112	Phorate	0.003	Potatoes	80	190
232	Prothioconazole Prothioconazole- desthio	1 0.01 [a]	all all	0-0.2 0-20[a]	0-0.2 NR
133/168	Triadimefon/triadimenol**	0.08	Grapes	80	220

[a] For women of childbearing age;

** from previous meeting

NR: not required

Possible risk assessment refinement when IESTI exceeds the ARfD

Carbofuran in banana

The Meeting noted that the short-term dietary risk assessment of bananas could be refined if a metabolism study on bananas or residue trials employing a very sensitive analytical method were

available. The ARfD was reviewed by the present Meeting due to a request by the CCPR (Chapter 3.2). The ARfD of 0.001 mg/kg bw was confirmed and it is unlikely that it could be refined

Cyfluthrin/beta-cyfluthrin in head cabbages

Alternative GAP was considered by the present Meeting, but the previous HR recommendation was confirmed due to insufficient residue data. Hence, a refinement of the IESTI was not possible with the current data. The Meeting established a group ARfD for cyfluthrin and beta-cyfluthrin in 2006 based on acute neurotoxicity observed in a 4 week study in rats and a safety factor of 25 and it is unlikely that this could be refined.

Indoxacarb in leaf lettuce

The Meeting noted that leaf lettuce is consumed as a raw commodity and there is no alternative GAP available for this crop. Hence, a refinement of the IESTI is not possible with the current data. Furthermore, the ARfD was set based on a single-dose study by the JMPR in 2005 and it is unlikely that it could be refined.

Phorate in potato

The Meeting noted that the intake estimation is already based on residues in processed potatoes, leaving little room for refinement. Furthermore, the ARfD established by the 2004 Meeting was based on a single-dose study in rats and therefore it is unlikely that it could be refined.

Triadimefon/triadimenol in grapes

Alternative GAP was reconsidered by the present Meeting, with the previous HR recommendation confirmed. As a consequence, a refinement of the IESTI assessment was not possible with the current data. The Meeting noted that although the ARfD is based on a study of acute neurotoxicity in rats given triadimefon and a safety factor of 25, the large dose spacing between the NOAEL and the LOAEL suggests possibility of a refinement of the ARfD (e.g., by benchmark dose calculations).

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 BENALAXYL (155)

RESIDUE AND ANALYTICAL ASPECTS

Benalaxyl [methyl N-phenylacetyl-N-2,6-xylyl-DL-alaninate] is a broad-spectrum phenylamide fungicide. Residue and analytical aspects of benalaxyl were evaluated by the JMPR in 1986, 1988, 1992, and 1993. It was evaluated for toxicological review by JMPR 2005. The ADI for benalaxyl was established at 0-0.07 mg/kg bw and an ARfD of 0.1 mg/kg bw was established for women of childbearing age. This compound was listed in the Periodic Re-Evaluation Program at the Fortieth Session of the CCPR for periodic review by the 2009 JMPR.

Residue studies were submitted by the manufacturer to support the use of benalaxyl in or on a variety of fruits and vegetables.

Chemical codes and structures of Benalaxyl and its plant and animal metabolites:

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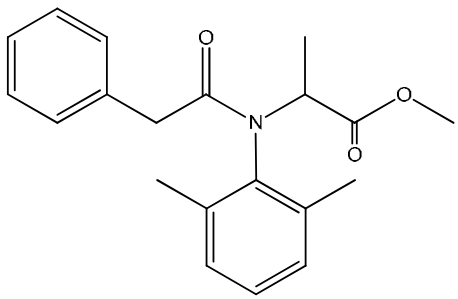
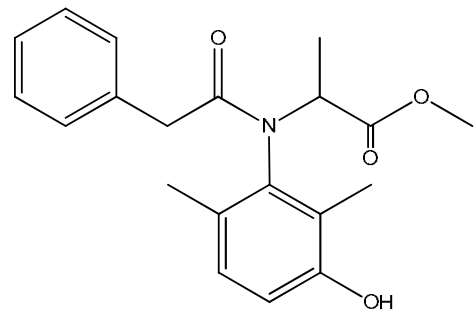
<td> 
Benalaxyl [Galben]</td>
<td> 
GX5c (Plants)</td>
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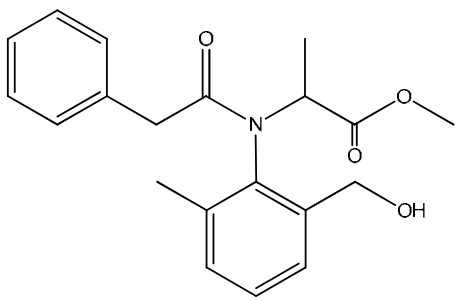
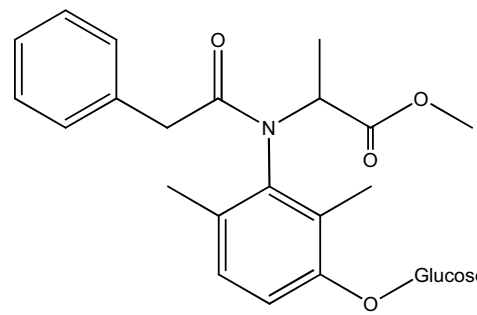
<td> 
GX5a and GX5b (Plants), G8 and G14 (Animals)</td>
<td> 
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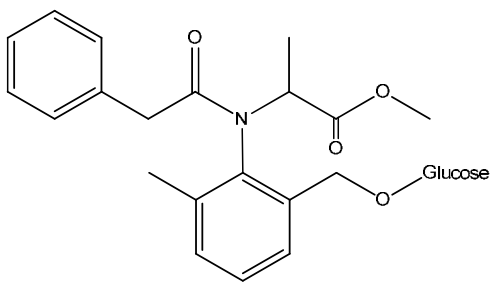
<td> 
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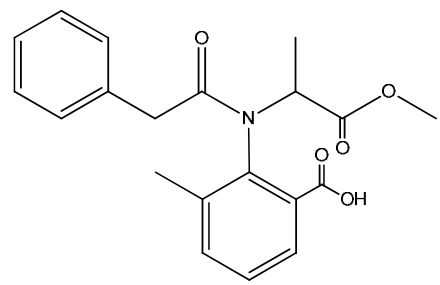
<td> 
G7a and G7b (Animals)</td>
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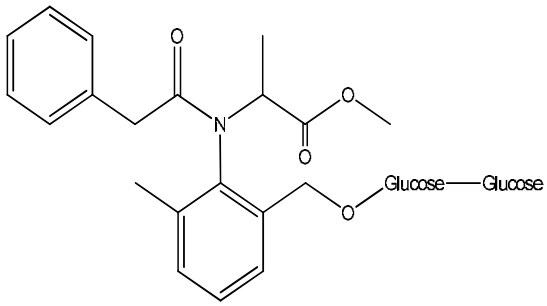

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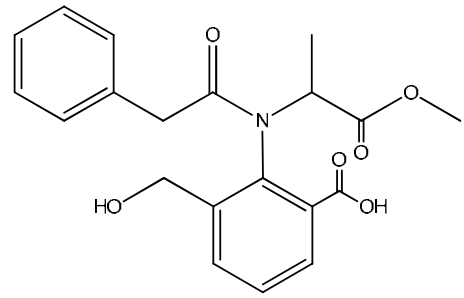
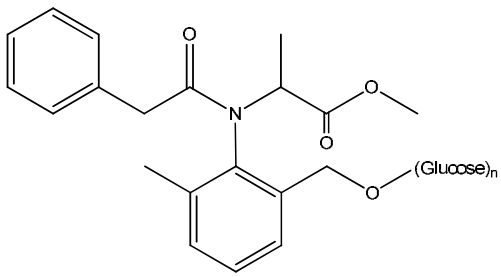
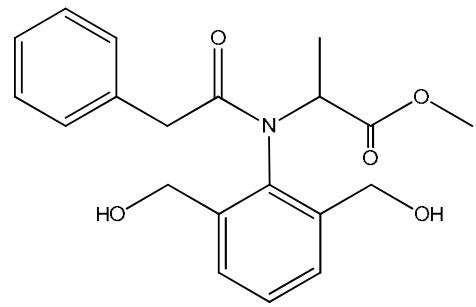


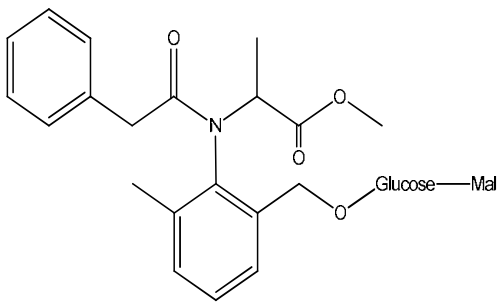
G6 (Animals)



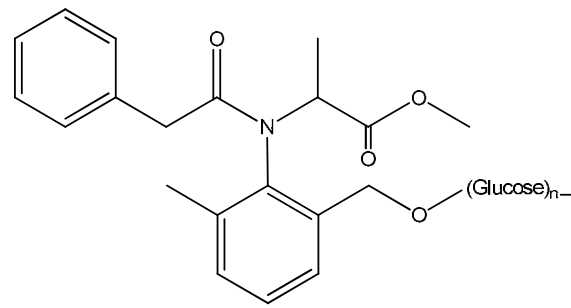
GX4 (Plants)



M4 (Plants and Animals)



GX11 (Plants)



GX16 (Plants)

Animal metabolism

The Meeting reviewed studies on the metabolism of ^{14}C-labelled benalaxyl in goats and hens. Two lactating goats received two daily oral administrations of benalaxyl at the equivalent of 40 ppm in the feed for seven consecutive days. The urine and faeces' contained about 80–90% of the administered dose of radioactivity. The maximum levels of radioactive residue in milk and tissues were as follows: milk, 0.011 mg/kg; muscle, 0.017 mg/kg; fat, 0.027 mg/kg; liver 1.1 mg/kg; and kidney 0.37 mg/kg. Minor amounts of benalaxyl (< 2% TRR) were identified in kidney or liver samples. The major metabolites identified in tissues were glucuronide and/or sulphate conjugates of the hydroxylated metabolites G8 and G14. However, poor extractability and analysis difficulties hampered metabolite identification, particularly in liver samples, resulting in 20–30% TRR being unidentified but characterized as polar species.

Ten laying hens were dosed once daily for fourteen days with capsules containing ^{14}C-labelled benalaxyl at a dose of approximately 60 mg/kg diet/day. The TRR levels were as follows: eggs, 0.35 mg/kg, fat, 0.04 mg/kg; kidney, 0.72 mg/kg; liver, 1.4 mg/kg; and muscle, 0.05 mg/kg. The residue profile was qualitatively similar to that of the goat. Benalaxyl was not found in any of the hen tissues except blood (9%). The major metabolite identified was the hydroxymethylcarboxy

metabolite G6 at 21% TRR in egg yolk. As with the goat metabolism study, large portions of the TRR were characterized as a sum of polar metabolites each comprising less than 10% TRR, with 10–15% TRR unidentified.

The 2005 JMPR Toxicological Evaluation provides a description of the metabolic profile of benalaxyl in rats that is qualitatively similar to that discussed above for goats and hens.

Based on the results of the goat and hen metabolism studies, a metabolic profile for benalaxyl was proposed. Benalaxyl is oxidised giving the G8 and G14 hydroxymethyl derivatives. The G8 and G14 compounds are further oxidised to form the G7A and G7B carboxy derivatives. The G6 hydroxymethylcarboxy metabolite is a further oxidation product. Conjugation appears to occur with all the compounds. Enzymatic hydrolysis increased the levels of extractable ^{14}C-residue in the tissues and egg yolk. Thus, it is likely that oxidation followed by conjugation is the main route of benalaxyl metabolism in animals.

Plant metabolism

The studies on plant metabolism show that [^{14}C]benalaxyl penetrates into grape, tomato, and potato plants. In grapes, more than 75% of radioactivity applied was found in the fruit 8 days after application while in tomato 40% of radioactivity was inside the fruit 28 days after treatment. Benalaxyl sprayed on potato plant leaves or present in soil, due to dripping after spraying, doesn't transfer to tuber since no significant radioactivity was found in tubers (< 0.005 mg/kg).

The rate of degradation depends on the plant species. In grapes, more than 50% of existing radioactivity corresponds to the active ingredient itself, 24 days after application; in tomato fruit, more than 15% was found as benalaxyl 35 days after treatment; in potato leaves, the parent compound percentage was more than 25%, 10 days after treatment.

The metabolites identified in grapes are GX1, GX5a, GX5b, GX5c and GX6; only GX1 and GX6 were present in significant levels (25% and 10%, respectively). In wine, besides some of those metabolites, minor levels of metabolites GX4, GX7 and GX8 were found. In tomato, several metabolites were found in low concentrations, except for GX11 which is significant (> 10% TRR).

The most important component of residue is the parent compound. However, metabolites GX1 and GX6 in grapes, and GX11 in tomatoes comprise more than 10% TRR. These metabolites result from oxidation and linkage of the parent compound to one (GX1) or more (GX6) molecules of glucose or (GX11) molecules of glucose plus malonic acid. Although these glucoside metabolites were not identified in the rat metabolism study, these plant metabolites are more polar and likely less toxic than the parent compound.

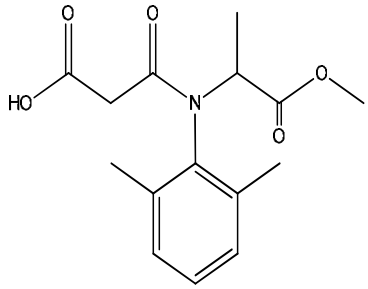
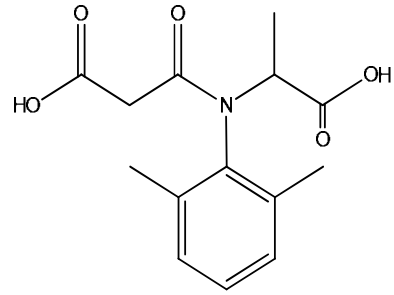
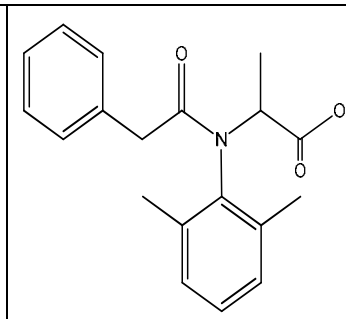
Environmental fate

Soil

The metabolism of [^{14}C-α position of the ester moiety] benalaxyl in aerobic conditions was investigated in previously sieved silt loam soil. Benalaxyl degraded very slowly in the first 28 days after treatment suggesting a lag phase followed by a steady degradation until the end of the incubation period (133 days after treatment). By this time the radioactivity associated with benalaxyl represented only 11.7% AR.

The DT_{50} of benalaxyl taking into account the lag period was estimated to be 77 days. Excluding the initial lag phase of 28 days acclimation/adaptation period during which very little benalaxyl degradation occurred, a shorter DT_{50} of approximately 42 days was estimated.

Chemical Codes and Structures of Benalaxyl Soil Metabolites:

		
Compound A: methyl-N-(2,6-xylyl)-N-malonyl alaninate	Compound B: N-(2,6-xylyl)-N-malonyl alanine	Benalaxyl acid: N-(2,6-xylyl)-N-(phenylacetyl) alanine

Two main degradation products were identified in soil extracts.

Compound A, identified as methyl-N-(2,6-xylyl)-N-malonyl alaninate and Compound B, identified as N-(2,6-xylyl)-N-malonyl alanine with maximum soil concentrations after treatment at 133 days (31% AR) and 98 days (34.1% AR), respectively.

Benalaxyl acid, identified as phenylacetyl-N-2,6-xylyl-DL-alanine was found with maximum soil concentration at 28 days (4.9% AR). In the first period (1–28 day) this is the only metabolite present in soil then from 56 to 133 day the other two metabolites (compound A and compound B) are detectable.

The results of a study of benalaxyl degradation rates in four different soil types (loam/sandy loam, loam, clay loam, and sandy loam) under identical incubation conditions demonstrated DT_{50} values ranging from 77–100 days. The same experiment with one-tenth the initial concentration of benalaxyl gave DT_{50} values of 36–85 days. These results demonstrate that benalaxyl is stable in most soils and show the range of half-life variability in four different soil types.

The degradation rate of benalaxyl in soil essentially depends on the presence of micro-organisms. The concentration and activity of these agents can vary significantly in different soils and account for the range of half-lives determined in the study cited above. The DT_{50} value in sterilized soil was reported as greater than 300 days. Evidence of microbial adaptation was also reported in this study.

Photolysis

Labelled [^{14}C]benalaxyl (≥ 98% radiochemical purity; 100 KBq/mg specific activity) was irradiated under natural sunlight conditions in a distilled sterilized buffer solution at pH 7 and test concentration of 10 mg ai/L for up to 64 days. After 64 days, 60% AR was still present as benalaxyl. At least 15 different compounds were recorded but none of them represented individually more than 5.0% of the applied radioactivity and therefore were not identified. No degradation of benalaxyl was observed under dark conditions. The study was conducted during June–August, 1984 in Milan, Italy.

In a separate experiment, the degree of photolytic degradation and the quantum yield of benalaxyl were determined by irradiation with xenon light at 306 + 12 nm at 20 °C. The absorption coefficients of benalaxyl in the relevant wavelength range around 300 nm were very low (approximately 5–10 mol/L^{-1} cm^{-1}). Just 2% benalaxyl degradation was found after 5 days and 3% degradation after 10 days. Degradation products could not be detected. The quantum yields of the

photodegradation as estimated from the 5 days and 10 days irradiations were both 0.01. Thus, benalaxyl may be considered a photolytically stable compound.

Rotational Crops

Rotational crop studies using radiolabelled benalaxyl are available showing very low levels of residues in the following crops (lettuce, tomato, carrot, and wheat) even after application at highly exaggerated rates (approximately 10×). Based on the behaviour of benalaxyl in soil and the findings in the radio-labelled studies, it is unlikely that residues above the limit of quantitation would occur in succeeding crops.

Methods of analysis

The Meeting received description and validation data for a single-residue analytical method for benalaxyl in samples of plant and animal origin. The method is based on extraction with acetone, followed by liquid-liquid extraction using water and dichloromethane and an additional clean-up on an alumina column. The determination of benalaxyl residues is performed using GC-NPD. The method was validated for grapes, lettuce, bovine milk, bovine meat and poultry eggs with a LOQ of 0.02 mg/kg. The recoveries for plant and animal matrices were in the range of 81–102% and 73–110%, respectively, with RSDs < 10%. The method was used in the supervised trials on plant commodities evaluated by this Meeting (grapes, onions, melons, tomatoes, lettuce, and potatoes) with concurrent recoveries within the range of 80–120% and RSD < 10%.

The Meeting noted that there are several multiresidue methods available (e.g., the German DFG S19 or the QuEChERS methods) that are used in routine monitoring laboratories for the analysis of benalaxyl residues (using GC-MS or GC-NPD for determination).

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

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of benalaxyl in freezer-stored samples of grapes, grape must and pomace, potatoes and tomatoes. The samples were fortified at different concentration levels and stored at –20° C for up to 3 years. The concurrent recoveries were in the range of 98–100%, with RSDs of 4.0–6.4%. The residues remaining after 3 years of storage were in the range of 95–106%, demonstrating very good freezer-storage stability of benalaxyl residues in the tested commodities during the period of 3 years, which well covers the storage intervals in the supervised trials evaluated by this Meeting.

Stability of benalaxyl residues in frozen livestock commodity samples was not demonstrated, but only livestock metabolism studies were conducted.

Definition of the residue

The plant metabolism studies indicate that significant portions of benalaxyl are oxidized and then converted to the corresponding glucoside in plant matrices. However, due to the low absolute levels of metabolites expected in crops at the label use rates and presumed lower toxicity of the polar conjugates formed, the Meeting concluded that the residue definition for plant commodities for purposes of enforcement is benalaxyl. The Meeting also concluded that for purposes of dietary intake considerations, the residue definition is also benalaxyl alone.

The ruminant and poultry metabolism studies showed an initial oxidation step as observed in plants. However, animal metabolism proceeds with further oxidation reactions to form carboxylic acids rather than the glucosides generated in plants. Noting the low levels of benalaxyl residues

expected in animal tissues, the Meeting concluded that the residue definition for animal commodities for purposes of enforcement and dietary intake considerations is benalaxyl.

The octanol-water partition coefficient of benalaxyl (log K_{OW} = 3.5) implied that benalaxyl may be fat-soluble. However, the results of the goat metabolism study were inconclusive about the fat solubility issue since such low levels of benalaxyl were found. The Meeting agreed that insufficient information was available to reach a conclusion regarding the fat solubility of benalaxyl.

Results of supervised trials on crops

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points is < 15 or when there are a large number of values < LOQ.

Grape

The Meeting received results from supervised trials with benalaxyl used on grapes in France, Italy, and Brazil.

The GAP in Italy specifies 0.20 kg ai/ha, four applications, and a 20 day PHI. There were four trials in Italy at the GAP with a PHI of 20–21 days and five trials in France conducted at the Italian GAP rate with four applications and a PHI of 15 days. Based on the decline results obtained in the same French trials, the benalaxyl residues at the GAP PHI of 20 days are expected to be within ± 25% of the residues obtained at a PHI of 15 days. The benalaxyl residues from trials in Italy and France, ranked order, were (n=9): 0.055, 0.092, 0.10, 0.11, 0.12, 0.14, 0.15, and 0.17 (2) mg/kg.

The GAP in Brazil specifies 0.24 kg ai/ha, four applications, and a 7 day PHI. Two trials in Brazil were conducted at the GAP. There were also two additional trials at a double rate. Benalaxyl residues were < 0.1 mg/kg in all four trials.

Based on the trials in France and Italy, the Meeting estimated a maximum residue level for benalaxyl in grapes of 0.3 mg/kg to replace the previous recommendation of 0.2 mg/kg, an STMR of 0.12 mg/kg, and an HR of 0.17 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.30 mg/kg, which was in agreement with the Meeting's estimation.

Onion, bulb

The Meeting received results from supervised trials with benalaxyl used on onions in Brazil, France, Italy, Greece, and Spain.

The GAP in Brazil for onions specifies 0.24 kg ai/ha, four applications, and a 7 day PHI. Three trials in Brazil were conducted at the GAP. There were also three additional trials conducted at a double rate. Benalaxyl residues were < 0.1 mg/kg in all six trials.

In Europe, the GAP of Cyprus, Spain, Italy, and France specify 0.20 kg ai/ha, 3 applications, and a PHI of 14, 15, 20 and 28 days, respectively. Ten trials in Greece, France and Italy were conducted at the GAP rate of Cyprus with a PHI of 14 days. Benalaxyl residues were < 0.02 (10) mg/kg. The Meeting noted that the residues were < LOQ of 0.02 mg/kg at PHIs from 0 to 30 days, concluding that benalaxyl residues are unlikely to occur in onions.

The Meeting estimated a maximum residue level for benalaxyl in onion, bulb of 0.02(*) mg/kg to replace the previous recommendation of 0.2 mg/kg, an STMR of 0 mg/kg and an HR of 0 mg/kg.

Cucumber

No residue data were available for cucumber. The Meeting withdrew the previous benalaxyl maximum residue level recommendation of 0.05 mg/kg for cucumber.

Melons, except watermelon

The Meeting received results from supervised trials with benalaxyl used on melons in Italy and Spain. The GAP of Spain for melon specifies 0.20 kg ai/ha, 3 applications, and a 7-day PHI.

Benalaxyl residues in whole fruit, in ranked order, were (n=9): 0.02 (2), 0.03, 0.04, 0.05, 0.06 (2), 0.08, and 0.15 mg/kg. For melon pulp (n=7), the ranked order of residues was: < 0.02 (4), 0.02, and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for melons, except watermelon to replace the previous recommendation of 0.1 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.05 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.25 mg/kg, which when rounded up, was in agreement with the Meeting's estimation.

Watermelon

The Meeting received results from supervised trials with benalaxyl used on watermelon in Italy and Spain. The GAP of Spain for watermelon specifies 0.20 kg ai/ha, 3 applications, and a 7 day PHI.

Benalaxyl residues in whole fruit, in ranked order, were (n=5): < 0.02 (4) and 0.03 mg/kg. In two trials from Spain, benalaxyl residues in watermelon pulp were < 0.02 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg for watermelon, an STMR of 0.02 mg/kg and an HR of 0.02 mg/kg.

Peppers

No residue data were available for peppers. The Meeting withdrew the previous benalaxyl maximum residue level recommendations of 0.05 mg/kg for peppers, sweet and 0.5 mg/kg for chilli peppers, dry.

Tomato

The Meeting received results from supervised trials with benalaxyl used on tomato in Brazil, France, Italy and Spain. The GAPs of Spain, Italy and France for tomato specify 0.24 kg ai/ha, 4 applications, and a PHI 3, 7, and 14 days.

Four trials in Italy were conducted according to the GAP of Spain with a PHI of 3 days. Benalaxyl residues, in ranked order, were (n=4): 0.10, 0.11, and 0.14 (2) mg/kg. The Meeting agreed that four tomato trials were insufficient for a maximum residue level estimate.

Eight trials in France, Italy and Spain were conducted according to the GAP of France with a PHI of 14 days. Benalaxyl residues, in ranked order, were (n=8): < 0.02 (2), 0.02, 0.03, 0.04 (2), and 0.05 (2) mg/kg.

The GAP of Brazil for tomato specifies 0.24 kg ai/ha, 4 applications, and a 7-day PHI. Five trials in Brazil were conducted at the GAP. There were also four additional trials conducted at a double rate. Benalaxyl residues were < 0.1 mg/kg in all nine trials.

Based on the trials in France, Italy, and Spain according to the French GAP, the Meeting estimated a maximum residue level of 0.2 mg/kg for tomato to replace the previous recommendation of 0.5 mg/kg, an STMR of 0.035 mg/kg and an HR of 0.05 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.15 mg/kg (making use of Maximum Likelihood Estimate [MLE] procedures to fit data points below the LOQ to a lognormal distribution), which when rounded up was in agreement with the Meeting's estimation.

Lettuce, Head

The Meeting received results from supervised trials with benalaxyl used on head lettuce in Italy and Spain. The GAP of Italy and Spain specify 0.20 kg ai/ha, 3 applications, and a PHI 15 days.

The trials in Spain (n=8) were conducted with 2 applications but, based on the data from Italian trials, the benalaxyl residues determined prior to the last application were insignificant in comparison with the residues determined on day 0 of the last application. Therefore, the Meeting considered the Spanish trials together with the trials in Italy (n=7), which were conducted at the GAP of Italy with 3 applications.

The benalaxyl residues in head lettuce, in ranked order, were (n=15): < 0.02 (4), 0.06 (3), 0.07, 0.08, 0.09, 0.11, 0.12, 0.15, 0.33, and 0.43 mg/kg.

The Meeting estimated a maximum residue level for benalaxyl in lettuce, head of 1 mg/kg, an STMR of 0.07 mg/kg, and an HR of 0.43 mg/kg.

The maximum residue level estimate derived from the use of the NAFTA statistical calculator was 1.0 mg/kg (making use of MLE procedures), which was in agreement with the Meeting's estimation.

Potato

The Meeting received results from supervised trials with benalaxyl used on potato in Brazil, France, and Italy.

The GAP of Brazil for potato specifies 0.24 kg ai/ha, 2 applications, and a 7 day PHI. Five trials in Brazil were conducted at the GAP. There were also five additional trials conducted at a double rate. Benalaxyl residues were < 0.1 mg/kg in all 10 trials.

The GAPs of France and Italy for potato specify 0.24 kg ai/ha, 4 applications, and a 7-day PHI. Six trials in France and Italy were conducted at the GAP rate, with benalaxyl residues being < 0.02 (6) mg/kg.

Based on the results of the potato metabolism study, which showed no transfer of radioactivity to the tubers, the Meeting agreed that no benalaxyl residues are expected in potatoes.

The Meeting estimated a maximum residue level for benalaxyl in potato of 0.02(*) mg/kg to confirm its previous recommendation, an STMR of 0 mg/kg and an HR of 0 mg/kg.

Hops, dry

No residue data were available for dry hops. The Meeting withdrew the previous benalaxyl maximum residue level recommendation of 0.2 mg/kg for hops, dry.

Fate of residues during processing

The Meeting received processing studies for grape and tomato. The residue definition recommended for plant commodities will suffice for processed plant commodities (parent only).

The processing (or transfer) factors derived from the processing studies and the resulting recommendations for STMR-P values 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).

Processing (Transfer) Factors from the Processing of Raw Agricultural Commodities (RACs) with Field-Incurred Residues from Foliar Treatment with Benalaxyl.

RAC	RAC STMR	Processed Commodity	Processing Factor[a]	Processed Commodity STMR-P
Grapes	0.12	Juice	0.11, 0.18, 0.15, 0.16 Median: 0.155	0.019
		Wet Pomace	3.3, 3.8 Mean: 3.5	0.42
		Bottled Wine	0.22, 0.36, 0.15, 0.16, Median:0.19	0.03
Tomato	0.035	Juice	0.22, 0.22 Mean: 0.22	0.0077
		Puree	0.21, 0.48 Mean: 0.344	0.012
		Preserve	0.10, 0.22 Mean: 0.16	0.0056

[a] Each value represents a separate study. The processing factor is the ratio of the total residue in the processed item divided by the total residue in the RAC.

Based on the STMR-P value of 0.42 mg/kg and dry-weight content of 15% for grape pomace, wet, the Meeting estimated an STMR-P value of 2.8 mg/kg and a maximum residue level of 3 mg/kg for benalaxyl in grape pomace, dry.

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).

Grape pomace, dry is the only potential cattle feed item.

Animal dietary burden, benalaxyl residue, ppm of dry matter diet				
		US-Canada	EU	Australia
Beef/Dairy cattle	Max	0	0	0.56
	Mean	0	0	0.56

Animal commodity maximum residue levels

A bovine feeding study was not provided. However, there are no cattle feed items resulting from the RACs for which the 2009 Meeting made maximum residue level recommendations, except for wet grape pomace, which is a feed item only for Australia. Moreover, as indicated in the *FAO Manual* [Second Edition] (Section 3.9), a bovine feeding study is not necessary when a ruminant metabolism

study with dosing at the equivalent of 10×, where 1× is the anticipated dietary burden, results in levels of the residue of concern below the limit of quantitation (LOQ) in all edible commodities. Accordingly, the Meeting determined that no bovine feeding study is necessary at this time.

The Meeting estimated maximum residue levels of 0.02(*) mg/kg and STMR and HR values of 0 mg/kg for benalaxyl in meat from mammals (other than marine mammals), edible offal (mammalian), and milks.

A poultry feeding study was not provided. However, as there are no poultry feed items resulting from the RACs for which the 2009 Meeting made maximum residue level recommendations, there was no need to recommend maximum residue levels for poultry commodities.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of benalaxyl has resulted in recommendations for MRLs and STMRs for raw and processed commodities. These commodities were included at the appropriate levels in the dietary intake calculations. The International Estimated Daily Intakes (IEDI) for the 13 GEMS/Food Consumption Cluster Diets, based on estimated STMRs were in the range 0–1% of the maximum ADI of 0.07 mg/kg bw The results are shown in Annex 3.

The Meeting concluded that the long-term intake of residues of benalaxyl 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 benalaxyl 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 benalaxyl, the IESTI varied from 0–4% of the ARfD (0.1 mg/kg bw) for women of childbearing age using the intake figures for the general population.

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

5.2 BIFENTHRIN (178)

TOXICOLOGY

Bifenthrin is the International Organization for Standardization (ISO) approved name for 2-methyl-3-phenylphenyl) methyl (1RS, 3RS)-3-[(Z)-2-chloro-3, 3, 3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropane-1-carboxylate (International Union of Pure and Applied Chemistry [IUPAC]), for which the Chemical Abstracts Service (CAS) No. is 82657-04-3. Bifenthrin is a synthetic pyrethroid insecticide and acaricide.

The toxicity of bifenthrin was first evaluated by the 1992 Joint FAO/WHO Meeting on Pesticide Residues (JMPR). The Meeting established an acceptable daily intake (ADI) of 0–0.02 mg/kg bw on the basis of a no-observed-adverse-effect level (NOAEL) of 1.5 mg/kg bw per day for decreased body-weight gain in males and dose-related tremors in a 1-year study of oral toxicity in dogs and with a safety factor of 100.

New studies of acute and dermal toxicity, sensitization, neurotoxicity, developmental toxicity, and genotoxicity and a pathology re-evaluation of the tumours observed in the study of carcinogenicity in mice became available since the last review by the JMPR. Bifenthrin was reviewed by the present Meeting within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). All pivotal studies with bifenthrin were certified as complying with good laboratory practice (GLP).

Biochemical aspects

In a toxicokinetic study, groups of male and female Sprague-Dawley rats were given bifenthrin labelled with ^{14}C in either the alcohol phenyl or acid (cyclopropyl) ring as a single dose at 4 or 35 mg/kg bw, or as 14 repeated doses at 4 mg/kg bw per day followed by a single oral dose of radiolabelled bifenthrin at 4 mg/kg bw. There were no significant differences in the results for the different doses and durations. All female rats received alcohol-labelled bifenthrin and all male rats received acid-labelled bifenthrin. Most of the radiolabel was excreted in the faeces (66–88%) and to some extent in the urine (13–25%) in the first 48 h. Approximately 3% of the administered dose was retained in the body. Fat contained the highest concentrations of bifenthrin-derived radioactivity. In bile-duct cannulated female rats receiving a dose of 2.7 mg/kg bw, mean excretion of radioactivity was 30.0%, 15.0% and 48.7% of the administered dose in the bile, urine, and faeces, respectively, 72 h after dosing. Approximately 4.8% of the administered dose was recovered in the gastrointestinal tract, skin and liver in female rats. In male rats at 5.0 mg/kg bw, mean excretion of radiolabel was 18.6%, 10.7% and 24.9% of the administered dose in the bile, urine, and faeces, respectively, 72 h after dosing. Approximately 6.3% of the administered dose was recovered in the gastrointestinal tract, skin and liver in male rats. The oral absorption of bifenthrin is estimated to be about 50%. In a study of distribution and bioaccumulation, rats were exposed to bifenthrin for 70 days and 15 days for the depuration phase. Maximum concentrations of radiolabel were detected in the fat (9.62 ppm; $t_{1/2}$, 51 days) and skin (1.75 ppm; $t_{1/2,}$ 51 days). The estimated half-lives were 19 days for liver and 28 days for kidneys. Bifenthrin was metabolized via hydrolysis, oxidation and subsequent glucuronide conjugation. In the faeces, unchanged bifenthrin was the major component (17–45% of the administered radiolabel). Twelve other products derived from hydrolysis and oxidation of the parent compound was also detected in the faeces. Almost no parent compound was detectable in the urine. Nine metabolites derived from hydrolysis and hydrolysis–oxidation products of bifenthrin were detected in the urine.

Toxicological data

Bifenthrin was moderately toxic when administered orally to mice and rats. Data from the studies of acute toxicity in rats suggested that bifenthrin is more toxic when given by gavage in diluted solution (median lethal dose, LD_{50} 53 mg/kg bw) than undiluted (melted) (LD_{50} 168 mg/kg bw). In addition, data from the studies of developmental toxicity in rats suggest that bifenthrin is more toxic when given via gavage (the NOAEL for maternal toxicity was 1.0 mg/kg bw) than when given in the diet (the NOAEL for maternal toxicity was 7.4 mg/kg bw). The LD_{50} in rats treated dermally was > 2000 mg/kg bw. The LC_{50} in rats treated by inhalation (nose only) was 0.8 mg/L air. Bifenthrin was not irritating to the eyes and skin of rabbits. Bifenthrin was a skin sensitizer as determined by the Magnusson & Kligman (maximization) test in guinea-pigs, but gave a negative response for sensitization in the Buehler test.

Bifenthrin produces characteristic type-I pyrethroid neurotoxicity in short-and long-term studies. Clinical signs of neurotoxicity such as tremors were observed in many studies. No reports of histopathological findings in the nervous system were found in the data submitted.

In a 28-day dietary study of toxicity in mice, clinical signs (tremors and convulsions) were observed at 500 ppm, equivalent to 75.0 mg/kg bw per day, and above and there were mortalities at 600 ppm and above. The NOAEL was 300 ppm, equivalent to 45 mg/kg bw per day. In a 28-day dietary study of toxicity in rats, tremors were observed at dietary concentrations of 200 ppm, equivalent to 20 mg/kg bw per day, and above. The NOAEL was 100 ppm, equivalent to 10 mg/kg bw per day. In a 90-day dietary study of toxicity in rats, the NOAEL was 50 ppm, equal to 3.8 mg/kg bw per day, on the basis of tremors observed at the LOAEL of 100 ppm, equal to 7.5 mg/kg bw per day.

In a 90-day study of toxicity in dogs fed capsules containing bifenthrin, clinical observations included tremors, ataxia, blinking, mydriasis, nystagmus, lacrimation and polypnea. The NOAEL was 2.5 mg/kg bw per day on the basis of tremors seen at the LOAEL of 5.0 mg/kg bw per day. In a 1-year study of toxicity in dogs fed capsules, the NOAEL was 1.5 mg/kg bw per day on the basis of an increased incidence of temors seen at the LOAEL of 3.0 mg/kg bw per day.

The carcinogenic potential of bifenthrin was studied in mice and rats. In mice, the NOAEL was 50 ppm, equal to 7.6 mg/kg bw per day, on the basis of tremors at the LOAEL of 200 ppm, equal to 29 mg/kg bw per day. In this study, males at the highest dose (600 ppm) showed an increased incidence of urinary bladder tumours (leiomyosarcomas). These lesions were re-evaluated by an expert panel of three pathologists, who concluded that the bladder tumours seen in the study in mice were benign, probably vascular in origin, occurred predominantly in males and apparently occurred only in mice, and had no relevance for humans. In the study in mice, there was some indication of increased combined incidences of adenoma and adenocarcinoma of the liver (males only), and increased incidences of bronchioalveolar adenomas and adenocarcinomas of the lung in females, but the results of the re-evaluation suggested that these tumour responses were not treatment-related.

In a long-term combined study of toxicity and carcinogenicity in rats, tremors were the most prevalent findings in both sexes. At the highest dose of 200 ppm, equal to 9.7 mg/kg bw per day, a slight decrease in body weights were noted and there was equivocal evidence for decreased food consumption. At the highest dose, retinal atrophy was noted in 28 females but not in males. The NOAEL was 50 ppm, equal to 2.3 mg/kg bw per day, on the basis of tremors seen at the LOAEL of 100 ppm, equal to 4.7 mg/kg bw per day. There were no treatment-related neoplastic findings in rats.

Bifenthrin gave negative responses in various studies of genotoxicity in vitro and in vivo except for a weakly positive response in vitro but not in vivo in the assay for unscheduled DNA synthesis and at low concentrations in a test in mouse lymphoma cells.

The Meeting concluded that bifenthrin 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 the fact that the carcinogenic effects observed in mice were not considered

to be relevant to humans, the Meeting concluded that bifenthrin 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 (100 ppm, equivalent to 5.0 mg/kg bw per day). The NOAEL for parental systemic toxicity and offspring toxicity was 60 ppm, equivalent to 3.0 mg/kg bw per day, on the basis of marginally reduced body weights in F_0 and F_1 females during gestation and lactation and tremors seen at the LOAEL of 100 ppm, equivalent to 5.0 mg/kg bw per day.

There were two studies of developmental toxicity in rats. In a gavage study in rats, the NOAEL for maternal toxicity was 1.0 mg/kg bw per day on the basis of increased incidence of tremors in 18 out of 25 dams during days 10–19 of gestation, seen at the LOAEL of 2.0 mg/kg bw per day. The NOAEL for developmental toxicity was 1.0 mg/kg bw per day on the basis of increased fetal and litter incidences of hydroureter without hydronephrosis seen at the LOAEL of 2.0 mg/kg bw per day. In the dietary study of developmental toxicity in rats, the LOAEL for maternal toxicity was 200 ppm, equal to 16.3 mg/kg bw per day, on the basis of clinical signs and decreased food consumption, body-weight gains, and adjusted (for gravid uterine weight) body-weight gains. The NOAEL for maternal toxicity was 90 ppm, equal to 7.4 mg/kg bw per day. The NOAEL for developmental toxicity was 200 ppm, equal to 16.3 mg/kg bw per day; the highest dose tested. In a study of developmental toxicity in rabbits treated by gavage, the NOAEL for maternal toxicity was 2.67 mg/kg bw per day on the basis of treatment-related increases in the incidence of head and forelimb twitching seen at the LOAEL of 4.0 mg/kg bw per day. In this study, no developmental toxicity was observed at doses of up to 8.0 mg/kg bw per day, the highest dose tested.

The Meeting concluded that bifenthrin caused developmental toxicity only at doses that were maternally toxic.

The Meeting concluded that bifenthrin is not likely to be teratogenic to humans.

In a study of acute neurotoxicity in rats given undiluted bifenthrin, the NOAEL was 35 mg/kg bw on the basis of mortality (females only), clinical signs and functional observation battery (FOB) findings and differences in motor activity was observed at the LOAEL of 75 mg/kg bw. In a published study by Wolansky et al. (2006), male rats were given bifenthrin via gavage as nine doses (8–18 rats per dose) ranging from 0.03 to 28 mg/kg bw in corn oil (1 mL/kg bw) and motor activity was assessed for 1 h during the period of peak effects (4 h after dosing). The data were modelled and a threshold dose was determined to be 1.28 mg/kg bw. The threshold dose is defined as an estimate of the highest no-effect dose level at which treated rats did not display any significant decreases in motor activity. In a 90-day study of neurotoxicity in rats, the NOAEL was 50 ppm, equal to 2.9 mg/kg bw per day, on the basis of neuromuscular findings (tremors, changes in grip strength and landing foot-splay) observed at the LOAEL of 100 ppm; equal to 6.0 mg/kg bw per day. In a study of developmental neurotoxicity in rats given diets containing bifenthrin, the NOAEL for maternal toxicity was 50 ppm, equal to 3.6 mg/kg bw per day, on the basis of tremors, clonic convusions and increased grooming counts seen at the LOAEL of 100 ppm, equal to 7.2 mg/kg per day. The NOAEL for offspring toxicity was 50 ppm; equal to 3.6 mg/kg bw per day, on the basis of increased grooming counts seen at the LOAEL of 100 ppm, equal to 7.2 mg/kg bw per day. In studies of delayed neurotoxicity in adult hens and rats, no evidence of delayed neurotoxicity was observed.

On the basis of the available data, the Meeting considered that bifenthrin was neurotoxic.

Workers in a bifenthrin-manufacturing plant reported mild and temporary paresthaesia (skin tingling) resulting from skin contact. Of emergency calls received by the manufacturer during 2002 from individuals applying products containing bifenthrin, the most common complaints were dermal sensations of burning/tingling and eye irritation, which mostly resolved within 24 h.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.01 mg/kg bw based on a NOAEL of 1.0 mg/kg bw per day in a study of developmental toxicity in rats (gavage) based on the increased incidence of tremors in dams during days 10–19 of gestation and increased fetal and litter incidences of hydroureter without hydronephrosis seen at the LOAEL of 2.0 mg/kg bw per day, and using a safety factor of 100. This ADI was supported by a threshold dose of 1.3 mg/kg bw identified on the basis of effects on motor activity in males in a study of acute toxicity in rats treated by gavage and using a safety factor of 100, as well as several other studies including the 1-year study of toxicity in dogs, a 2-year combined study of toxicity/carcinogenicity in rats and a 90-day study of neurotoxicity in rats, all with NOAELs in the range of 1.5 to 2.9 mg/kg bw per day.

The Meeting established an ARfD of 0.01 mg/kg bw based on a threshold dose of 1.3 mg/kg bw for motor activity in a study of acute toxicity in male rats treated by gavage and using a safety factor of 100. Although this study was conducted with males only, it was considered appropriate since there was no evidence of sex-specific differences among the data on bifenthrin. This ARfD was supported by the study of developmental toxicity in rats treated by gavage in which the NOAEL of 1.0 mg/kg bw per day was based on the increased fetal and litter incidences of hydroureter without hydronephrosis seen at the LOAEL of 2.0 mg/kg bw per day and which thereby was also protective for developmental effects.

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	50 ppm, equal to 7.6 mg/kg bw per day	200 ppm, equal to 29.0 mg/kg bw per day
		Carcinogenicity	600 ppm, equal to 92.0 mg/kg bw per day[c]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	50 ppm, equal to 2.3 mg/kg bw per day	100 ppm, equal to 4.7 mg/kg bw per day
		Carcinogenicity	200 ppm, equal to 9.7 mg/kg bw per day[c]	—
	Acute motor activity assessment[b]	Neurotoxicity	Threshold dose, 1.28± 0.31 mg/kg bw[e]	3.21 ± 0.32 mg/kg bw[e] (ED_{30})
	Multigeneration study of reproductive toxicity[a]	Parental toxicity	60 ppm, equivalent to 3.0 mg/kg bw per day	100 ppm, equivalent to 5.0 mg/kg bw per day[c]
		Offspring toxicity	60 ppm, equivalent to 3.0 mg/kg bw per day	100 ppm, equivalent to 5.0 mg/kg bw per day[c]
	Developmental toxicity[b]	Maternal toxicity	1 mg/kg bw per day	2 mg/kg bw per day[c]
		Embryo and fetal toxicity	1 mg/kg bw per day	2 mg/kg bw per day[c]
	Developmental toxicity[a]	Maternal toxicity	90 ppm, equal to 7.4 mg/kg bw per day	200 ppm, equal to 16.3 mg/kg bw per day[c]
		Embryo and fetal toxicity	200 ppm, equal to 16.3 mg/kg bw per day[c]	—

Species	Study	Effect	NOAEL	LOAEL
	Developmental Neurotoxicity[a]	Maternal toxicity	50 ppm, equal to 3.6 mg/kg be per day	100 ppm, equal to 7.2 mg/kg be per day
		Offspring toxicity	50 ppm, equal to 3.6 mg/kg be per day	100 ppm, equal to 7.2 mg/kg be per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	2.7 mg/kg bw per day	4.0 mg/kg bw per day
		Embryo and fetal toxicity	8.0 mg/kg bw per day[c]	—
Dog	90-day toxicity[b]	Toxicity	2.5 mg/kg bw per day	5.0 mg/kg bw per day
	1-year toxicity[b]	Toxicity	1.5 mg/kg bw per day	3.0 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

[e] The threshold dose is defined as an estimate of the highest no-effect dose level at which treated rats did not display any decreases in motor activity. ED_{30} is defined as the dose associated with a 30% decrease in motor activity. From: Wolansky MJ, Gennings C, Crofton, KM (2006) Relative potencies for acute effects of pyrethroids on motor function in rats. Toxicol Sci 89: 271–277.

Estimate of acceptable daily intake for humans

0–0.01 mg/kg bw

Estimate of acute reference dose

0.01 mg/kg bw

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

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

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

Absorption, distribution, excretion, and metabolism in mammals	
Rate and extent of oral absorption	Rapid and about 50% oral absorption
Dermal absorption	Moderate, 50%
Distribution	Widely distributed in tissues
Potential for accumulation	Low, no evidence of significant accumulation except fat and skin
Rate and extent of excretion	Approximately 82–90% (70–80% in faeces, 5–25% in urine and 20–30% in bile) within 48 h
Metabolism in animals	Moderate; metabolic pathways include hydrolysis, oxidation and conjugation
Toxicologically significant compounds (animals, plants and environment)	Bifenthrin

Acute toxicity

Rat, LD_{50}, oral	53.4 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	0.8 mg/L , dust (4 h exposure, nose only)
Rabbit, dermal irritation	Not an irritant
Rabbit, ocular irritation	Not an irritant
Guinea-pig, dermal sensitization	Sensitizer (Magnusson & Kligman test)
	Not a sensitizer (Buehler)
Short-term studies of toxicity	
Target/critical effect	Tremors
Lowest relevant oral NOAEL	1.5 mg/kg bw per day (1-year study in dogs)
Lowest relevant dermal NOAEL	50 mg/kg bw per day (rat)
Genotoxicity	
	Unlikely to be genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Tremors
Lowest relevant NOAEL	2.3 mg/kg bw per day (2-year study in rats)
Carcinogenicity	Not carcinogenic in rats and in mice
Reproductive toxicity	
Reproduction target/critical effect	No toxicologically relevant effects
Lowest relevant reproductive NOAEL	5.0 mg/kg bw per day (rats; highest dose tested)
Developmental target/critical effect	Developmental toxicity only at maternally toxic dose in rats
Lowest relevant developmental NOAEL	2.0 mg/kg bw per day (rats; highest dose tested)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity	Decreased in motor activity, (threshold dose) 1.28 mg/kg bw (rats)[a]
Short-term study of neurotoxicity	NOAEL: 2.9 mg/kg bw per day (rats)
Developmental neurotoxicity	No neurodevelopmental toxicity observed, NOAEL: 125 ppm, equal to 9.0 mg/kg bw per day (rats), the highest dose tested
Mechanistic data	
	No studies were submitted
Medical data	
	No major effects and typical symptoms of pyrethroid exposure were reported

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.01 mg/kg bw	Rats, study of developmental toxicity (gavage)	100

ARfD	0.01 mg/kg bw	Rats, acute motor activity assessment	100

[a] The threshold dose is defined as the highest no-effect level at which treated rats would respond with 100% performance of the controls.

DIETARY RISK ASSESSMENT

Deferred to 2010, when residue re-evaluation is scheduled

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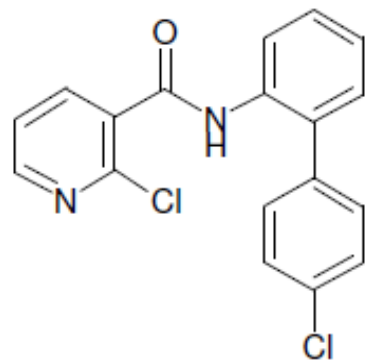
5.3 BOSCALID (221)

RESIDUE AND ANALYTICAL ASPECTS

Boscalid is a systemic fungicide first evaluated by JMPR in 2006 for residues and toxicology as a new active substance. An ADI of 0–0.04 mg/kg bw was established for boscalid, while no ARfD was considered necessary. Due to incomplete data submission for residues in follow crops the Meeting decided that a chronic risk assessment under consideration of these residues in rotational crops could not be finalized during the 2006 Meeting. In 2008 additional uses involving banana and kiwifruit were review for residues. In response to the request of the Forty-first CCPR (ALINORM 09/32/24, para 124) the Meeting reconsidered all data available for a finalisation of the dietary risk assessment for boscalid.

New data were submitted for metabolism and degradation of boscalid in soil, uptake in follow-up crops and livestock feeding to the 2009 JMPR. Further studies, GAP information and supervised residue trials referred to in this document are described in the evaluation of boscalid as a new active substance by the 2006 JMPR.



The following abbreviations are used for the metabolites discussed below:

boscalid	2-chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
M510F01	2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide
M510F02	4'-chloro-6-{[(2-chloro-3-pyridinyl)carbonyl]amino}biphenyl-3-yl glycopyranosiduronic acid

Environmental fate in soil

The Meeting received data on the degradation of boscalid in soil under aerobic and anaerobic conditions, investigation on the uptake of boscalid from newly treated and aged soil, confined metabolism of boscalid in rotational crops and field trials on succeeding crops for various commodities.

The aerobic soil metabolism of boscalid is very limited. Most of the radioactivity used in the studies was either recovered as unchanged parent substance, $^{14}CO_2$, or remained as unextracted radioactivity. Metabolites were found, but their levels were less than 1% of the applied doses. Estimated half-life times under assumption of first order kinetics ranged from 133 to 384 days.

The anaerobic soil metabolism gave comparable results. In one of the studies 2-chloronicotinic acid (M510F47) was found in amounts of 6.7% of the applied doses. Estimated half-life times under assumption of first order kinetics ranged from 261 to 345 days.

Field dissipation studies were submitted indicating that boscalid did not show a tendency to move into deeper layers of soil and was primarily detected in the top 10 cm soil layer during field dissipation trials (four different soils) of durations up to 12–18 months. Boscalid concentrations declined to half of their initial values in 28 days to 208 days. In all trials a DT_{90} could not be reached within one year after application to bare soil.

In a further study investigation of the soil dissipation of soil newly treated with boscalid, and soil treated over several years, revealed that a much slower dissipation of the active substance was observed in aged soil. DT_{50} values determined under laboratory conditions were estimated with 336 days for new soil and 746 days for aged soil.

In field studies on the accumulation of boscalid in soil over 11 years, a three year rotation was used to simulate the typical agricultural practices in Northern Europe. In the first two years lettuce/carrots and green beans/cauliflower were treated with annual application rates of 2.1 and 1.7 kg ai/ha, respectively. The third year of the cycle contained wheat, which was not treated with boscalid. The results indicate that boscalid residues increased during the time frame of the study, reaching a plateau equivalent to an application rate of boscalid to bare soil between 2 and 3 kg ai/ha.

In a confined rotational crop study in Germany, soil was treated directly with [^{14}C]boscalid labelled in the diphenyl ring or the pyridine ring. Lettuce, radish and wheat were sown into the treated soil at intervals of 30, 120, 270 and 365 days after treatment, grown to maturity, and harvested for analysis. The residues in the edible parts of succeeding crops destined for human consumption were low for lettuce and radish root, and slightly higher for wheat grain after all four plant-back intervals. The major part of the residues was identified as parent. The concentration of boscalid in lettuce leaf ranged from 55.6–94.1% TRR, in radish leaf from 69.4–90.2% TRR, in radish root from 52.6–92.8% TRR and in wheat straw from 50.0–87.5% TRR. In wheat grain the concentration of parent was lower (1.9–35.4% TRR, < 0.028 mg/kg).

In addition to the confined study further field trials investigating the uptake of boscalid under more realistic conditions were conducted on various crops in Europe, Japan and the US. All trials were conducted at a target annual application rate of 2.0 to 2.15 kg ai/ha per year. Pre-planting intervals and PHIs of the succeeding crops corresponded to the common agricultural practices. The results are summarized in the following table.

Group	Commodity	No. of trials	Mean in mg/kg	Median in mg/kg	Highest residue in mg/kg
Root and tuber vegetables	Radish roots	4	0.08	0.065	0.17
	Sugar beet roots	7	0.05	0.05	0.05
	Garden beet roots	2	0.05	0.05	0.05
	Turnip roots	5	0.05	0.05	0.05
	Potatoes	4	0.06	0.055	0.06
	Carrot roots	4	0.13	0.065	0.37
	TOTAL	26	0.07	0.05	0.37
Brassica vegetables	Cabbage	4	0.03	0.035	0.05
Fruiting vegetables	Sweet corn cobs	4	0.05	0.05	0.05
Pulses and oilseeds	Alfalfa seeds	1	0.05	0.05	0.05
	Soya bean seeds	15	0.05	0.05	0.06
	Cotton seed	9	0.05	0.05	0.05
	TOTAL	25	0.05	0.05	0.06

Group	Commodity	No. of trials	Mean in mg/kg	Median in mg/kg	Highest residue in mg/kg
Cereal grains	Maize grain	9	0.05	0.05	0.05
	Rice grain	6	0.06	0.05	0.12
	Sorghum grain	6	0.05	0.05	0.05
	Wheat grain	9	0.05	0.05	0.07
	TOTAL	30	0.05	0.05	0.12
Legume animal feeds	Soya bean forage	15	0.08	0.065	0.18
	Soybean hay	13	0.15	0.105	0.45
	Alfalfa forage	17	0.11	0.05	0.49
	Alfalfa hay	17	0.29	0.1	1.46
	Clover forage	7	0.15	0.01	0.53
	Clover hay	7	0.24	0.22	0.48
	Pea vines	9	0.05	0.05	0.05
	Pea hay	9	0.09	0.09	0.15
	Cow pea forage	9	0.24	0.05	1.0
	Cow pea hay	9	0.34	0.24	0.99
	TOTAL	112	0.17	0.08	1.46
Straw and fodder of cereal grains	Wheat Forage	11	0.45	0.29	1.1
	Wheat hay	11	0.50	0.265	1.5
	Wheat straw	11	1.1	0.81	2.8
	Maize forage	12	0.06	0.05	0.13
	Maize stover	13	0.12	0.06	0.49
	Rice straw	6	0.30	0.13	1.1
	Sorghum forage	6	0.08	0.05	0.23
	Sorghum stover	6	0.09	0.05	0.30
	Grass forage	12	0.46	0.25	1.9
	Grass hay	12	1.5	0.61	6.8
	Grass straw	2	0.18	0.175	0.2
	TOTAL	102	0.5	0.21	6.8
Root leaves and tops	Radish tops	4	0.26	0.14	0.77
	Sugar beet tops	7	0.05	0.05	0.05
	Garden beet tops	2	0.05	0.05	0.05
	Turnip tops	5	0.05	0.05	0.07
	Carrot tops	4	0.23	0.03	0.84
	TOTAL	22	0.12	0.05	0.84

An additional study was conducted to investigate the uptake behaviour of boscalid into plants grown in newly treated soil and aged soil. Wheat, radish and spinach were used as representative crops in this study. The results indicate that multiple applications of boscalid over several years resulted in a decreased uptake into the succeeding crops. On average only 52.8% of the residues were found in plants grown in aged soil in comparison to soil treated for the first time.

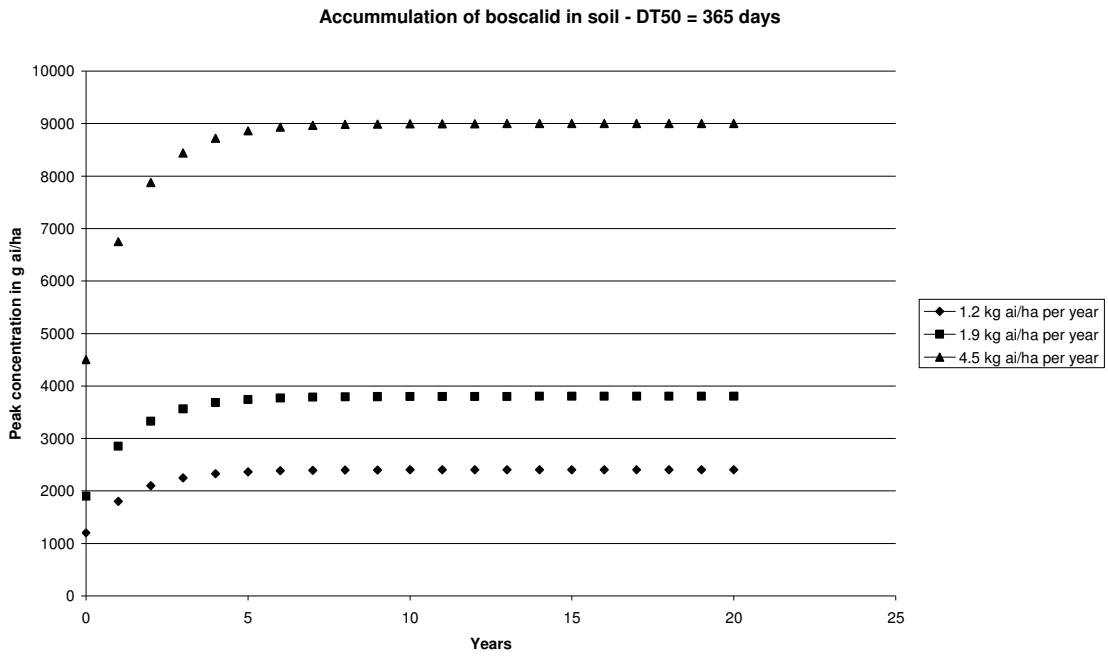
Estimation of boscalid residues in soil

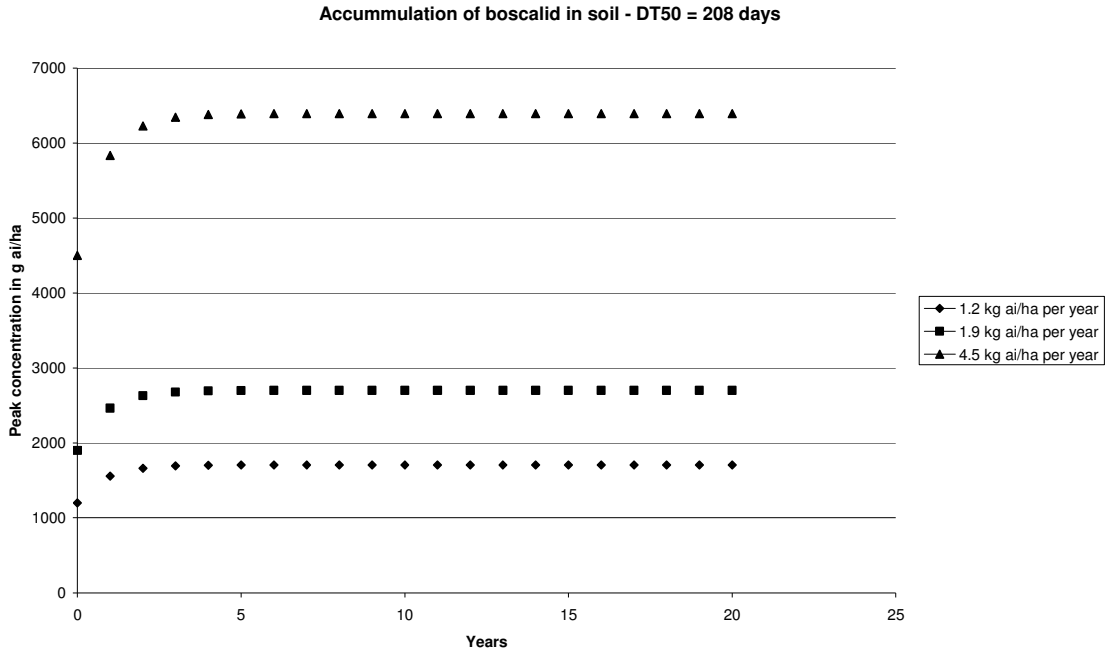
Boscalid is used in a broad variety of crops at various annual application rates. For the estimation of the highest boscalid levels in soil relevant for the evaluation of residues in follow crops, it must be assumed that boscalid is applied for several consecutive years due to the broad use pattern. Under consideration of the annual application rates for non-permanent crops and the DT_{50} values obtained from aerobic soil degradation and field dissipation studies, a 1st order kinetic model can be used to estimate the boscalid plateau reached in soil.

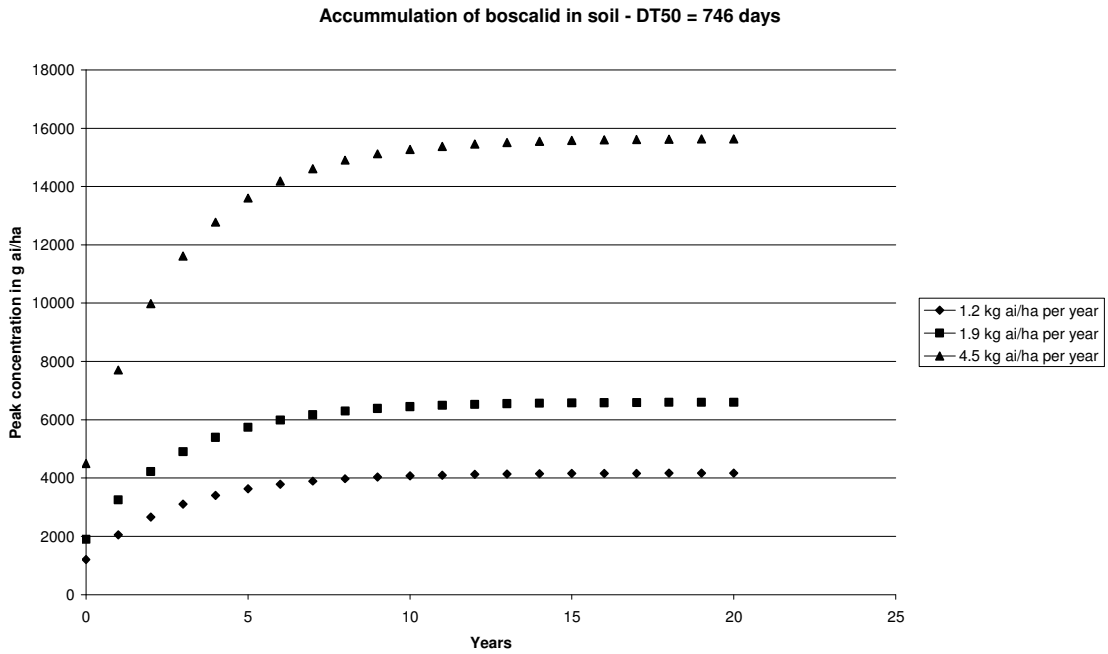
Annual application rates of boscalid on non-permanent crops are normally in the magnitude of 0.9 to 1.2 kg ai/ha per year (see GAP list in JMPR Evaluation 2006). The only uses involving higher application rates are reported from the US for bulb vegetables with 1.9 kg ai /ha per year (6 × 0.32 kg ai/ha) and various uses from Japan at the maximum rate of 4.5 kg ai/ha per year (up to 3 × 1.5 kg ai/ha).

Concerning the rate of degradation DT_{50} values were determined for up to 208 days in field dissipation studies. Under laboratory conditions most DT_{50} values were in the magnitude of 1 year (365 days), while in aged soil receiving several consecutive applications the DT_{50} values were determined at up to 746 days.

Under consideration of these input parameters, the plateau levels of boscalid equivalent to an application rate to bare soil after consecutive applications over several years can be estimated (1st order kinetics assumed):







The results for the estimation are dependent on the DT_{50} values for boscalid in soil. For a DT_{50} value of 208 days estimated in field dissipation studies, the plateau is reached after five annual applications of boscalid. Plateau levels were equivalent to an application rate of 1.7 kg ai/ha to bare soil for a treatment using 1.2 kg ai/ha per year, 2.7 kg ai/ha for 1.9 kg ai/ha per year and 6.4 kg ai/ha for 4.5 kg ai/ha per year, respectively.

Under the assumption of a DT_{50} value of 1 year (365 days) mainly found in aerobic soil metabolism and dissipation studies on soil treated for the first time plateau levels equivalent to an

application rate to bare soil were estimated at 2.4 kg ai/ha for a treatment rate of 1.2 kg ai/ha per year, 3.8 kg ai/ha for 1.9 kg ai/ha per year and 9 kg/ha for 4.5 kg ai/ha per year.

The highest DT_{50} value for boscalid was found in aged soil under laboratory conditions with a half-live time of 746 days. The resulting plateau levels equivalent to application rates to bare soil estimated in were 4.1 kg ai/ha following treatment at 1.2 kg ai/ha per year, 6.6 kg ai/ha for 1.9 kg ai/ha per year and 15.6 kg ai/ha after treatment at 4.5 kg ai/ha per year.

The Meeting noted that boscalid shows a reduced uptake into plants from soil (52.8% on average) when applied for several consecutive years. Since the plateau in soil is reached after 5 years at a minimum, the Meeting decided to apply an additional factor of 0.5 to the plateau concentration reflecting the reduced uptake of residues from aged soil. Field trials on succeeding crops were normally conducted using unaged soils resulting in higher residues potentially available for an uptake via the roots of the plants. The following table shows the derivation of the predicted plateau levels for boscalid residues in soil after the GAP application rates.

Application rate	Assumed DT_{50} value in days	Predicted plateau level equivalent to an application to bare soil	Adjusted plateau level equivalent to an application to bare soil available for uptake from aged soil (factor 0.5)
1.2 kg ai/ha per year	208	1.7 kg ai/ha	0.85 kg ai/ha
	365	2.4 kg ai/ha	1.2 kg ai/ha
	746	4.1 kg ai/ha	2.05 kg ai/ha
1.9 kg ai/ha per year	208	2.7 kg ai/ha	1.35 kg ai/ha
	365	3.8 kg ai/ha	1.9 kg ai/ha
	746	6.6 kg ai/ha	3.3 kg ai/ha
4.5 kg ai/ha per year	208	6.4 kg ai/ha	3.2 kg ai/ha
	365	9 kg ai/ha	4.5 kg ai/ha
	746	15.6 kg ai/ha	7.8 kg ai/ha

The Meeting noted that most of the GAPs globally reported involve an annual application rate of 1.2 kg ai/ha or less. Even under assumption of the most critical DT_{50} value of 746 days the level of boscalid available for an uptake into plants is at, or below, the dose range of the field trial data submitted for succeeding crops.

Under the assumption of the DT_{50} value of 208 days or the DT_{50} value of 365 days, the next higher GAP from the US on bulb vegetables using 1.9 kg ai/ha still results in a plateau within the treatment range of the field studies on succeeding crops.

The national GAPs involving up to 4.5 kg ai/ha per year may lead to a predicted plateau of at least 50% above the application rate of the field trial on succeeding crops submitted.

The Meeting decided that the field trial data submitted on succeeding crops represents the maximum residues in soil available for an uptake via the roots for all GAPs submitted, except for GAPs using more than 1.9 kg ai/ha per year. These results are also confirmed by field accumulation studies over eleven years, leading to plateau residue levels equivalent to an application rate to bare soil between 2 and 3 kg ai/ha. For the estimation of boscalid residues in commodities obtained from follow crops, the results from the field trial data on succeeding crops may be taken into account without further adjustment.

Definition of the residue

The consideration leading to the residue definition for boscalid was presented in the JMPR Report 2006. Results were:

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* [a] *including its conjugate, expressed as boscalid.*

The residue is fat soluble.

[a] Metabolite code: M510F01

Estimation of residues in plant commodities grown as potential succeeding crops

For a recommendation on boscalid residues in plant commodities the addition of probable residues arising from direct treatment in combination with root uptake of boscalid applied in previous years must be taken into account. The Meeting decided to use the overall groups for plant food and feed established in the Codex Classification System to give recommendations on the overall residue levels of boscalid expected in these commodities.

The evaluation of residues in follow-up crops was conducted according to the principles outlined in the 2008 JMPR Report, as per General consideration item 2.9. The corresponding residue values from supervised field trials are obtained from the previous evaluation of boscalid as a new active substance by JMPR 2006.

The Meeting recognised that the use of statistical methods for the estimation of maximum residue levels is not possible in cases of potential carryover residues in following crops, since the bias arising from the additional root uptake cannot be adequately expressed within the models. All maximum residue levels recommended for boscalid are therefore based on the expertise of the Meeting only.

Apples

Apples are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendation of a maximum residue level and an STMR value for boscalid in apples of 2 and 0.365 mg/kg respectively.

Stone fruit

Stone fruits are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendation of a maximum residue level and an STMR value for boscalid in stone fruit of 3 and 1.21 mg/kg respectively.

Berries and other small fruits

In 2006 the Meeting recommended maximum residue levels and STMR values for berries and other small fruits (except strawberries) and grapes as well as for grapes individually. These crops are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil.

The Meeting confirms its previous recommendations of maximum residue levels and STMR values for boscalid in berries and other small fruits (except strawberries) and grapes of 10 and 2.53 mg/kg respectively.

The Meeting also confirms its previous recommendation of a maximum residue level and an STMR value for boscalid in grapes of 5 and 1.09 mg/kg respectively.

For strawberries supervised field trials according to GAP were available, but no recommendation could be given due to the outstanding evaluation of the uptake through the soil. In

2006 the Meeting identified the following residues of boscalid in strawberries: 0.15, 0.19, 0.20, 0.23, 0.27 (2), 0.28, 0.31, 0.34, 0.35, 0.38, 0.41, 0.42, 0.45, 0.46 (2), 0.47, 0.49, 0.55, 0.57, 0.68 (2), 0.69, 0.89, 1.74 and 1.87 mg/kg.

No data from studies on follow crops on strawberries are available. In field studies on succeeding crops highest mean and median residue values of 0.12 mg/kg and 0.05 mg/kg respectively were found in non-dry commodities (leaves and tops of root vegetables, Brassica vegetables and fruiting vegetables). The Meeting concluded that residues in strawberries may be influenced significantly by an additional uptake of boscalid from the soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.12 mg/kg to the median residue obtained from supervised field trials on strawberries of 0.435 mg/kg for an overall STMR for boscalid in strawberries of 0.555 mg/kg.

For the estimation of maximum residue levels the highest residue found in non-dry commodities in succeeding crops field trials was 0.84 mg/kg in carrot tops. The Meeting concluded that a maximum residue level of 3 mg/kg for boscalid in strawberries poses an acceptable value in view of a possible addition of the highest residue of 1.87 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in non-dry commodities in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in strawberries of 3 mg/kg and 0.555 mg/kg respectively.

Bananas

Bananas are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendation from 2008 of a maximum residue level and an STMR value, (based on banana pulp), for boscalid in banana, of 0.6 and 0.05 mg/kg respectively.

Kiwifruit

Kiwifruit were evaluated by JMPR 2008 for the application of boscalid as a post-harvest treatment. The Meeting confirms its previous recommendation from 2008 of a maximum residue level and an STMR value for boscalid in kiwifruit of 5 and 0.073 mg/kg respectively.

Bulb vegetables

In 2006 the following residues were identified by the Meeting for green onions, bulb onions and leeks. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in ranked order on green onions were: 1.13, 2.01, 2.20, 2.39 and 2.73 mg/kg.

The residues in ranked order on bulb onions were: < 0.05, 0.05, 0.1, 0.11, 0.13, 0.22, 0.78, 0.92, 0.93 and 2.61 mg/kg.

The residues of boscalid in leeks in ranked order were: 0.58, 0.62, 0.8, 0.9, 0.93, 1.02, 1.16, 1.31 (2), 1.90 and 2.30 mg/kg.

The Meeting concluded that the dataset on green onions represents the highest residue population within the group of bulb vegetables. Although the number of field trial results is considered very small for a recommendation, the data on bulb onions and leeks support the approach of using green onions as the critical case for an estimation of maximum residue levels and STMR values for the whole group.

In field studies on succeeding crops data for root and tuber vegetables are available indicating mean, median and highest residues of 0.07 mg/kg, 0.05 mg/kg and 0.37 mg/kg, respectively in the roots, and 0.12 mg/kg, 0.05 mg/kg and 0.84 mg/kg respectively in the tops of the plants. In

view of these residue levels the Meeting decided that in comparison to the STMR value of 2.2 mg/kg for bulb vegetables (based on the use on green onions) the impact on the overall residue levels due to an additional uptake from soil is insignificant for the estimation of the dietary intake.

For the estimation of maximum residue levels the highest residue found in tops of root and tuber vegetables was 0.84 mg/kg.

The Meeting concluded that a maximum residue level of 5 mg/kg for boscalid in bulb vegetables poses an acceptable value in view of a possible addition of the highest residue of 2.73 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in tops of root and tuber vegetables in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in bulb vegetables of 5 mg/kg and 2.2 mg/kg respectively.

Brassica vegetables

In 2006 the following residues were identified by the Meeting for broccoli (USA and UK GAP), cabbage, cauliflower and Brussels sprouts. A recommendation on STMR values and maximum residue levels could not be made due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on broccoli according to UK GAP in ranked order were: < 0.05, < 0.05 and 0.20 mg/kg.

The residues on broccoli according to US GAP in ranked order were: 0.81, 0.98, 1.45, 1.59, 1.70 and 2.70 mg/kg.

The residues on cabbage according to US GAP in ranked order were: 0.64, 0.73, 1.06, 1.78, 2.22 and 2.33 mg/kg.

The residues on cauliflower according to UK GAP in ranked order were: < 0.05 (5), 0.06 and 0.55 mg/kg.

The residues on Brussels sprouts according to UK GAP in ranked order were: < 0.05 (2), 0.06, 0.10, 0.15, 0.16, 0.23, 0.34 and 0.40 mg/kg.

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to broccoli and cabbage according to the US GAP for brassicas results in a comparable residue population and may be combined for a recommendation of an STMR value and a maximum residue level for the whole group of Brassica vegetables. In summary, residues of boscalid in broccoli and cabbage from the 12 US trials in rank order were: 0.64, 0.73, 0.81, 0.98, 1.06, 1.45, 1.59, 1.70, 1.78, 2.22, 2.33 and 2.70 mg/kg.

In field studies on succeeding crops mean, median and highest residues in Brassica vegetables were 0.03 mg/kg, 0.035 mg/kg and 0.05 mg/kg, respectively. The Meeting concluded that residues due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level, an STMR value and a highest residues value for boscalid in Brassica vegetables of 5 mg/kg, 1.52 mg/kg and 2.7 mg/kg respectively.

Fruiting vegetables, other than Cucurbits (except fungi, mushrooms and sweet corn)

In 2006 the following residues were identified by the Meeting for cucumbers, cantaloupe, melons, summer squash, tomatoes and bell and non-bell peppers. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on cucumber in ranked order were: 0.05, 0.07 (3), 0.12, 0.13, 0.14 (2), 0.26 and 0.31 mg/kg.

The residues on cantaloupe in ranked order were: 0.14, 0.23, 0.29, 0.39, 0.56, 0.57, 0.71 and 1.27 mg/kg.

The residues on melons in ranked order were: < 0.05(8) mg/kg.

The residues in ranked order on summer squash were: 0.11, 0.12, 0.14, 0.16 (2), 0.19, 0.27, 0.31 and 0.95 mg/kg.

The residues on tomatoes in ranked order were: 0.17, 0.21, 0.22, 0.24, 0.25, 0.27, 0.28, 0.3, 0.59, 0.61, 0.79 and 0.92 mg/kg.

The residues on bell peppers in ranked order were: < 0.05, 0.08, 0.09, 0.14, 0.16 and 0.3 mg/kg.

The residues on non-bell peppers in ranked order were: 0.14, 0.30 and 0.83 mg/kg.

The Meeting concluded that the application of boscalid to cantaloupe results in the highest residue population in fruiting vegetables, except fungi, mushrooms and sweet corn and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

For fruiting vegetables, except fungi, mushrooms and sweet corn no data from studies on follow crops are available. The Meeting decided that the highest mean and median residue values of 0.12 mg/kg and 0.05 mg/kg respectively found in non-dry commodities in these studies (leaves and tops of root vegetables, Brassica vegetables and sweet corn) indicate a deviation of less than 25% in comparison to the STMR value derived from supervised field trials on cantaloupe of 0.565 mg/kg. The Meeting concluded that the STMR value of 0.565 mg/kg for boscalid in cantaloupe may be used directly for the estimation of the dietary intake of the whole group. No separation of pulp and peel was conducted for cantaloupe.

For the estimation of maximum residue levels the highest residue found in non-dry commodities in succeeding crops field trials was 0.84 mg/kg in carrot tops.

The Meeting concluded that a maximum residue level of 3 mg/kg for boscalid in fruiting vegetables, except fungi, mushrooms and sweet corn (based on cantaloupe) poses an acceptable value in view of a possible addition of the highest residue of 1.27 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in non-dry commodities in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in fruiting vegetables, cucurbits and fruiting vegetables, non-cucurbits (except fungi, mushrooms and sweet corn) of 3 mg/kg and 0.565 mg/kg respectively.

The Meeting agreed to apply the default transfer factor of 10 for dried chilli peppers to the STMR and highest residue found for bell and non-bell peppers and estimated a maximum residue level and an STMR of 10 mg/kg and 1.4 mg/kg for boscalid in dried chilli peppers.

Leafy vegetables

In 2006 the following residues were identified by the Meeting for mustard greens, head and leafy lettuce (US GAP) and lettuce (European GAP, indoor and outdoor). A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on mustard greens in ranked order were: 0.45, 0.54, 0.92, 2.80, 3.1, 6.04, 12.9 and 14.4 mg/kg.

The residues on head and leafy lettuce (US GAP) in ranked order were: 0.11, 0.74, 0.98, 1.6, 1.63, 1.77, 1.91, 2.53, 2.68, 2.73, 3.18, 4.87, 5.14, 5.42, 9.36 and 9.55 mg/kg.

The residues on lettuce (European GAP, outdoor) in ranked order were: < 0.05, 0.09, 0.15, 0.21, 0.33, 0.36, 0.38, 0.39, 0.43, 0.45, 0.50, 0.64, 0.65, 0.73, 0.76, 0.86, 1.19 and 1.58 mg/kg.

The residues on lettuce (European GAP, indoor) in ranked order were: 0.37, 0.71, 1.52, 2.31, 2.50, 5.63, 5.96 and 6.11 mg/kg.

The Meeting concluded that the application of boscalid to mustard greens results in the highest residue population in leafy vegetables and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In field studies on succeeding crops mean, median and highest residues in Brassica vegetables were 0.03 mg/kg, 0.035 mg/kg and 0.05 mg/kg, respectively. The Meeting concluded that the results obtained for Brassica vegetables are also applicable to estimated possible residues of boscalid in leafy vegetables. The residues due to an additional uptake of boscalid via the roots are considered insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level and an STMR value for boscalid in leafy vegetables of 30 mg/kg and 2.95 mg/kg respectively.

Legume vegetables

In 2006 the following residues were identified by the Meeting for green beans with pods (French GAP, indoor and outdoor), shelled and podded peas (US GAP), immature soybeans (US GAP), snap beans (UP GAP) and lima beans (US GAP). A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on green beans with pods (French GAP, outdoor) in ranked order were: 0.13, 0.22, 0.26, 0.29, 0.47, 0.50, 0.53, 0.62, 0.67, 0.83 and 0.95 mg/kg.

The residues on green beans with pods (French GAP, indoor) in ranked order were: 0.06, 0.28, 0.28, 0.29, 0.61, 0.69, 1.65 and 1.67 mg/kg.

The residues on shelled peas (US GAP) in ranked order were: < 0.05 (2), 0.06, 0.07, 0.15, 0.19, 0.24 and 0.37 mg/kg.

The residues on podded peas (US GAP) in ranked order were: 0.64, 0.97 and 1.39 mg/kg.

The residues on immature soybeans (US GAP) in ranked order were: < 0.05 (11), 0.05, 0.06, 0.08, 0.09, 0.2 and 1.18 mg/kg.

The residues on snap beans (US GAP) in ranked order were: 0.13, 0.28, 0.36, 0.41, 0.42, 0.46, 0.52, 0.54, 0.72 and 0.97 mg/kg.

The residues on lima beans (US GAP) in ranked order were: < 0.05 (2), 0.07 (2), 0.08 (2) and 0.47 mg/kg.

The 2006 Meeting concluded that the application of boscalid to beans according to French GAP results in the highest residues may be extrapolated to the whole group. Based on the outcome of the Mann-Whitney-U-Test the use in field and glasshouse results in a comparable residue population, and may be combined. In summary, residues of boscalid in green beans with pods (French GAP, indoor and outdoor) in rank order were: 0.06, 0.08, 0.13, 0.22, 0.26, 0.28, 0.29, 0.29, 0.47, 0.50, 0.53, 0.61, 0.62, 0.67, 0.69, 0.83, 0.95, 1.65 and 1.67 mg/kg.

For legume vegetables no data from studies on follow crops are available. Data on pulses and oilseeds are available, but the high fat and low water content of the seeds are not representative for legume vegetables. The Meeting decided that the highest mean and median residue values of 0.12 mg/kg and 0.05 mg/kg respectively found in non-dry commodities (root and tuber vegetables, Brassica vegetables and fruiting vegetables) indicate a deviation of less than 25% in comparison to the STMR value derived from supervised field trials on green beans with pods of 0.5 mg/kg. The

Meeting concluded that the STMR value of 0.5 mg/kg for boscalid in green beans with pods may be used directly for the estimation of the dietary intake of the whole group.

For the estimation of maximum residue levels the highest residue found in non-dry commodities in succeeding crops field trials was 0.84 mg/kg in carrot tops. The Meeting concluded that a maximum residue level of 3 mg/kg for boscalid in legume vegetables poses an acceptable value in view of a possible addition of the highest residue of 1.67 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in non-dry commodities in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in legume vegetables of 3 mg/kg and 0.5 mg/kg respectively.

Pulses

In 2006 the following residues were identified by the Meeting for dry beans, peas and soya beans according to US GAP. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on dry beans in ranked order were: < 0.05 (4), 0.06, 0.09, 0.12, 0.14, 0.37 and 1.92 mg/kg.

The residues on dry peas in ranked order were: 0.05, 0.09, 0.11, 0.12, 0.16, 0.17, 0.23, 0.31 and 0.46 mg/kg.

The residues on dry soya beans in ranked order were: < 0.05 (17) mg/kg.

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to beans and peas according to the US GAP for pulses results in a comparable residue population and may be combined for a recommendation of an STMR value and a maximum residue level for the whole group of pulses. In summary, residues of boscalid in beans and peas from the 19 US trials in rank order were: < 0.05(4), 0.05, 0.06, 0.09, 0.09, 0.11, 0.12, 0.12, 0.14, 0.16, 0.17, 0.23, 0.31, 0.37, 0.46 and 1.92 mg/kg.

In field studies on succeeding crops mean, median and highest residues in alfalfa and soybean seeds were 0.05 mg/kg, 0.05 mg/kg and 0.06 mg/kg, respectively, with most of the values below the LOQ of 0.05 mg/kg. The Meeting concluded that residues in pulses due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level and an STMR value for boscalid in pulses of 3 mg/kg and 0.12 mg/kg respectively.

Root and tuber vegetables

In 2006 the following residues were identified by the Meeting for carrots and potatoes. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on carrots in ranked order were: < 0.05, 0.06, 0.12, 0.17, 0.18, 0.19, 0.28 and 0.34 mg/kg.

The residues on potatoes in ranked order were: < 0.05 (16) mg/kg.

The Meeting concluded that the application of boscalid to carrots results in the highest residue population in root and tuber vegetables and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In all field studies on succeeding crops mean, median and highest residues in root and tuber vegetables were 0.07 mg/kg, 0.05 mg/kg and 0.37 mg/kg, respectively. For carrot roots residues found were slightly higher with mean, median and highest residues of 0.13 mg/kg, 0.065 mg/kg and 0.37 mg/kg, respectively. The Meeting concluded that residues in carrots are the representative

commodity for all root and tuber vegetables and may be influenced significantly by an additional uptake of boscalid from the soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.13 mg/kg to the median residue obtained from supervised field trials on carrot roots of 0.175 mg/kg for an overall STMR for boscalid in carrot roots of 0.305 mg/kg.

For the estimation of maximum residue levels the highest residue found in root and tuber vegetables in succeeding crops field trials was 0.37 mg/kg in carrot roots. The Meeting concluded that a maximum residue level of 2 mg/kg for boscalid in root and tuber vegetables poses an acceptable value in view of a possible addition of the highest residue of 0.34 mg/kg found in supervised field trials and the highest residue of 0.37 mg/kg for carrot roots in the succeeding crops field trials. For the estimation of the livestock animals' dietary burden, both values are added for an overall highest residue in root and tuber vegetables of 0.71 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and a highest residue value for boscalid in root and tuber vegetables of 2 mg/kg, 0.305 mg/kg and 0.71 mg/kg respectively.

Barley, oats, rye and wheat grain

In 2006 the following residues were identified by the Meeting for barley and wheat grain. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on barley in ranked order were: < 0.01(2), 0.02, 0.03, 0.12 and 0.19 mg/kg.

The residues on wheat in ranked order were: < 0.01, 0.01(3), 0.03, 0.06(2), and 0.27 mg/kg.

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to barley and wheat grain results in a comparable residue population, and may be combined for a recommendation of an STMR value and a maximum residue level. In summary, residues of boscalid in barley and wheat grain in rank order were: < 0.01(3), 0.01(3), 0.02, 0.03, 0.03, 0.06, 0.06, 0.12, 0.19 and 0.27 mg/kg.

In all field studies on succeeding crops mean, median and highest residues in wheat grain were 0.05 mg/kg, 0.05 mg/kg and 0.07 mg/kg, respectively. The Meeting concluded that residues in barley and wheat grain may be influenced significantly by an additional uptake of boscalid from soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.05 mg/kg to the median residue obtained from supervised field trials of 0.025 mg/kg for an overall STMR for boscalid in barley and wheat grain of 0.075 mg/kg.

For the estimation of maximum residue levels the highest residue found in wheat grain in succeeding crops field trials was 0.071 mg/kg. The Meeting concluded that a maximum residue level of 0.5 mg/kg for boscalid in barley and wheat grain poses an acceptable value in view of a possible addition of the highest residue of 0.27 mg/kg found in supervised field trials and the highest residue of 0.07 mg/kg for wheat grain in the succeeding crops field trials. In addition it was noted by the Meeting that residues on barley and wheat grain may be extrapolated to oats and rye.

The Meeting estimated a maximum residue level and an STMR value for boscalid in barley, oats, rye and wheat grain of 0.5 mg/kg and 0.075 mg/kg respectively.

Cereal grain except barley, oats, rye and wheat

Although boscalid is not used for treatment of further cereal grains (except barley, oats, rye and wheat), these crops may still be subject to crop rotation and therefore contain boscalid residues after uptake via the roots. The Meeting decided to use the mean, median and highest residue found in wheat grain in field studies on succeeding crops of 0.05 mg/kg, 0.05 mg/kg and 0.07 mg/kg respectively for an estimation of STMR and maximum residue values in cereal grains except barley, oats, rye and wheat.

The Meeting estimated a maximum residue level and an STMR value for boscalid in cereal grains, except barley, oats, rye and wheat grain of 0.1 mg/kg and 0.05 mg/kg respectively.

Tree nuts

Tree nuts are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in tree nuts, except pistachio of 0.05 (*) mg/kg and 0.05 mg/kg respectively. The Meeting also confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in pistachio of 1 mg/kg and 0.27 mg/kg respectively.

Oilseeds

In 2006 the following residues were identified by the Meeting for sunflowers and peanuts. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in sunflower seeds in ranked order were: < 0.05, 0.08, 0.09, 0.13, 0.16, 0.16, 0.23 and 0.45 mg/kg.

The residues in peanut in ranked order were: < 0.05 (11) and 0.05 mg/kg.

The Meeting concluded that the application of boscalid to sunflowers results in the highest residues in oilseeds and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In field studies on succeeding crops mean, median and highest residues in alfalfa, soybean and cotton seeds were 0.05 mg/kg, 0.05 mg/kg and 0.06 mg/kg, respectively with most of the values below the LOQ of 0.05 mg/kg. The Meeting concluded that residues in oilseeds due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level and an STMR value for boscalid in oilseeds of 1 mg/kg and 0.145 mg/kg respectively.

Coffee

Coffee plants are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in coffee of 0.05 (*) mg/kg and 0.05 mg/kg respectively.

Animal feedstuffs

Almond hulls

Almond trees are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in almond hulls of 15 mg/kg and 4.1 mg/kg respectively (dry weight). A highest residue level of 13 mg/kg was estimated for calculating the dietary burden of farm animals.

Straw and fodder of barley, oats, rye and wheat

In 2006 the following residues were identified by the Meeting for barley and wheat straw. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in barley straw in ranked order were: 0.51, 2.5, 5.8, 13, 14 and 27 mg/kg (fresh weight).

The residues in wheat straw in ranked order were: 3.0, 3.1, 5.3, 5.8, 7.9, 7.9, 11 and 15 mg/kg (fresh weight).

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to barley and wheat straw results in a comparable residue population and may be combined for a recommendation of an STMR value and a maximum residue level. In summary, residues of boscalid in barley and wheat straw in rank order were: 0.51, 2.5, 3.0, 3.1, 5.3, 5.8, 7.9, 7.9, 11, 13, 14, 15 and 27 mg/kg (fresh weight).

In field studies on succeeding crops mean, median and highest residues in fresh wheat straw were 1.1 mg/kg, 0.81 mg/kg and 2.8 mg/kg, respectively. The Meeting concluded that residues in barley and wheat straw due to an additional uptake of boscalid via the roots contribute less than 25% to the total residue in comparison to residue levels following direct treatment and are therefore considered as non-relevant for the estimation of STMR values and maximum residue levels.

Under the assumption of a default dry-matter content of 88% the Meeting calculated boscalid residues in barley and wheat straw in rank order were: 0.58, 2.8, 3.4, 3.5, 6.0, 6.6, 9.0, 9.0, 12.5, 14.8, 15.9, 17.1 and 30.7 mg/kg (dry-matter). The Meeting concluded that residues on straw and fodder from barley and wheat may be extrapolated to straw and fodder from oats and rye.

The Meeting estimated a maximum residue level and an STMR value for boscalid in straw and fodder from barley, oats, rye and wheat of 50 mg/kg and 9 mg/kg respectively (dry-matter). A highest residue level of 30.7 mg/kg (dry-matter) was estimated for calculating the dietary burden of farm animals.

Straw and fodder of cereal grain, except barley, oats, rye and wheat

Although boscalid is not used for treatment of further cereal straw and fodder plants (except barley, oats, rye and wheat), these crops may still be subject to crop rotation and therefore contain boscalid residues after uptake via the roots. The Meeting decided to use the mean, median and maximum residues found in wheat straw in field studies on succeeding crops of 1.1 mg/kg, 0.81 mg/kg and 2.8 mg/kg (fresh-weight) respectively for an estimation of STMR and maximum residue values in straw and fodder of cereal grain, except barley, oats, rye and wheat.

Under the assumption of a default dry-matter content of 88% the Meeting calculated mean, median and highest boscalid residues of 1.25 mg/kg, 0.92 mg/kg and 3.2 mg/kg (dry-weight) in straw and fodder of cereal grain, except barley, oats, rye and wheat.

The Meeting estimated a maximum residue level, an STMR value and a highest residue value for boscalid in straw and fodder of cereal grain, except barley, oats, rye and wheat of 5 mg/kg, 1.25 mg/kg and 3.2 mg/kg respectively (dry-matter).

Legume animal feeds

In 2006 the following residues were identified by the Meeting for peanut and soybean fodder although a recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in peanut hay in ranked order were: 3.2, 5.8, 6.7, 6.7, 7.8, 9.0, 13, 20, 24, 28 and 29 mg/kg (fresh weight).

The residues in soybean hay in ranked order were: 1.3, 1.4, 1.8, 2.0, 2.1, 2.3, 2.8, 3.6, 4.6, 4.8, 5.3, 6.7, 7.1, 7.3, 7.8, 11 and 21 mg/kg (fresh weight).

The Meeting concluded that the application of boscalid to peanuts results in the highest residues in legume animal feeds and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In field studies on succeeding crops mean, median and highest residues in legume animal feeds were 0.17 mg/kg, 0.079 mg/kg and 1.46 mg/kg, respectively. The Meeting concluded that residues in peanut fodder due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated an STMR and a highest residue value for boscalid in legume animal feeds of 9 mg/kg and 29 mg/kg respectively (fresh weight).

Fate of residues during processing

Processing data on various commodities are reported in the initial evaluation from 2006 for boscalid. All data relevant for a recommendation of maximum residue levels in processed commodities or for dietary intake calculations are summarized in the following table.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Apples	Fresh juice	0.05, 0.06, 0.08(2), < 0.09, < 0.10	0.08
	Wet pomace	2.08, 3.90, 5.73, 6.38, 6.77, 8.26	6.06
Plums	Prunes	0.52, 2.42, 2.80, 3.15, 3.66	2.8
Grapes	Raisins	2.42	2.42
	Wet pomace	1.95, 2.40, 2.60, 3.41	2.5
	Wine	0.09, 0.34, 0.36, 0.47	0.35
	Juice	0.42	0.42
Tomato	Canned juice	0.09, 0.13, 0.16, 0.27	0.15
	Puree	0.19, 0.24(2), 0.73	0.24
	Paste	0.53, 0.63, 0.82, 2.24	0.73
Soya bean	Hulls	1.74	1.74
	Meal	< 0.16	0.16
	Refined oil	0.42	0.42
Barley	Pot barley	0.22, 0.29, 0.37(2)	0.33
	Beer	0.01, 0.02, 0.02, 0.02	0.02
Wheat	Wholemeal flour	1.10, 1.14, 1.29, 1.82	1.22
	Flour type 550	0.22, 0.23, 0.45, 0.47	0.34
	Wheat bran	3.29, 3.87, 4.64, 5.44	4.26
	Wheat germs	0.97, 1.29, 1.36, 1.58	1.33

The processing factors for wet apple pomace (6.06) and apple juice (0.08) were applied to the estimated STMR for apple (0.365 mg/kg) to produce STMR-P values for wet apple pomace (2.2 mg/kg) and apple juice (0.03 mg/kg).

The processing factor for plum to dried plums (prunes) (2.80) was applied to the estimated STMR for plums (1.21 mg/kg) to produce an STMR-P value for prunes (3.39 mg/kg).

The Meeting estimated a maximum residue level for boscalid in prunes of 10 mg/kg.

The processing factors for dried grapes (raisins) (2.42), wet pomace (2.50), wine (0.35) and juice (0.42) were applied to the estimated STMR for grapes (1.09 mg/kg) to produce STMR-P values for raisins (2.6 mg/kg), wet pomace (2.7 mg/kg), wine (0.38 mg/kg) and grape juice (0.46 mg/kg).

The Meeting confirmed its recommendation on a maximum residue level for boscalid in dried grapes (currants, raisins and sultanas) of 10 mg/kg.

The processing factors for tomato to juice (0.15), puree (0.24) and paste (0.73) were applied to the estimated STMR for tomatoes (0.565 mg/kg) to produce STMR-P values for tomato juice (0.085 mg/kg), tomato puree (0.136 mg/kg) and tomato paste (0.413 mg/kg).

The processing factors for soya bean hulls (1.74), soybean meal (0.16) and refined soya bean oil (0.42) were applied to the estimated STMR for soya beans (0.145 mg/kg) to produce a STMR-P value of 0.25 for soya bean hulls, 0.023 for soya bean meal and 0.061 mg/kg for refined soya bean oil.

The processing factors for pot barley (0.33) and beer (0.02) were applied to the estimated STMR for barley grain (0.075 mg/kg) to produce STMR-P values for pot barley (0.025 mg/kg) and beer (0.002 mg/kg).

The processing factors for wheat wholemeal flour (1.22), wheat flour type 550 (0.34), wheat bran (4.26) and wheat germs (1.33) were applied to the STMR value for wheat grain (0.075 mg/kg) to produce STMR-P values for wheat wholemeal flour (0.092 mg/kg), wheat flour type 550 (0.026 mg/kg), wheat bran (0.32 mg/kg) and wheat germ (0.1 mg/kg).

The Meeting concluded that the STMR-P values for wholemeal flour of 0.092 mg/kg and flour type 550 of 0.026 mg/kg also apply to rye wholemeal flour and barley, and rye and triticale flour, respectively.

Residues in animal commodities

Livestock dietary burden

The Meeting received two feeding studies of boscalid on lactating dairy cows which provided information on likely residues resulting in animal tissues and milk from residues in the animal diet.

The first study on dairy cattle was submitted to the 2006 JMPR. The results presented in 2006 are amended by adding individual data for boscalid parent and the metabolite M510F01.

Lactating Holstein cows were dosed with boscalid at the equivalent of 1.5 (1×), 4.5 (3×) and 18 (12×) ppm in the dry-weight diet for 28 consecutive days. Milk was collected twice daily for analysis. Animals were sacrificed within 23 hours after the final dosing, except for one cow of the 12× group which was sacrificed seven days after the final dose to determine residue levels post dosing.

No residues were detected in milk samples taken from the control and the 1× dose groups. In a few samples from the 3× dose group, residues just above the LOQ of 0.01 mg/kg for boscalid parent were detected, but no residues of M510F01 or M510F02 were observed. In the group average, residues were below the LOQ. In the 12× dose group, residues of boscalid parent occurred regularly from day one onward with residues reaching a plateau on day 14 with average residues between 0.04 mg/kg and 0.05 mg/kg. M510F53 was below LOQ (< 0.01 mg/kg) in milk from all three treatment groups.

Separation of milk and cream indicated that residues are only detectable in cream (0.03 mg/kg, 0.11 mg/kg and 0.32 mg/kg for 1×, 3× and 10× samples, respectively) while most of the

results in skim milk were below the LOQ of 0.01 mg/kg. In all cream samples only boscalid parent was found.

In the tissues, the mean residues of the sum of boscalid and M510F01, expressed for boscalid at the three dosing levels were: muscle (< 0.05, < 0.05 and < 0.05 mg/kg); fat (0.06, 0.11 and 0.27 mg/kg); liver (< 0.05, 0.06 and 0.18 mg/kg); kidney (< 0.05, 0.07 and 0.24 mg/kg). Individual results indicate that boscalid parent is the only analyte detectable in fat, whilst being at or below the LOQ in liver and kidney. M510F53 was below LOQ (< 0.01 mg/kg) in liver from the 1× and 3× dose groups, and up to 0.09 mg/kg from the 12× dose group.

Residues depleted quickly from the milk of a high-dose animal after dosing was stopped, falling below LOQ (0.01 mg/kg) after 2 days. Residues fell to below the LOQ (< 0.05 mg/kg) in all tissues. It was shown by samples from the withdrawal animal that no residues in milk was observed two days after dosing had stopped, and boscalid was rapidly excreted.

In an additional study submitted to JMPR in 2009 lactating Holstein cows were dosed with boscalid at the equivalent of 35.8 and 116.3 ppm in the dry-weight diet for 28 consecutive days. Milk was collected twice daily for analysis. Animals were sacrificed within 23 hours after the final dosing. All samples were analysed for residues of boscalid and its metabolite M510F01.

In milk obtained from the 35.8 ppm group boscalid mean residues above the LOQ of 0.01 mg/kg were detected, but their levels were relatively low, ranging up to 0.019 mg/kg. In the high dose group (116.3 ppm) boscalid was measured in all samples at levels of up to 0.078 mg/kg. The data indicates that a residue plateau in milk is reached after 7 days. No residues of M510F01 above the LOQ of 0.01 mg/kg were found in both dose groups.

Milk collected on day 22 and 28 of the dosage period was separated into skim milk and cream. The data indicated that most of the boscalid is present in the cream. For the 35.8 ppm group mean residues in whole milk, skim milk and cream were: day 22 (0.016, < 0.01 and 0.066 mg/kg); and day 28 (0.011, < 0.01 and 0.056 mg/kg). For the 116.3 ppm dose group the following residues were found: day 22 (0.05, < 0.01 and 0.23 mg/kg); and day 28 (0.044, 0.01 and 0.23 mg/kg).

In tissues, the mean residues of boscalid at the two dosing levels were: muscle (< 0.025 and < 0.025 mg/kg); fat (0.16 and 0.22 mg/kg); liver (0.051 and 0.085 mg/kg); and kidney (< 0.025 and 0.026 mg/kg).

The maximum residues within each dose group were: muscle (< 0.025 and < 0.025 mg/kg); fat (0.22 and 0.25 mg/kg); liver (0.061 and 0.091 mg/kg); and kidney (< 0.025 and 0.029 mg/kg).

For M510F01 detectable residues above the LOQ of 0.025 mg/kg were found in liver and kidney only. Mean residues were: liver (0.048 and 0.12 mg/kg); and kidney (0.084 and 0.16 mg/kg). Highest residues, within each dose group, were: liver (0.054 and 0.14 mg/kg); and kidney (0.09 and 0.22 mg/kg).

Estimated maximum and mean dietary burdens of livestock

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, boscalid, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Beef cattle	28.4	9.3	25.8	9.3	34.0[a]	12.1[b]
Dairy cattle	27.0	8.8	27.1	9.5	33.4	12.0
Poultry - broiler	0.13	0.14	0.82	0.41	0.13	0.13

	Livestock dietary burden, boscalid, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Poultry - layer	0.11	0.12	8.4[c]	2.82[d]	0.13	0.13

[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 broiler or laying hens burden suitable for MRL estimates for poultry meat and eggs

[d] Highest mean broiler or laying hens burden suitable for STMR estimates for poultry meat and eggs

Animal commodities, MRL estimation

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	Cream	Muscle	Liver	Kidney	Fat
MRL	mean	mean	highest	highest	highest	highest
MRL beef or dairy cattle [a] (34.0) [18]	0.055 [0.029]	0.62 [0.33]	0.062 [0.033]	0.15 [0.08]	0.083 [0.044]	0.51 [0.27]
STMR	mean	mean	mean	mean	mean	mean
STMR beef or dairy cattle [b] (12.1) [4.5, 18]	0.033 [0.02, 0.05]	0.32 [0.12, 0.34]	0.035 [< 0.05, 0.053]	0.12 [0.057, 0.177]	0.16 [0.074, 0.236]	0.18 [0.105, 0.268]

[a] based on boscalid

[b] based on sum of boscalid and M510F01

For the estimation of maximum residue levels the Meeting recognised that residues found in tissues and milk found in the feeding study submitted in 2006 using a maximum dose level of 18 ppm were at higher levels than residues found in the 35.8 ppm group of the study submitted in 2009. The Meeting decided that the results obtained from the 18 ppm dose group should be extrapolated beyond the dose range of the study to the maximum dietary burdens estimated for beef and dairy cattle of 34.0 and 33.4 ppm to reflect the critical case of boscalid residues in animal tissues and milk. For the estimation of STMR values the results for the sum of boscalid and M510F01 obtained from the 4.5 and 18 ppm dose groups are interpolated to the mean dietary burdens for beef and dairy cattle of 12.1 and 12.0 ppm.

Under consideration of an average fat content in cream of 40–60% resulting in a factor of 2 the Meeting estimated a maximum residue level for boscalid (parent only) in whole milk and milk fat of 0.1 mg/kg and 2 mg/kg respectively. On the fat basis, the Meeting estimated maximum residue levels for meat (fat) from mammals (other than marine mammals) of 0.7 mg/kg. For edible offal (mammalian) the maximum residue level was estimated at 0.2 mg/kg based on liver.

Under consideration of an average fat content in cream of 40–60% resulting in a factor of 2 the Meeting estimated STMR values based on the sum of boscalid and M510F01 for whole milk and milk fat of 2 × 0.033 mg/kg = 0.066 mg/kg and 2 × 0.32 = 0.64 mg/kg respectively. For meat (fat) an STMR value of 0.18 mg/kg was estimated. STMR values for meat (muscle) and edible offal (based on kidney) were estimated at a level of 0.035 mg/kg and 0.16 mg/kg respectively.

For poultry no livestock feeding studies using boscalid were submitted to the Meeting. In the metabolism study on laying hens described in the Evaluation 2006 the animals were dosed with a rate of approx. 12.5 ppm over 10 consecutive days. In muscle boscalid and M510F01 were found at a very low level of 0.0025 mg/kg. Fat tissue contained boscalid at a concentration of 0.023 mg/kg and M510F01 at < 0.0025 mg/kg. In liver no residues above the LOD of 0.0025 mg/kg were found, after solvent extraction, but minor residues of M510F01 could be released after microwave treatment. Eggs gave residues of 0.02 mg/kg for boscalid and 0.015 mg/kg for M510F01.

Under consideration of the maximum dietary burden for laying hens of 8.4 ppm and the LOQ of the analytical method for animal commodities the Meeting estimated maximum residue levels and STMR values of 0.02 mg/kg for poultry meat, fat and edible offal as well as for eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of boscalid 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 GEMS/Food Consumption Cluster Diets, based on the estimated STMRs were 10–30% of the maximum ADI (0.04 mg/kg bw). The Meeting concluded that the long-term intake of residues of boscalid from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2006 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of boscalid residues is unlikely to present a public health concern.

5.4 BUPROFEZIN (173)

RESIDUE AND ANALYTICAL ASPECTS

Buprofezin, (an insecticide), was evaluated by JMPR in 1991 for the first time and then in 1995 and 1999. It was reviewed under the Periodic Re-evaluation Programme of CCPR in 2008 for toxicity and residues. The 2008 JMPR allocated an ADI of 0–0.009 mg/kg bw and ARfD of 0.5 mg/kg bw. It concluded that the residue definition for compliance with the MRL and for estimation of dietary intake, both for animal and plant commodities should be buprofezin, and recommended eight maximum residue levels while withdrawing one previous recommendation.

The current Meeting received information on use patterns and trials concerning pome fruits, stone fruits, berry fruits, tropical fruits, cucurbits, fruiting vegetables other than cucurbits, beans, olives, tree nuts and coffee. The Meeting also received information on some storage stability studies additional to those submitted to the 2008 JMPR.

Stability of pesticide residues in stored analytical samples

The Meeting received storage stability studies conducted in 2006 on banana, potato, wheat, almond, grape, orange, and some of their processed products.

Buprofezin, which is the only component of the definition of residue, was generally stable when stored at –20 ± 5° C for the longest interval tested for each matrix. Among those crops for which supervised residue trials were conducted and submitted to the current Meeting, buprofezin was stable up to 881 days in almond nutmeat, 78 days in almond hulls, 368 days in grapes and 374 days in dried grapes.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for buprofezin on apple, pear, peach, plum, cherry, grapes, strawberry, olive, lychee, avocado, guava, papaya, cucumber, cantaloupe, summer squash, tomato, peppers, common bean (pods and/or immature seeds), almond nutmeat and hulls, and coffee. The trials in the USA were conducted outdoors.

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Pome fruits

Supervised trials were conducted on apples in the USA with one application of 1.67–1.71 kg ai/ha in one trial with an exaggerated rate of 3.38 kg ai/ha. The residues of buprofezin from supervised trials in compliance with the maximum US GAP for apple (1.69 kg ai/ha × 1, PHI 14 days) were in rank order: 0.02, 0.05, 0.11, 0.15, 0.18, 0.24, 0.32, 0.55, 0.58, 0.75, 0.85 and 0.99 mg/kg (n=12).

The Meeting estimated a maximum residue level of 3 mg/kg, a STMR of 0.28 mg/kg and a HR of 0.99 mg/kg for apples.

The value derived from use of the NAFTA calculator was 3.0 mg/kg (UCLMedian95th), which was in agreement with the maximum residue level of 3 mg estimated by the current Meeting.

Supervised trials were conducted on pears including oriental pears in the USA with two applications at 1.70–2.02 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for pears (2.26 kg ai/ha × 2, not more than 3.37 kg ai/ha per growing season, PHI 14 days) were: 0.40, 0.60, 0.86, 1.09, 1.11, 1.31 and 3.64 mg/kg (n=7).

The Meeting estimated a maximum residue level of 6 mg/kg, STMR of 1.09 mg/kg and HR of 3.64 mg/kg for pears.

The value derived from use of the NAFTA calculator was 6.0 mg/kg (95/99 Rule), which was in agreement with the maximum residue level of 6 mg by estimated by the present Meeting.

Stone fruits

Supervised trials were conducted on peaches, plums and cherries in the USA with two applications at 1.70–1.87 kg ai/ha except two trials on peaches.

In the two trials on peaches, one in California and the other in New Jersey, application was made three times and four times. However, since the last application contributes most to the residues of buprofezin in harvested fruits, the Meeting agreed to use the results of these trials despite more applications being made than specified in GAP. In the trial with three applications, the rate of the last application was not sufficiently high and lower than that of all other trials, but duplicate samples showed the high residues of 5.58 and 8.13 mg/kg.

The residues of buprofezin in peaches from trials in accordance with the maximum US GAP for stone fruits (2.26 kg ai/ha × 2, not more than 3.37 kg ai/ha per growing season, PHI 14 days) and the two other trials were: 0.12, 0.40, 0.45, 0.84, 0.89, 1.31, 1.40, 1.77, 2.20, 2.36, 3.11 and 8.13 mg/kg (n=12).

The residues of buprofezin in plums from trials in accordance with the maximum US GAP for stone fruits were: 0.05, 0.08, 0.08, 0.23, 0.26 and 0.55 mg/kg (n=6).

The residues of buprofezin in cherries, both sweet and tart, from trials in accordance with the maximum US GAP for stone fruits were: 0.31, 0.45, 0.46, 0.54, 0.57, 0.89, 1.00, 1.01, 1.20 and 1.32 mg/kg (n=10).

Two trials were conducted on cherries in Italy but no GAP information was available for Southern Europe.

Since the residue populations of peaches, plums and cherries were significantly different (Kruskal-Wallis test), the Meeting agreed to estimate maximum residue levels separately for these commodities.

The Meeting estimated a maximum residue level, STMR and HR of 9, 1.355 and 8.13 mg/kg respectively for peaches. The Meeting agreed to extrapolate this maximum residue level for peaches to nectarines.

The value derived from use of the NAFTA calculator was 9.0 mg/kg (UCLMedian95th) which was in agreement with the maximum residue level estimated by the current Meeting.

The Meeting estimated a maximum residue level, STMR and HR of 2, 0.155 and 0.55 mg/kg respectively, for plums.

The value derived from use of the NAFTA calculator was 1.3 mg/kg (95/99 Rule and UCLMedian 95th). With the maximum application rate in the trials about 25% less than that specified in GAP, the Meeting agreed there was a need for a higher maximum residue level and with rounding up the value obtained from the calculator was in agreement with the estimate of the current Meeting.

The Meeting estimated a maximum residue level, STMR and HR of 3, 0.73 and 1.32 mg/kg respectively for cherries.

The value derived from use of the NAFTA calculator was 2.5 mg/kg (95/99 Rule). With the maximum application rate in the trials about 25% less than that specified in GAP, the Meeting agreed there was a need for a higher maximum residue level. Rounding up the value obtained from use of the calculator results in 3 mg/kg which was in agreement with the maximum residue level estimated by the current Meeting.

Berries and other small fruits

Supervised trials were conducted on grapes in the USA with two applications at 0.52–0.56 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for grapes (0.59 kg ai/ha × 2, PHI 7 days) were: 0.04, 0.05, 0.09, 0.13, 0.14, 0.14, 0.17, 0.18, 0.28, 0.38, 0.39, 0.55 and 0.74 mg/kg (n=13). The Meeting estimated a maximum residue level, STMR and HR at 1, 0.17 and 0.74 mg/kg respectively for grapes.

The value derived from use of the NAFTA calculator was 1.1 mg/kg (UCLMedian95th) which was comparable to the 1 mg/kg estimate of the current Meeting.

Supervised trials on strawberries were conducted in the USA with two applications at a rate of 0.38–0.40 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for low-growing berries (0.38 kg ai/ha × 2, 10 days apart, PHI 3 days) were: 0.09, 0.15, 0.39, 0.44, 0.55, 0.85 and 1.24 mg/kg (n=7). The Meeting estimated a maximum residue level, STMR and HR at 3, 0.44 and 1.24 mg/kg respectively for strawberries.

The value derived from use of the NAFTA calculator was 3.5 mg/kg (95/99 Rule, UCLMedian95th). However, based on experience of previously evaluated residue data on strawberries for a range of pesticides the Meeting agreed that a value of 3 mg/kg was sufficiently high to cover residues arising from the use of buprofezin.

Assorted tropical and sub-tropical fruit-edible peel

Supervised trials were conducted on olives in the USA with two applications at 2.37–2.44 kg ai/ha. One trial was conducted at an exaggerated rate in order to investigate effect of processing on residues. The residues of buprofezin from trials in accordance with the maximum US GAP for olives (2.26 kg ai/ha × 2, PHI 21 days) were: 0.56, 1.10, 1.15 and 1.66 mg/kg (n=4).

The Meeting estimated a maximum residue level, STMR and HR at 5, 1.125 and 1.66 mg/kg respectively.

The value derived from use of the NAFTA calculator was 3.0 mg/kg (95/99 Rule). The number of trials is smaller than 5. To accommodate the likely variation of residues a higher maximum residue level was estimated.

Assorted tropical and sub-tropical fruit-inedible peel

Supervised trials were conducted on lychees in the USA with two applications at 1.72–1.78 kg ai/ha. The residues of buprofezin from trials, in accordance with the maximum US GAP for lychees (1.69 kg ai/ha × 2, PHI 21 days) were: 0.26 mg/kg. The Meeting concluded that data were insufficient to recommend a maximum residue level.

Supervised trials were conducted on avocadoes in the USA with two applications at 1.70–1.91 kg ai/ha. The residues of buprofezin from trials, in accordance with the maximum US GAP for avocadoes (1.69 kg ai/ha × 2, PHI 21 days) were: 0.23 mg/kg. The Meeting concluded that the data were insufficient to recommend a maximum residue level for avocadoes.

Supervised trials were conducted on guavas in the USA with two applications at 1.77 kg ai/ha. No trial matched the maximum US GAP for guava (1.69 kg ai/ha × 2, PHI 21 days). The Meeting concluded that data were insufficient to recommend a maximum residue level.

Supervised trials were conducted on papaya in the USA with five applications at 0.42–0.47 kg ai/ha. As only one trial (residues: 0.62 mg/kg) matched the US GAP, the Meeting concluded that data were insufficient to recommend a maximum residue level.

Fruiting vegetables, Cucurbits

The Meeting received information on supervised trials conducted on cucumber, cantaloupe and summer squash in the USA with two applications at 0.39–0.47 kg ai/ha, except that in one trial the rate of the last application was 0.71 kg ai/ha. The GAP in the USA for cucurbits requires the maximum application rate of 0.43 kg ai/ha, maximum of four applications with the minimum of a 7 day interval, and PHI of 7 days except in California where PHI is 10 days for crops other than cucumber.

In most trials, the interval between applications was five days—shorter than the minimum interval of seven days specified in GAP. The 2008 JMPR reviewed the same US trial data on cucumber as those provided to the current Meeting and regarded them not in compliance with US GAP. Nonetheless, the current Meeting decided to use the results of those trials with 5 day intervals between applications for estimating a maximum residue level as, for the fast growing fruits, 5 day intervals were acceptable.

Supervised trials were conducted on cucumbers, (both cucumbers for consuming fresh and for pickling), in the USA with four applications at 0.43 kg ai/ha. The residues of buprofezin from trials on cucumbers for consuming fresh in accordance with the maximum US GAP for cucurbits were: 0.01, 0.03, 0.04, 0.08 and 0.20 mg/kg. The residues of buprofezin from trials on cucumbers for pickling in accordance with the maximum US GAP for cucurbits were: 0.02, 0.02, 0.03, 0.03, 0.03, 0.03, 0.05, 0.09, 0.09 and 0.30 mg/kg (n=10). The residue populations from trials on cucumbers for consuming fresh and for pickling were not significantly different (Mann-Whitney U-test).

Supervised trials were conducted on cantaloupes in the USA with four applications at 0.41–0.46 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for cucurbits were: 0.15, 0.16, 0.18, 0.19, 0.19, 0.20, 0.21, 0.33, 0.37 and 0.41 mg/kg (n=10).

Supervised trials were conducted on summer squash in the USA with four applications at 0.41–0.47 kg ai/ha. The residues of buprofezin from trials in accordance with the maximum US GAP for cucurbits were: 0.02, 0.03, 0.03, 0.04, 0.04, 0.04, 0.05, 0.05, 0.05 and 0.11 mg/kg (n=10).

The Meeting estimated a maximum residue level, STMR and HR for cucurbits, on a basis of trials on cantaloupe which led to higher residues, to be 0.7, 0.195 and 0.41 mg/kg. The Meeting withdrew the previously recommended maximum residue level of 0.2 mg/kg for cucumbers.

The value derived from use of the NAFTA calculator was 0.60 mg/kg (95/99 Rule). However, in order to cover all crops in the group of Fruiting vegetables, Cucurbits, the Meeting agreed a higher maximum residue level was necessary.

Fruiting vegetables, other than Cucurbits

The Meeting received information on supervised trials conducted on tomatoes and peppers in the USA with two applications at 0.41–0.47 kg ai/ha. The GAP in the USA for fruiting vegetables other than cucurbits requires a maximum application rate of 0.43 kg ai/ha, with a maximum of two applications and PHI of 1 day.

Supervised trials were conducted on tomatoes in the USA with two applications at 0.41–0.47 kg ai/ha with the application interval of 24–30 days (GAP: minimum of 5 days). No trial matched the maximum US GAP. The Meeting, therefore, did not revise the previous recommendation of 1 mg/kg for tomatoes.

Supervised trials were conducted on peppers in the USA with two applications at 0.42–0.45 kg ai/ha. The residues of buprofezin in bell peppers from trials in accordance with the maximum

US GAP for fruiting vegetables other than cucurbits were: 0.12, 0.16, 0.19, 0.31, 0.33, 0.34, 0.52 and 0.96 mg/kg. The residues of buprofezin in non-bell peppers from trials in accordance with the maximum US GAP for fruiting vegetables other than cucurbits were: 0.17, 0.54 and 1.1 mg/kg. The residue populations from trials on bell pepper and non-bell pepper were not significantly different (Mann-Whitney U-test); the Meeting decided to merge these results for the estimation of a maximum residue level. Combined residues were in rank order: 0.12, 0.16, 0.17, 0.19, 0.31, 0.33, 0.34, 0.52, 0.54, 0.96 and 1.1 mg/kg (n=11).

The Meeting estimated a maximum residue level for peppers to be 2 mg/kg.

The Meeting estimated an STMR and HR of 0.33 and 1.1 mg/kg respectively for peppers.

The value derived from use of the NAFTA calculator was 1.9 mg/kg (95/99 Rule). The common practice of JMPR is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up of the value to one significant figure resulted in 2 mg/kg which was in agreement with the recommendation of the present Meeting.

Legume vegetables

Supervised trials were conducted on common beans (pods and immature seeds) in the USA with two applications at 0.42–0.44 kg ai/ha. The residues of buprofezin from trials, in accordance with the maximum US GAP for snap beans (0.43 kg ai/ha × 2, PHI 14 days) were: < 0.02 mg/kg (3).The Meeting concluded that the data was insufficient to recommend a maximum residue level.

Tree nuts

Supervised trials were conducted on almonds in the USA with one application at 2.24 kg ai/ha. The residues of buprofezin in nutmeat from trials in accordance with the maximum US GAP for almond (2.26 kg ai/ha × 1, PHI 60 days) were: < 0.05 mg/kg (6).

The Meeting estimated a maximum residue level, STMR and HR of 0.05(*), 0.05 and 0.05 mg/kg respectively for almonds.

As the residues from all the trials matching GAP were below the LOQs, the NAFTA calculator was not used.

Coffee

Supervised trials were conducted on coffee in Hawaii in the USA with four applications at 1.12–1.23 kg ai/ha. The residues of buprofezin in green coffee beans from trials, in accordance with the maximum US GAP for coffee (1.12 kg ai/ha × 4, PHI 0 day) were: 0.10, 0.12, 0.16 and 0.24 mg/kg. The Meeting concluded that data were insufficient to recommend a maximum residue level.

Almond hulls

The residues of buprofezin in hulls from trials, in accordance with the maximum US GAP for almonds (2.26 kg ai/ha × 1, PHI 60 days) were: 0.07, 0.09, 0.15, 0.23, 0.25, 0.55 and 1.76 mg/kg (n=7).

The Meeting estimated a maximum residue level, STMR and highest residue of 2, 0.23 and 1.76 mg/kg respectively, for almond hulls.

The value derived from use of the NAFTA calculator was 1.7 mg/kg (UCLMedian95th). The common practice of JMPR is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up the NAFTA calculator derived value to one significant figure results in 2 mg/kg, which was in agreement with the recommendation of the Meeting.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of buprofezin in apples, plums, cherries, olives and coffee under simulated processing conditions.

Processing factors were calculated for apple (juice and wet pomace), plums (prunes), cherries (juice and jam), grapes, olives (olive oil) and coffee (roasted coffee and freeze-dried coffee) and are shown in the table below. STMR-Ps were calculated for commodities for which maximum residue levels were estimated by the current Meeting using the respective STMR and processing factor and are shown in the following table together with processing factors.

Processing factors and STMR-Ps for apples, plums, cherries, grapes, olives and their processed commodities.

Commodity	Median or best estimate of processing factor	STMR/ STMR-P, mg/kg
Apple		0.28
Apple juice	0.57	0.16
Apple wet pomace	2.0	0.56
Plums		0.155
Prunes	3.0	0.465
Cherries		0.73
Cherry juice	< 0.17	0.12
Cherry jam	< 0.17	0.12
Grape		0.17
Grape juice (pasteurized)	0.58	0.098
White wine	0.88	0.15
Red wine	0.60	0.10
Dried grapes	2.2	0.37

Apple pomace (wet), prunes, dried grapes and olive oil are expected to contain higher residues than the respective raw agricultural commodities.

Multiplying the STMR of apple found in the supervised trials by the processing factor of 2.0 and adjusting for a dry weight basis, resulted in an STMR-P estimate of 1.4 mg/kg for apple pomace (dry basis). Since the recommended maximum residue level for apple was 3 mg/kg, no maximum residue level was necessary for apple pomace.

Multiplying the HR of plums found in the supervised trials (0.55 mg/kg) by the processing factor of 3.0 resulted in an HR estimate of 1.65 mg/kg for prunes. Since the recommended maximum residue level for plums was 2 mg/kg, no maximum residue level was necessary for prunes.

Multiplying the HR of grapes found in the supervised trials (0.74 mg/kg) by the processing factor of 2.2 resulted in an HR estimate of 1.63 mg/kg for dried grapes. The Meeting estimated a maximum residue level of 2 mg/kg for dried grapes.

Since the calculated STMR-P for olive oil was 3.49 mg/kg and the recommended maximum residue level for olives was 5 mg/kg, the residues of buprofezin in olive oil is covered by the maximum residue level for olives.

On the basis of the STMR and HR for peppers and the default dehydration factor of 7, an STMR and HR for chilli peppers (dry) were calculated to be 2.31 and 7.7 mg/kg, respectively. Based on the HR, the Meeting recommended a maximum residue level for chilli peppers (dry) at 10 mg/kg.

Residues of animal commodities

The Meeting estimated the dietary burden of buprofezin residues in farm animals from the diets listed in Annex 6 of the 2006 JMPR Report. Among commodities reviewed by the 2008 and current JMPR, almond hulls (STMR-P, 0.24 mg/kg), apple pomace (wet) (STMR-P, 0.56 mg/kg) and citrus pulp, dry

(STMR-P, 1.2 mg/kg) can be fed to beef and dairy cattle. Poultry dietary burdens, through exposure to treated feed items were evaluated by the 2008 JMPR or the current Meeting.

The 2008 JMPR estimated a maximum and mean dietary burden of 0.40 ppm of dry matter diet for beef and dairy cattle in Australia. The current Meeting re-calculated animal dietary burden using almond hulls, apple wet pomace and citrus pulp, dry as shown in the table below.

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

	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	0.28	0.28	0.28	0.28	0.40[a]	0.40[a]
Dairy cattle	0.14	0.14	0.26	0.26	0.40[b]	0.40[b]

[a] Suitable for estimating maximum residue levels and STMRs for meat and edible offal.

[b] Suitable for estimating a maximum residue level and STMRs for milk.

Since the maximum and mean animal dietary burdens calculated by the current Meeting were the same as those by the 2008 JMPR, the Meeting confirmed the maximum residue levels recommended by the 2008 JMPR for meat (from mammals other than marine mammals, edible offal (mammalian) and milks at 0.05(*), 0.05(*) and 0.01(*) mg/kg respectively. It also confirmed that STMRs and HRs for these commodities were 0 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of buprofezin were calculated for the 13 GEMS/Food Consumption Cluster Diets using STMRs and STMRPs estimated by the 2008 and current Meeting (Annex 3). The ADI is 0–0.009 mg/kg bw and the calculated IEDIs were 1–50% of the maximum ADI. The Meeting concluded that the long-term intake of residues of buprofezin resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intakes (IESTI) of buprofezin were calculated for food commodities and their processed commodities using HRs/HR-Ps or STMRs/STMR-Ps estimated by the current Meeting (see Annex 4). The ARfD is 0.5 mg/kg and the calculated IESTIs were 0–30% of the ARfD for the general population and 0–50% of the ARfD for children. The Meeting concluded that the short-term intake of residues of buprofezin, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.5 CADUSAFOS (174)

TOXICOLOGY

Cadusafos is the ISO approved common name for S,S-di-sec-butyl O-ethyl phosphorodithioate (IUPAC) or O-ethyl S,S-bis(1-methylpropyl) phosphorodithioate (CAS) and has the CAS No. 95465-99-9. Cadusafos is an organothiophosphate insecticide.

The toxicity of cadusafos was first evaluated by the 1991 JMPR, when an ADI of 0–0.0003 mg/kg bw per day was established on the basis of a NOAEL of 0.03 mg/kg bw per day for the inhibition of cholinesterase activity in plasma and erythrocytes in a multigeneration study in rats and with a safety factor of 100. Cadusafos was reviewed by the present Meeting within the periodic review programme of the CCPR.

In addition to the studies evaluated in 1991, the present Meeting evaluated four new studies, a study of acute neurotoxicity and a short-term study of neurotoxicity in rats, a short-term study of dermal toxicity in rats and an assay for reverse mutation assay.

Biochemical aspects

Studies in male and female rats given [butyl-^{14}C]cadusafos at a dose of 1 mg/kg bw showed that the radiolabel was absorbed (highest blood concentrations being reached at about 4–8 h) and rapidly excreted (> 80% of the administered dose within 24 h). Of the recovered radiolabel, 70–80% was excreted in the urine, 4–14% in the faeces and 12–18% as CO_2. The results of a study with intravenous application of radiolabelled cadusafos suggested that approximately 5% of faecal excretion is attributable to biliary excretion. Oral absorption in males is therefore estimated to be close to 100% and > 90% in females. Cadusafos was widely distributed among the organs, a peak of 1.2% of the administered dose being found in the body at 7 days after dosing. Highest concentrations were observed in the liver, fat, kidney and lungs. There was no evidence for accumulation of cadusafos in the body. Cadusafos is extensively metabolized in rats. Metabolism starts by cleavage of one of the thio-butyl groups to give butyl-mercaptan and O-ethyl-S-(2-butyl) phosphorothioic acid, which can then be cleaved to S-(2-butyl) phosphorothioic acid or O-ethyl phosphorothioic acid. Butyl-mercaptan is biotransformed to methyl sec-butyl sulfide and sulfoxide and sulfone and finally to hydroxysulfones. Alternatively, butyl mercaptan can be oxidized to butyl sulfonic acid, then ethyl and methyl sulfonic acid. The results suggested that there are no significant differences between males and females in the toxicokinetic parameters and the metabolic profile observed with cadusafos a dose of 1 mg/kg bw.

Toxicological data

Cadusafos was of high to moderate toxicity by the oral route, with an LD_{50} of 30–131 mg/kg bw in rats and 68–82 mg/kg bw in mice. By the dermal route, the LD_{50} was 12–42 mg/kg bw in rabbits. By inhalation, the LC_{50} was 0.04 mg/L air in rats. In rabbits, cadusafos was not irritating to the eye or the skin. In a Buehler test, no evidence for delayed contact hypersensitivity was observed.

In studies with repeated doses, the main effect was the inhibition of cholinesterase activity in plasma, erythrocytes and brains of treated animals and related clinical and behavioural signs of intoxication.

In a 4-week feeding study in mice, the only effect was the inhibition of erythrocyte cholinesterase activity at 10 ppm and of brain cholinesterase activity at 33 ppm. The NOAEL was 3 ppm, equal to 0.83 mg/kg bw per day, on the basis of inhibition of erythrocyte cholinesterase activity at 10 ppm.

In a 4-week feeding study in rats, a NOAEL could not be identified because marked inhibition of cholinesterase activity and concomitant clinical signs were observed at the lowest dietary concentration tested, 50 ppm, equal to 4.7 mg/kg bw per day. In a 13-week feeding study in rats, very high mortality was observed at 800 ppm and one female died at the next lower dietary concentration of 5 ppm. At 800 ppm, typical clinical signs of cholinesterase inhibition were identified. Inhibition of erythrocyte cholinesterase activity was seen in males and females at 5 ppm towards the end of the study and in males and females at 800 ppm at all time-points. Brain cholinesterase activity was inhibited in females at 5 and 800 ppm and in males at 800 ppm. The NOAEL for rats was 1 ppm, equal to 0.067 mg/kg bw per day, on the basis of reduced erythrocyte and brain cholinesterase activity at 5 ppm.

In a 2-week study in dogs given capsules containing cadusafos, no treatment-related effects were observed up to 0.02 mg/kg bw per day, the highest dose tested. In a 13-week study in dogs given capsules, no effects on erythrocyte and brain cholinesterase activity was observed up to 0.09 mg/kg bw per day, the highest dose tested. The only effect was a decrease in mean testes weights at 0.03 mg/kg bw per day and above. Therefore, the NOAEL was 0.01 mg/kg bw per day. In a second 13-week study in dogs given a newer batch of cadusafos, the effect on testes weights was no longer observed up to 0.1 mg/kg bw per day, the highest dose tested. In a 1-year study in dogs fed capsules, no treatment-related clinical effects were observed and erythrocyte and brain cholinesterase activity were not inhibited at up to 0.02 mg/kg bw per day, the highest dose tested. The only finding was inhibition of plasma cholinesterase activity in females at 0.005 and 0.02 mg/kg bw per day. The Meeting considered that this effect was not toxicologically relevant, and the NOAEL was thus 0.02 mg/kg bw per day, the highest dose tested. The overall NOAEL for 13-week and 1-year studies in dogs was 0.09 mg/kg bw per day on the basis of the absence of any toxicologically relevant effects at the highest dose tested in the 13-week study.

Cadusafos was tested for genotoxicity in an adequate range of studies. In the submitted studies, there was no evidence for genotoxicity in vitro or in vivo.

The Meeting concluded that cadusafos was unlikely to be genotoxic.

In a 94–97 week feeding study in mice, plasma and erythrocyte cholinesterase activity was reduced in males and females and brain cholinesterase activity in males at the highest dietary concentration of 5 ppm, equal to 0.705 mg/kg bw per day. The incidence of non-neoplastic lesions such as cortical atrophy and hypertrophy/hyperplasia in the adrenals were increased in rats at 5 ppm when compared with controls, but there was no consistent dose–response relationship. Duodenal epithelial hyperplasia was increased in females at 5 ppm, and necrotizing arteritis of the kidneys was increased in males at 1 ppm and 5 ppm. Non-dose-related increases in the incidences of lung and liver tumours in males were not considered to be treatment-related. In males, an increase in the incidence of lymphoreticular tumours was observed (8 out of 49 and 11 out of 50 at 1 and 5 ppm, respectively, versus 6 out 49 in the controls) that was also greater than the incidence observed in one contemporary historical-control group. As the increase was not statistically significant and lymphoreticular tumours are common in aging mice, the effect was not considered to be treatment-related. The NOAEL was 0.5 ppm, equal to 0.072 mg/kg bw per day, on the basis of histological changes in the kidneys of male mice at 1 ppm. The Meeting concluded that cadusafos is not carcinogenic in mice.

In a 100–104 week feeding study in rats, females receiving the highest dietary concentration of 5 ppm showed decreased locomotion activity. Additionally, slightly more males showed lacrimation at this dietary concentration than did all other groups. Although brain cholinesterase activity was not inhibited at 12 months or at study termination in any group, plasma and erythrocyte acetylcholinesterase activity was inhibited (mostly statistically significantly) throughout the whole dosing period in males and females at 5 ppm. No increase in the frequency of any non-neoplastic or neoplastic changes was observed. The NOAEL was 1 ppm, equal to 0.045 mg/kg bw per day, on the basis of inhibition of erythrocyte acetylcholinesterase activity and depressed locomotor activity at 5 ppm. The Meeting concluded that cadusafos is not carcinogenic in rats.

In the absence of genotoxic and carcinogenic potential, the Meeting concluded that cadusafos is unlikely to pose a carcinogenic risk to humans.

The reproductive toxicity of cadusafos has been investigated in a two-generation study in rats. No treatment-related clinical signs were observed in any parental group. A slight and not dose-related decrease in the body weights of lactating F_1 females was observed at all doses. The Meeting considered this effect to be of questionable toxicological relevance. In F_1 males, a mild decrease in absolute liver and brain weights was observed without any histological correlates at 5 ppm, equal to 0.262 mg/kg bw per day. At 5 ppm, male and female F_0 and F_1 rats had statistically significantly lowered plasma and erythrocyte acetylcholinesterase activity in the pre-mating phase and at weaning. Reproductive performance, litter data and postnatal development were not affected by treatment. The NOAEL for parental toxicity was 0.5 ppm, equal to 0.026 mg/kg bw per day, on the basis of erythrocyte cholinesterase inhibition at 5 ppm. The NOAEL for reproductive and developmental toxicity was 5 ppm, the highest dose tested.

The developmental toxicity of cadusafos has been investigated in rats and rabbits. In the study in rats, maternal body weights and food intake were decreased at the highest dose of 18 mg/kg bw per day. One rat in the group at 6 mg/kg bw per day and all rats at the highest dose showed severe signs of intoxication starting on day 7 of gestation. Litter data were not affected by treatment in any group. Body weights of male and female pups at the highest dose were reduced by 8% and 6%, respectively. The incidence of fetuses with absent sternebrae and partially ossified supraoccipital bone, sternebrae and absent metcarpals was increased at 18 mg/kg bw per day, and there were more fetuses with absent xiphoid at 6 and 18 mg/kg bw per day. A non-statistically significant increase in the incidence of dilated ureters in litters and fetuses was found at 18 mg/kg bw per day. The NOAEL for maternal toxicity was 2 mg/kg bw per day on the basis of clinical signs in dams at 6 mg/kg bw. The NOAEL for developmental toxicity was 2 mg/kg bw on the basis of absent xiphoids in fetuses at 6 mg/kg bw.

In a range-finding study of developmental toxicity in rabbits, an increase in mortality (one death at study day 8 and another one at day 20) was observed at 1.0 mg/kg bw per day and above and the surviving rabbits showed lower body-weight gain compared with the controls. In the main study in rabbits, one rabbit died on day 15 at 0.3 mg/kg bw per day, two rabbits at 0.9 mg/kg bw per day aborted on day 27, one rabbit delivered on day 28 and two rabbits died (one on day 20 and the other on day 23). Additionally, an increased incidence of several other clinical signs of neurotoxicity induced by cholinesterase inhibition were observed at doses of 0.3 mg/kg bw per day and above, starting on day 15. At a dose of 0.2 mg/kg bw per day, there was marked inhibition of erythrocyte acetylcholinesterase activity in the range-finding study. At 0.3 and 0.9 mg/kg bw per day, the frequency of early resorptions was increased while the frequency of late resorptions decreased. The Meeting did not consider this finding to be treatment-related, because the total number of resorptions was only minimally increased and because the ratio of early to late resorptions is highly variable. No treatment-related effects were observed on fertility, the number of corpora lutea, the implantation sites, litter size, sex ratio, viability, fetal body weight, skeletal or visceral development. The NOAEL for maternal toxicity was 0.1 mg/kg bw per day on the basis of clinical signs at 0.3 mg/kg bw per day. The NOAEL for developmental toxicity was 0.9 mg/kg bw per day, the highest dose tested. The Meeting concluded that cadusafos was not teratogenic at doses that were not toxic to dams.

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

In a study of delayed neurotoxicity in hens, one out of ten hens given cadusafos at a dose of 8 mg/kg bw (a potentially lethal dose) showed axonal degeneration in the spinal cord, but not in the peripheral nervous system. In view of the fact that clinical signs of delayed neuropathy were not observed and that axonal lesions in the spinal cord were observed occasionally in hens in the control group, the Meeting concluded that cadusafos is unlikely to cause delayed neuropathy at lethal doses.

In a study of acute neurotoxicity in rats, two females at 40 mg/kg bw group died on treatment days 2 and 3, respectively. Treatment-related clinical signs were noted in rats at 25 or 40 mg/kg bw.

These signs resolved within 5 days. Females at 40 mg/kg bw were soiled by body fluids on day 0 and were limp when handled, showed abnormal posture, tremors, staggered gait, splayed hindlimbs and reduced motor activity in the open field, reduced hindlimb grip strength and a significant increase in tail-flicking latency. At day 7 and 14, no FOB effects were observed in any group. At study termination, no gross lesions or microscopic changes in nervous tissues were observed. At 25 and 40 mg/kg bw, plasma and erythrocyte cholinesterase activity was inhibited. Brain cholinesterase activity was not statistically significantly inhibited at any dose, but individual data showed an increase in the incidence of rats with low brain cholinesterase activity at 25 and 40 mg/kg bw. The NOAEL was 0.02 mg/kg bw on the basis of inhibition of erythrocyte and brain cholinesterase activity, FOB effects and clinical signs at 25 mg/kg bw. The Meeting noted the large dose spacing in the study of acute neurotoxicity. In a 13-week feeding study of neurotoxicity in rats, females at 300 ppm showed increased hypersensitivity and males displayed a reduction in the landing foot-splay parameter and forelimb grip strength was reduced. No other FOB effects were observed and motor activity was not affected at any dose and no treatment-related gross lesions or histological changes in the nervous system were seen. In the groups at 300 ppm at study termination, plasma, erythrocyte and brain cholinesterase activity was reduced statistically significantly in males and females (erythrocyte cholinesterase activity was not statistically significantly reduced in females). The NOAEL was 0.5 ppm, equal to 0.031 mg/kg bw per day, on the basis of clinical signs, reduced body weights and reduced erythrocyte and brain cholinesterase activity at 300 ppm. The Meeting considered that cadusafos is neurotoxic.

No reports on health effects in personnel exposured to cadusafos were submitted.

Toxicological evaluation

The Meeting established an ADI of 0–0.0005 mg/kg bw based on a NOAEL of 1 ppm, equal to 0.045 mg/kg bw per day, identified on the basis of inhibition of erythrocyte cholinesterase activity at 5 ppm, equal to 0.222 mg/kg bw per day, in the long-term study in rats. A safety factor of 100 was applied.

The Meeting established an ARfD of 0.001 mg/kg bw based on a NOAEL of 0.1 mg/kg bw per day identified on the basis of clinical effects in dams at 0.3 mg/kg bw per day in the study of developmental toxicity in rabbits. A safety factor of 100 was applied. The large dose spacing between the LOAEL and the NOAEL in the study of acute neurotoxicity made this study unsuitable for the derivation of an ARfD. The Meeting also noted that the ARfD established might be conservative because it was derived using clinical signs that occurred only after administration of several doses.

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	0.5 ppm, equal to 0.072 mg/kg bw per day	1 ppm, equal to 0.141 mg/kg bw per day
		Carcinogenicity	5 ppm, equal to 0.705 mg/kg bw per day[d]	—
Rat	Two-year study of toxicity and carcinogenicity[a]	Toxicity	1 ppm, equal to 0.045 mg/kg bw per day	5 ppm, equal to 0.222 mg/kg bw per day
		Carcinogenicity	5 ppm, equal to 0.222 mg/kg bw per day[d]	—
	Two-generation study of	Reproductive	5 ppm, equal to	—

	reproductive toxicity[a]	toxicity	0.262 mg/kg bw per day[d]	
		Parental toxicity	0.5 ppm, equal to 0.0262 mg/kg bw per day	5 ppm, equal to 0.262 mg/kg bw per day
		Offspring toxicity	5 ppm, equal to 0.262 mg/kg bw per day[d]	—
	Developmental toxicity[b]	Maternal toxicity	2 mg/kg bw per day	6 mg/kg bw per day
		Embryo/fetotoxicity	2 mg/kg bw per day	6 mg/kg bw per day
	Acute neurotoxicity[b]	Toxicity	0.02 mg/kg bw	25 mg/kg bw
Rabbit	Developmental toxicity[b]	Maternal toxicity	0.1 mg/kg bw per day	0.3 mg/kg bw per day
		Embryo/fetotoxicity	0.9 mg/kg bw per day[d]	—
Dog	Combined from a 13-week and a one-year studies[c]	Toxicity	0.09 mg/kg bw per day[d]	—

[a] Dietary administration.

[b] Gavage administration.

[c] Capsule administration.

[d] Highest dose tested.

[e] Lowest dose tested.

Estimate of acceptable daily intake for humans

0–0.0005 mg/kg bw

Estimate of acute reference dose

0.001 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 cadusafos

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid, 90–100%
Distribution	Extensive, highest levels in liver, fat, kidney and the lungs
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid, nearly complete within 48 h, mainly via urine
Metabolism in animals	Extensive, primarily via oxidation and cleavage
Toxicologically significant compounds (animals, plants and the environment)	Cadusafos

Acute toxicity	
Rat, LD_{50}, oral	30 mg/kg bw
Rabbit, LD_{50}, dermal	12 mg/kg bw
Rat, LC_{50}, inhalation	0.04 mg/L air
Rabbit, dermal irritation	Not an irritant
Rabbit, ocular irritation	Not an irritant
Guinea-pig, dermal sensitization (test method used)	Not a sensitizer (Buehler)
Short-term studies of toxicity	
Target/critical effect	Erythrocyte cholinesterase inhibition (rat)
Lowest relevant oral NOAEL	0.067 mg/kg bw per day (rat)
Genotoxicity	
	Not genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Erythrocyte cholinesterase inhibition and decreased locomotor activity (rat)
Lowest relevant NOAEL	1 ppm, equal to 0.045 mg/kg bw per day (rat)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans
Reproductive toxicity	
Reproduction target/critical effect	No reproductive effects
Lowest relevant reproductive NOAEL	5 ppm, equal to 0.262 mg/kg bw per day, highest dose tested (rat)
Developmental target/critical effect	Skeletal findings at overtly maternally toxic doses (rat)
Lowest relevant developmental NOAEL	2 mg/kg bw per day (rat)
Neurotoxicity/delayed neurotoxicity	
	Organothiophosphorous compound, neurotoxic. No evidence of delayed neuropathy

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.0005 mg/kg bw	Long-term study; rat	100
ARfD	0.001 mg/kg bw	Study of development toxicity; rabbit	100

DIETARY RISK ASSESSMENT

Deferred to 2010, when residue re-evaluation is scheduled

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5.6 CARBOFURAN (096)

RESIDUE AND ANALYTICAL ASPECTS

Carbofuran, 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate, is a systemic insecticide, nematicide, and acaricide. Its uses include seed treatment, at-planting soil application, and directed or foliar applications. Carbosulfan, a pesticide in itself, produces carbofuran as a major metabolite. The main use of carbosulfan is on citrus fruits. In evaluating carbofuran, account should be taken of its residues arising from the use of carbosulfan on citrus.

A periodic review of the toxicology of carbofuran was carried out by the 1996 JMPR. An ADI of 0–0.002 mg/kg bw was established. In 2002, an ARfD of 0.009 mg/kg bw was established. The 2008 JMPR evaluated newly submitted studies on acute toxicity and re-examined relevant data which had been considered by previous Meetings. The 2008 Meeting established an ARfD of 0.001 mg/kg bw. The Meeting noted that this ARfD was lower than the current ADI of 0–0.002 mg/kg bw. The Meeting 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.

A periodic review of the residue and analytical aspects of both carbofuran and carbosulfan was carried out by the 1997 JMPR. The carbofuran residue is defined as carbofuran + 3-hydroxycarbofuran for compliance with MRLs. For the purposes of dietary intake, the residue definition for carbofuran arising from use of carbosulfan and carbofuran is carbofuran + free and conjugated 3-OH carbofuran, expressed as carbofuran. The analytical methods include an acid hydrolysis step to release the conjugate. The residue definition for carbosulfan for compliance with MRLs and estimation of dietary intake is carbosulfan.

When carbofuran was re-evaluated by the JMPR in 2002 and 2003, short-term risks were assessed for commodities for which recommendations had been made at those Meetings, i.e., rice, sweet corn, maize and potato. In 2003, the CCPR at its Thirty-fifth Session, taking into account concerns expressed by the Delegation of Australia and the Observer from the European Commission, requested GEMS/Food to perform a full short-term intake assessment of carbofuran, to include all the commodities for which recommendations existed, but were not evaluated previously due to a lack of an ARfD. The assessment was presented to the Thirty-sixth Session of the CCPR (CX/PR 03/4). Except for the consumption of oranges (sweet and sour) by children, none of the IESTI values exceeded the ARfD of 0.009 mg/kg bw. The assessment for oranges was conducted with the highest residue (HR) level in the edible portion of 0.5 mg/kg, as recommended by the 1997 JMPR for oranges, sweet, sour. Coming from a residue data set in whole oranges derived from 53 supervised trials conducted with carbosulfan according to GAP. A maximum residue level of 0.5 mg/kg and a STMR of 0.1 mg/kg were also recommended.

At its Thirty-sixth Session, the Committee noted (ALINORM 04/27/24) that the European Commission had established an ARfD 10 times lower than that established by the JMPR. The Committee decided to return to Step 6 the draft MRLs for cantaloupe, cucumber, mandarin, oranges, sweet and sour, summer squash; and sweet corn (corn-on-the-cob) to address short-term intake concerns.

JMPR 2004 evaluated data on residues in orange pulp in supervised trials conducted with carbosulfan previously submitted to the 1997 JMPR. The Meeting estimated an STMR and a highest residue level of 0.05 mg/kg for carbofuran in orange pulp. Using the HR of 0.05 mg/kg for citrus and the contemporary ARfD of 0.009 mg/kg bw, no acute intake concerns were noted.

However, following the re-evaluation of the toxicology which resulted in lowering the ARfD to 0.001 mg/kg bw, JMPR 2008 noted that the IESTI was higher than the ARfD for banana, cucumber, cantaloupe, milks, oranges, potato, summer squash and sweet corn on the cob (from 120 to 510% ARfD; general population). For children, the IESTI was higher than the ARfD also for mandarins (from 280 to 810% ARfD).

In 2008, the CCPR at its Fortieth Session decided to return the draft MRLs for cantaloupe, cucumber, mandarin, oranges, sweet and sour, potato, summer squash and sweet corn (corn-on-the-cob) to Step 6 due to acute intake concerns, awaiting a review of toxicology by the 2008 JMPR. A delegation indicated that they would provide carbosulfan metabolism data on citrus fruit in order to refine the acute dietary risk assessment.

In 2009, at its Forty-first Session the Committee decided to withdraw the draft MRLs for cantaloupe, cucumber, potato, summer squash, and sweet corn (corn-on-the-cob) due to the lack of new data available to resolve the dietary intake concerns, and to retain the draft MRLs for mandarin and orange, sweet and sour at Step 7 awaiting the 2009 JMPR dietary intake estimation. The Committee also decided to recommend revocation of the Codex MRLs for potato and milk because of dietary intake concerns. The Committee noted the concern form submitted by EC relating to the use of different ARfDs and agreed to reconsider the Codex MRLs for banana; edible offal; maize; meat; milks, rice husked, sugar beet, sugarcane and sunflower seed for the further discussion at its next meeting based on the JMPR response.

The Meeting received information on the metabolism of carbosulfan residues in oranges from a Delegation to the CCPR. In addition the manufacturer supplied comments on the current carbofuran dietary risk assessment for bananas and citrus fruit.

Plant metabolism/Results of supervised residue trials on crops

No new data were received for the current assessment. Both the Delegation to the CCPR and the manufacturer suggested a re-evaluation of the data, already available to JMPR 1997. The manufacturer resubmitted the relevant original study reports (metabolism of carbosulfan in/on oranges, residues in bananas and residues in oranges and mandarins).

Citrus fruits

Previously, for the citrus fruits oranges sweet, sour and mandarins, JMPR has recommended two maximum residue levels to cover carbosulfan-treated crops. One recommendation is for the parent compound carbosulfan. The other relates to the major metabolites, carbofuran + 3-hydroxy carbofuran. The maximum residue level for carbofuran gives rise to intake concerns, see above. The maximum residue level for carbosulfan does not give rise to intake concerns, but cannot go forward in the Codex step procedure because it arises from the same use as the carbofuran level.

JMPR 1997 evaluated 30 supervised field trials with carbosulfan on clementines, mandarins and oranges, conducted in 1993–4 in Brazil, Mexico and Spain. GAP on oranges was available for Brazil (2 applications of 0.93–1.69 g ai/tree, PHI 7 days) and Mexico (3–4 applications of 250 g ai/ha, PHI 7 days). Furthermore, Spanish GAP was available for oranges (2 applications of 2.83–3.14 g ai/tree or 937.5 g ai/ha, PHI 112–147 days) and mandarins and clementines (2 applications of 3.2–3.6 g ai/tree or 937.5 g ai/ha, PHI 110–115 days). The 1997 Meetings estimations were based on a dataset derived from both GAPs.

JMPR 2004 re-evaluated data on residues in orange pulp in supervised trials conducted with carbosulfan and submitted to the 1997 JMPR. The Meeting agreed that it is unlikely that residues of carbamates arising from the use of carbosulfan will be present in orange pulp at levels higher than the LOQ (0.05 mg/kg). The Meeting estimated an STMR and a highest residue level of 0.05 mg/kg for carbofuran in oranges, sweet, sour. This estimate was supported by a study on metabolism evaluated by the 1997 JMPR, in which the pulp of oranges treated with [^{14}C]carbosulfan contained no more than 0.3% of the total radioactive residues 30 days after treatment.

The present Meeting noted again that the carbosulfan metabolism study in oranges (evaluated by 1997 JMPR and resubmitted to the present Meeting both by the Belgian Delegation to the CCPR and the manufacturer) demonstrated that at day 0, 7, 15 and 30 less than 0.3% of the total radioactivity was found in the edible pulp of the fruit (as was also concluded by the 2004 JMPR). In

the 1997 JMPR evaluation, the highest residue (carbofuran + 3-hydroxycarbofuran) in whole fruit from the dataset selected for maximum residue level-setting was 0.5 mg/kg. This would equal a residue of 0.0015 mg/kg in the pulp (0.3% × 0.5 mg/kg).

In addition, the Meeting noted that in six of the Spanish trials evaluated by JMPR 1997, residues in peel and pulp were measured (JMPR Evaluation 1997, Table 22, page 228–233). All of these trials were considered to be relevant for estimating the maximum residue level. The LOQ of the method was 0.05 mg/kg. For samples where analysis resulted in residues below LOQ, but above LOD, estimated residue values were reported and marked as such in the JMPR evaluation. Not in all cases was peel/pulp data available at all sampling dates, sometimes only at days lower than the PHI (110–147 days for the various citrus varieties), see Table 5. In the pulp, estimated carbofuran residues were 0.01 mg/kg (PHI 45 days) (2); < 0.01 mg/kg (PHI 104/5 days), and 0.02 mg/kg (PHI 92 days). However, in the latter trial the control sample was also estimated to contain 0.02 mg/kg. The Meeting concluded that these data support the observation from the metabolism study that residues in pulp would be below 0.01 mg/kg.

Table 5 Estimated residues of carbofuran and 3-hydroxycarbofuran in orange and mandarin pulp resulting from supervised trials in Spain after 2 applications of a 250 EC formulation at 937.5 g ai/ha, 3000 L/ha. (Annex 5, reference *81*, Table 22, p 228–233)

Year, location, variety	PHI (days	Estimated residue [a] (furan + HO-furan) mg/kg	Reference
1993, Sueca, Newhall oranges	45	0.01	Gill, 1995d
1993, Benifay, Navel oranges	0	0.6 (c=1.1)	Gill, 1995d
	45	0.01	
1994, Catadau, Clementines	0	0.03	Gill, 1996a
	30	0.02	
	60	< 0.01	
	104	< 0.01	
1994, Sueca, Satsumas	0	0.07	Gill, 1996b
	45	0.03	
	92	0.02 (c=0.02)	
1994, Carlet, Naveline oranges	0	< 0.01	Gill, 1996c
	45	< 0.01	
	105	< 0.01	
	140	< 0.01	
1994, Sueca, Newhall oranges	0	< 0.01	Gill, 1996c
	45	< 0.01	
	105	< 0.01	
	140	< 0.01	

[a] 'estimated residue' indicates a residue below the LOQ, but above the LOD

The Meeting estimated an STMR and a highest residue level of 0.01 mg/kg for carbofuran in oranges, sweet, sour to replace the previous estimation of 0.05 mg/kg. The Meeting extrapolated these values to mandarin.

Banana

In bananas, carbofuran residues arise from the use of carbofuran directly. The 1997 JMPR concluded the following on the banana supervised field trials available.

"Field trials in Spain, Central America and South America with the application of carbofuran to banana trees were reported. No residues of carbofuran plus 3-hydroxycarbofuran (< 0.02–< 0.1 mg/kg, n=8) were found in any trial. GAP was available only for Spain, where the trial was according to GAP and undetectable residues were < 0.02 mg/kg. Because none of the trials, some of

which were at higher rates than GAP, yielded detectable residues the Meeting estimated a maximum residue level of 0.1(*) mg/kg, the same as the existing Codex MRL, and an STMR of 0.1 mg/kg."

The present Meeting noted that in the eight Central and South American trials, no residues of carbofuran or 3-hydroxy carbofuran were found in any sample. The LOQ was 0.05 mg/kg both for carbofuran and for 3-hydroxy carbofuran, so the two compounds together are quantifiable at 0.1 mg/kg. However, no residue was detected in whole fruit up to the limit of detection of 0.01 mg/kg for each of the compounds. Some peel and pulp samples were also analysed and showed the same results.

In an additional Brazilian trial no residues were found higher than the LOQ of 0.1 mg/kg (the report was much summarized; it is assumed that this level refers to the sum of carbofuran and 3-hydroxy carbofuran). In another summarized report on a Spanish trial no residues were detected in either pulp or peel below the LOQ of 0.05 mg/kg (again it is assumed that this level refers to the sum of carbofuran and 3-hydroxy carbofuran). In this trial, no residue was detected above the LOD of 0.02 mg/kg.

Monitoring data from the United States Department of Agriculture (USDA) show that in the period of 1994 to present, almost 4000 banana samples have been analysed and in all cases, no carbofuran or 3-hydroxy carbofuran residues have been detected above the LOD. The reported LOD varied depending on the year and the laboratory that performed the measurements. No information was provided on the analytical methods employed. Furthermore, no information on the percentage of crop treated during this period was available. The Meeting noted that carbofuran is not registered for use on bananas in the USA. The Meeting considered that bananas are not generally grown in the USA. Therefore, a significant part of the bananas tested presumably originate from countries where carbofuran can be used on bananas, such as countries in Central and South America. The Meeting agreed that the monitoring data provide supporting evidence that residues are not to be expected in bananas.

The Meeting also considered that in the case of bananas, a zero-residue situation seems plausible. The Meeting decided to use the LODs for carbofuran and 3-hydroxy carbofuran as reported in the eight Central and South American trials (0.01 mg/kg for each of them) for the estimation of the STMR and HR.

The Meeting estimated an STMR and a highest residue level of 0.02 mg/kg for carbofuran in bananas to replace the previous estimation of 0.1 mg/kg.

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 by the 2008 JMPR for the 13 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by previous Meetings. 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 banana, oranges and mandarins using an HR of 0.01 mg/kg for oranges and mandarins and an HR of 0.02 mg/kg for bananas. The results are shown in Annex 4. For the general population, the IESTI was 80% of the ARfD for banana, 20% for mandarins, and 30% for oranges. For children, the IESTI was 150% of the ARfD for banana, 40% for mandarins, and 60% for oranges. The information provided to the 2009

JMPR precludes an estimate that the short-term intake of residues of carbofuran from the consumption of banana, will be below the ARfD. The short-term intake of residues of carbofuran from uses of carbosulfan on mandarins and oranges is unlikely to present a public health concern.

The Meeting noted that the short-term dietary risk assessment of bananas could be refined if a metabolism study on banana were available, or residue trials employing a very sensitive analytical method. The ARfD was reviewed by the present Meeting on a request by CCPR (Section 3.2). The ARfD of 0.001 mg/kg bw was confirmed and it is unlikely that it could be refined.

5.7 CHLOROTHALONIL (081)

TOXICOLOGY

Chlorothalonil is the ISO approved common name for tetrachloroisophthalonitrile. Chlorothalonil (CAS No. 1897-45-6) is a non-systemic foliar fungicide used to control a wide range of fungal diseases in a variety of crops.

Chlorothalonil was previously evaluated by the JMPR in 1974, 1977, 1978, 1979, 1981, 1983, 1985, 1987, 1990 and 1992. In 1990, an ADI of 0–0.03 mg/kg bw was established based on the NOAEL of 3 mg/kg body weight per day, identified in a 2-year study in dogs, which was evaluated in 1974.

Chlorothalonil was re-evaluated by the present Meeting as part of the periodic review programme of the CCPR. The present Meeting evaluated newly submitted studies, including mechanistic studies in rats into the effects of chlorothalonil on the kidneys and studies on SDS-3701, a metabolite that is found in plants, soil and ruminants. Both the new data and the relevant data from previous studies were considered by the present Meeting.

All critical studies complied with GLP.

Biochemical aspects

In rats given a single oral dose of chlorothalonil at 1.5–50 mg/kg bw, absorption was about 31%, with 17–21% being excreted in the bile and about 8–12% being excreted in the urine. At 200 mg/kg bw, excretion in the bile (8%) and the urine (5%) was lower, suggesting that saturation of absorption was occurring. In females, biliary excretion was lower (–20%) and urinary excretion was higher (about +35%) than in males. Urinary excretion in mice and dogs was about 5–10% and 1.4%, respectively. In rats, the highest tissue concentrations were found in the kidney, probably due to binding to kidney proteins. Chlorothalonil is metabolized via initial glutathione conjugation and subsequent enzymatic processing of the di-and triglutathion substituents via the mercapturic acid and cysteine conjugate β-lyase pathways yielding N-acetyl cysteine, cysteinyl-glycine and S-methyl-derivates.

Toxicological data

The acute oral and dermal toxicity of chlorothalonil is low (oral and dermal LD_{50}, > 5000 mg/kg bw). A study of acute inhalation yielded a LC_{50} of 0.1 mg/L air. Chlorothalonil is a mild skin irritant and is severely irritating to the eye. No valid test for sensitization was available. In EHC 183, it is reported that the results of studies of skin sensitization in guinea-pigs were inconclusive[29].

Studies of toxicity with repeated doses showed that in mice and rats, but not in dogs, the kidney is the prime target organ for systemic toxicity attributable to chlorothalonil. In studies in mice and rats, chlorothalonil also caused local toxicity in the forestomach. In a 90-day study in mice, the NOAEL for systemic effects was 275 ppm, equal to 48 mg/kg bw per day, on the basis of an increased incidence of hyperplasia in the proximal tubules of the kidneys and increased kidney weight at 750 ppm, equal to 124 mg/kg bw per day. In a 13-week study in rats, the NOAEL for systemic effects was 10 mg/kg bw per day on the basis of increased kidney weights and hyperplasia in the kidneys at 40 mg/kg bw per day.

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[29] IPCS (1996) Chlorothalonil. Environmental Health Criteria 183. (http://www.inchem.org/documents/ehc/ehc/ehc183.htm#SectionNumber:8.1)

Studies of acute toxicity in rats have demonstrated that chlorothalonil, given by gavage, induces renal tubular necrosis in the S2 segment of the proximal convoluted tubules (hyper-eosinophilic cells, multi-focal hydropic vacuolation). These effects were observed at doses of 175 mg/kg bw and higher. The overall NOAEL for toxic effects on the kidney in studies of acute toxicity was 60 mg/kg bw per day.

In a 90-day study in dogs, the NOAEL for systemic effects was 15 mg/kg bw per day on the basis of reductions in body-weight gain and changes in clinical chemistry parameters, (not related to kidney toxicity) at 150 mg/kg bw per day. In a 1-year study in dogs, the NOAEL was 150 mg/kg bw per day on the basis of reduced body-weight gain, reduced serum albumin and total protein, and increased relative liver weight and serum cholesterol at 500 mg/kg bw per day.

In a 2-year study of carcinogenicity in mice, the LOAEL was 750 ppm, equal to 119 mg/kg bw per day (the lowest dose tested), on the basis of increased kidney weights, macroscopic changes in the kidney and forestomach, microscopic changes in the kidney, forestomach and oesophagus. In addition, at the LOAEL renal tubular adenomas and carcinomas in males and forestomach tumours, mainly squamous cell carcinomas in males and females were found. In a second 2-year study of carcinogenicity in mice, no pre-neoplastic changes in the forestomach were observed at 10/15 ppm, equal to 1.9 mg/kg bw per day. Increased incidences in hyperplasia and hyperkeratosis of the forestomach were observed at dietary concentrations of 40 ppm and higher, equal to 5.1 mg/kg bw per day. A slightly higher incidence in forestomach tumours was observed at doses of 750 ppm, equal to 98 mg/kg bw per day. In this study, increased incidences in renal tubular hyperplasia and karyomegaly were observed at doses of 175 ppm and higher, equal to 23 mg/kg bw per day. No effects on kidneys were observed at 40 ppm, equal to 5.1 mg/kg bw per day.

Three long-term studies of toxicity in rats were available. In the first study, the LOAEL was 40 mg/kg bw per day (the lowest dose tested) on the basis of macroscopic and histopathological lesions of the kidneys, increased incidence of kidney tumours, changes in urine-analysis parameters, increased kidney weights, histological changes in the oesophagus, forestomach, glandular stomach and duodenum and an increased incidence of forestomach papillomas. In a second study in rats, the NOAEL was 1.8 mg/kg bw per day on the basis of an increased incidence of renal tubular epithelial hyperplasia in females at 3.8 mg/kg bw per day. In a third study in rats, the NOAEL was 2.7 mg/kg bw per day and the LOAEL was 10.6 mg/kg bw per day on the basis of increased kidney weight, changes in kidney macroscopy and histology and haematological changes.

In the long-term studies of toxicity in rats, kidney tumours, predominantly tubular adenomas and carcinomas, were observed at dietary doses equal to 15 mg/kg bw per day in males or higher in males and females. The overall NOAEL for kidney tumours in rats was 3.8 mg/kg bw per day. Also in the three long-term studies of toxicity in rats, forestomach tumours (papillomas and carcinomas) were observed at doses of 3.8 mg/kg bw per day and higher.

Chlorothalonil was tested for genotoxicity in vitro and in vivo in an adequate range of studies. Chlorothalonil was not mutagenic in bacteria or in tests for gene mutation in vitro in the absence or presence of metabolic activation. The results of a test for chromosomal aberration in CHO cells in vitro were positive in the absence of metabolic activation but negative in the presence of metabolic activation. However, the results of numerous tests for clastogenicity in vivo in several species (i.e., mice, rats, Chinese hamsters) given single or repeated doses were negative, except for a few inconclusive or equivocal findings.

Considering all the results of studies of genotoxicity, the Meeting concluded that it is unlikely that chlorothalonil is genotoxic.

Repeated dosing with chlorothalonil resulted in hyperplasia and tumour formation in the forestomach in rats and mice. Oral administration of a mono-glutathione conjugate of chlorothalonil did not cause forestomach toxicity, suggesting that forestomach lesions are a consequence of a direct irritant effect of chlorothalonil. Chlorothalonil did not cause tumours in the oesophagus, which also has squamous epithelium. This indicates that this substance needs to be in prolonged contact with

squamous epithelium in order to induce tumours. The data indicate a process that starts with irritation and cytotoxicity, followed by cell proliferation, ulceration and erosion, regenerative hyperplasia and hyperkeratosis and ultimately resulting in forestomach tumours. Chlorothalonil did not induce tumours in the glandular stomach in rats and mice. Unlike rats and mice, humans and dogs do not have a forestomach. In a 1-year study in dogs, no stomach lesions were observed at doses up to 500 mg/kg bw per day. In a 2-year dietary study in dogs, which was evaluated by JMPR in 1992, moderate to severe gastritis was found irregularly at dietary concentrations of 15000 ppm, equivalent to 375 mg/kg bw per day, and higher. The Meeting considered the forestomach tumours induced by chlorothalonil to be a rodent-specific lesion that is not relevant for humans, because of differences in anatomy and function.

The studies of mode of action of chlorothalonil in kidney toxicity in rats and studies with repeated doses show that chlorothalonil-induced renal tumours occur as a direct consequence of sustained damage to the S2 segment of the proximal tubules of the kidney. The occurrence of tumours is preceded by renal cytotoxicity, which is followed by regenerative cell proliferation/hyperplasia. Renal cytotoxicity and regenerative cell proliferation occur at doses lower or similar to those causing tumours. Cytotoxicity/regenerative proliferation is a well-established mode of action for the formation of kidney tumours, although the cause of the initial cytotoxicity may differ. On the basis of information on other chlorinated compounds, it is possible that the nephrotoxicity caused by chlorothalonil may be due to reactive metabolites formed from the renal β-lyase cleavage of cysteine-S conjugates transported in the renal tubular cells. This mode of action is supported by the finding that when a mono-glutathion conjugate of chlorothalonil is administered orally, similar kidney lesions are observed at a comparable dose. Because human β-lyase activity is lower in human kidney tissue than in that of rodents, rodents would be expected to be more sensitive to this bioactivation pathway. In a 2-year dietary study in dogs, which was evaluated by JMPR in 1992, renal glomerulosclerosis and degenerative renal tubular changes (tubular hypertrophy and dilation) were found at dietary concentrations of 15000 ppm and higher, equivalent to 375 mg/kg bw per day. The kidney toxicity in dogs given high doses of chlorothalonil only is likely be due to species differences in bioactivation (as well as absorption). However, there is insufficient data on chlorothalonil to quantitatively characterize this differential difference in renal-enzyme activity/bioactivation between rodents, dogs, and humans.

The Meeting concluded that the formation of kidney tumours was the result of prolonged renal cytotoxicity and regenerative cell proliferation, and is consistent with a threshold phenomenon.

In a two-generation study of reproductive toxicity with chlorothalonil in rats, the LOAEL for parental toxicity was 500 ppm, equal to 22 mg/kg bw per day, i.e.,the lowest dose tested, on the basis of effects on kidneys and forestomach in males and females observed at all doses. One tubular adenoma and one tubular carcinoma were found the kidneys of males at 145 mg/kg bw per day. The NOAEL for offspring toxicity was 1500 ppm, equal to 68 mg/kg bw per day, on the basis of a decrease in body weight of the F1 pups at the highest dose. The NOAEL for reproductive effects was 3000 ppm, equal to 138 mg/kg bw per day, i.e., the highest dose tested.

In a study of developmental toxicity in rats, the NOAEL for maternal toxicity was 100 mg/kg bw per day on the basis of increased mortality, clinical signs, reduced body weight and food consumption observed at 400 mg/kg bw per day. The NOAEL for fetal toxicity was 100 mg/kg bw per day on the basis of increased post-implantation loss and reduced viable litter size. In a study of developmental toxicity in rabbits, the NOAEL for maternal toxicity was 10 mg/kg bw per day on the basis of body-weight loss during treatment with chlorothalonil at 20 mg/kg bw per day. The NOAEL for fetal toxicity was 20 mg/kg bw per day, i.e., the highest dose tested.

No data on chlorothalonil in humans were provided. In the published literature it is reported that chlorothalonil may cause dermatitis[30].

Studies on the metabolite SDS-3701

4-Hydroxy-2,5,6-trichloroisophthalonitrile (company code, SDS-3701) is a soil and plant metabolite of chlorothalonil and has also been identified as a metabolite in ruminants. The toxicology of this metabolite had been tested extensively.

Biochemical aspects of the metabolite SDS-3701

After single oral doses of ^{14}C-ring labelled SDS-3701 at 4.3 or 62.4 mg/kg bw in rats, about 65–74% and 7.5–9.7%, was recovered from the faeces and urine, respectively. Radiolabel was found in the blood (5–6.9%), muscle (4.7–7.9%), fat (3.1–3.6%), liver (1–2%) and kidneys (0.4–0.7%). The highest concentrations of radiolabel were found in the liver. The tissue and urine concentrations indicate an oral absorption of at least 26–30% of the administered dose. Biliary excretion was not measured, so actual oral absorption may be higher than indicated.

Toxicological data

SDS-7301 is moderately toxic after acute oral administration (LD_{50}, 242–422 mg/kg bw). Mortality was observed after single oral doses of 150 mg/kg bw or higher.

In a 2-year dietary study with SDS-3701 in mice, in which a limited number of parameters were evaluated, a reduction in body weight and an increase in food consumption were observed at 1500 ppm, equivalent to 225 mg/kg bw per day. Absolute and relative liver weights were increased in females at 750 ppm, equivalent to 113 mg/kg bw per day, and higher. No treatment-related effects on the incidences of non-neoplastic and neoplastic lesions were observed at dietary concentrations of up to and including 1500 ppm, equivalent to 225 mg/kg bw per day (the highest dose tested).

Dietary studies of toxicity in rats given repeated doses (60-day, 2-year) of SDS-3701 show that the haemopoietic system is the prime target organ for toxicity. The overall NOAEL in studies in rats given repeated doses of SDS-3701 was 3 mg/kg bw per day on the basis of increased mortality, clinical signs, reduced body weight gain, changes in haematological and clinical chemistry parameters, hypoplastic bone marrow, increased spleen weight, haemosiderin deposition in liver and bone marrow and degenerative tissue changes observed at 10/15 mg/kg bw per day in a 2-year dietary study. No treatment-related changes in the incidence of neoplastic lesions were observed at doses up to and including 30/20 mg/kg bw per day.

In a 90-day study in dogs, the NOAEL was 100 ppm, equivalent to 2.5 mg/kg bw per day, on the basis of severe toxicity resulting in death observed at 200 ppm, equivalent to 5 mg/kg bw per day. In a 1-year study in dogs, the NOAEL was 30 ppm, equal to 0.83 mg/kg bw per day, on the basis of reductions in body-weight gain and increased serum concentrations of glucose observed at 60 ppm, equal to 1.8 mg/kg bw per day.

SDS-3701 was tested in an adequate range of tests of genotoxicity. Most of the tests showed that SDS-3701 was not mutagenic or clastogenic. A test for chromosomal aberration in vitro in CHO cells gave positive results with and without metabolic activation. However, SDS-3701 gave negative results in vivo in a test for chromosomal aberration in Chinese-hamster bone marrow and in dominant lethal tests in rats and mice. The Meeting concluded that it is unlikely that SDS-3701 will show mutagenic activity in vivo.

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[30] IPCS (1996) Chlorothalonil. Environmental Health Criteria 183. (http://www.inchem.org/documents/ehc/ehc/ehc183.htm#SectionNumber:8.1).

In view of the lack of genotoxicity in vivo and the absence of carcinogenicity in mice and rats, the Meeting concluded that SDS-3701 is unlikely to pose a carcinogenic risk to humans.

In two studies of reproductive toxicity in rats, the overall NOAEL for parental toxicity was 120 ppm, equivalent to 8 mg/kg bw per day, the highest dose tested. The overall NOAEL for offspring toxicity was 30 ppm, equivalent to 2 mg/kg bw per day, on the basis of reduction in body weight at 60 ppm. The NOAEL for reproductive toxicity was 120 ppm, equivalent to 8 mg/kg bw per day, the highest dose tested.

In a study of developmental toxicity in rats, the NOAEL for maternal toxicity was 5 mg/kg bw per day on the basis of reductions in body-weight gain and food consumption at 15 mg/kg bw per day. The NOAEL for fetal toxicity was 5 mg/kg bw per day on the basis of an increase in number of early and late resorptions, a decrease in fetal weight at and an increase in the frequency of 14th rudimentary ribs at 15 mg/kg bw per day. In a study of developmental toxicity in rabbits, the NOAEL for maternal toxicity was 1 mg/kg bw per day on the basis of a mortality and an abortion observed at 2.5 mg/kg bw per day. It was not reported at which day of treatment the mortality and abortion occurred. The NOAEL for developmental toxicity was 2.5 mg/kg bw per day on the basis of early post-implantation loss at 5 mg/kg bw per day. In these studies, no teratogenic effects were observed with SDS-3701.

The Meeting concluded that the existing database on chlorothalonil and its soil and plant metabolite SDS-3701 was sufficient to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

Chlorothalonil

The Meeting established an ADI for chlorothalonil of 0–0.02 mg/kg bw based on a NOAEL of 1.8 mg/kg bw per day identified on the basis of kidney toxicity observed in long-term studies of toxicity in rats and using a safety factor of 100. This ADI provides a margin of 200 for the induction of renal tumours in rats. This ADI is similar to the one derived by JMPR in 1974 and 1990 from a 2-year study in dogs in which the NOAEL was 3 mg/kg bw per day. Previously the JMPR has based the ADI on data from dogs, arguing that the rat is particularly sensitive to kidney toxicity induced by chlorothalonil. The Meeting concluded that whilst there were some uncertainties it was possible to establish a plausible mode of action for the renal carcinogenesis of chlorothalonil. This comprises initial conjugation with glutathione followed by sequential biotransformation to thiol derivatives in renal proximal tubule cells by β-lyase. The thiol metabolites are cytotoxic, resulting in renal proximal tubule cell necrosis followed by regenerative proliferation. The final step is the appearance of tumours. As there are no fundamental qualitative differences between rodents and in humans in the processes underlying these key events, it was not possible to dismiss human relevance on qualitative grounds. Whilst quantitative differences in some of the metabolic steps, such as the cysteine S-conjugate β-lyase pathway, have been demonstrated between rodents and humans for some other compounds sharing this mode of action, specific information on chlorothalonil was not available. Hence, the Meeting concluded that while it is plausible that humans are less sensitive to the renal effects of chlorothalonil, it was not possible to dismiss relevance to humans on quantitative grounds, nor was it possible to quantify any difference in sensitivity.

Studies of acute toxicity have demonstrated that exposure to chlorothalonil on a single day may induce kidney toxicity in rats. The overall NOAEL for kidney toxicity in studies of acute toxicity was 60 mg/kg bw. Based on this NOAEL, the Meeting established an ARfD of 0.6 mg/kg bw, using a safety factor of 100.

Given the species differences in the β-lyase bioactivation pathway, the ADI and ARfD are likely to be conservative.

SDS-3701 (4-Hydroxy-2,5,6-trichloroisophthalonitrile)

The Meeting established an ADI for SDS-3701 of 0–0.008 mg/kg bw based on a NOAEL of 0.83 mg/kg bw per day identified on the basis of a reduction in body-weight gain in females, a reduction in erythrocytes in males and increased serum concentrations of glucose in males and females in a 1-year study in dogs, and using a safety factor of 100.

In a study of developmental toxicity with SDS-3701 in rabbits, early implantation loss was observed at a dose of 5 mg/kg bw per day. The NOAEL for this effect was 2.5 mg/kg bw per day. On the basis of these findings, the Meeting established an ARfD of 0.03 mg/kg bw using a safety factor of 100. The Meeting considered that the abortions and deaths observed in this study in rabbits at 2.5 and 5 mg/kg bw per day were considered to be unlikely to be induced by a single dose of SDS-3701. In studies of acute oral toxicity in rats, in which LD_{50}s of 242–422 mg/kg bw were identified, deaths were observed at doses of 150 mg/kg bw or higher. In view of information from the LD_{50} studies and the absence of other adequate data on acute toxicity, the ARfD of 0.03 mg/kg bw applies to the general population as well as women of childbearing age.

A toxicological monograph was prepared.

Levels relevant for risk assessment of chlorothalonil

Species	Study	Effect	NOAEL	LOAEL
Rat	Acute toxicity [b]	Toxicity	60 mg/kg bw per day [c]	175 mg/kg bw per day [c]
	Two-year study of toxicity and carcinogenicity [a]	Toxicity	1.8 mg/kg bw per day	3.8 mg/kg bw per day
		Carcinogenicity	3.8 mg/kg bw per day	15 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Parental	— [d]	500 ppm, equal to 21.7 mg/kg bw per day
		Offspring toxicity	1500 ppm, equal to 68 mg/kg bw per day	3000 ppm, equal to 138 mg/kg bw per day
		Reproductive toxicity	3000 ppm, equal to 138 mg/kg bw per day	— [e]
	Developmental toxicity[b]	Maternal toxicity	100 mg/kg bw per day	400 mg/kg bw per day
		Fetotoxicity	100 mg/kg bw per day	400 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	10 mg/kg bw per day	20 mg/kg bw per day
		Fetotoxicity	20 mg/kg bw per day	— [e]
Dog	Two-year study[a,f]	Toxicity	120 ppm, equal to 3 mg/kg bw per day	— [e]

[a] Dietary administration.

[b] Gavage administration.

[c] Overall NOAEL and LOAEL for several studies.

[d] Lowest dose tested.

[e] Highest dose tested.

[f] Evaluated by JMPR in 1974 and 1992.

Levels relevant for risk assessment of SDS-3701

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of carcinogenicity [a]	Carcinogenicity	1500 ppm, equivalent to 225 mg/kg bw per day	— [c]
Rat	Two-year study of toxicity and carcinogenicity [a]	Toxicity	3 mg/kg bw per day	10 mg/kg bw per day
		Carcinogenicity	20 mg/kg bw per day	— [c]
	One-generation study of reproductive toxicity[a]	Parental	120 ppm, equivalent to 8 mg/kg bw per day	— [c]
		Offspring toxicity	30 ppm, equivalent to 2 mg/kg bw per day	60 ppm, equivalent to 4 mg/kg bw per day
		Reproductive toxicity	120 ppm, equivalent to 8 mg/kg bw per day	— [c]
	Developmental toxicity[b]	Maternal toxicity	5 mg/kg bw per day	15 mg/kg bw per day
		Fetotoxicity	5 mg/kg bw per day	15 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	1 mg/kg bw per day	2.5 mg/kg bw per day
		Fetotoxicity	2.5 mg/kg bw per day	5 mg/kg bw per day
Dog	One-year study[a]	Toxicity	0.83 mg/kg bw per day	1.8 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

Chlorothalonil 0–0.02 mg/kg bw

SDS-3701[31] 0–0.008 mg/kg bw

Estimate of acute reference dose for:

Chlorothalonil 0.6 mg/kg bw

SDS-3701 0.03 mg/kg bw

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

Results from epidemiological, occupational health and other such observational studies of exposures in humans

[31] 4-Hydroxy-2,5,6-trichloroisophthalonitrile

Critical end-points for setting guidance values for exposure to chlorothalonil and its metabolite SDS-3701 (4-Hydroxy-2,5,6-trichloroisophthalonitrile)

Absorption, distribution, excretion and metabolism in animals		
	Chlorothalonil	SDS-3701
Rate and extent of absorption	Rapid, incomplete and dose-dependent oral absorption (31% at 1.5–50 mg/kg bw; 13% at 200 mg/kg bw).	Rapid, incomplete oral absorption (26–30% at 4–62 mg/kg bw)
Distribution	Highest concentration in kidney (rat)	Percentage of administered dose in blood (5–6.9%), muscle (4.7–7.9%), fat (3.1–3.6%), liver (1–2%) and kidneys (0.4–0.7%) 4 days after dosing. Highest concentrations of radiolabel were found in liver.
Potential for accumulation	Low (rat)	Moderate, in view of amount in tissue after 4 days (rat)
Rate and extent of excretion	Plasma half lives, 6–7 h at 5–50 mg/kg bw, > 10 h at 200 mg/kg bw (rat)	75–82% in 4 days (rat)
Metabolism in animals	Extensive, metabolized by enzymatic processing of the di-and triglutathion substituents via the mercapturic acid and cysteine conjugate β-lyase pathways yielding N-acetyl cysteine, cysteinyl-glycine and S-methyl-derivates.	No data
Toxicologically significant compounds (in animals, plants and the environment)	Chlorothalonil	SDS-3701
Acute toxicity		
LD_{50}, oral, rat	> 5000 mg/kg bw	242–422 mg/kg bw
LD_{50}, dermal, rat	> 5000 mg/kg bw	No data
LC_{50}, inhalation, rat	0.1 mg/L air	No data
Rat, dermal irritation	Not an irritant	No data
Rabbit, ocular irritation	Severely irritating	No data
Dermal sensitization	Inconclusive	No data
Short-term studies of toxicity		
Target/critical effect	Kidney (rat, rabbit)	Haemopoietic system (rat); body weight (dog)
Lowest relevant oral NOAEL	1.8 mg/kg bw per day (rat)	0.83 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	Systemic: 2.5 mg/kg bw per day (rabbit) Local: 2.5 mg/kg bw per day (rabbit)	No data
Long-term studies of toxicity and carcinogenicity		
Target/critical effect	Kidney: tubular epithelial necrosis/hyperplasia (mouse, rat, dog)	Haemopoietic system (rat)
Lowest relevant	1.8 mg/kg bw per day (rat)	3 mg/kg bw per day (rat)

Absorption, distribution, excretion and metabolism in animals		
	Chlorothalonil	SDS-3701
NOAEL		
Carcinogenicity	Carcinogenic, secondary to renal toxicity (mice, rats)	Not carcinogenic (mice, rats)
Genotoxicity		
	Not genotoxic	Not genotoxic
Reproductive toxicity		
Reproduction target/critical effect	No reproductive effects (rats)	No reproductive effects (rats)
Lowest relevant reproductive NOAEL	3000 ppm, equal to 138 mg/kg bw per day, i.e.,highest dose tested (rats)	120 ppm, equivalent to 8 mg/kg bw per day, i.e.,highest dose tested (rats)
Developmental target	Increased post-implantation loss, observed at maternally toxic doses only (rats)	Increased early and late post-implantation loss, decreased fetal weight, increased frequency of 14th rudimentary rib, observed at maternally toxic doses only (rats)
		Increased early post-implantation loss, observed at maternally toxic doses only (rabbits)
Lowest relevant developmental NOAEL	100 mg/kg bw per day (rats)	5 mg/kg bw per day (rats)
	20 mg/kg bw per day i.e.,highest dose tested (rabbits)	2.5 mg/kg bw per day (rabbits)
Neurotoxicity/delayed neurotoxicity		
Neurotoxicity	No data. No indication of neurotoxic potential	No data. No indication of neurotoxic potential.
Medical data		
	Dermatitis reported in published literature	No data

Summary for chlorothalonil

	Value	**Study**	**Safety factor**
ADI	0–0.02 mg/kg bw	2-year study in rat	100
ARfD	0.6 mg/kg bw	Studies of acute toxicity, rat	100

Summary for SDS-3701

	Value	**Study**	**Safety factor**
ADI	0–0.008 mg/kg bw	1-year study, dog	100
ARfD	0.03 mg/kg bw	Study of developmental toxicity, rabbit	100

DIETARY RISK ASSESSMENT

Deferred to 2010, when residue re-evaluation is scheduled.

5.8 CHLORPYRIFOS-METHYL (090)

TOXICOLOGY

Chlorpyrifos-methyl is the ISO approved name for O,O-dimethyl O-3,5,6-trichloro-2-pyridyl phosphorothioate (CAS No.5598-13-0). Chlorpyrifos-methyl is an organophosphorus compound that acts against insects. The mechanism of action is inhibition of acetylcholinesterase activity. Chlorpyrifos-methyl was evaluated previously by the JMPR in 1975, 1991 and 1992 when an ADI of 0–0.01 mg/kg bw was established. In 2001, the Meeting concluded that an ARfD for chlorpyrifos-methyl was not necessary. Chlorpyrifos-methyl was reviewed at the present Meeting as part of the periodic review programme of the CCPR. New studies of dermal and inhalation exposure in rats, genotoxicity in vivo, reproductive toxicity and inhibition of neuropathy target esterase (NTE) had been made available since the last full review in 1992.

Most of the pivotal studies met the basic requirements of the relevant Organisation for Economic Co-operation and Development (OECD) or national test guidelines, although the level of detail in some of the reports did not always match current requirements. A number of studies did not contain certificates of compliance with GLP. The available studies in human volunteers were considered to have been performed according to contemporary ethical standards. The overall database is considered adequate for deriving reference doses.

Biochemical aspects

Chlorpyrifos-methyl is rapidly and extensively absorbed in rats given a single oral dose at 16 or 30 mg/kg bw. Excretion was rapid (largely within 24 h) and primarily in the urine. Urinary metabolites were identified as the glucuronide conjugate of 3,5,6-trichloro-2-pyridinol (68.6%), the desmethyl metabolite O-methyl-O-(3,5,6-trichloropyridyl) phosphorothioate (17.8%) and free 3,5,6-trichloro-2-pyridinol (13.8%). Although these results were reported very briefly, they are broadly consistent with data for the closely-related compound chlorpyrifos (Annex 5, reference 86). The fate of the phosphorothioate moiety was not investigated.

Toxicological data

Chlorpyrifos-methyl is of low acute toxicity when administered orally, dermally (LD_{50}s > 2000 mg/kg bw) or by inhalation (LC_{50} > 0.67 mg/L). Chlorpyrifos-methyl is a slight, transient irritant to skin and eye and has been found to produce skin sensitization in a Magnussen & Kligman maximization test, but not in a Buehler test.

Short-term studies of toxicity identified decreased cholinesterase activity and adrenal vacuolation as the most sensitive indicators of toxicity caused by chlorpyrifos-methyl. Studies did not show any consistent time-related progression in the inhibition of plasma or erythrocyte cholinesterase activity with repeated or prolonged administration of chlorpyrifos-methyl, suggesting that inhibition reaches a “steady state” relatively rapidly. There was evidence of significant but not complete recovery of cholinesterase activities after 2 or more weeks. In the 28-day study in mice, the NOAEL was 10 ppm, equal to1.3 mg/kg bw per day, on the basis of reduced brain acetylcholinesterase activity and vaculation of the zona fasciculata of the adrenals. The same end-points were the basis for the NOAEL of 1 mg/kg bw per day in the 90-day study in rats. Decreased brain cholinesterase activity, decreased body-weight gain, clinical chemistry and haematological findings were noted at the highest dose of 50 mg/kg bw per day in a 90-day study in dogs, with a NOAEL of 10 mg/kg bw per day. No evidence of toxicity, including brain acetylcholinesterase activity, was reported in a 6-month study in Rhesus monkeys given doses of up to 5 mg/kg bw per day.

The potential genotoxicity of chlorpyrifos-methyl has been investigated in an adequate battery of tests in vitro and in vivo. No evidence of mutagenicity was noted; however, chlorpyrifos-

methyl was found to be clastogenic in Chinese hamster ovary cells in the presence of metabolic activation. Studies in vivo on micronucleus formation in bone marrow and on unscheduled DNA synthesis (UDS) gave negative results.

The Meeting concluded that chlorpyrifos-methyl is unlikely to be genotoxic.

No evidence of carcinogenicity was seen in long-term studies of toxicity/carcinogenicity with chlorpyrifos-methyl in rats or mice. Adrenal pathology (vacuolation of the adrenal cortex zona fasciculata consistent with lipid accumulation) was noted in rats and mice. Having considered the outcome of a pathology review by a group that re-examined the slides of adrenal tissues obtained in the study in rats, the Meeting concluded that the findings at 1 mg/kg bw per day were not adverse. Decreased brain acetylcholinesterase activity was found to be a consistent and sensitive indicator of chronic toxicity caused by chlorpyrifos-methyl. The inhibition of cholinesterase activity by chlorpyrifos-methyl seen in the long-term studies did not increase with duration of dosing. The NOAEL was 1 mg/kg bw per day in rats, and 3.9 mg/kg bw per day in mice. Toxicity in a limited 2-year study in dogs was limited to reduced body-weight gain at the highest dose of 3 mg/kg bw per day, with a NOAEL of 1 mg/kg bw per day.

The Meeting concluded that chlorpyrifos-methyl is not carcinogenic.

Marginal effects on fertility were seen at the highest dose of 3 mg/kg bw per day in an early three-generation study in rats; the NOAEL was 1 mg/kg bw per day. A subsequent, more extensive, two-generation study in rats found no effects on reproduction or pup development at 10 mg/kg bw per day; the NOAEL for parental toxicity was 1 mg/kg bw per day on the basis of findings in the adrenal gland. In an initial study of developmental toxicity in rats, there was no indication of teratogenicity at 200 mg/kg bw per day. Indications of delayed fetal development were seen at all doses (50 mg/kg bw per day and above) but without a clear dose–response relationship. In a range-finding study of developmental toxicity in rats, there was no indication of teratogenicity at 200 mg/kg bw per day, a dose producing salivation immediately after the second and subsequent doses and significant inhibition of cholinesterase activity. At 12.5 mg/kg bw per day, there was slight inhibition (10%) of brain acetylcholinesterase activity 1 day after the final dose. The NOAEL for maternal toxicity was considered to be 1 mg/kg bw per day. The Meeting considered that the salivation was unlikely to be a result of systemic toxicity as it occurred immediately after dosing, whereas the C_{max} was at 5 h, and there was evidence that chlorpyrifos-methyl tasted unpleasant at high concentrations. In a full study of developmental toxicity in rats, the NOAEL for maternal toxicity (brain cholinesterase activity 4 days after the final dose) and pup development (overall rate of anomalies) was 12.5 mg/kg w per day with a NOAEL for teratogenicity of 50 mg/kg bw per day, the highest dose tested. The only study of developmental toxicity in rabbits given chlorpyrifos-methyl was not performed to modern standards, but was considered adequate to assess the potential for teratogenicity. The NOAEL for maternal toxicity was 4 mg/kg bw per day on the basis of reductions in body-weight gain and food consumption. The NOAEL for teratogenicity and fetal developmental toxicity was 16 mg/kg w per day, the highest dose tested.

The Meeting concluded that chlorpyrifos-methyl caused developmental toxicity only at doses that were maternally toxic, but that it was not teratogenic.

The primary plant and mammalian metabolite of chlorpyrifos-methyl, 3,5,6-trichloropyridinol (TCP), was considered by the 1999 JMPR during the review of chlorpyrifos (Annex 5, references *86*, *88*). The acute oral toxicity of TCP is moderate, with LD_{50}s in the range of 380 to 1000 mg/kg bw. In studies of toxicity with repeated doses, the liver was the main target organ, with the lowest NOAEL of 12 mg/kg bw per day being identified in a study in dogs. TCP was not genotoxic in vitro or in vivo. There were no developmental effects at doses of up to 150 mg/kg bw per day in rats, but rabbits showed increased incidences of abnormalities, primarily dilatation of the cerebral ventricles and hydrocephaly at 100 mg/kg bw per day and above, and the NOAEL was 25 mg/kg bw per day.

Some histopathological evidence of neuropathy was noted in hens given a single potentially lethal dose of chlorpyrifos-methyl at 5000 mg/kg bw. Equivocal histopathological findings noted in a

short-term study of delayed neurotoxicity were considered to be similar to background findings and not consistent with delayed neuropathy. No assessment of neuropathy target esterase (NTE) activity was made in the studies of neurotoxicity, but a study in vitro showed that chloryrifos-methyl oxon had a potency for inhibiting acetylcholinesterase activity that was more than 100-fold that of NTE. This study also showed that chlorpyrifos-methyl oxon was less potent than chlorpyrifos oxon as an inhibitor of brain acetylcholinesterase activity in hens.

The Meeting concluded that chlorpyrifos-methyl was unlikely to produce delayed neuropathy in the absence of very severe cholinergic toxicity.

In two studies in human volunteers exposed orally to chlorpyrifos-methyl for 21 or 28 days, there were no adverse findings concerning clinical signs, clinical chemistry or cholinesterase activity. The NOAEL was 0.3 mg/kg bw per day over 21 days, the highest dose tested. A single oral dose of (the closely-related compound) chlorpyrifos of up to 1 mg/kg bw did not significantly inhibit erythrocyte acetylcholinesterase activity in human volunteers. The studies in human volunteers were considered to have been performed according to contemporary ethical standards.

There were no reports of adverse effects in production-plant workers.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.01 mg/kg bw based on the NOAEL of 1 mg/kg bw per day identified on the basis of inhibition of brain acetylcholinesterase activity and adrenal vacuolation in the 2-year study of toxicity and carcinogenicity in rats and with a safety factor of 100. This value is supported by the NOAEL of 1 mg/kg bw per day for inhibition of parental brain acetylcholinesterase activity in the multigeneration study of reproductive toxicity in rats and by the NOAEL of 1 mg/kg bw per day for inhibition of maternal brain acetylcholinesterase activity in the study of developmental toxicity in rats. The Meeting did not consider changes observed in the adrenals of rats given a dose of 1 mg/kg bw per day in the 2-year study to be treatment-related, a conclusion that is consistent with that of the pathology review group. Limited studies in human volunteers, while not of sufficient quality (e.g. too few subjects, limited duration of treatment and the fact that no assessment of the adrenals was possible) to support their use in the derivation of an ADI, provide no basis for concern that the proposed ADI would not be adequately protective. In a number of studies, erythrocyte acetylcholinesterase activity was more sensitive than brain acetylcholinesterase activity to inhibition by chlorpyrifos-methyl. However, the Meeting noted that after oral administration the sensitivity of heart acetylcholinesterase activity to inhibition by chlorpyrifos-methyl was similar to that of brain acetylcholinesterase. It was further noted that the differential sensitivity of acetylcholinesterase was the same as that observed with the close structural analogue chlorpyrifos.[32] In vivo, the sensitivity of the enzyme in peripheral neuronal tissue is similar to that in the brain, while the enzyme in erythrocytes is more sensitive. The Meeting therefore concluded that inhibition of brain acetylcholinesterase activity, not erythrocyte acetylcholinesterase activity, was the appropriate end-point for use in the risk assessment of chlorpyrifos-methyl.

The Meeting established an ARfD of 0.1 mg/kg bw based on the NOAEL of 1.0 mg/kg bw identified on the basis of the absence of inhibition of erythrocyte acetylcholinesterase activity in a single-dose study in human volunteers given the closely-related compound chlorpyrifos, and with a safety factor of 10. The Meeting discussed whether an ARfD was necessary for chlorpyrifos-methyl, given the absence of any clear indications of systemic toxicity after single exposures. In the absence

[32] Marable BR, Maurissen JP, Mattsson JL and Billington R (2007) Differential sensitivity of blood, peripheral, and central cholinesterases in beagle dogs following dietary exposure to chlorpyrifos. Regul Toxicol Pharmacol 47:240–248.

of adequate single-dose studies with extensive investigations of cholinesterase activity and clinical signs, the Meeting considered that it was not able to discount the possibility that chlorpyrifos-methyl could produce acute effects. The Meeting considered basing the ARfD on the repeat-dose study in human volunteers given chlorpyrifos-methyl, in which an overall NOAEL of 0.3 mg/kg bw per day was identified. It was noted that this was somewhat inconsistent with the higher NOAEL of 1.0 mg/kg bw in a single-dose study in humans given the closely-related, but more potent, compound chlorpyrifos. Having considered data on the kinetics and acetylcholinesterase-inhibition characteristics of chlorpyrifos and chlorpyrifos-methyl, the Meeting concluded that, although likely to be conservative, it was appropriate to use data from the single-dose study in humans given chlorpyrifos to establish the ARfD for chlorpyrifos-methyl. No other potentially acute effect that might serve as the basis for derivation of an ARfD was identified in studies in experimental animals.

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	50 ppm, equal to 3.9 mg/kg bw per day	500 ppm, equal to 41 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 41 mg/kg bw per day[c]	—
Rat	Two-year studies of toxicity and carcinogenicity [a]	Toxicity	1 mg/kg bw per day	50 mg/kg bw per day
		Carcinogenicity	50 mg/kg bw per day[c]	—
	Multigeneration study of reproductive toxicity[a]	Reproductive toxicity	10 mg/kg bw per day[c]	—
		Parental toxicity	1 mg/kg bw per day	3 mg/kg bw per day
		Offspring toxicity	10 mg/kg bw per day[c]	—
	Developmental toxicity[b]	Maternal toxicity	1.0 mg/kg bw per day	12.5 mg/kg bw per day
		Embryo/fetotoxicity	12.5 mg/kg bw per day	50 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	4 mg/kg bw per day	12–16 mg/kg bw per day
		Embryo/fetotoxicity	16 mg/kg bw per day[c]	—
Dog	90-day study	Toxicity	10 mg/kg bw per day	50 mg/kg bw per day
	Two-year study of toxicity[a]	Toxicity	1 mg/kg bw per day	3 mg/kg bw per day
Rhesus monkey	26-week study of toxicity[b]	Toxicity	5 mg/kg bw per day[c]	—
Humans	28-day study of toxicity[d]	Toxicity	0.2 mg/kg bw per day[c]	-
	21-day study of toxicity[d]	Toxicity	0.3 mg/kg bw per day[c]	-
Humans	Single-dose study of toxicity with chlorpyrifos[d]	Toxicity	1.0 mg/kg bw[c]	-

[a] Dietary administration.

[b]Gavage administration.

[c]Highest dose tested.

[d]Capsule administration.

Estimate of acceptable daily intake for humans

0–0.01 mg/kg bw

Estimate of acute reference dose

0.1 mg/kg bw

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

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

Critical end-points for setting guidance values for exposure to chlorpyrifos-methyl

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rats: rapid and extensive, >80%
Dermal absorption	Low: < 5%, concentrated and diluted, rat epidermis in vitro
Distribution	Widely distributed.
Potential for accumulation	No potential for accumulation.
Rate and extent of excretion	Rapid and almost complete, within 72 h, mainly via urine (83–85%), after a single dose.
Metabolism in animals	Extensively metabolized. De-methylation, hydrolysis, conjugation , oxidative desulfuration
Toxicologically significant compounds (animals, plants and the environment)	Parent and oxon
Acute toxicity	
Rat, LD_{50}, oral	2814 mg/ kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 0.67mg/L air (nose only)
Rabbit, dermal irritation	Slight, transient irritant
Rabbit, ocular irritation	Slight, transient irritant
Guinea-pig, dermal sensitization (test method used)	Negative results in Buehler test; positive results in Magnussen & Kligman maximization test
Short-term studies of toxicity	
Target/critical effect	Inhibition of acetylcholinesterase activity, adrenal vacuolation
Lowest relevant oral NOAEL	1 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	10 mg/kg bw per day (systemic)
Lowest relevant inhalation NOAEC	18 ppb (approximately 100 μg/m^3)

Genotoxicity	
	No genotoxic potential in vivo
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Inhibition of acetylcholinesterase activity, adrenal vacuolation
Lowest relevant NOAEL	1 mg/kg bw per day
Carcinogenicity	Not carcinogenic
Reproductive toxicity	
Reproduction target/critical effect	Not toxic to reproduction
Lowest relevant reproductive NOAEL	10 mg/kg bw per day
Developmental target/critical effect	Not teratogenic. Delayed fetal development, slight increase in abnormalities at maternally toxic doses.
Lowest relevant developmental NOAEL	12.5 mg/kg bw per day (rat)
Neurotoxicity/delayed neurotoxicity	
	Histopathological indications of neuropathy at 5000 mg/kg bw. No indications of delayed neuropathy at 500 mg/kg bw per day for 13 weeks. Very weak inhibitor of neuropathy target esterase (NTE) in vitro
Other toxicological studies	
Studies in human volunteers	No adverse effects at doses of up to 0.3 mg/kg bw per day for 21 days
Single-dose study in human volunteers given chlorpyrifos	No adverse effects at doses of up to 1.0 mg/kg bw
Medical data	
	No adverse effects in production-plant workers

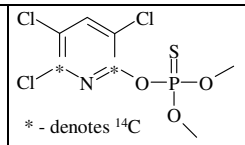
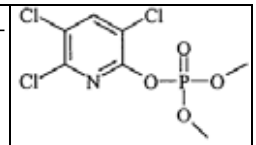
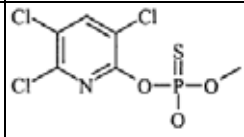
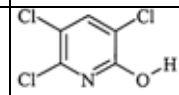
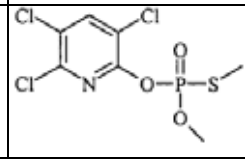
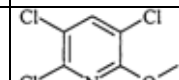
Summary

	Value	**Study**	**Safety factor**
ADI	0–0.01 mg/kg bw	Rat, 2-year, dietary	100
		Rat, reproductive toxicity	
		Rat, developmental toxicity	
		Dog, 2-year	
ARfD	0.1 mg/kg bw	Single-dose study in human volunteers given chlorpyrifos	10

RESIDUE AND ANALYTICAL ASPECTS

Chlorpyrifos-methyl, an organophosphate insecticide has been evaluated by the JMPR several times since 1975. The compound was listed at the Thirty-ninth Session of the CCPR for periodic review by the 2009 JMPR for both toxicology and residues. An ADI of 0–0.01 mg/kg bw and a ARfD of 0.1 mg/kg bw was established by the Meeting. The manufacturer submitted data on metabolism of chlorpyrifos-methyl in farm animals and plants, environmental fate, methods of analysis, GAP information, supervised residue trials on citrus, pome fruit, stone fruits, cherries, grapes, strawberries, kiwi fruit, onion, tomato, peppers, sugar beet, potato, carrot, artichoke, green beans, oilseed rape, cotton and cereals, and processing studies on various crops. Additionally, metabolism studies on

chlorpyrifos in plants and of TCP and TMP in soils were submitted. The structure of the parent compounds and main metabolites are shown below.

^{14}C-labelled chlorpyrifos-methyl (O,O-dimethyl O-3,5,6-trichloro-2-pyridinyl phosphorothioate)		OXM -Chlorpyrifos-methyl oxon	
DEM Des-methyl chlorpyrifos-methyl		TCP 3,5,6-trichloro-2-pyridinol	
S-methyl isomer chlorpyrifos-methyl		TMP 2-methoxy-3,5,6-trichloropyridine	

Animal metabolism

The metabolism of chlorpyrifos-methyl in rats was evaluated by the WHO panel at the present Meeting. The compound was found to be rapidly and extensively absorbed in the rat following a single oral dose (16 or 30 mg/kg bw). Excretion was rapid (largely within 24 hours) and primarily in the urine. Urinary metabolites were identified as the glucuronide conjugate of TCP (68.6%), free TCP (13.8%) and DEM (17.8%). The fate of the phosphorothioate moiety was not investigated.

Two lactating goats were fed [^{14}C]chlorpyrifos-methyl at 32 mg/kg feed, administered in gelatin capsules, twice a day for 7 days then sacrificed 14 h after the final dose and samples taken. Liver, kidney, fat and milk fat were extracted with acetonitrile (ACN), the extract partitioned with hexane and the ACN layer analysed by radio TLC and HPLC. The non-extracted residue (NER) was subject to base hydrolysis. Recovery was > 91% of administered dose and approximately 95% of recovered radioactivity was in the urine (~22 mg/kg chlorpyrifos-methyl eq.). Highest total radioactive residues (TRR) were found in kidney and liver (0.62 and 0.40 mg/kg chlorpyrifos-methyl eq., respectively). Residues in fat and skeletal muscle were 0.14 and 0.047 mg/kg, respectively. In milk, residues concentrated in milk fat (0.115 mg/kg), with levels over 4 times that found in whole milk. The majority of the residues found in liver and kidney were TCP, 66.7% TRR (0.24 mg/kg) and 74.2% TRR (0.45 mg/kg) respectively. In fat and milk fat, the parent compound was predominant (55.3 and 61.8% TRR, respectively), at levels of 0.06 mg/kg. The S-methyl isomer and DEM were also detected in all matrices, at levels < 10% TRR each. Base extracts of liver and kidney showed no parent compound and only TCP as metabolite (10.56% TRR in liver and 6.8% TRR in kidney). Base extracts of insoluble tissue showed traces of chlorpyrifos-methyl (up to 0.2% TRR), TCP plus S-methyl isomer (up to 9% TRR) and up to 1% TRR of DEM in kidney.

Four laying hens received a daily dose of labelled [^{14}C]chlorpyrifos-methyl at a dietary intake level equivalent to 25 mg/kg feed for 10 days. The birds were sacrificed approximately 16 h after the tenth dose for tissue collection. Tissue and egg samples were extracted using ACN, the extracts partitioned with hexane and analysed by TLC and HPLC. The unextracted residues in egg yolk and kidney were subjected to base hydrolysis and the extracts analysed by LSC. The majority of the radioactivity (approximately 70% applied radioactivity) was present in the excreta. Radioactivity was low in tissues, exceeding 0.1 mg/kg only in fat (0.07–0.35 mg/kg chlorpyrifos-methyl eq.), kidney (0.09–0.15 mg/kg) and egg yolk (< 0.01–0.10 mg/kg). The highest level in muscle was 0.02 mg/kg. The majority of the residues present in kidney were the TCP (approximately 77% TRR) and DEM

metabolites (22% TRR). Fat contained mainly the parent (approximately 75% TRR) and egg yolk contained roughly equal quantities of all three components (16 to 23% TRR).

In summary, chlorpyrifos-methyl is metabolized in goats and hens primarily to TCP (over 60% TRR). Residues concentrated in fat tissue and milk fat. This metabolic pathway was also found in rats.

Plant metabolism

The Meeting received plant metabolism studies with chlorpyrifos-methyl on tomato and cereal grains, and chlorpyrifos on citrus, cabbage, peas and radish.

Structurally, chlorpyrifos (O,O-diethyl O-3,5,6-trichloro-2-pyridinyl phosphorothioate) differs from chlorpyrifos-methyl (O,O-dimethyl O-3,5,6-trichloro-2-pyridinyl phosphorothioate) only in the phosphorothioester moiety, as the first is a diethyl and the second a dimethyl ester. Consequently, knowledge of chlorpyrifos metabolism in plants is useful in determining the relevant residues of chlorpyrifos-methyl, for enforcement purposes.

Chlorpyrifos-methyl

In a tomato study [^{14}C]chlorpyrifos-methyl was applied to plants at a rate equivalent to 0.99 kg ai/ha, within the seasonal label rate range of 0.5 to 3.0 kg ai/ha. Fruit and leaf samples were collected at 0, 5, 13, 26 and 42 days after application (DAT), rinsed first with dichloromethane (DCM) and then with ACN. A concentrate of the 26 DAT fruit extracted aqueous phase was subjected to treatment using ß-glucosidase. The stability of DEM during extraction was evaluated by adding [^{14}C]-DEM (76% purity) to a 5 DAT rinsed control tomato fruit sample. An aliquot of a [^{14}C]-DEM solution (74.8% purity) was also subjected to the enzyme procedure. In rinsed fruit, the radioactivity decreased from 86.7% TRR at 0 DAT to 0.8% TRR at 26 DAT. TRR values also declined over the time in leaves. By 13 DAT, 15% remained in the tissues. About 100% of the [^{14}C]-DEM radioactivity was recovered during the procedure. Up to 5 DAT, most of the residues were identified as chlorpyrifos-methyl, which was metabolized primarily to TCP (11.3% TRR at 13 DAT) and polar residues (19.6% TRR at 13 DAT). For all fruit samples, no more than 2.5% of TRR was found in the region where DEM was expected to elute. TMP, the S-methyl isomer, and OXN were not detected in any sample. The β-g1ucosidase treatment liberated 6.5% TRR, eluting in the TCP region. About 62 and 24% TRR of [^{14}C]-DEM solution submitted to the enzyme procedure eluted in the DEM and TCP regions, respectively; about 17% of the radioactivity was lost during the procedure. As was found for fruit extracts, chlorpyrifos-methyl was metabolized in leaf rinses primarily to TCP and to polar residues.

An EC formulation of [^{14}C]chlorpyrifos-methyl was applied to wheat and maize grain at a rate equivalent to 32.4 mg ai/kg grain with samples of the treated grain stored at 25±1 °C for 180 days. At the end of the experiment, the parent compound represented about ⅓ of the applied radioactivity (AR) in maize and 45% in wheat. TCP and DEM represented 39 and 24% AR in maize, respectively, and 19% AR each in wheat.

Chlorpyrifos

A single orange tree (Washington navel) was sprayed with [^{14}C]chlorpyrifos at a rate equivalent to 3.97 kg ai/ha. TRR levels in both leaves and fruit declined by 50% or more after 21 days after treatment. Over 99% of the whole fruit TRR remained associated with the peel, mostly as chlorpyrifos. OXON, TCP and DES were found at low levels (up to 0.5% TRR; 0.22 mg/kg chlorpyrifos eq.). Enzyme hydrolysis of the leaf aqueous soluble fraction, approximately 60% of the sample radioactivity was extracted into organic solvent, being 32.0% TCP. A base hydrolysis of this same fraction showed 80% of the residues as TCP. About 5% of NER was solubilised by enzyme digestion, 15% by acid hydrolysis; approximately 85% of the bound radioactivity remained

associated with the acid detergent fibre. About 90% of the leaf NER was solubilised by base hydrolysis. Subsequent partitioning of the aqueous phase from this step resulted in the extraction of 82.9% of the solubilised radioactivity into organic solvent, composed of at least seven components, with TCP representing 36.7% TRR.

Cabbage plants received one foliar spray application of [^{14}C]chlorpyrifos at a rate equivalent to 1.43 kg ai/ha. Plants were sampled at 0, 7, 14, 21 and 42 days after application (DAT) with TRR values declining over the 42 days. At 7 DAT, organic extracts contained 42% of TRR, mostly as chlorpyrifos. TCP levels increased from 2% TRR at 7 DAT to 6.1% TRR at 21 DAT. The maximum level of DES was found at 14 DAT (5.3% TRR). Chlorpyrifos appears to be metabolized to TCP, which is extensively conjugated with glucose and malonic acid.

Potted pea plants were treated with one application of [^{14}C]chlorpyrifos, applied at a rate equivalent to 1.9 kg ai/ha, with samples collected weekly up to 28 DAT. Radioactivity declined rapidly during the first 7 days; in pods, the levels had reached 0.25% of TRR at the end of the study. There was a steady decrease of chlorpyrifos over time (from 89.6% of TRR at 0 DAT to 3.8% of TRR by day 28 in pea pods), while TCP and TCP conjugates increased during this period (8.7 and 42.5% of TRR, respectively). Conjugates consisted of at least five different sugar or sugar plus malonic acid conjugates of TCP.

A single foliar spray of [^{14}C]chlorpyrifos was applied to radish plants at rate equivalent to 1.92 kg ai/ha then sampled weekly up to 35 days DAT. TRR in the rinsed tops decreased from 58.7 mg/kg chlorpyrifos eq. on Day 0 to 1.6 ma/kg at 35 DAT. Whereas the levels in roots remained relatively unchanged during the course of the study at about 2 mg/kg. Residues in the aqueous phase increased during the course of the experiment (from 0.06 to 38.5% of TRR in roots), representing mostly TCP conjugates. Chlorpyrifos residues decreased to 14.8% TRR in tops and 41.5% of TRR in roots at 35 DAT, while TCP reached 2.5% of TRR in tops at the end of the experiment. Enzyme digestion was more effective at releasing NER residues (up to 20% of TRR), with over 80% of this radioactivity being aqueous soluble.

In summary, metabolism studies conducted with chlorpyrifos-methyl and chlorpyrifos in plants indicates a single primary metabolic pathway that involves hydrolysis of the phosphate ester to give primarily TCP and polar residues, mainly TCP conjugates of glucose and malonic acid.

Environmental fate

The Meeting received information on soil aerobic metabolism and soil photolysis.

In four agricultural soils [^{14}C]Chlorpyrifos-methyl, at a rate equivalent to 0.5 kg ai/ha, was incubated under aerobic conditions at 40% moisture-holding capacity (MHC) and 20 °C. Samples were taken at regular intervals up to 100 DAT, extracted with solvent and analysed by LSC and HPLC. The initial degradation product in all soils was TCP, accounting for up to 65% of applied radioactivity (AR) within 7 days, which was subsequently mineralised to $^{14}CO_2$ (23–69% of AR at 100 days, depending upon soil type). Nine minor degradation products were also observed (up to 16% of AR), one of which at approximately 2% of AR co-chromatographed with TMP. Levels of NER reached 17–26% of AR at 100 days, and little or no organic volatiles were observed. Soil half-lives, estimated by best-fit kinetics, ranged from 0.63 days (sandy clay loam) to 3.6 days (loamy sand).

The route of aerobic degradation of [^{14}C]TCP was investigated in the laboratory in four European soils treated at 250 g/ha in a soil depth of 5 cm and a soil bulk density of 1.5 g/cm^3, adjusted to 40% maximum water holding capacity (WHC_{max}) and incubated at 20 °C in the dark. The amounts of TCP and its degradation products in the extracts were determined by HPLC and confirmed by TLC. For the non-sterile soils, the overall recovery ranged between 83.1 and 103.7% of AR. The level of radioactivity in the soil extracts declined to between 6.6 and 50.8% of AR after 120 days. The level of NER and of evolved $^{14}CO_2$ increased throughout the incubation period (up to 58% of AR), whilst the levels of ^{14}C organic volatiles were very low throughout (< 0.5% of AR).

TCP was the major component present in all soil extracts, dropping to about 32% of AR after 120 days in the Marcham sandy clay loam soil. At this time, TMP level reached 13% of AR.

In top soil taken from three USA sites [^{14}C]TMP was assayed at a concentration of approximately 1.0 mg/kg of soil at 100% or 35% moisture content, ⅓ bar soil moisture tension and 25 °C. Extensive mineralization to CO_2 (in the order of 70% of AR) was observed in the two silty soils but not in the sandy soil, a known poor degrader, where TMP accounted for about 70% of AR after 300 days. Low levels of TCP (about 10% of AR) were observed in all three soils.

The aerobic degradation of [^{14}C]Chlorpyrifos-methyl was investigated in sandy loam and clay loam water/sediments treated at 0.5 kg ai/ha. The samples were incubated under an aerobic/anaerobic gradient in the dark at 17–20 °C. $^{14}CO_2$ and other volatile organic compounds accounted for up to 11% of AR. The radioactivity associated with surface water declined from about 80% at time zero to 21–38% at the end of the experiment. Degradation of chlorpyrifos-methyl was rapid in both systems with less than 2% of AR remaining after 100 days. DT_{50} values in the sandy loam and clay loam systems were 2.6 and 25.4 days, respectively. The principal degradation product was TCP, which was detected at maximum levels of 83 and 62% in 30 day sandy loam and clay loam samples, respectively.

The aqueous photolytic degradation rate and quantum yield of [^{14}C]chlorpyrifos-methyl solutions (8.8–13.7 mg/L) in water/ACN (9:1) were determined at 20 °C irradiated under a 450 W Xenon high-pressure lamp at 290 nm for periods of up to eight hours. Chlorpyrifos-methyl degraded with a calculated quantum yield of 2.6×10^{-3} and DT_{50} varying according to season and weather conditions, from 1.8 days to 3.8 months.

In summary, chlorpyrifos-methyl is degraded in soils and sediments to TCP, which is either directly mineralized to CO_2, or via TMP.

Methods of residue analysis

The Meeting received data on analytical methods for chlorpyrifos-methyl in various plant and animal commodities. In general, for plant commodities the methods involved extraction with acetone/water. The extract was partitioned into hexane and quantified by GC/FPD or cleaned-up with C_{18} SPE and quantified by HPLC/MS/MS or GC/NCI-MS. The methods were satisfactorily validated at a LOQ of 0.01 mg/kg, with a LOD of 0.002 or 0.003 mg/kg.

In kidney, liver, milk, muscle and egg the compound was extracted with acetone, the extract cleaned-up in a C_{18} SPE and chlorpyrifos-methyl quantified by GC/NCI-MS. LOQ for chlorpyrifos-methyl was 0.01 mg/kg.

Although a multiresidue method to analyse chlorpyrifos-methyl was not provided, the Meeting is aware of the availability of multiresidue methods that include the compound.

Stability of pesticide residues in stored analytical samples

The Meeting received data on the stability of residues in various plant and animal commodities.

In one study conducted with oranges, grapes, wine, tomato, tomato juice and wheat fortified at 0.10 mg/kg chlorpyrifos-methyl, from 80 to 106 % of the compound remained after 90 days of storage at -20 °C. Another study on various plant commodities, fortified at 0.10 mg/kg, chlorpyrifos-methyl was shown to be stable for up to 18 months when stored at -18 °C, with over 70% of the compound remaining on completion of the study.

In a study conducted with cattle tissues and milk, chlorpyrifos-methyl remained stable (75–85% remained) in samples fortified at 0.10 mg/kg after 90 days under frozen conditions (-20 °C). Almost half of chlorpyrifos-methyl present in fortified egg samples was lost during storage, suggesting instability of the compound in this matrix.

Definition of the residue

Chlorpyrifos-methyl was shown to metabolize in animals and plants primarily to TCP. This metabolite is the major residue in goat liver and kidney and hen kidney; it represented over 20% TRR in tomato 26 days after the last treatment and 39% TRR in maize after 180 days of storage. TCP is also the main metabolite in plants treated with chlorpyrifos.

Residues of chlorpyrifos-methyl were found to concentrate in fat tissue and milk fat. The compound has a log K_{ow} of 4.

Even though TCP can be a significant part of the residues in plant and animals treated with chlorpyrifos-methyl, it is also a major metabolite formed following the application of chlorpyrifos. As a consequence, TCP is not considered as a specific residue marker of the use of chlorpyrifos-methyl.

TCP lacks the phosphate ester moiety, responsible for the cholinesterase inhibiting capacity of chlorpyrifos-methyl. Data from repeated dose studies show that TCP is about 10 times less toxic than the parent compound. Also, TCP levels in crops and animal products are generally not higher than those of the parent compound. As a consequence the Meeting agreed that dietary human exposure to this metabolite is not considered of toxicological concern.

The current residue definition for chlorpyrifos-methyl in plant and animal commodities, for both enforcement and dietary risk assessment purposes is: *Chlorpyrifos-methyl (fat-soluble).*

The Meeting agreed to confirm this residue definition of chlorpyrifos-methyl: *Chlorpyrifos-methyl*.

The residue is fat soluble.

Results of supervised trials on crops

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

As no chlorpyrifos-methyl residue trial data was submitted for the following crops; cabbage head, Chinese cabbage, common beans, date, lettuce head, mushrooms, radish, rice and tea green black, the Meeting withdrew its previous maximum residue level recommendations.

Citrus fruits

Chlorpyrifos-methyl is registered in oranges, mandarins, clementines and lemons in Italy at a GAP rate of 0.055 kg ai/hL. In Spain, the approved rate is 0.068–0.09 kg ai/hL. In both countries the PHI is 15 days. Residue data from 51 trials conducted on various citrus fruits conducted from 1991 to 2006 were submitted.

Fifteen trials were conducted in Italy in oranges, mandarins and clementines. In seven trials conducted according to maximum Spanish GAP rate, residues (whole fruit) at 15 days PHI in mandarins and clementines were 0.18, 0.23 and 0.52 mg/kg and in oranges 0.16, 0.26, 0.58 and 0.89 mg/kg. Residues in mandarin pulp were < 0.01 (< LOD of 0.003 mg/kg) and 0.01 mg/kg. Eight trials did not match GAP.

Thirty six trials were conducted in Spain in lemons, oranges, mandarins and clementines. In eight trials conducted according to the maximum Spanish GAP rate, residues at 15 days PHI (whole fruit) were 0.09, 0.21, 0.33 and 0.69 mg/kg in mandarins and 0.09, 0.11, 0.11 and 0.18 mg/kg in

oranges. Residues were < 0.01 (< LOD of 0.003 mg/kg) and 0.01 mg/kg in mandarin pulp. Twenty eight trials did not mach GAP.

The Meeting noted that the residue populations of chlorpyrifos-methyl in mandarins, clementine and oranges from 15 trials conducted according to Spanish GAP are within the same range and agreed to use a combined data set of: 0.09, 0.09, 0.11, 0.11, 0.16, 0.18, 0.18, 0.21, 0.23, 0.26, 0.33, 0.52, 0.58, 0.69 and 0.89 mg/kg. Residues in pulp from four trials were < 0.01 (2) (< LOD of 0.003 mg/kg) and 0.01 (2) mg/kg.

There is no current GAP for chlorpyrifos-methyl covering the citrus crop group; however the GAPs for the individual crops within the group are comparable. The Meeting agreed that as the registered uses cover the main crops within the group an estimate could be done for citrus crop group.

The Meeting estimated a maximum residue level of 2 mg/kg for chlorpyrifos-methyl in citrus fruit. The Meeting also estimated a HR of 0.01 mg/kg and a STMR of 0.01 mg/kg based on the residue data in citrus pulp.

A maximum residue level estimate of 1.4 mg/kg was derived from the use of the NAFTA calculator. The Meeting applied the JMPR procedure of using one significant figure for residues below 10 mg/kg.

The Meeting withdraws its previous recommendation of 0.5 mg/k for chlorpyrifos-methyl in oranges.

Pome fruits

Chlorpyrifos-methyl is registered in apples and pears in Italy (maximum rate of 0.077 kg ai/hL), in pome fruit in Spain (maximum rate of 0.09 kg ai/hL) and in Hungary (maximum rate of 0.76 kg ai/ha; 800–1000 L/ha), with a 15 day PHI. It is also approved for use in pome fruit in Switzerland, (maximum rate of 0.76 kg ai/ha), Poland (maximum rate of 0.6 kg ai/ha; 500–750 L/ha) and Greece (maximum rate of 0.056 kg ai/hL), with a PHI of 21 days. A total of 72 trials conducted in Europe from 1999 to 2007 in apple and pears were submitted. Decline studies showed that residues were still decreasing between 15 and 21 days after application

In two trials conducted in Austria, residues were 0.02 mg/kg in apple at 21 days PHI, matching GAP in Poland, and 0.05 mg/kg in pear at 14 days PHI, matching GAP in Hungary.

Two trials conducted in Belgium did not match GAP.

Thirty six trials were conducted in France (north and south). In 14 trials conducted in the south matching Spanish GAP, residues at 15 days PHI were: < 0.01 (< LOD of 0.003 mg/kg), 0.03 and 0.16 mg/kg in pears and 0.02, 0.03, 0.04, 0.07 (2), 0.08, 0.10 (2), 0.19, 0.20, 0.22 mg/kg in apples. In 13 trials matching Swiss or Polish GAP, residues at 21 days PHI were: < 0.01 (< LOD of 0.003 mg/kg), < 0.01, 0.02, 0.03, 0.05, 0.07 and 0.08 mg/kg in pears and 0.02, 0.03, 0.04, 0.08, 0.09 and 0.15 mg/kg in apples. Eighteen trials did not match any GAP.

Seven trials were conducted in Germany in apples. In four trials matching Hungarian GAP, residues within 15 days PHI were 0.02 (2), 0.05 and 0.56 mg/kg. One trial matched Swiss GAP with residues at 21 days PHI of 0.03 mg/kg. Two trials did not match GAP.

Four trials were conducted in Greece matched Spanish GAP. Residues at 15 days PHI were 0.02 and 0.04 mg/kg in pear and 0.15 and 0.19 mg/kg in apple.

Seven trials were conducted in Italy. In five trials matching Spanish GAP, residues at 15 days PHI were 0.02 (2) mg/kg in pears and 0.03, 0.06 and 0.08 mg/kg in apple. Two trials did not match GAP.

In three trials conducted in Poland according to GAP, residues at 21 days PHI were < 0.01 (< LOD of 0.003 mg/kg) and 0.01 mg/kg in apple and 0.02 mg/kg in pears.

Nine trials were conducted in Spain. In two trials conducted according to GAP, residues at 15 days PHI were 0.03 mg/kg in apple and 0.08 mg/kg in pears. Seven trials did not match GAP.

Two trials conducted in the United Kingdom did not match GAP.

Residues in pears from nine trials with a PHI of 15 days were: < 0.01 (< LOD of 0.003 mg/kg), 0.02 (3), 0.03, 0.04, 0.05, 0.08 and 0.16 mg/kg.

Residues in apples from 21 trials conducted at a 15 day PHI were: 0.02 (2), 0.03 (3), 0.04, 0.05, 0.06, 0.07 (3), 0.08 (2), 0.10 (2), 0.15, 0.19 (2), 0.20, 0.22 and 0.56 mg/kg

Residues in pears from nine trials conducted at a 21 day PHI were: < 0.01 (< LOD of 0.003 mg/kg), < 0.01, 0.02 (3), 0.03, 0.05, 0.07 and 0.08 mg/kg

Residues in apples from nine trials conducted at a 21 day PHI were: < 0.01 (< LOD of 0.003 mg/kg), 0.01, 0.02, 0.03 (2), 0.04, 0.08, 0.09 and 0.15 mg/kg.

The Meeting decided that data from trials in apples and pears, done according to GAP, were from different populations (Mann-Whitney U test) and could not be combined. The Meeting agreed that the residue data from apples at a PHI of 15 days, which had the highest residues and reflected the critical GAP in Europe, could be used for the estimation for pome fruits.

The Meeting estimated a maximum residue level of 1 mg/kg, a HR of 0.56 mg/kg and a STMR of 0.07 mg/kg for chlorpyrifos-methyl in pome fruits.

The maximum residue level estimate derived from use of the NAFTA calculator was 0.6 mg/kg. The Meeting noted that the majority of trials were conducted at the lower 25% range of the GAP rate, including the trial that gave rise to the highest residue (0.56 mg/kg). As a consequence the Meeting considered that the estimate derived from the calculation using the NAFTA spreadsheet may not accommodate all uses of chlorpyrifos-methyl in pome fruit that followed GAP.

The Meeting agreed to withdraw its previous recommendations of 0.5 mg/kg for chlorpyrifos-methyl in apple

Stone fruits

Chlorpyrifos-methyl is registered in Italy peaches and in Spain in peaches and nectarines at a maximum rate of 0.09 kg ai/h, with a PHI of 15 days. In Bulgaria, the rate is up to 0.055 kg ai/hL for stone fruits with a PHI of 14 days. In Greece, the PHI for stone fruit is 21 days (0.056 kg ai/hL) and 30 days (0.6 kg ai/ha) in Hungary for peaches and apricots. A total of 34 European trials were submitted for peaches and apricots completed between 1992 and 2007. Decline studies showed that residues were still decreasing between 15 and 21 days after application

Ten trials were conducted in southern France. In five trials matching Spanish GAP, residues in whole fruit at 14–15 days PHI were < 0.01 and 0.02 mg/kg in apricots and < 0.01, 0.01 and 0.02 mg/kg in peaches; residues in pulp (pitted fruit) were < 0.01 (2), 0.01 and 0.02 (2) mg/kg. Three trials matched GAP in Greece, with residues in whole fruit and pulp of apricots (1 trial) and peaches at 21 days PHI of < 0.01 (3) mg/kg. Two trials did not match GAP

From five trials conducted in Greece, according to Italian GAP, residues in whole fruit at a PHI of 15 days were: < 0.01 (< LOD of 0.003 mg/kg), 0.01 and 0.04 mg/kg in apricots and < 0.01 and 0.17 mg/kg in peaches. Residues in pulp were < 0.01 (< LOD of 0.003 mg/kg), 0.01 and 0.04 mg/kg in apricot and < 0.01 mg/kg in peaches.

Eleven trials were conducted in Italy. In eight trials conducted according to GAP, residues at a PHI of 15 days were: < 0.01 mg/kg in apricots and 0.01, 0.02 (3), 0.06, 0.07 and 0.08 mg/kg in peaches; residues in pulp were < 0.01 mg/kg in apricot and 0.01, 0.02 (3), 0.06, 0.07 and 0.09 mg/kg in peaches. One trial matching Greek GAP, residues at a PHI of 21 days was < 0.01 mg/kg in peach whole fruit and pulp.

Eight trials were conducted in Spain. In three trial matching GAP, residues in whole fruit at a PHI of 15 days were: < 0.01 mg/kg (< LOD of 0.003 mg/kg) in apricots and 0.02 and 0.23 mg/kg in peaches; in pulp, residues were < 0.01 mg/kg (< LOD of 0.003 mg/kg) in apricots and 0.02 and 0.26 mg/kg in peaches. Five trials matched Greek GAP with residues at a PHI of 21 days of < 0.01 (2) (< LOD of 0.002 mg/kg) and < 0.01 in apricots and 0.02 and 0.03 mg/kg in peaches; in pulp, residues were < 0.01 (2) (< LOD of 0.002 mg/kg), < 0.01 and 0.02 mg/kg.

Residues in whole fruit and pulp of apricots from seven trials matching GAP with a PHI of 15 days were: < 0.01 (2) (< LOD of 0.003 mg/kg), < 0.01 (2), 0.01, 0.02 and 0.04 mg/kg.

Residues in whole fruit of peaches from 14 trials matching GAP with a PHI of 15 days were: < 0.01 (2), 0.01 (2), 0.02 (5), 0.06, 0.07, 0.08, 0.17 and 0.23 mg/kg. In pulp (pitted fruit), residues were: < 0.01 (3), 0.01 (2), 0.02 (5), 0.06, 0.07, 0.09 and 0.26 mg/kg.

Residues in whole fruit and pulp of apricots from four trials according to GAP at 21 days PHI were: < 0.01 (2) (< LOD of 0.002 mg/kg) and < 0.01 (2) mg/kg,

Residues in peaches from five trials matching GAP at a PHI of 21 days were: < 0.01 (3), 0.02 and 0.03 mg/kg. In pulp, residues were < 0.01 (2) (< LOD of 0.002 mg/kg), < 0.01 (2) and 0.02 mg/kg.

Chlorpyrifos-methyl is registered for use in cherries in Hungary at 0.6 kg ai/ha and 800–1000 L/ha (0.048–0.072 kg ai/hL) with a 30 day PHI. Eleven trials were conducted in Austria, Germany, Hungary and Poland in 2006/2007. Decline studies showed that residues declined rapidly during the first 5 days following application then relatively slowly thereafter. Consequently, data from samples collected 21 days after application (30% shorter PHI than GAP of 30 days) were accepted as being comparable to GAP. Residues from the 11 trials were < 0.01 (9) (< LOD of 0.003 mg/kg) and < 0.01 (2) mg/kg in whole fruit and pulp.

The Meeting agreed that the residue population from trials conducted at a PHI of 15 days in peaches had the highest residues and could be used for the estimation of a maximum residue level for stone fruit.

The Meeting estimated a maximum residue level of 0.5 mg/kg for chlorpyrifos-methyl in stone fruits. Based on the residue data in peach pulp (pitted fruit), the Meeting also estimated a HR of 0.26 mg/kg and a STMR of 0.02 mg/kg.

The maximum residue level estimate derived from use of the NAFTA calculator was 0.15 mg/kg. However, the Meeting noted that most of the trials were conducted at the lower 25% range of the GAP rate, including the trial that gave rise to the highest residue (0.23 mg/kg). The Meeting considered that the estimate derived from the NAFTA spreadsheet calculation may not accommodate all uses of chlorpyrifos-methyl in stone fruit that followed maximum GAP.

The Meeting withdraws its previous recommendations of 0.5 mg/kg for chlorpyrifos-methyl in peaches.

Grapes

Chlorpyrifos-methyl is registered in grapes in Italy at a rate up to 0.045 kg ai/hL and in Spain at up to 0.09 kg ai/hL, both with a PHI of 15 days. In France, the PHI is 21 days (0.338 kg ai/ha) and in Hungary 30 days (0.52–0.60 kg ai/ha; 800–1000L/ha). In Chile, the compound is recommended as a post-harvest treatment. Data was submitted from 63 trials conducted in red and white grapes (table and wine) from 1998 to 2007.

Three trials were conducted in Austria, from which one matched French GAP, with residues at a PHI of 21 days of < 0.01 mg/kg.

One trial conducted in Chile using foliar application did not matched GAP.

Twenty three trials were conducted in France. In two trials conducted in the south according to Spanish GAP, residues at a 15 day PHI were: < 0.01 and 0.07 mg/kg. Nine trials matched the French or Hungarian GAP, and residues were: < 0.01 (2) (< LOD of 0.003 mg/kg), < 0.01 (2), 0.01 (2), 0.03, and 0.04 mg/kg at a 21 day PHI and < 0.01 mg/kg at a 30 day PHI. The remaining trials did not match GAP.

Eleven trials were conducted in Germany, from which seven matched the French or Hungarian GAP, where residues found were: < 0.01 (2), 0.01 and 0.02 (3) mg/kg at a 21 day PHI and < 0.01 mg/kg at a 30 day PHI. The remaining trials did not match GAP.

Five trials were conducted in Greece, two matched the Italian GAP with residues at a 15 day PHI of 0.03 and 0.07 mg/kg. One trial matching French GAP gave residues at a 21 day PHI of < 0.01 mg/kg (< LOD of 0.003 mg/kg). Two trials did not match southern European GAP.

Two trials were conducted in Hungary, one matching French GAP, with residues at a PHI of 21 days of 0.01 mg/kg. One trial did not match any GAP from northern Europe.

Six trials were conducted in Italy, of which four matched GAP, where residues found at a PHI of 15 days were: < 0.01 (< LOD of 0.003 mg/kg), < 0.01, 0.01 and 0.12 mg/kg. One trial conducted in the north matched French GAP with residues at a 21 day PHI of < 0.01 mg/kg. One trial did not match GAP.

One trial was conducted in Poland according to French GAP with residues at a 21 day PHI of 0.04 mg/kg.

Twelve trials were conducted in Spain. In nine trials conducted according to GAP, residues at a 15 day PHI were: < 0.01 (< LOD of 0.003 mg/kg) (3), < 0.01 (< LOD of 0.003 mg/kg), < 0.01 (2), 0.04, 0.05 and 0.53 mg/kg. The remaining three trials did not match GAP.

Residues in grapes from 17 combined trials matching GAP at a 15 day PHI were: < 0.01 (4) (< LOD of 0.003 mg/kg), < 0.01 (< LOD of 0.002 mg/kg), < 0.01 (4), 0.01, 0.03, 0.04, 005, 0.07 (2), 0.12 and 0.53 mg/kg

Residues in grapes from 20 trials according to GAP at PHIs of 21 and 30 days could be also combined resulting in residues of: < 0.01 (3) (< LOD of 0.003 mg/kg), < 0.01 (8), 0.01 (4), 0.02 (3), 0.03 and 0.04 mg/kg

The residue populations from trials conducted according to 15 days PHI gave the highest levels and were used as the basis for the maximum residue level estimation for grapes.

The Meeting estimates a maximum residue level of 1 mg/kg, a HR of 0.53 mg/kg and a STMR of 0.01 mg/kg for chlorpyrifos-methyl in grapes.

The maximum residue level estimate derived from use of the NAFTA calculator was 0.70 mg/kg. The Meeting noted that most of the trials were conducted at the lower 25% range of the GAP rate, including the trial that gave rise to the highest residue (0.53 mg/kg). The Meeting considered that the estimate derived from the NAFTA spreadsheet calculation may not accommodate all uses of chlorpyrifos-methyl in grapes following the critical GAP.

Strawberries

Chlorpyrifos-methyl is registered for use in strawberries at a rate of 0.068–0.09 kg ai/hL in Italy and Spain, with PHIs of 15 and 5 days, respectively. No GAP information for northern Europe was provided. Data from 23 European trials were submitted.

Of five trials conducted in France, three were conducted in the south and matched Spanish GAP, residues found were: < 0.01 and 0.02 (2) mg/kg at 5 days PHI. Two trials conducted in northern France gave residues in the same range. Eight trials conducted in Italy and Spain at GAP rate, resulted in residues at 5 days PHI of: < 0.01 (< LOD of 0.003 mg/kg), < 0.01 (2), 0.02 (2), 0.01 (2),

and 0.04 mg/kg. Ten trials were conducted in northern Europe (Austria, Germany, Hungary, Poland and the UK) matching southern Europe GAP, giving residues in the same range.

From 11 trials conducted in southern Europe matching Spanish GAP residues found were: < 0.01 (< LOD of 0.003 mg/kg), < 0.01 (3), 0.01 (2), 0.02 (4) and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a HR of 0.04 mg/kg and a STMR of 0.01 mg/kg for chlorpyrifos-methyl in strawberries.

The maximum residue level estimate derived from use of the NAFTA calculator (> 10% of non-detects; maximum likelihood estimation (MLE) approach) was 0.08 mg/kg. The Meeting noted that all the trials were conducted at the lower 25% range of the GAP rate, including the one that gave rise to the highest residue (0.04 mg/kg). The Meeting considered that the estimate derived using the NAFTA spreadsheet calculator may not accommodate all uses of chlorpyrifos-methyl in strawberries following critical GAP.

Kiwifruit

Four European trials were submitted where 2 applications of chlorpyrifos-methyl were made at a rate of 0.049 kg ai/hL. Residues after 15 days ranged from 0.07 to 0.30 mg/kg and dropped to < 0.01 mg/kg (< LOD of 0.003 mg/kg) after 21 days. However, chlorpyrifos-methyl is currently not approved for use on kiwifruit in Europe.

As there was no GAP provided to support the trials, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in kiwifruit.

Onions

Chlorpyrifos-methyl is registered for use in onions at a rate of 0.48 kg ai/ha in Hungary (PHI of 30 days) and at 0.36 kg ai/ha in Poland (PHI of 21 days). Six trials in onions were submitted however none were according to GAP.

As there was no GAP information provided to support the trials, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in onions.

Tomatoes

Chlorpyrifos-methyl is registered in Italy, at a rate of 0.028–0.04 kg ai/hL (PHI of 15 days) and in Spain at up to 0.068–0.09 kg ai/hL (PHI of 5 days). Fifty five field and protected trials were conducted in Europe from 1999 to 2007. Ten trials were conducted in France. In seven trials conducted in southern France matching the Spanish GAP rate, residues at a PHI of 5 days were: 0.06, 0.20 and 0.42 mg/kg in field trials and 0.03, 0.08, 0.13 and 0.20 mg/kg in protected cropping trials. Three trials did not match GAP.

In four field trials conducted in Greece matching Spanish GAP, residues at a PHI of 5 days were: 0.03 (2), 0.06 and 0.31 mg/kg.

Seventeen trials were conducted in Italy. In nine trials conducted matching Spanish GAP, residues at 5 days PHI were: 0.05 (2), 0.07 (3), 0.08 and 0.92 mg/kg in field trials and < 0.01 and 0.05 mg/kg in protected cropping trials. Six trials did not match any GAP.

Fourteen trials were conducted in Spain. In six trials matching GAP, residues at 5 days PHI were: 0.01, 0.02, 0.04, 0.05 and 0.06 mg/kg in field trials and 0.03 mg/kg in protected cropping trials. Eight trials did not match GAP.

Ten trials conducted in northern Europe (the Czech Republic, Hungary, Germany, Poland and the UK) could not be evaluated due to the lack of an approved GAP for the region.

Residues on tomato from 19 trials conducted according to GAP in the field at 5 days PHI were: 0.01, 0.02, 0.03 (2), 0.04, 0.05 (3), 0.06 (3), 0.07 (3), 0.08, 0.20, 0.31, 0.42 and 0.92 mg/kg.

Residues on tomato from eight trials conducted matching GAP in the protected cropping at 5 days PHI were: < 0.01 (2), 0.03 (2) and 0.05 (2), 0.13 and 0.20 mg/kg.

Trials conducted matching Spanish GAP in field and protected cropping situations were not similar (Mann-Whitney U test) and could not be combined. The Meeting agreed that the residues coming from the field trials, having the highest residue population, could be used for the maximum residue level estimation.

The Meeting estimates a maximum residue level of 1 mg/kg, a HR of 0.92 mg/kg and a STMR of 0.06 mg/kg for chlorpyrifos-methyl in tomato.

The maximum residue level estimate derived from use of the NAFTA calculator was 0.90 mg/kg. The Meeting noted that most of the trials were conducted at the lower 25% range of the most critical GAP rate and that the NAFTA calculator value was lower than the highest residue found in the trials (0.92 mg/kg). The Meeting agreed that the value derived from the use of the NAFTA calculator spreadsheet may not accommodate all uses of chlorpyrifos-methyl in tomatoes where chlorpyrifos-methyl is applied according to critical GAP.

Peppers

Chlorpyrifos-methyl is registered to be used in peppers and egg plant in Italy at a rate of 0.34–0.45 kg ai/ha (PHI of 15 days) and 0.068–0.09 kg ai/hL in Spain for peppers (PHI of 5 days). Twenty four trials were conducted in Europe from 1999 to 2007 in the field and protected cropping.

Three trials were conducted in southern France, with one in protected cropping matching Spanish GAP, with residues of 0.14 mg/kg at a 5 day PHI.

Five trials were conducted in Greece. In three protected cropping trials matching Spanish GAP, residues at 5 days PHI were 0.03 and 0.16 (2) mg/kg. Three trials conducted at double rate gave residues in the same range.

Five trials were conducted in Italy. In two protected cropping trials matching Spanish GAP, residues at 5 days PHI were 0.04 and 0.06 mg/kg.

Fourteen trials were conducted in Spain. Five protected trials matching GAP gave residues at a PHI of 5 days were: 0.03, 0.04, 0.06, 0.52 and 0.72 mg/kg and three field trials conducted at GAP gave residues of 0.01, 0.04 and 0.09 mg/kg. Six trials conducted at double rate or higher PHI gave residues in the same range.

Residues from protected cropping trials, conducted according to Spanish GAP were: 0.03 (2), 0.04 (2), 0.06 (2), 0.14, 0.16 (2), 0.52 and 0.72 mg/kg.

Residues found from field trials, conducted according to Spanish GAP, were: 0.01, 0.04 and 0.09 mg/kg.

Trials conducted according to Spanish GAP in the field and protected cropping were not similar (Mann-Whitney U test) and could not be combined. The Meeting agreed that as the residues coming from the protected cropping had the highest residue population, they be used for the maximum residue level estimation.

The Meeting estimated a maximum residues level of 1 mg/kg, a HR of 0.72 mg/kg and a STMR of 0.06 mg/kg for chlorpyrifos-methyl in peppers.

The maximum residue level estimate derived from use of the NAFTA calculator was 0.5 mg/kg. The Meeting noted that most of the trials were conducted at the lower 25% range of the most critical GAP rate and that NAFTA calculator value was lower than the highest residue found in the trials (0.72 mg/kg). The Meeting agreed that value derived from the use of the NAFTA calculator

might not accommodate all uses in peppers where chlorpyrifos-methyl is applied according to critical GAP.

Using the default dehydration factor of 10 to extrapolate from peppers to dried chilli peppers, the Meeting estimated a maximum residue level of 10 mg/kg (based on a highest residue of 7.2 mg/kg) and a STMR of 0.6 mg/kg for chlorpyrifos-methyl in Peppers, chilli dried.

In Italy, the approved GAP is for both peppers and egg plant. The Meeting agreed to use the residue data in peppers and estimates a maximum residues level of 1 mg/kg, a HR of 0.72 mg/kg and a STMR of 0.06 mg/kg for chlorpyrifos-methyl in egg plants.

The Meeting withdraws its previous chlorpyrifos-methyl recommendations of 5 mg/kg in peppers, chilli dry and of 0.1 mg/kg in egg plant

Green beans and peas

The Meeting received data from six residue trials in green beans and peas conducted in Europe at a rate of 2 × 0.20 to 0.52 kg ai/ha. Residues at 10 or 15 days after the last application ranged from < 0.01 (< LOD of 0.002 mg/kg) to 0.02 mg/kg.

However, as there was no GAP information provided to support the trials, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in green beans or peas.

Carrot

The Meeting received data from four trials conducted in carrots in France, Italy and Spain, at a rate of 2 ×× 0.48 to 0.52 kg ai/ha. Residues after 3 days of the last application ranged from < 0.01 to 0.07 mg/kg.

However, as there was no GAP information provided to support the trials, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in carrots.

Potatoes

Chlorpyrifos-methyl is approved for use in potatoes in Italy at a rate up 0.045 kg ai/hL or 0.45 kg ai/ha and in Spain up to 0.09 kg ai/hL. In both countries the PHI is 15 days. Data from 21 trials conducted in Europe from 2000 to 2007 were provided to the Meeting.

Seven trials were conducted in South of France. In two trials matching Spanish GAP, residues at a PHI of 15 days were: < 0.01 mg/kg (2) (< LOD of 0.003 mg/kg). No residues were detected in trials conducted at double rate (two trials), lower (one trial) or higher PHI (two trials).

Five trials were conducted in Italy. In three trials matching either the Italian or Spanish GAP rate, residues at a PHI of 15 days were: < 0.01 (2) (< LOD of 0.002 mg/kg) and < 0.01 mg/kg (< LOD of 0.003 mg/kg). No residues were detected in two trials conducted at doubled rate or one at a lower PHI.

Three trials were conducted in Spain. One trial matching GAP, resulted in residues at the 15 day PHI of < 0.01 mg/kg (< LOD of 0.003 mg/kg). No residues were detected in two trials conducted at lower or higher PHIs.

Six trials were conducted at 0.07 kg ai/hL in northern Europe (Germany, Poland, Hungary and the UK), for which no GAP information was provided. No residues were detected at any sampling point (0 to 21 days).

In six trials conducted in southern Europe according to GAP residues found were: < 0.01 (< LOD of 0.002 mg/kg) and < 0.01 (4) mg/kg (< LOD of 0.003 mg/kg). In all trials submitted, no residues were detected at the day of the last application, indicating that it is unlikely the use of chlorpyrifos-methyl, at the GAP rate, will leave detectable residues in potato tubers.

The Meeting estimated a maximum residue for chlorpyrifos-methyl of 0.01(*) mg/kg and a HR and STMR of 0 for chlorpyrifos-methyl in potato.

The NAFTA calculator was not used to derive an estimate as all residue values considered by the Meeting were below the LOQ, making its application unsuitable.

Sugar beet

Chlorpyrifos-methyl is registered for use on sugar beet in Poland at a rate of 0.36 kg ai/ha (PHI of 30 days) and up to 0.05 kg ai/hL in Spain (PHI of 15 days). Data from four trials conducted in Italy and Spain in 2000/2001 were submitted where sampling occurred at more than harvest interval of greater than 100 days.

As no trials were conducted that matched GAP, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in sugar beet.

Artichoke (globe)

No GAP information on the use of chlorpyrifos-methyl in artichokes was provided to the Meeting. Four trials were conducted in Greece and Spain, at a 1 kg ai/ha. Residues at a PHI of 5 days ranged from 0.11 to 1.2 mg/kg.

As there is no GAP to support the trials, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in artichoke.

The Meeting withdraws its previous recommendations of 0.1 mg/kg for chlorpyrifos-methyl in artichoke, globe

Cereal grains – post-harvest use

Chlorpyrifos-methyl is registered for use as a grain storage treatment in a number of countries. The application rate for cereal grains ranges from 2.5 g ai/tonne seed (storage interval of 21 days in Hungary to 120 days in Belgium) to 4.5 g ai/tonne seed (storage interval of 90 days) in the UK. In Spain, the GAP for wheat, barley and maize is 2.2 g ai/tonne seed with no storage interval specified.

Twelve trials were conducted in barley in Europe from 1994 to 1995. The formulation was applied to the grain in a rotary mixer using hand-held trigger application equipment at the GAP use rates and timings. Nine trials conducted at 4.5–5 g ai/tonne seed, gave residues within 90 days storage interval of 1.6, 1.9, 2.3, 2.6, 2.9, 3.0, 31, 3.2 and 3.3 mg/kg. One trial conducted at the GAP rate gave a large variation of residues during the period of storage, starting with 6.2 mg/kg at the day of treatment, reaching a highest residue of 10 mg/kg at 99 days of storage and dropping to 6.7 mg/kg after 182 days. The highest value from this trial is twice the application rate (5g ai/tonne), an unexpected in large scale post-harvest application in cereals. The Meeting agreed that this variation indicates a lack of homogeneity in mixing during treatment and the trial should not be considered in the estimation.

In two trials conducted at 2.5 g ai/tonne seed matching Spanish GAP, samples were collected from 0 to 181 days after the treatment; the highest residues were found after 7 days at 2.0 (2) mg/kg.

Twelve trials were conducted in wheat in Europe. Ten trials conducted at 4.5–5 g ai/tonne seed, gave residues within 90 days storage interval of 1.9, 2.2, 2.4, 2.9, 3.0, 3.1, 3.2 (2), 3.5 and 4.7 mg/kg.

In two trials conducted at 2.5 g ai/tonne seed matching Spanish GAP, samples were collected from 0 to 181 days after the treatment; the highest residues were found at 0 days were 2.2 (2) mg/kg.

Residue data from 19 trials conducted at the highest application rate in barley and wheat can be combines as follow: 1.6, 1.9 (2), 2.2, 2.3, 2.4, 2.6, 2.9 (2), 3.0 (2), 3.1 (2), 3.2 (3), 3.3, 3.5 and 4.7 mg/kg.

Residues from trials conducted in wheat and barley at 2.5 g ai/tonne seed are 2.0 (2) and 2.2 (2) mg/kg

Based on the residue data from the highest application rate, the Meeting estimated a maximum residue level of 5 mg/kg, a HR of 4.7 mg/kg and a STMR of 3.0 mg/kg for chlorpyrifos-methyl in cereal grain group, post-harvest.

Long-term dietary risk assessment indicates an exceedance of the ADI for 10 of the 13 GEMS/Food Consumption Cluster Diets (up to 260 % ADI).

Taking the alternative GAP approach, the Meeting considered the residue data set coming from trials conducted according to Spanish GAP in wheat and barley for maximum residue level estimation. The Meeting estimated a maximum residue level of 3 mg/kg, a HR of 2.2 mg/kg and a STMR of 2.1 mg/kg for chlorpyrifos-methyl in wheat, barley and maize, post-harvest.

The maximum residue level estimate derived from use of the NAFTA calculator was 2.5 mg/kg. The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up the value obtained from the calculator results in 3 mg/kg which corresponds to the recommendation of the current Meeting.

The Meeting withdraws its previous recommendations of 10 mg/kg for chlorpyrifos-methyl in wheat and sorghum, post-harvest

Maize

Chlorpyrifos-methyl is registered to be used in maize in Italy (0.06 kg ai/hL) and Spain (0.068–0.09 kg ai/hL), with a 15 days PHI.

Eight trials were conducted with maize in France, Italy and Spain in 2007 at a rate of 0.84–0.94 kg ai/ha (0.225 kg ai/hL). Samples collected from 22 to 93 days after the application gave residues < 0.01 mg/kg (< LOD of 0.003 mg/kg).

As no trial was conducted according to GAP, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in maize.

Cotton

Chlorpyrifos-methyl is registered to be used in cotton in Spain (up to 0.09 kg ai/hL, 15 days PHI) and in Greece (up to 0.67 kg/ha; 500–800 L/ha with a 21 day PHI). Twelve trials were conducted in Greece and Spain in 2006/2007 at the Greek GAP rate, with residues in cotton seed ranging from < 0.003 to 0.02 mg/kg 15 days after the last application (eight trials) and < 0.01 mg/kg (< LOD of 0.003 mg/kg) 28 days after the last application.

As no trial was conducted according to GAP, the Meeting could not estimate a maximum residue level for chlorpyrifos-methyl in cotton seed.

Rape seed

The Meeting received no information on registered GAP for chlorpyrifos-methyl in rape seed. Data was submitted from 16 trials conducted in 2006/2007 where chlorpyrifos was applied at a rate of 0.45 to 0.49 kg ai/ha, which resulted in no detectable residues in samples collected at harvest intervals of 31 to 120 days.

As there was no GAP provided to support the trials, the Meeting could not recommend a maximum residue level for chlorpyrifos-methyl in rape seed.

Animal feed

Chlorpyrifos-methyl is registered for pre-harvest use in maize in Italy (0.06 kg ai/hL) and Spain (0.068–0.09 kg ai/hL), with a PHI of 15 days. In 28 trials conducted in Europe, samples of cobs, whole plant and stover (rest of the plant) were analysed. In four trials conducted in southern France and Spain, matching Spanish GAP, residues in maize whole plant, at a PHI of 15 days were: < 0.01, 0.04, 0.16 and 1.4 mg/kg. Twenty four trials were conducted at double rate and or samples were collected 28 days after the last application, i.e., did not match GAP

The trials matching GAP with chlorpyrifos-methyl in maize were considered insufficient for making estimations for chlorpyrifos-methyl in animal feed.

In two trials conducted in cotton in Spain, matching Greek GAP, residues in cotton, whole plant, at a 15 day PHI were: 0.86 and 1.6 mg/kg.

The trials conducted with chlorpyrifos-methyl in cotton were considered insufficient to make estimations for chlorpyrifos-methyl in animal feed.

In 16 trials conducted with rape seed, samples of animal feed were analysed. As no registered GAP information for use in rape seed was provided, the trials could not be evaluated. Four trials were conducted in sugar beet and samples of animal feed were analysed (tops/leaves and whole plant).

As no registered GAP information was provided to support the trials, the Meeting could not make estimations for chlorpyrifos-methyl in animal feed from sugar beet.

Fate of residues during processing

Two processing studies on oranges were conducted in Spain in 2004–2005. Orange trees received 2 applications of chlorpyrifos-methyl at 2.7 kg ai/ha. The fruit was harvested 21 days after the second application and underwent processing that simulated standard industrial procedures. Residues of chlorpyrifos-methyl in whole fruit were 0.13 and 0.24 mg/kg. Mean (n=2) processing factors (PF) for chlorpyrifos-methyl were calculated as 0.046 for orange juice and 40.2 for essential oil.

In three French studies, two applications were made to apple trees at 0.6 or 0.78 kg ai/ha with harvested fruit processed following standard commercial practices. Residues of chlorpyrifos-methyl in the fruit ranged from 0.02 to 0.07 mg/kg. No residues were detected in apple juice, PF estimated as < 0.05, < 0.04 and < 0.15 (mean of < 0.08). No residues of chlorpyrifos-methyl were detected in apple purée, with a mean PF of < 0.15.

In a study conducted in 2004 on peaches in France, trees received two applications of chlorpyrifos-methyl at 0.833 and 0.904 kg ai/ha. Treated fruit was sampled 28 days after the last application and processed to juice and purée according to commercial practices. Chlorpyrifos-methyl residues in whole fruit were < 0.01 mg/kg. No residues were found in juice and purée, but were detected in dry pomace at the LOQ level. No PF for chlorpyrifos-methyl could be estimated as no residues were detected in the raw commodity.

In seven studies conducted on grapes, chlorpyrifos-methyl was applied twice at 0.07 kg ai/hL. Samples were taken 21 or 28 days after the last application and were processed to raisins and wine according to commercial practices. Residues of chlorpyrifos-methyl in grapes ranged from < 0.01 to 0.11 mg/kg but were not detected in wine (PF < 0.15), raisins (PF < 0.09) and must (PF < 0.15). Residues concentrated in grape wet pomace (mean PF of 4.2, n=2) and in dry pomace (median of > 7.5, n=4).

Three processing studies were conducted in tomatoes in Italy and Spain. Tomatoes were treated with chlorpyrifos-methyl at 0.24 or 0.07 kg ai/hL with samples processed according do commercial practice. Residues in tomatoes ranged from 0.17 to 0.22 mg/kg but were not detected in the juice (mean PF < 0.033) or the canned tomato (mean PF < 0.025). Residues were reduced in purée, with a mean PF of 0.27 and in washed tomato (PF of 0.75).

Two processing studies were conducted during 2004–2006 on barley grain stored for 6 months after receiving chlorpyrifos-methyl at 5 g ai/tonne grain. Residues of chlorpyrifos-methyl in grain at 0 or 180 days after treatment ranged from 2.1 to 3.2 mg/kg and were not detected in beer (mean PF < 0.001).

In one processing study conducted in France, maize treated twice at 0.56 kg ai/ha was processed according to commercial practices to flour and oil. Residues in grain were not reported and no residues of chlorpyrifos-methyl (< LOD of 0.002 mg/kg) were detected in the processed commodities.

Four processing studies were conducted on wheat grain stored for up to 6 months after being treated with chlorpyrifos-methyl at 1.25 to 5 g ai/tonne grain. Residues of chlorpyrifos-methyl in grain after treatment ranged from 0.52 to 3.2 mg/kg. Residues were reduced in white flour (mean PF of 0.25; n=6), white bread (mean PF of 0.05; n=6) and wholemeal bread (mean PF of 0.48, n=3). Residues remained unchanged in wholemeal flour (n=3) and concentrated in wheat germ (mean PF=1.9; n=3) and in bran (mean PF=2.45 n=6).

One processing study was conducted cotton after the plant was treated twice with chlorpyrifos-methyl at 0.675 kg ai/ha. Seed samples were collected 56 days after the last application and processed according to commercial practices. No residues were detected in cotton seed, pressed cake, raw oil or refined oil.

Two processing studies were conducted in rape seed treated with chlorpyrifos-methyl at a rate of 0.45 kg ai/ha. Seed samples were collected 105 days after treatment and processed according to commercial practices. No residues were detected in seed, pressed cake, raw or refined oil.

Summary of processing factors from the processing of Raw Agricultural Commodities (RACs)

Processed commodity	Processing factor	Residue in the raw commodity	STMR-P, mg/kg	HR-P, mg/kg	Maximum residue level, mg/kg
Orange juice	0.046	0.21 (median, citrus)	0.01		-
Apple juice	< 0.08	0.07 (STMR, pome)	0.0056		-
Apple wet pomace	6.5	0.07 (STMR, pome)	0.455		-
Apple dried pomace	3.1	0.56 (HR, pome)	-		2
Grape pomace, wet	4.2	0.01 (STMR)	0.042		-
Grape pomace, dry	>7.5	0.53 (HR)	-		5
Grape Wine	< 0.15	0.01 (STMR)	0.002		-
Raisins	< 0.09	0.01 (STMR)	0.001		-
Tomato juice	< 0.033	0.06 (STMR)	0.002		-
Beer	< 0.001	2.1 (STMR, barley)	0.002		-
Wheat bran	2.45	2.1 (STMR, wheat) 2.2 (HR, wheat)	5.14	5.39	6
Wheat white flour	0.25	2.1 (STMR, wheat) 2.2 (HR, wheat)	0.525	0.55	-
Wheat germ	1.9	2.1 (STMR, wheat) 2.2 (HR, wheat)	3.99	4.18	5
Wheat wholemeal	1	2.1 (STMR, wheat) 2.2 (HR, wheat)	2.1	2.2	-
Wheat white bread	0.05	2.1 (STMR, wheat) 2.2 (HR, wheat)	0.105	0.11	-
Wheat wholemeal bread	0.48	2.1 (STMR, wheat) 2.2 (HR, wheat)	1.01	1.06	-

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of chlorpyrifos-methyl 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. Dietary burden calculations are provided in Annex 6. Only residue values for grain and fruit pomace, wet were available for use in the calculation of the dietary burden

		Animal dietary burden for chlorpyrifos-methyl, ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	3.95	3.59	4.2[a]
	mean	3.77	3.42	3.77[b]
Dairy cattle	max	3.69 [c]	2.95	3.56
	mean	3.52[d]	2.85	3.4
Swine breed	max	5.04[a]	4.31[a]	3.95
	mean	4.8	4.11 [b]	3.77
Swine finish	max	4.31	4.31	3.95
	mean	4.11	4.11	3.77
Poultry broiler	max	4.31[e]	2.98	1.6
	mean	4.11[f]	2.84	1.53
Poultry layer	max	3.68[g]	1.97	2.96
	mean	3.52[h]	1.88	2.84

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

[b.] Highest mean cattle or swine dietary burden suitable for STMR estimates for mammalian meat.

[c.] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

[d.] Highest mean dairy cattle dietary burden suitable for STMR estimates for 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.

[g.] Highest maximum poultry dietary burden suitable for MRL estimates for eggs.

[h.] Highest mean poultry dietary burden suitable for STMR estimates for eggs.

The chlorpyrifos-methyl dietary burdens for animal commodity MRL estimation (residue levels in animal feeds expressed on dry weight) reached a maximum of 5 ppm for swine and of 3.68 ppm for poultry. The chlorpyrifos-methyl dietary burdens for animal commodity STMR estimation (residue levels in animal feeds expressed on a dry weight basis) reached a maximum of 4.11 ppm for swine and of 3.52 ppm for poultry.

Animal feeding studies

In one feeding study conducted in dairy cows, the animals were fed 0, 1, 3, 10, 30, and 100 ppm chlorpyrifos-methyl in the diet starting at the lowest level and increasing the dosage every two weeks. The highest feeding level was followed by a two week period where no chlorpyrifos-methyl was added to the feed. In milk, chlorpyrifos-methyl was not detected 13 days after 3 and 10 ppm dosing but was detected at the LOQ level 9–11 days after dosing at 30 ppm. In milk cream, the levels detected at 30 ppm were 0.08–0.09 mg/kg. Cream samples from the 3 or 10 ppm dose levels were not analysed.

In another study, calves were fed rations containing 1, 3, 10, 30 and 100 ppm chlorpyrifos-methyl for 28 days. Residues of chlorpyrifos-methyl in fat samples were 0.01 mg/kg at 3 ppm,

0.03 mg/kg at 10 ppm and 0.09 mg/kg at 30 ppm. Muscle, liver and kidney samples were only analysed from the 30 or 100 ppm feeding level, and were not detected (< 0.01 mg/kg).

In a study on swine, animals were fed rations containing 1 to 100 ppm of chlorpyrifos-methyl for 28 days. In muscle, residues were only found above the LOQ (0.01 mg/kg) at the 30 ppm level or 100 ppm (0.03 and 0.14 mg/kg). No residues were found at any feeding level in liver or kidney. In fat, residues increased proportionally with the feeding level (mean/high levels at 3 ppm: 0.02/0.02 mg/kg; 10 mg/kg: 0.07/011 mg/kg).

In one study conducted with laying poultry, the birds were fed rations containing 1, 3, 10, 30 and 100 ppm chlorpyrifos-methyl for 28 days. No residues of chlorpyrifos-methyl were detected (< 0.01) in muscle, fat and eggs at or below the feeding level of 10 mg/kg. At 30 ppm, residues were detected only in fat at the LOQ and at 100 ppm in fat (0.15 mg/kg) and eggs (0.02 mg/kg).

Animal commodity maximum residue levels

Dietary burden (mg/kg) Feeding level [ppm]		Chlorpyrifos-methyl residues, mg/kg					
		Milk	Milk cream	Muscle	Liver	Kidney	Fat
mrl cattle beef, highest residue	(4.2) [1; 3; 10; 30]			(< 0.01) [-; -; -; < 0.01]	(< 0.01) [-; -; -; < 0.01]	(< 0.01) [-; -; -; < 0.01]	(0.013) [< 0.01;0.01; 0.03; 0.12]
STMR cattle beef, mean residue	(3.8) [1; 3; 10; 30]			(0) [-; -; -; < 0.01]	(0) [-; -; -; < 0.01]	(0) [-; -; -; < 0.01]	(0.013) [< 0.01; 0.01; 0.03 0.09]
mrl milk, mean residue	(3.7) [3; 10; 30]	(< 0.01) [-; < 0.01; < 0.01]	(0.009) [-; -; 0.07]				
STMR milk, mean residue	(3.5) [3; 10; 30]	(0) [-; < 0.01; < 0.01]	(0.008) [-; -; 0.07]				

Dietary burden (mg/kg) Feeding level [ppm]		Chlorpyrifos-methyl residues, mg/kg			
		Muscle	Liver	Kidney	Fat
mrl swine highest residue	(5.0) [3; 10]	(< 0.01) [< 0.01; < 0.01]	(< 0.01) [< 0.01; < 0.01]	(< 0.01) [< 0.01; < 0.01]	(0.055) [0.02; 0.11]
STMR swine mean residue	(4.1) [3; 10]	(0) [< 0.01; < 0.01]	(0) [< 0.01; < 0.01]	(0) [< 0.01; < 0.01]	(0.03) [0.02; 0.07]

Dietary burden (mg/kg) Feeding level [ppm]		Chlorpyrifos-methyl residues, mg/kg			
		Eggs	Muscle	Liver	Fat
mrl poulty meat highest residue	(4.3) [10; 30]		(< 0.01) [< 0.01; < 0.01]	(< 0.01) [-; < 0.01]	(0.004) [0.01; < 0.01]
STMR poulty meat, mean residue	(4.1) [3; 10]		(0) [< 0.01; < 0.01]	(0) [-; < 0.01]	(0.004) [0.01; < 0.01]
mrl eggs highest residue	(3.7) [10; 30]	(< 0.01) [< 0.01; < 0.01]			
STMR eggs, mean residue	(3.5) [3; 10]	(0) [< 0.01; < 0.01]			

Feeding study and the dietary burden calculations for cattle were the basis for the estimations in milk. Based on the residues on milk cream (0.009 and 0.008 mg/kg) and the default assumption that milk cream is 50% fat, the Meeting recommends a maximum residue level of 0.02 mg/kg and a STMR of 0.016 mg/kg for chlorpyrifos-methyl in milk fats. The Meeting estimated a maximum

residue level of 0.01(*) mg/kg in milks; assuming milk to contain 4% fat, the Meeting estimated a STMR of 0.0006 mg/kg for chlorpyrifos-methyl in milks (4% of milk fat STMR of 0.016 mg/kg).

Based on the feeding studies and the dietary burden calculations for swine, the Meeting recommends a maximum residue level of 0.01(*) mg/kg, a STMR and a HR of 0 mg/kg for chlorpyrifos-methyl in edible offal (mammalian); a maximum residue level of 0.1 mg/kg (fat) for meat (from mammalian other than marine mammals); a STMR of 0.03 mg/kg and HR of 0.055 mg/kg in the fat portion of the meat and a STMR and HR of 0 in the muscle portion of the meat.

Based on the feeding study and the dietary burden calculation for chickens, the Meeting estimates a maximum residue level of 0.01(*) mg/kg and a STMR and HR of 0 mg/kg for chlorpyrifos-methyl in eggs and poultry edible offal; a maximum residue level of 0.01 mg/kg in poultry meat (fat), a STMR and HR of 0.004 mg/kg in the fat portion of the poultry meat and a STMR and HR of 0 in the muscle portion of the poultry meat.

The Meeting withdraws its previous recommendations for chlorpyrifos-methyl in cattle fat, cattle meat, cattle edible offal, chicken fat, chicken meat, chicken edible offal, milks and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The ADI for chlorpyrifos-methyl is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDI) for chlorpyrifos-methyl was estimated for the 13 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the current Meeting. The results are shown in Annex 3. The IEDI ranged from 20 to 140% of the ADI. The information provided to the JMPR precludes an estimate that the long-term intake of residues of chlorpyrifos-methyl would be below the ADI.

The IEDI exceeded the maximum ADI for the Cluster diets C (110% ADI) and H (140% ADI), with 42.7 and 72.8% of the total intake, respectively, coming from the consumption of maize. The estimation of a STMR made by the Meeting considered the alternative GAP approach. However, in the absence of suitable information this could not be done. To refine the long-term intake estimates information on expected residues in maize processed commodities, such as maize flour and cooked maize would need to be assessed. The ADI for chlorpyrifos-methyl was established by the present Meeting on the basis of a NOAEL of 1 mg/kg bw/d from a 2-year study in rats and a safety factor of 100. However, two other studies had LOAELs of 3 mg/kg bw/d, suggesting it is unlikely that the ADI itself could be refined.

Short-term intake

The ARfD for chlorpyrifos-methyl is 0.1 mg/kg bw. The International Estimated Short Term Intake (IESTI) for chlorpyrifos-methyl was calculated for the plant and animal commodities for which STMR(P)s and HR(P)s were estimated and for which consumption data were available. The results are shown in Annex 4. The IESTI ranged from 0 to 30% of the ARfD for the general population and from 0 to 40% for children. The Meeting concluded that the short-term intake of residues from the uses of chlorpyrifos-methyl considered by the Meeting is unlikely to present a public health concern.

5.9 CYCLOXYDIM (179)

TOXICOLOGY

Cycloxydim is the ISO approved name for (5RS)-2-[(EZ)-1-(ethoxyimino)butyl]-3-hydroxy-5-[(3RS)-thian-3-yl]cyclohex-2-en-1-one (IUPAC). The CAS chemical name for cycloxydim is 2-[1-(ethoxyimino)butyl]-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)-2-cyclohexen-1-one and the CAS No. is 101205-02-1. Cycloxydim is a cyclohexene oxime herbicide that is used for the control of grass weeds of many agricultural and horticultural broad-leaved crops.

Cycloxydim was evaluated previously by the JMPR in 1992 when an ADI of 0–0.07 mg/kg bw was established. Cycloxydim was reviewed by the present Meeting as part of the periodic re-evaluation programme of the CCPR. New studies evaluated by the Meeting included studies with repeated percutaneous doses, studies of acute toxicity and genotoxicity with various metabolites, and 28-day and 90-day studies of toxicity in rats given repeated oral doses of metabolites.

Cycloxydim was used in the free acid form in most of the toxicological studies. However, because of chemical instability of the acid in animal feed and because of its low solubility in water, the sodium salt of cycloxydim was used in those studies that required water or feed as vehicle. The name “cycloxydim” refers to the acid form unless otherwise indicated. All the pivotal studies met the basic requirements of the relevant OECD guidelines and certificates of compliance with GLP and QA were provided.

Biochemical aspects

Both the free acid and the sodium salt of cycloxydim are well absorbed; bioavailability was approximately 100%. The results of excretion-balance studies indicated that most (74–86%) of a single oral dose of the sodium salt of cycloxydim at 10 mg/kg bw per day is eliminated via the urine, most being excreted within 24 h. Biliary excretion (50–65% of the administered dose) and enterohepatic circulation play an important role in the elimination of cycloxydim. The highest concentrations of radiolabel were found in the liver and the kidneys. Quantities of radiolabel in all organs rapidly declined over time. There was no evidence for bioaccumulation of cycloxydim. The pattern of metabolites in the urine was similar for the free acid and the sodium salt of cycloxydim and AUC data indicated that elimination was saturable at higher doses. The major metabolite in the urine and bile was the sulfoxide of cycloxydim, BH 517-TSO. Additional metabolites identified were BH 517-T1SO (derived from N-de-ethoxylation of BH 517-TSO), BH 517-T1SO_2 and BH 517-T2SO. Only small amounts of unchanged parent compound were detected in the urine.

Toxicological data

Cycloxydim is of low acute toxicity when administered orally, dermally or by inhalation.

The oral LD_{50} of cycloxydim was 3940 mg/kg bw in rats and > 5000 mg/kg bw in mice. No specific clinical signs were observed. Macroscopic findings in rats that died after receiving high oral doses by gavage indicated irritation of the gastric mucosa. The dermal LD_{50} in rats was > 2000 mg/kg bw, a dose of 2000 mg/kg bw causing neither mortality nor systemic toxicity. No local skin reaction was observed at the application site. When cycloxydim is administered by inhalation, the LC_{50} is > 5.28 mg/L of air (4 h exposure). Cycloxydim was not an irritant in a study of ocular and dermal irritation in rabbits, nor a dermal sensitizer in the Magnussen & Kligman maximization test in guinea-pigs.

Short-term and long-term studies of oral toxicity in mice, rats and dogs were conducted using cycloxydim sodium salt or cycloxydim free acid. In all the studies described below, the dose or

dietary concentration of the test substance is expressed as cycloxydim free acid rather than its sodium salt.

The results of these studies are characterized by clinico-chemical changes, associated with changes in water and food consumption, and effects on the liver. Effects on erythrocytes were only seen in dogs at high doses. Where the test substance was administered in the drinking-water, the reduction in water consumption is regarded to be a palatability effect rather than a specific adverse effect.

With the few available parameters measured in two 4-week range-finding studies in mice, an overall NOAEL was set at 1000 ppm, equal to 189 mg/kg bw per day, on the basis of a significant increase in relative liver weights at concentrations of 3000 ppm and 9000 ppm in combination with altered clinico-chemical parameters, and the occurrence of hydropic vacuolar parenchymal degeneration of hepatocytes in the first study.

In rats, a 90-day study of oral toxicity indicated that the target organs were the kidney and liver on the basis of increases in concentrations of creatinine, urea and cholesterol in females, and increases in the activity of alanine aminotransferase in males and females at 900 ppm. The NOAEL was 300 ppm, equal to 22 mg/kg bw per day.

In the 4-week study of oral toxicity in dogs, the NOAEL was 40 mg/kg bw per day in males on the basis of effects on the liver. The results of a 3-month study of oral toxicity in dogs showed changes in haematological parameters and liver effects, with a NOAEL of 1500 ppm, equal to 50 mg/kg bw per day. In a 1-year study of toxicity in dogs, the NOAEL was 400 ppm, equal to 12 mg/kg bw per day, on the basis of effects on erythrocytes and the liver and altered clinico-chemical parameters.

The 2-year study of carcinogenicity in mice did not demonstrate any substance-related change at any dietary concentration and the NOAEL was 240 ppm, equal to 32 mg/kg bw per day, i.e., the highest dose tested. The study was not adequate for the evaluation of carcinogenicity as the doses delivered were not sufficiently high; the highest dose used was much less than the NOAEL of 1000 ppm identified in the dose range-finding studies.

In an 18-month study in rats, there was a statistically significant reduction in body weight, body-weight gain and triglyceride concentrations at dietary concentrations of 400 ppm and above, with a NOAEL of 100 ppm, equal to 7.0 mg/kg bw per day. In a 2-year study of carcinogenicity in rats, administration of drinking-water containing cycloxydim at concentrations of 400 ppm and 1600 ppm resulted in a reduction in body weight. Consumption of drinking-water was reduced in the group at 1600 ppm. In female rats, there was a reduction in concentrations of triglycerides. The NOAEL was 100 ppm, equal to 7 mg/kg bw per day, on the basis of a reduction in body weights and a a reduction in concentrations of triglycerides in rats given drinking-water containing cycloxydim at concentrations of 400 ppm and above.

The Meeting concluded that cycloxydim was not carcinogenic in rats but had not been adequately tested in mice.

Cycloxydim was tested for genotoxicity in an adequate range of assays, both in vitro and in vivo. Cycloxydim acid and the sodium salt gave negative results throughout, except at cytotoxic concentrations in studies of chromosomal aberration in vitro.

The Meeting concluded that cycloxydim is unlikely to be genotoxic.

Although the carcinogenic study in mice was not adequate, it was still possible to reach a conclusion on carcinogenicity to humans, in view of the lack of genotoxicity and the absence of carcinogenicity in rats. The Meeting concluded that cycloxydim is unlikely to pose a carcinogenic risk to humans.

In a multigeneration study in rats, the NOAEL for offspring toxicity was 400 ppm, equal to 38 mg/kg bw per day, on the basis of reduced survival, growth and developmental retardation in pups

at 1600 ppm, equal to 129 mg/kg bw per day, the highest dose tested. Reproductive toxicity was not affected by treatment at dietary concentrations of up to 1600 ppm. The NOAEL for parental toxicity was 100 ppm, equal to 9.7 mg/kg bw per day, on the basis of reductions in feed consumption, body weight and body-weight gain in dams at 400 ppm.

Studies of developmental toxicity have been carried out in rats and rabbits. In the study of developmental toxicity in rats, the NOAEL for maternal toxicity and embryo/fetotoxicity was 200 mg/kg bw per day. Increased numbers of fetuses/litters with retardations and a statistically significant increase in the frequency of anomalies of the vertebral column and the sternebrae with involvement of the cartilage and incomplete ossification were observed. Maternal toxicity and fetal effects were also observed in two subsequent supplementary studies. In the study of developmental toxicity in rabbits, the NOAEL for maternal toxicity was 100 mg/kg bw per day. The maternal toxicity observed at doses of 200 and 400 mg/kg bw per day occurred late in the study, indicating that repeated dosing over several days was required to elicit the effect. At 400 mg/kg bw per day, the percentage of viable implantations per dam was decreased and the incidence of several skeletal anomalies, e.g. asymmetrical sternebra(e) and fused sternebrae, was increased above the range for the historical controls. The NOAEL for embryo/fetotoxicity was 200 mg/kg bw per day. The Meeting concluded that cycloxydim causes maternal toxicity that occurred at a late stage during the study. The dose that caused maternal toxicity also caused embryo/fetotoxicity. The Meeting concluded that cycloxydim was not teratogenic.

Some toxicological studies and studies of genotoxicity have been undertaken for four compounds that are either present as impurities in technical cycloxydim or are metabolites in plants and not in animals.

BH 517-5-OH-TSO is of low acute oral toxicity in rats; no mortality or clinical symptoms were observed at the limit dose of 2000 mg/kg bw. Repeated exposure to diets containing BH 517-5-OH-TSO for 90 days did not cause any adverse effects at a dose of 50 mg/kg bw per day. In a 28-day study in rats, the NOAEL for BH 517-$TGSO_2$ was greater than 440.5 mg/kg bw per day.

BH 517-5-OH-TSO, BH 517-TGSO, BH 517-$TGSO_2$ and BH 517-TSO were tested for genotoxicity in vitro. All gave negative results.

No reports of adverse health effects or poisoning in manufacturing-plant personnel or in operators and workers exposed to cycloxydim were available except for three cases of eye irritation that occurred during production/filling of an old formulation “Focus ultra”; after replacement of this formulation by a new formulation, no more such cases have occurred.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.07 mg/kg bw based on the NOAEL of 7 mg/kg bw per day identified on the basis of a reduction in body weights and a reduction in concentrations of serum triglycerides at concentrations of 400 ppm and above in the long-term dietary study in rats and using a safety factor of 100.

An ARfD of 2 mg/kg bw was established for women of childbearing age, based on a NOAEL of 200 mg/kg bw per day identified on the basis of certain skeletal anomalies at 400 mg/kg bw per day in the studies of developmental toxicity in rats and rabbits, and with a safety factor of 100. The Meeting could not exclude the possibility that these skeletal anomalies were the result of a single exposure.

The Meeting concluded that the establishment of an ARfD for the general population was not necessary on the basis of the low acute toxicity of cycloxydim, the lack of evidence for any acute neurotoxicity and absence of any other toxicologically relevant effect that might be attributable to a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effects	NOAEL	LOAEL
Mouse	Two-year study of carcinogenicity[d]	Carcinogenicity	240 ppm, equal to 32 mg/kg bw per day [c]	—
Rat	18-month study of toxicity [d]	Toxicity	100 ppm, equal to 7 mg/kg bw per day	400 ppm, equal to 28 mg/kg bw per day
	Two-year study of toxicity [d]	Carcinogenicity	1600 ppm, equal to 99 mg/kg bw per day [c]	—
	Two-generation study of reproductive toxicity[d]	Offspring toxicity	400 ppm, equal to 38 mg/kg bw per day	1600 ppm, equal to 129 mg/kg bw per day
		Reproductive toxicity	1600 ppm equal to 129mg/kg bw per day [c]	—
		Parental toxicity	100 ppm, equal to 9.7 mg/kg bw per day	400 ppm, equal to 38 mg/kg bw per day
	Developmental toxicity [b]	Maternal toxicity	200 mg/kg bw per day	400 mg/kg bw per day
		Embryo/fetotoxicity	200 mg/kg bw per day	400 mg/kg bw per day
Rabbit	Developmental toxicity [b]	Maternal toxicity	100 mg/kg bw per day	200 mg/kg bw per day
		Embryo/fetotoxicity	200 mg/kg bw per day	400 mg/kg bw per day
Dog	One-year study of toxicity [a]	Toxicity	400 ppm, equal to 12 mg/kg bw per day	1600 ppm, equal to 49 mg/kg bw per day

[a] Dietary administration.

[b] Gavage administration.

[c] Highest dose tested.

[d] Administration in drinking-water.

Estimate of acceptable daily intake for humans

0–0.07 mg/kg bw

Estimate of acute reference dose

2 mg/kg bw for women of childbearing age

Unnecessary for the general population

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

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and almost completely absorbed (> 90%) within 24 h
Distribution	Widely distributed; highest concentration in liver and kidney
Potential for accumulation	No evidence for accumulation
Rate and extent of excretion	About 78–85% of the administered dose is eliminated via the urine within 5 days. Faeces contained approximately 12–25%; enterohepatic recirculation occurred.
Metabolism in animals	Extensive. The major metabolite was the sulfoxide (TSO)
Toxicologically significant compounds (animals, plants and the environment)	Cycloxydim
Acute toxicity	
Rat, LD_{50}, oral	3940 mg/kg bw
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rat, LC_{50}, inhalation	> 5.28 mg/L air
Rabbit, dermal irritation	Not an irritant
Rabbit, ocular irritation	Not an irritant
Guinea-pig, dermal sensitization (test method used)	Not a sensitizer (Magnussen &Kligman test)
Short-term studies of toxicity	
Target/critical effect	Body weight and liver
Lowest relevant oral NOAEL	1000 ppm (189 mg/kg bw per day) (4-week study in mice)
	300 ppm (22 mg/kg bw per day) (3-month study in rats)
	400 ppm (12 mg/kg bw per day) (1-year study in dogs)
Lowest relevant dermal NOAEL	300 mg/kg bw per day (28-day study in rats)
Genotoxicity	
	Not genotoxic
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight
Lowest relevant NOAEL	100ppm (7 mg/kg bw per day), (rat)
Carcinogenicity	No carcinogenic potential
Reproductive toxicity	
Reproduction target/critical effect	Reduced survival growth and development in pups at parentally toxic doses
Lowest relevant reproductive NOAEL	400 ppm (38 mg/kg bw per day)

Developmental target/critical effect	Increase in the number of skeletal anomalies at maternally toxic doses
Lowest relevant developmental NOAEL	200 bw per day (rats and rabbits)
Neurotoxicity/delayed neurotoxicity	
	No data; no concerns raised by other studies
Medical data	
	No significant health effects were reported among manufacturing personnel.

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.07mg/kg bw	Rat, 2-year study	100
ARfD*	2 mg/kg bw	Rat and rabbit; study of developmental toxicity	100

*For women of childbearing age, unnecessary for the general population.

DIETARY RISK ASSESSMENT

Deferred to 2010, when residue re-evaluation is scheduled.

5.10 CYPERMETHRIN (118)

RESIDUE AND ANALYTICAL ASPECTS

Cypermethrin was subject to a periodic review for residues in 2008. Further information has now been provided on the registration of cypermethrin as a grain protectant.

Cereal grains

A cypermethrin UL formulation containing 20 g/L cypermethrin and 57 g/L piperonyl butoxide is registered in France for post-harvest use on cereal grains as a grain protectant with an application rate equivalent to 1.7 g cypermethrin per tonne of grain. The authorisation is for 'céréales à paille'. In France, this is understood as barley, oats, rye and wheat.

In four supervised post-harvest trials on wheat in Belgium, the grain (12–20 kg) was treated with a UL cypermethrin formulation at a rate equivalent to 1.7 g ai/tonne and stored for 7 days (two trials) and 270 days (two trials).

Cypermethrin residues one day after treatment were 1.11, 1.17, 1.2 and 1.35 mg/kg and at day 7 were: 1.07, 1.3, 1.4 and 1.5 mg/kg. As can often occur with the application of grain protectants, the concentration on the grain was less than the intended application rate. Residues on samples taken at days 180 (1.3 and 0.96 mg/kg) and 270 (1.3 and 0.99 mg/kg) after treatment suggest that the residues are quite stable during grain storage at the conditions of the trials (10 °C and 13.6–13.8% moisture).

The highest residue measured in each of the four trials (median underlined) was: 1.11, <u>1.35</u>, <u>1.40</u> and 1.5 mg/kg.

In estimating the maximum residue level, the Meeting also took account of the application rate (1.7 g ai/tonne) which would theoretically produce a residue of 1.7 mg/kg.

The Meeting estimated an STMR value of 1.38 mg/kg and a maximum residue level of 2 mg/kg for wheat. The HR was 1.5 mg/kg.

The same values are recommended for barley, oats and rye.

The previous recommendation of 0.3 mg/kg for cereal grains except rice is changed to 0.3 mg/kg for cereal grains except rice, barley, oats, rye and wheat.

The group MRL for 'cereals, except …..' should be maintained even though major cereals (rice, wheat and barley) are exceptions. Three compounds are involved – cypermethrin, alpha-cypermethrin and zeta-cypermethrin – and pre-harvest and post-harvest uses, which produce quite different residue levels. Also, alpha-cypermethrin has registered pre-harvest uses for the crop group 'cereals', so residues could legitimately occur on the non-major cereals.

The 2008 JMPR summarised studies on wheat (post-harvest treatment with cypermethrin, pre-harvest treatment with zeta-cypermethrin) and barley (pre-harvest treatment with alpha-cypermethrin) that investigated the fate of residues during food processing.

The processing factors (post-harvest treatment with cypermethrin) for cypermethrin residues for wheat grain → bran were: 2.4 and 2.6 – median 2.5. <u>*Note*</u>: bran produced by the milling of wheat is described as the Codex commodity 'Wheat bran, unprocessed'.

The processing factors (post-harvest treatment with cypermethrin) for cypermethrin residues for wheat grain → flour were: 0.27 and 0.43 – median 0.35.

A small-scale processing study for wheat following pre-harvest treatment with zeta-cypermethrin was reported by the 2008 JMPR. Information was also available in the open literature (1985) on the fate of cypermethrin during commercial scale milling of post-harvest treated wheat. The results of the zeta-cypermethrin study and the commercial scale milling trial with cypermethrin

both supported the current processing study in the sense that residue levels in flour were less than in the grain and residue levels in the bran exceeded the levels in the grain.

The Meeting agreed to use the processing factors from the recent post-harvest wheat study. The processing factors for bran (2.5) and flour (0.35) were applied to the estimated STMR and HR for wheat (1.38 and 1.5 mg/kg) to produce STMR-P and HR-P values for bran (3.45 and 3.75 mg/kg) and flour (0.48 and 0.53 mg/kg).

The estimate for flour falls below the maximum residue level for wheat (2 mg/kg), so a maximum residue level for flour is not needed.

The Meeting estimated an STMR-P value of 3.45 mg/kg and a maximum residue level of 5 mg/kg for wheat bran, unprocessed.

The 2008 JMPR reported on the fate of alpha-cypermethrin residues in barley (from pre-harvest uses) during processing. The processing factors for alpha-cypermethrin residues for barley → beer were: < 0.03, < 0.04, < 0.04, < 0.09, < 0.17, and < 0.5 – best estimate < 0.03.

The processing factor for beer (< 0.03) was applied to the estimated STMR for barley (1.38 mg/kg) to produce an STMR-P value for beer (0.04 mg/kg).

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	21.2	8.47	24.4	8.48	31.4 [a]	11.3 [b]
Dairy cattle	15.9	6.79	17.1	7.73	21.6 [c]	8.47 [d]
Poultry - broiler	2.98	2.74	2.05	1.89	2.05	1.88
Poultry - layer	2.98	2.74 [f]	3.89 [e]	2.27 [f]	1.80	1.36

[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 commodities, MRL estimation

Cattle

The estimated maximum dietary burden (31.4 ppm) for beef cattle and dairy cattle (21.6 ppm) have not changed from the estimates by the 2008 JMPR, so there is no change in estimated maximum residue levels for meat, offal and milk.

The STMR dietary burdens for beef cattle (11.3 ppm) and dairy cattle (8.5 ppm) are very little changed from previous values (11.3 and 8.3 ppm) and the changes do not influence the calculated residues in tissues and milk.

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 (3.9) [0, 1.6, 7.2]	0.0060 [0, < 0.01, 0.011]	0.007 [0, < 0.05, < 0.05]	0.007 [0, < 0.05, < 0.05]	0.048 [0, < 0.05, 0.088]
STMR				
	mean	mean	mean	mean
STMR laying hens (2.74) [0, 1.6, 7.2]	0.0042 [0, < 0.01, 0.011]	0.002 [0, < 0.05, < 0.05]	0.002 [0, < 0.05, < 0.05]	0.0.034 [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 changes to dietary burden made no difference.

The Meeting estimated an STMR value of 0.034 mg/kg for poultry fat to replace the previous value (0.008 mg/kg). The HR was 0.048 mg/kg, replacing 0.027 mg/kg. Cypermethrin is fat-soluble, so allowance should be made for the fact that the feeding study was on laying hens where some residue is eliminated from the hen via the eggs, a process that would not occur for broilers. Higher residues could therefore, be expected in the fat of broilers.

The Meeting estimated a maximum residue level of 0.1 mg/kg for poultry meat (fat). The previous recommendation of 0.05(*) mg/kg for poultry meat (fat) was withdrawn.

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 (2.74 ppm) by 7.2 ppm and multiplying by the residue at that dosing level (0.011 mg/kg) to produce a value of 0.0042 mg/kg. Similarly, a calculation for the HR for eggs produced a value of 0.0060 g/kg.

There is no change to the recommended maximum residue level of 0.01(*) mg/kg for eggs from 2008. The Meeting estimated an STMR value and an HR value of 0.0042 and 0.0060 mg/kg respectively for eggs to replace recommendations from 2008 of 0.001 and 0.0033 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 thirteen GEMS/Food Consumption Cluster Diets. The calculated intakes were essentially unchanged from the values calculated in 2008.

The IEDIs in the thirteen GEMS/Food Consumption Cluster Diets, based on estimated STMRs were 7–30% 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 by the present Meeting and for which consumption data were available. The results are shown in Annex 4.

The IESTI varied from 0–20% of the ARfD (0.04 mg/kg bw) for the general population and from 0–40% 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.

5.11 FENBUCONAZOLE (197)

RESIDUE AND ANALYTICAL ASPECTS

Fenbuconazole was evaluated for residues and toxicology by the JMPR in 1997. An ADI of 0-0.03 mg/kg bw was established and a number of maximum residue levels were recommended.

Fenbuconazole was scheduled by the Fortieth Session of the CCPR for a residue evaluation for additional crops (ALINORM 08/31/24, Appendix X). Information on current GAPs and new supervised trial data were submitted to the 2009 JMPR for lemons, blueberry, cranberry, plums, peppers, almonds and peanuts and additional residue trial information was also provided for grapefruit, oranges and apples.

Results of supervised residue trials on crops

The NAFTA calculator was used as a tool in the estimation of the maximum residue levels from the selected residue data sets obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statically calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statically estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

As the last application contributed most to the residues of fenbuconazole at harvest, the Meeting agreed to use the data from trials where the application number exceeded that specified in the matching GAP.

Citrus fruits

The GAP for citrus in the USA is 3 × 0.135 kg ai/ha with a PHI of 0 day. Information from nine trials on grapefruit, 16 trials on oranges and five trials on lemons were conducted in the USA (3 × 0.280 kg ai/ha, PHI 0 day). However, as the application rate did not match the US GAP the Meeting was unable to estimate a maximum residue level for fenbuconazole in citrus.

Pome fruits

The GAP on apples in France is 3 × 0.04–0.05 kg ai/ha and in Spain 4 × 0.05 kg ai/ha, with a PHI of 28 days. In Southern European trials conducted in accordance with French and Spanish GAP, fenbuconazole residues in rank order (n=18) were: 0.01, < 0.02, 0.02 (2), 0.03 (4), 0.04 (3), 0.05, 0.06 (2), 0.16, 0.17, 0.18 and 0.33 mg/kg.

The GAP on apples in the UK is 10 × 0.07 kg ai/ha with a PHI of 28 days. In Northern European trials conducted in accordance with the GAP of the UK, fenbuconazole residues in rank order (n=14) were: 0.02 (3), 0.03 (4), 0.04 (3), 0.05 (2) and 0.06 (2) mg/kg.

The GAP on apples in the USA is 4 × 0.105–0.13 kg ai/ha with a PHI of 14 days. In the US trials matching US GAP, fenbuconazole residues in rank order (n=16) were: 0.02, 0.05, 0.06 (2), 0.07, 0.08, 0.09, 0.12 (2), 0.13, 0.15, 0.17, 0.18, 0.20 (2) and 0.28 mg/kg.

The supervised residue trials for pears in Southern Europe submitted to the 1997 JMPR did not match Italian or Spanish GAP.

The residues in pears were lower than those in apples. The Meeting agreed that the dataset for apples could be used to estimate a maximum residue level for pome fruits.

Based on the US trials, which led to higher residues, the Meeting estimated a maximum residue level, an STMR value and an HR value for fenbuconazole in pome fruits of 0.5, 0.12 and 0.28 mg/kg, respectively. The Meeting withdrew the previous recommendation of a maximum residue level of 0.1 mg/kg for pome fruits.

The maximum residue level estimate derived from use of the NAFTA calculator (95/99 Rule 99th percentile) was 0.5 mg/kg, which was in agreement with the estimate made by the Meeting.

Plums

The GAP on plums in France is 5 × 0.05–0.075 kg ai/ha with a PHI of 3 days. In trials from northern France, conducted in accordance with French GAP, fenbuconazole residues (n=5) in rank order were: 0.04, 0.06, 0.08, 0.10 and 0.17 mg/kg.

Based on the trials from northern France, the Meeting estimated a maximum residue level, an STMR value and an HR value for fenbuconazole in plums of 0.3, 0.08 and 0.17 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA calculator (95/99 Rule 99th percentile) was 0.3 mg/kg, which agreed with the estimate made by the Meeting.

Blueberries

The GAP on blueberries in the USA is 4 × 0.11–0.14 kg ai/ha with a PHI of 30 days. In the US trials conducted with foliar application in accordance with the US GAP, fenbuconazole residues in rank order (n=9) were 0.01, 0.03 (2), 0.06 (2), 0.07 (2), 0.10 and 0.20 mg/kg.

Based on the US trials, the Meeting estimated a maximum residue level, an STMR value and an HR value for fenbuconazole in blueberries of 0.5, 0.06 and 0.20 mg/kg respectively.

The maximum residue level estimate derived from use of the NAFTA calculator was 0.4 mg/kg (95/99 Rule and UCLMedian95th). The Meeting noted that the maximum application rate in the trials was 25% less than that specified in the matching maximum GAP. The Meeting considered that the estimate derived from use of the NAFTA calculator may not accommodate all uses of fenbuconazole in blueberries and agreed that a higher maximum residue level recommendation was warranted.

Cranberries

The GAP on cranberries in the USA is 4 × 0.105–0.211 kg ai/ha with a PHI of 30 days. In the US trials conducted in accordance with the US GAP, fenbuconazole residues (n=5) in ranked order were: 0.09 (2), 0.13, 0.15 and 0.45 mg/kg.

Based on the US trials, the Meeting estimated a maximum residue level, an STMR value and an HR value for fenbuconazole in cranberries of 1, 0.13 and 0.45 mg/kg respectively.

The maximum residue level estimate derived from use of the NAFTA calculator (95/99 Rule 99th percentile) of 0.7 mg/kg differed from the estimate of 1 mg/kg made by the Meeting. The Meeting considered that due to the level of uncertainty involved with estimates based on small datasets a higher estimate was more appropriate.

Peppers

The GAP on peppers in the USA is 4 × 0.105–0.211 kg ai/ha with a PHI of 7 days. In the US trials on bell peppers and non-bell peppers, conducted in accordance with the US GAP, fenbuconazole residues (n=6) in rank order were 0.04, 0.05, 0.12, 0.15 (2) and 0.20 mg/kg for bell peppers, and (n=3) 0.05, 0.20 and 0.21 mg/kg for non-bell peppers. As the residue populations from trials on bell peppers and non-bell peppers were not significantly different (Mann-Whitney U-test), the Meeting

agreed that they could be combined. The residues in peppers in rank order (n=9) were 0.04, 0.05 (2), 0.12, 0.15 (2), 0.20 (2) and 0.21 mg/kg.

Based on the US trials, the Meeting estimated a maximum residue level, an STMR value and an HR value for fenbuconazole in peppers of 0.6, 0.15 and 0.21 mg/kg respectively.

The maximum residue level estimate derived from use of the NAFTA calculator (95/99 Rule 99th percentile) of 0.6 mg/kg corresponded to the estimate made by the Meeting.

Tree nuts (Almonds and Pecans)

The GAP on almonds in the USA is 3 × 0.067–0.105 kg ai/ha with a PHI of 160 days. In the US trials conducted in accordance with the US GAP, fenbuconazole residues in nutmeat (n=5) were < 0.010 (5) mg/kg.

The 1997 JMPR recommended a maximum residue level of 0.05(*) mg/kg for pecan based on supervised residue trials from the USA conducted in 1990 and 1994. In ten US trials conducted in accordance with the US GAP, fenbuconazole residues were < 0.01 (10) mg/kg in pecan kernels.

Based on the US trials for almonds and pecans, the Meeting estimated a maximum residue level of 0.01(*) mg/kg, and an STMR value and HR value of 0 mg/kg for fenbuconazole in tree nuts. The Meeting withdrew the previous recommendation of 0.05(*) mg/kg for pecan.

The NAFTA calculator was not used to derive an estimate as all residue values were below the LOQ, making its application unsuitable.

Peanuts

The GAP on peanuts in the USA is 4 × 0.069–0.135 kg ai/ha with a PHI of 14 days. In US trials, conducted with six or eight foliar applications at a rate of 0.140 kg ai/ha and a PHI of 14 days, fenbuconazole residues in peanuts in rank order (n=13) were: < 0.03 (11), 0.04 and 0.05 mg/kg.

Based on the US trials, the Meeting estimated a maximum residue level, an STMR value and an HR value for fenbuconazole in peanuts of 0.1, 0.03 and 0.05 mg/kg respectively.

The NAFTA calculator was not used to derive an estimate as the residues from eleven, of thirteen trials matching GAP, were below the LOQ, making its application unsuitable.

Animal feed commodities

Almond hulls

In US trials conducted in accordance with the GAP of the USA (0.105 kg ai/ha, PHI of 160 days), fenbuconazole residues in almond hulls, in rank order (n=5), were: 0.10, 0.13, 0.45, 0.51 and 0.77 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for fenbuconazole in almond hulls of 3 and 0.45 mg/kg respectively.

The maximum residue level estimate derived from use of the NAFTA calculator was 2.5 mg/kg (95/99 Rule 99th percentile). The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up the value derived from use of the calculator corresponded to the Meeting's recommendation.

Peanut fodder

In US trials conducted in accordance with the GAP of the USA, i.e., 0.135 kg ai/ha with a PHI of 14 days, fenbuconazole residues in peanut hay, in rank order (n=13), were: 0.78, 1.1, 1.2 (2), 1.3, 1.6, 2.3, 3.9, 4.1, 4.4, 4.7, 5.8 and 7.1 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and a highest residue value for fenbuconazole in peanut fodder of 15, 2.3 and 7.1 mg/kg respectively.

The normal JMPR procedure is to round the value to the nearest 5 for maximum residue levels between 10 and 30 mg/kg. Rounding up the value obtained from NAFTA calculator of 14 mg/kg (95/99 Rule and UCLMedian 95th) results in an estimate of 15 mg/kg, corresponding to the recommendation of the current Meeting.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of fenbuconazole during the processing of citrus (grapefruit and oranges), apples and peanuts. Based on the results of processing studies processing factors were calculated for apples and peanuts and are shown in the Table below. As no maximum residue level for citrus was estimated, processing factors are not reported.

Processing (Transfer) factors from the processing of Raw Agricultural Commodities (RACs) with field-incurred residues from foliar treatment with fenbuconazole

Commodity	Processing factor	STMR-P mg/kg
Apple		
Unwashed fruit	-	0.12 (STMR for RAC)
Wet pomace	2.5	0.30
Unpasteurized juice	0.06	0.01
Pasteurized juice	< 0.16	0.02
Peanut		
Nutmeat		0.03 (STMR for RAC)
Meal	0.50	0.02
Refined oil	1.3	0.04

As the STMR-P value of unpasteurized apple juice is higher than that of pasteurized juice, the value for unpasteurized juice is used for dietary risk assessment

The Meeting estimated a maximum residue level of 1 mg/kg (0.12 × 2.5 × 100/40 = 0.75 mg/kg) on a dry weight basis for apple pomace, dry.

On the basis of the STMR and HR for bell peppers and the default dehydration factor of 10, the Meeting estimated an STMR value and an HR value for dried chilli peppers of 1.5 and 2.0 mg/kg respectively. Based on the HR value, the Meeting recommended a maximum residue level of 2 mg/kg for chilli peppers (dry).

Residues in animal commodities

Farm animal feeding studies

A lactating dairy cow feeding study and a laying hen feeding study were previously submitted to the 1997 JMPR.

Farm animal dietary burden

The Meeting estimated the dietary burden of fenbuconazole in livestock on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops), and the

STMR or highest residue levels estimated at the present Meeting. 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 in a dry weight basis.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle, dairy cattle, broilers and layers are provided in Annex 6 of the 2009 Report of the JMPR. 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, fenbuconazole, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	2.6	1.0	1.0	0.48	6.2[a]	2.1[b]
Dairy cattle	2.1	0.80	0.93	0.41	5.7	2.0[c]
Poultry – broiler	0.03	0.03	0.03	0.03	0.02	0.02
Poultry – layer	0.03	0.03	0.31[d]	0.13[e]	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

Because of the changes in the animal dietary burden, the residue concentrations in animal products were re-calculated by the current Meeting.

The calculated maximum dietary burden for beef and dairy cattle was 6.2 ppm. In the cattle feeding study described in the 1997 JMPR Monograph, no residues were found above the LOQ of 0.01 mg/kg in milk at feeding level of 6.5 ppm.

Residues of fenbuconazole in muscle were < 0.01 (2) and 0.01 mg/kg at dose level of 6.5 ppm. Residues in kidneys were below the LOQ of 0.01 mg/kg for all dose groups. Residues in liver were 0.04, 0.06 and 0.09 mg/kg at dose level of 6.5 ppm.

Summary of residues corresponding to the estimated dietary burden

Dietary burden (ppm) Feeding level [ppm]	Muscle	Liver
MRL	highest	highest
MRL beef or dairy cattle (6.2) [6.5]	 (0.01) [0.01]	 (0.09) [0.09]
STMR	mean	mean
STMR beef or dairy cattle (2.1) [6.5]	 (0.003) [0.01]	 (0.02) [0.06]

The Meeting estimated a maximum residue level of 0.01 mg/kg in mammalian meat, 0.1 mg/kg in mammalian edible offal and 0.01(*) mg/kg in milks, and an HR of 0.01 mg/kg in mammalian meat and 0.09 mg/kg in mammalian edible offal. The Meeting withdrew the previous

recommendations of maximum residue levels of 0.05(*) mg/kg for cattle meat, cattle fats, cattle kidney and cattle milk.

The mean estimated dietary burden for dairy cattle was 2.0 ppm. No detectable fenbuconazole residues (< 0.01 mg/kg) were found in any sample of milk at the 6.5 ppm feeding level. The Meeting therefore estimated an STMR of 0 mg/kg in milk.

The mean estimated dietary burden for beef cattle was 2.1 ppm. In kidney, no fenbuconazole residues were detected at the 6.5 ppm feeding level. Since residues above the LOQ were found in muscle and liver at a dose of 6.5 ppm, detectable residues of fenbuconazole were expected in muscle and liver at the mean dietary burden of 2.1 ppm. The Meeting estimated an STMR of 0.003 mg/kg in meat, 0.02 mg/kg in offal.

The calculated maximum dietary burden for poultry was 0.31 ppm. In the poultry feeding study, residues of fenbuconazole were below the LOQ of 0.01 mg/kg in muscle, liver and eggs at all feeding level tested (0.12–1.13 ppm).

The Meeting estimated a maximum residue level of 0.01(*) mg/kg in poultry meat, poultry edible offal and eggs. The Meeting withdrew the previous recommendations of 0.05(*) mg/kg in poultry meat, poultry fats, poultry edible offal and eggs.

The mean estimated dietary burden for poultry was 0.13 ppm. The Meeting estimated STMRs and HRs of 0 mg/kg in poultry meat, offal and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

In the current evaluation STMRs were estimated for 17 commodities. Where consumption data were available the STMRs were used in dietary intake estimates together with previous MRL recommendations for 18 other food commodities. The results are shown in Annex 3.

The estimated daily intakes for the 13 GEMS/Food Consumption Cluster Diets were in the range of 0 to 2% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intake of residues of fenbuconazole resulting 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 fenbuconazole was calculated for 16 food commodities (and their processed fractions) for which maximum residue levels were estimated at the present meeting and for which consumption data were available. The results are shown in Annex 4.

As the Meeting has not yet considered the need of an ARfD, the acute risk assessment for fenbuconazole was not finalized

5.12 FLUOPICOLIDE (235)

TOXICOLOGY

Fluopicolide is the ISO approved common name for 2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl] benzamide (IUPAC nomenclature), which has the CAS No. 239110-15-7. Fluopicolide is a systemic fungicide of the novel chemical class of acylpicolide fungicides and targets oomycetes that cause diseases in a wide range of crops, including potatoes, vegetables and grape vines. Fluopicolide has a new mode of action, which is probably based upon delocalization of spectrin-like proteins. A number of metabolites have been detected in rotational-crop studies and are identified in the present document as M-01 (also known as BAM), M-02, M-04 and M-05. Some studies of metabolism and toxicity have been conducted to investigate the properties of these metabolites.

Fluopicolide is being reviewed for the first time by the present Meeting at the request of the CCPR. All critical studies complied with GLP. Non-GLP studies are identified as such.

Biochemical aspects

In rats given [^{14}C]fluopicolide labelled in either the pyridyl or phenyl rings as a single oral dose at 10 or 100 mg/kg bw, the radiolabel was moderately rapidly absorbed from the gastrointestinal tract (about 70% and 85% of the pyridyl and phenyl labels, respectively). Based on the results of one study of biliary excretion and only for the single dose at 10 mg/kg bw, the extent of oral absorption was 80% for the phenyl radiolabel and 62% for the pyridyl radiolabel. However, blood and plasma kinetic data show that systemic exposure was similar for both the radiolabels and for males and females. The bioavailability of the radiolabel, taking into account the material undergoing enterohepatic recirculation, was calculated to be 75–88% of the administered dose. The t_{max} calculated from plasma concentrations was 7–10 h. There were no significant differences related to sex, high or low doses or multiple doses.

Distribution investigated by dissection and liquid-scintillation counting methods and confirmed by whole-body autoradiography demonstrated that the highest concentrations of radiolabel were in the liver and kidney and, to a lesser extent, in spleen and blood. Tissue concentrations of radiolabel were consistently low and ranged from 0.46% to 1.25 % of the administered dose for the single-dose studies, with a mean of 0.38% for the repeat-dose study.

Elimination from tissues was moderately rapid such that most radioactivity was eliminated within 48 h after dosing; a subsequent slower terminal elimination phase had a a mean $t_{½}$ of about 103 h. Excretion of the 10 and 100 mg/kg bw oral doses was extensive for pyridyl (69–72%) and for phenyl (82–88%) ring radiolabels and was mainly in the faeces. More than 70% of the administered dose was eliminated within 24 h, but the rate of excretion was low thereafter. Extensive biliary excretion (90%) was demonstrated in bile-duct cannulated rats, in which there was also evidence for enterohepatic recirculation. There was a tendency towards a higher urinary excretion of the pyridyl radiolabel (approximately 20% for the dose at 10 mg/kg bw) compared with the phenyl radiolabel (approximately 10 % for the dose at 10 mg/kg bw). This suggests that a proportion of the metabolites that were formed differed between the two radiolabels and were presumably linked to the hydrolysis of the amido group and the formation of M-02 (3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid) from the pyridyl ring moiety and M-01 (2,6-dichlorobenzamide) from the phenyl ring.

Fluopicolide was extensively metabolized in the rat. The formation of the metabolites M-01 and M-02 that are also residues in plants was confirmed during the course of the biotransformation investigations. Generally, the biotransformations observed included aromatic-ring hydroxylation, hydrolysis, dealkylation, acetylation, oxidative N-dealkylation and conjugation with glucuronic acid, sulfate and glutathione. The glutathione conjugates were further metabolized by loss of glycine and

glutamic acid to leave cysteine conjugates. The cysteine conjugates were further metabolized either by acetylation to form the mercapturic acids or by carbon–sulfur cleavage followed by S-methylation to form S-methyl metabolites. The S-methyl metabolites were oxidized to both sulfones and sulfoxides.

Toxicological data

The acute toxicity of fluopicolide is low, the oral LD_{50} being > 5000 mg/kg bw in rats. Signs of toxicity at this high dose included piloerection within 1–2.5 h after dosing in all rats. Later on day 1, piloerection was accompanied only by hunched posture and abnormal gait. Recovery was complete by day 3. The acute dermal LD_{50} of fluopicolide in rats was > 5000 mg/kg bw. The 4-h acute inhalation median lethal concentration (LC_{50}) of fluopicolide in rats was > 5.16 mg/L air (the mean achieved concentration). Fluopicolide was not irritating to rabbit skin and was only transiently, slightly irritating to the rabbit eye. Fluopicolide was not a skin sensitizer in the Magnusson and Kligman test in guinea-pigs.

Short-term studies of toxicity with fluopicolide have been performed in rats, mice and dogs. The liver was consistently identified as a target organ in short-term studies in rats, mice and, the kidney was also a target in male and female rats given higher doses. Increased liver weights were observed in mice, rats and dogs in 28-day and 3-month studies and in dogs in a 1-year study. Microscopic changes observed in the liver included centrilobular hepatocyte hypertrophy in mice and rats and an increased incidence and severity of granulated lymphocytes in rats in the 28-day dietary study. Plasma cholesterol concentrations were increased in rats in the 28-day and 3-month studies and in female dogs in the 1-year study, but they were reduced in mice in the 3-month study. Serum albumin concentrations were also reduced in mice in the latter study. The Meeting considered that these observations were suggestive of impairment of hepatic function at high doses. Renal effects were observed only in rats and consisted of kidney-weight increases in males at 28 days and at 3 months and histopathological changes (accumulation of hyaline droplets, single-cell necrosis in the proximal tubule epithelium and small foci of basophilic tubules and granular casts) in males and females at 3 months. Reversibility of the hepatic effects, but not the renal effects, was demonstrated in rats after 3 months of exposure followed by a 28-day recovery period. Other observations made in these short-term studies were restricted to a particular species, sex or treatment duration. They included treatment-related reductions in haemoglobin and erythrocyte volume fraction in male rats and increased urine volume and specific gravity and spleen weight in female rats in the 3-month study.

The NOAELs derived from short-term studies in which fluopicolide was administered orally were between 7 and 17 mg/kg bw per day in mice and rats, and the overall oral NOAEL in dogs was 70 mg/kg bw per day.

In long-term dietary studies in rats and mice, the primary target organs were the liver and kidney. In mice, liver weights were increased at 400 ppm and 3200 ppm in males after 1 year and in males and females after 18 months. Liver masses and nodules were also increased at these doses after 18 months. High incidences of centrilobular hepatocyte hypertrophy were recorded at 400 ppm and 3200 ppm in male and female mice after 18 months. Foci of altered hepatocytes (eosinophilic foci) and hepatocellular adenoma were increased in male and female mice at 3200 ppm, but there was no increase in the occurrence of hepatocellular carcinoma. In rats, liver weights were increased only in males at the highest dose at 2 years and microscopically there was a dose-related increase in the incidence and severity of centrilobular hepatocyte hypertrophy, again in males, at both 1 year and at 2 years. No cytochrome P450-related enzymes were measured in this study. Cystic degeneration of the liver was reported in males in the group at the highest dose at 2 years and there was an increase in the incidence of eosinophilic foci in both males and females at 2 years.

No significant renal changes were observed in mice. Kidney weights of rats were slightly increased at 2 years and renal lesions (cortical tubule-cell basophilia and hyaline droplets and granular and hyaline casts) were reported in male rats, mainly at the highest dietary concentration of

2500 ppm after 1 year, although an increased incidence of cortical tubule cell basophilia was also observed at 750 ppm. After 2 years, there was no further progression of these renal lesions, which were again confined to males and only at the highest dose. The NOAEL was 50 ppm, equal to 7.9 mg/kg bw per day in males and 11.5 mg/kg bw per day in females, on the basis of increased liver weights, enlarged liver, masses and nodules in the liver, and hepatocellular hypertrophy at 400 ppm, equal to 64.5 mg/kg bw per day in males and 91.9 mg/kg bw per day in females, in the 18-monthsdietary study in mice. Fluopicolide induced hepatocellular adenomas in male and female mice at 3200 ppm, equal to 551 mg/kg bw per day in male mice and 772 mg/kg bw per day in female mice. The NOAEL was 200 ppm, equal to 8.4 mg/kg bw per day, on the basis of increased centrilobular hypertrophy of the liver and increased kidney weights at 750 ppm, equal to 32 mg/kg bw per day, in the 2-year dietary study of toxicity and carcinogenicity in rats.

A short-term investigation of the neoplastic hepatic effects in mice given fluopicolide at a dietary concentration of 3200 ppm demonstrated increased cell proliferation after 7 days, but not after 28 days. Biochemical measurements made in these mice after 7 days demonstrated increases in hepatic cytochrome P450 content and hepatic activities of benzyloxyresorufin O-de-ethylase (BROD), ethoxyresorufin O-deethylase (EROD) and pentylresorufin O-dealkylase (PROD) enzymes, some of which were consistent with the induction of CYP2B. A reduction in the hydroxylation of lauric acid also occurred. This pattern of changes is almost identical to the profile reported in mice treated with phenobarbital at 80 mg/kg bw per day and is indicative of a constitutive androstane receptor (CAR)-mediated response. These data are biomarkers for a proposed mode of action for fluopicolide in mouse liver that is similar to that of phenobarbital.

The genotoxic potential of several batches of fluopicolide was investigated in a range of studies in vitro and in vivo. A small number of significant or equivocal responses were observed. A significant response with one batch in a test for mutation in bacteria was not confirmed upon repetition of the study. Another batch was associated with an equivocal response in a test for micronucleus formation in mouse bone marrow and was used in the long-term studies of toxicity and carcinogenicity in mice and rats. Current production batches are of higher purity than those used in the genotoxicity-testing programme. In conclusion, the overall weight of evidence suggested that some batches of fluopicolide can have weak mutagenic properties in vitro or in vivo at toxic doses. The Meeting considered that fluopicolide at current purity levels was unlikely to present a genotoxic hazard to humans.

A significantly increased incidence of hepatocellular adenoma was observed in mice, but is the Meeting proposed that these were induced by a mode of action in which CAR activation is involved. The profile of hepatotoxicology of fluopicolide, including CAR activation, is similar to that observed with phenobarbital, a chemical for which there is extensive experience of exposure in humans, but no evidence for carcinogenicity in humans. The Meeting therefore considered the liver tumours in mice to be of no relevance to humans.

On the basis of the available studies, the Meeting considered that there was no evidence of carcinogenic potential for fluopicolide administered to rats.

The Meeting concluded that fluopicolide was unlikely to be carcinogenic in humans.

In a two-generation study of fluopicolide in rats, there were increased mean absolute and relative kidney and liver weights and reduced spleen weights in males and females at 2000 ppm, the highest dose, but not at lower doses. The NOAEL for systemic toxicity in the parental generation was 500 ppm, equal to 25.5 mg/kg bw per day, on the basis of increases in liver and kidney weights of rats at 2000 ppm, equal to 103.4 mg/kg bw per day. In the multigeneration study in rats, the NOAEL for reproductive toxicity was 2000 ppm, equal to 103.4 mg/kg bw per day (the highest dose tested) for F_0 rats for the period before pairing. The overall NOAEL for pups and developing offspring was 500 ppm, equal to 25.5 mg/kg bw per day, on the basis of reduced body-weight gains of pups during lactation and reduced absolute spleen and thymus weights in males and females of the F_1 and F_2 generations at 2000 ppm, equal to 103.4 mg/kg bw per day.

In a study of developmental toxicity in which rats were given fluopicolide by gavage on days 7–20 of gestation, the NOAEL for maternal toxicity and fetotoxicity was 60 mg/kg bw per day on the basis of slightly decreased body weight in dams and reduction in mean fetal body weights and crown–rump lengths in fetuses at 700 mg/kg bw per day. Further evidence for fetotoxicity at this dose was provided by increased incidences of anomalies of the thoracic vertebrae, sternebrae and ribs as well as delayed ossification.

In a study of developmental toxicity in which rabbits were given fluopicolide by gavage on days 6–28 of gestation, the NOAEL for maternal toxicity and fetotoxicity in rabbits was 20 mg/kg bw per day on the basis of mortality, a high incidence of premature delivery and reduction in body-weight gain and food consumption in dams and reduction in fetal body weights and fetal crown–rump lengths in fetuses at doses of 60 mg/kg bw per day.

The Meeting concluded that fluopicolide causes fetotoxicity and skeletal anomalies only at doses that are also maternally toxic.

In a study of neurotoxicity in rats given a single dose of fluopicolide by gavage, the NOAEL was 100 mg/kg bw on the basis of reduction in body temperature and increased incidence of excessive grooming in females at 2000 mg/kg bw. In a 90-day study of neurotoxicity in rats given diets containing fluopicolide, the NOAEL was 200 ppm, equal to 15.0 mg/kg bw per day, on the basis of impaired growth and histopathological changes in the liver and kidney at 1400 ppm, equal to 106.6 mg/kg bw per day. The NOAEL for neurotoxicity was 10 000 ppm, equal to 781 mg/kg bw per day, the highest dose tested.

The Meeting concluded that fluopicolide is unlikely to cause neurotoxicity in humans.

Toxicological data on metabolites

Some aspects of the toxicology of four metabolites of fluopicolide – M-01 (BAM) or 2,6-dichlorobenzamide, M-02 or 3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid, M04 or 2,6-dichloro-3-hydroxybenzamide M-05 or 3-(methylsulfinyl)-5-(trifluoromethyl)pyridine-2-carboxylic acid – were reported. These metabolites are also found as residues in crops. The radiolabelled phenyl metabolite, M-01, has been subjected to kinetic and metabolic studies in rats given oral doses. The highest tissue concentrations were seen in the kidney and liver of rats at 10 mg/kg bw and in the skin and fur, kidneys and liver of rats at 150 mg/kg bw. Tissue concentrations increased by approximately five-fold for a fifteen-fold increase in dose and multiple dosing did not indicate any bioaccumulation. The radiolabel was eliminated mostly in the urine (approximately 82% of the administered dose), with low levels eliminated in the faeces (approximately 13% of the administered dose). The rate of elimination was relatively slow. Biotransformation showed no sex-specific or dose-dependent differences and consisted of hydrolysis of the amide group, hydroxylation and subsequent conjugation with either glucuronic acid or sulfate, and the loss of a chlorine atom followed by glutathione conjugation and further metabolism of the glutathione group to mercapturic acid or S-methyl metabolites.

The pyridyl metabolite, M-02, was well absorbed, with minimum mean absorption calculated to be 87%. Elimination was rapid from both male and female rats, with at least 90% of the total administered radioactivity eliminated within the first 48 h after dosing. The total recovery in urine accounted for about 80% of the administered dose, with faecal elimination accounting for about 7% of the administered dose. Unchanged M-02 accounted for most of the eliminated material.

The acute toxicity of M-01 is relatively low, with an oral LD_{50} of 2000 mg/kg bw in male rats and 500 mg/kg bw in female rats, while the acute toxicity of M-02, M-04 and M-05 can be described as very low, oral LD_{50} values being > 2000 mg/kg bw for with M-02 and M-04 in rats and > 5000 mg/kg bw for M-05. Thus, only M-01 has an acute toxicity that is higher than that of fluopicolide.

In a 28-day study of dietary toxicity with M-02 in rats, no treatment-related change was seen in mean terminal body weights, mean absolute and relative organ weights, gross post-mortem or microscopic examination. The NOAEL for M-02 was 20000 ppm, equal to 1574 mg/kg bw per day, the highest dose tested.

In a 28-day study of dietary toxicity with M-04 in rats, the NOAEL was 2000 ppm, equal to 159.2 mg/kg bw per day, on the basis of lower body weights, reduced haemoglobin concentration, increased plasma cholesterol concentration, liver and kidney weights and histological findings in the liver, kidney and thyroid at 20000 ppm, equal to 1775 and 1931 mg/kg bw per day in males and females, respectively.

In a 28-day dietary study of toxicity with M-05 in rats, the NOAEL was 2000 ppm, equal to 152 mg/kg bw per day, on the basis of clinical signs, reductions in body weight and food consumption and renal effects at 20000 ppm, equal to 1775 mg/kg bw per day. An increase in liver weight at this, the highest, dose was not accompanied by microscopic changes.

In a 13-week dietary study of toxicity with M-01 in rats, no effects on liver or kidney function were observed. The NOAEL for M-01 was 180 ppm, equal to 14 mg/kg bw per day, on the basis of reductions in food consumption and body-weight gain and reduced skeletal muscle tone at 600 ppm, equal to 49 mg/kg bw per day.

In a 13-week study of dietary toxicity with M-01 in dogs, the NOAEL was 300 ppm, equivalent to 22.5 mg/kg bw per day, on the basis of clinical signs and increases in liver weight and serum alkaline phosphatase activity at 2000 ppm, equivalent to 150 mg/kg bw per day. Increased liver weight at 300 ppm was not considered to be toxicologically significant.

In a 2-year dietary study with M-01 in dogs, the NOAEL was 180 ppm, equal to 4.5 mg/kg bw per day, on the basis of reduced body-weight gain at 500 ppm, equal to 12.5 mg/kg bw per day.

In a 2-year study with M-01 in rats, the liver was the primary target for toxicity. These effects were largely confined to females and consisted of increased incidences of vacuolation, fat deposition, hepatocyte degeneration, eosinophilic foci and basophilic foci in the liver. There was also an increased incidence of hepatocellular adenomas that was marginally statistically significant ($p = 0.05$). No relevant data on historical controls were available to assist in an evaluation of this result. The NOAEL was 60 ppm, equal to 2.0 mg/kg bw per day, based on body-weight reductions, increased incidences of eosinophilic and basophilic foci in the livers and fat deposition and cellular degeneration in the liver at 100 ppm, equal to 3.5 mg/kg bw per day.

These metabolites were tested for genotoxicity in an adequate range of assays. M-01 and M-04 were tested in vitro and in vivo, while M-02 was tested in vitro. M-05 was tested in vitro for mutagenicity in bacteria and V79 cells. No evidence of genotoxicity was observed for M-01, M-02 or, in a more limited test profile, M-05. There was no evidence for mutagenicity with M-04 in bacteria or V79 cells, although there the proportion of chromosomal aberrations was increased in treated human lymphocytes in culture. In a test for unscheduled DNA synthesis in rat liver in vivo and an assay for micronucleus formation in mouse bone-marrow cells in vivo, there was no evidence for genetic toxicity or mutagenicity with M-04. The Meeting noted, for consideration of ARfDs, that clinical signs of toxicity were observed in the dose-range finding study in mice given a single dose of 100 mg/kg bw (the lowest dose tested) by gavage. Thus the mutagenic (clastogenic) activity observed in vitro was not confirmed in vivo. The Meeting concluded that M-01, M-02 and M-04 are unlikely to be genotoxic.

In a three-generation study with M-01 in rats, the NOAEL for parental toxicity and for reproductive toxicity was 180 ppm, equal to 13.5 mg/kg bw per day (the highest dose tested), on the basis of the absence of parental toxicity and reproductive toxicity. The NOAEL for fetal toxicity was 100 ppm, equal to 7.5 mg/kg bw per day, on the basis of increased liver weights relative to body weights at 180 ppm, equal to 13.5 mg/kg bw per day.

In a study of developmental toxicity in rabbits given M-01 by gavage on days 7–19 of gestation, the NOAEL for maternal toxicity and fetoxocity was 30 mg/kg bw per day on the basis of maternal mortality and abortions in dams and slightly reduced birth weights at 90 mg/kg bw per day. M-01 was not teratogenic in the study of developmental toxicity in rabbits. Data for individual rabbits were examined for effects that may have been produced by a single or small number of doses, but none were found.

In conclusion, in studies of acute toxicity and in long-term studies of toxicity, M-01 is more toxic than fluopicolide, while the data show that the metabolites M-02, M-04 and M-05 are less toxic than parent fluopicolide. In the case of M-04, there are clear similarities with the toxicity profile of fluopicolide. A weak tumorigenic response to M-01 in the liver of female rats would appear to have no significance for an interpretation of the fluopicolide-associated liver tumours, which were found in male and female mice, but not in rats. In view of the lack of genotoxicity and the occurrence of benign tumours only at a high dose, the Meeting concluded that M-01 was unlikely to be carcinogenic in humans at estimated dietary levels of exposure.

No reported incidents of adverse reactions during the pilot-scale manufacture or formulation of fluopicolide. No further information on medical surveillance or poisoning incidents was available.

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

Toxicological evaluation

Fluopicolide and M-01 (2,6-dichlorobenzamide)

Fluopicolide

An ADI of 0–0.08 mg/kg bw was established for fluopicolide based on the NOAEL of 7.9 mg/kg bw per day, identified on the basis of organ weight increases and gross and microscopic changes in the liver and kidneys in an 18-month dietary study of toxicity and carcinogenicity in mice, supported by the NOAEL of 8.4 mg/kg bw per day identified on the basis of histopathological changes in the liver and increased kidney weights in a 2-year dietary study of toxicity and carcinogenicity in rats, and with a safety factor of 100.

An ARfD of 0.6 mg/kg bw was established for women of child-bearing age based on a NOAEL of 60 mg/kg bw per day identified on the basis of a marginally increased incidence of skeletal defects of the vertebrae and sternebrae, which might be attributable to a single exposure to fluopicolide at 700 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 for fluopicolide 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.

M-01 (2,6-dichlorobenzamide)

An ADI of 0–0.02 mg/kg bw was established for the fluopicolide metabolite M-01 based on the NOAEL of 2.0 mg/kg bw per day identified on the basis of microscopic changes in the liver in a 2-year dietary study of toxicity and carcinogenicity in rats, supported by the NOAEL of 4.5 mg/kg bw per day, identified on the basis of reduced body weight gain in a 2-year dietary study of toxicity in dogs, and with a safety factor of 100.

The Meeting concluded that the establishment of an ARfD for the general population should be considered based on the finding of mortality at single oral doses of less than 500 mg/kg bw in

female rats. An LOAEL of 100 mg/kg bw was identified on the basis of clinical signs of toxicity in a dose range-finding study in mice given a single dose of M-01, but this study did not provide sufficient detail for it to be used as the basis for an ARfD by itself. In the absence of adequate data, an ARfD for the general population was established for the metabolite, based on the value of 0–0.6 mg/kg bw for the parent compound. This value is derived from a study of developmental toxicity in rats and a safety factor of 100, as described above. The ARfD derived from a study with fluopicolide is sufficiently protective for application to the metabolite M-01, owing to the large dose-spacing between the LOAEL and the NOAEL.

A toxicological monograph was prepared.

Levels relevant to risk assessment for fluopicolide

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month study of toxicity and carcinogenicity	Toxicity	50 ppm equal to 7.9 mg/kg bw per day	400 ppm equal to 64.5 mg/kg bw per day
		Carcinogenicity	400 ppm equal to 64.5 mg/kg bw per day	3200 ppm equal to 552 mg/kg bw per day
Rat	Two-year studies of toxicity and carcinogenicity	Toxicity	200 ppm equal to 8.4 mg/kg bw per day	750 ppm equal to 32 mg/kg bw per day
		Carcinogenicity	2500 ppm equal to [a]109.4 mg/kg bw per day	—
	Two-generation study of reproductive toxicity	Reproductive toxicity	2000 ppm equal to [a]103.4 mg/kg bw per day	—
		Parental toxicity	500 ppm equal to 25.5 mg/kg bw per day	2000 ppm equal to 103.4 mg/kg bw per day
		Offspring toxicity	500 ppm equal to 25.5 mg/kg bw per day	2000 ppm equal to 103.4 mg/kg bw per day
	Developmental toxicity	Maternal toxicity	60 mg/kg bw per day	700 mg/kg bw per day
		Embryo and fetal toxicity	60 mg/kg bw per day	700 mg/kg bw per day
Rabbit	Developmental toxicity	Maternal toxicity	20 mg/kg bw per day	60 mg/kg bw per day
		Embryo and fetal toxicity	20 mg/kg bw per day	60 mg/kg bw per day
Dog	Three-month study of toxicity	Toxicity	70 mg/kg bw per day	1000 mg|kg bw per day

[a] Highest dose tested.

Levels relevant to risk assessment for M-01 (2,6-dichlorobenzamide)

Species	Study	Effect	NOAEL	LOAEL
Mouse	Dose-range finding study of toxicity for a test of micronucleus formation	Toxicity	—	100 mg/kg bw
Rat	Two-year studies of toxicity and carcinogenicity	Toxicity	60 ppm, equal to 2.0 mg/kg bw per day	100 ppm, equal to 3.5 mg/kg bw per day
		Carcinogenicity	180 ppm equal to 5.7 mg/kg bw per day	500 ppm equal to 17.6 mg/kg bw per day
	Two-generation study of reproductive toxicity	Reproductive toxicity	180 ppm equal to 13.5 mg/kg bw per day	—
		Parental toxicity	180 ppm equal to 13.5 mg/kg bw per day	—
		Offspring toxicity	100 ppm equal to 7.5 mg/kg bw per day	180 ppm equal to 13.5 mg/kg bw per day
Rabbit	Developmental toxicity	Maternal toxicity	30 mg/kg bw per day	90 mg/kg bw per day
		Embryo- and fetal toxicity	30 mg/kg bw per day	90 mg/kg bw per day
Dog	Two-year study of toxicity	Toxicity	180 ppm, equal to 4.5 mg/kg bw per day	500 ppm, equal to 12.5 mg/kg bw per day

Estimate of acceptable daily intake for humans

Fluopicolide	0–0.08 mg/kg bw
M-01[33]	0–0.02 mg/kg bw

Estimates of acute reference doses

Fluopicolide	0.6 mg/kg bw for women of child-bearing age
	Unnecessary for the general population
M-01	0.6 mg/kg bw

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

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

[33] 2,6-dichlorobenzamide

Critical end-points for setting guidance values for exposure to fluopicolide and its metabolite M-01 (2,6-dichlorobenzamide)

Absorption, distribution, excretion and metabolism in mammals		
Rate and extent of oral absorption	Moderately rapid and moderately extensive, at least 80%	
Distribution	Distributed throughout the body; higher concentrations in liver, kidney and blood	
Potential for accumulation	No evidence for accumulation	
Rate and extent of excretion	Moderately rapid, > 70% within 24 h, but subsequently low rate with 95% within 48 h, mainly in faeces	
Metabolism in animals	Extensively metabolised; biotransformations observed included aromatic ring hydroxylation, hydrolysis, dealkylation, acetylation, oxidative N-dealkylation and conjugation with glucuronic acid, sulfate and glutathione. Up to 46 radiolabelled components in urine and faeces	
Toxicologically significant compounds (animals, plants and environment)	Parent, M-01	
Acute toxicity	Fluopicolide	2,6-Dichlorobenzamide (M-01)
Rat, LD_{50}, oral	> 5000 mg/kg bw	2000 mg/kg bw in males, 500 mg/kg bw in females
Rat, LC_{50}, inhalation	> 5.2 mg/L[a] (4 h)	No data
Rat, LD_{50}, dermal	> 5000 mg/kg bw[a]	No data
Rabbit, dermal irritation	Not an irritant	No data
Rabbit, ocular irritation	Slightly, transiently irritating	No data
Guinea-pig, dermal sensitization	Not sensitizing (Magnusson and Kligman test)	No data
Short-term studies of toxicity		
Target/critical effect	Liver, kidney	Body-weight gain; muscle tone
Lowest relevant oral NOAEL	7.4 mg/kg bw per day (3-month study in rats)	14 mg/kg bw per day (3-month study in rats
	300 mg/kg bw per day (1-year study in dogs)	4.5 mg/kg bw per day (2-year study in dogs)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day[a] (28-day study in rats)	No data
Genotoxicity	A small number of inconsistent positive or equivocal responses were observed, but the overall weight of evidence is that it is unlikely to be genotoxic.	Not genotoxic

Long-term studies of toxicity and carcinogenicity		
Target/critical effect	Liver	Liver
Lowest relevant NOAEL	7.9 mg/kg bw per day (18-month study in mice)	60 ppm equal to 2 mg/kg bw per day (2-year study in rats
Carcinogenicity	Benign liver tumours in mice that are of no human relevance, based on mode of action	Benign liver tumours in rats that are unlikely to pose a risk to humans
Reproductive toxicity		
Reproductive target/critical effect	No reproductive toxicity	No reproductive toxicity
Lowest relevant reproductive NOAEL	2000 ppm equal to 103 mg/kg bw per day	180 ppm equal to 13.5 mg/kg bw per day
Developmental target/critical effect	Not teratogenic; abortions, total litter loss, reduced fetal body weight and pup body weight during lactation, delayed ossifications, vertebral and sternebral defects	Not teratogenic; abortions, reduced fetal body weight, increased relative liver-to-body weight
Lowest relevant developmental NOAEL	60 mg/kg bw per day (rat), 20 mg/kg bw per day (rabbit)	30 mg/kg bw per day (rabbit)
Neurotoxicity/delayed neurotoxicity		
	No signs of neurotoxicity	No data
Other toxicological studies		
	Induction of liver xenobiotic metabolizing enzymes in female mice and male and female rats	No data
	Several metabolites that are also crop residues have been investigated, but only M-01 (2,6-dichlorobenzamide) was more toxic than fluopicolide in a single-dose and a long-term study.	
Medical data		
	No reports of toxicity in workers exposed during pilot scale manufacture or formulation	

[a] Highest dose tested

Summary

Fluopicolide	**Value**	**Study**	**Safety factor**
ADI	0–0.08 mg/kg bw	Mouse, 18-month study of toxicity and carcinogenicity	100
ARfD	0.6 mg/kg bw for women of child-bearing	Rat, study of developmental toxicity	100

	age		
M-01 (2,6-dichlorobenzamide)			
ADI	0–0.02 mg/kg bw	Rat, 2-year study of toxicity and carcinogenicity	100
ARfD	0.6 mg/kg bw general population	Rat, study of developmental toxicity on the parent compound	100

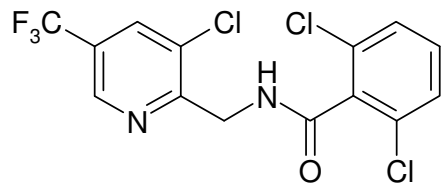
[a] Only dose tested.

RESIDUE AND ANALYTICAL ASPECTS

Fluopicolide belongs to the benzamide and pyridine class of fungicide. It is a meso-systemic fungicide; it translocates toward the stem tips via the xylem but it does not translocate toward the roots. Fluopicolide is effective against a wide range of Oomycete (Phycomycete) diseases including downy mildews (Plasmopara, Pseudoperonospora, Peronospora and Bremia), late blight (Phytophthora), and some Pythium species. The Meeting received information on fluopicolide metabolism and environmental fate, methods of residue analysis, freezer storage stability, national registered use patterns, supervised residue trials, farm animal feeding studies and fates of residues in processing.

The 2009 JMPR established ADIs for fluopicolide and 2,6-dichlorobenzamide of 0–0.08 and 0–0.02 mg/kg bw respectively. For fluopicolide the ARfD is 0.6 mg/kg bw for women of child-bearing age with an ARfD not necessary for other groups of the population. The Meeting set an ARfD for 2,6-dichlorobenzamide of 0.6 mg/kg bw for the general population.

Fluopicolide is 2,6-dichloro-N-{[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl}benzamide.



The following abbreviations are used for the metabolites discussed below:

M-01 or BAM:	2,6-dichlorobenzamide
M-02:	3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid
M-04:	2,6-dichloro-3-hydroxybenzamide
M-05:	3-(methylsulfinyl)-5-(trifluoromethyl)pyridine-2-carboxylic acid
M-06:	2,6-dichloro-N-[(3-chloro-5-trifluoromethylpyridin-2-yl) methyl]-3-hydroxybenzamide
M-07	2,6-dichloro-N-[(3-chloro-5-trifluoromethylpyridin-2-yl) methyl]-4-hydroxybenzamide

M-18: 2,4-dichloro-3-[({[3-chloro-5-(trifluoromethyl)pyridin-2-yl]methyl}amino)carbonyl] phenyl hydrogen sulphate or 3,5-dichloro-4-[({[3-chloro-5-(trifluoromethyl)pyridin-2-yl]methyl}amino)carbonyl] phenyl hydrogen sulfate

M-19: 3,5-dichloro-4-[({[3-chloro-5-(trifluoromethyl)pyridin-2-yl]methyl}amino)carbonyl] hydroxyphenyl hydrogen sulfate

Animal metabolism

Radiolabelled fluopicolide (separately ^{14}C-labelled at the [pyridyl-2,6-^{14}C]- and [phenyl-U-^{14}C]-rings) 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.

Lactating cows were orally dosed with [pyridyl-2,6-^{14}C]- or [phenyl-U-^{14}C]-fluopicolide at doses equivalent to approximately 1 or 10 ppm in the feed for 7 consecutive days.

The majority of the administered doses were recovered in excreta (55–69% in faeces, 11–19% in urine) with an additional 0.87–2.1% recovered from the cage wash. Radioactivity retained in tissues, bile or secreted in milk accounted for less than 1% of the administered dose. Overall 76–84% of administered radioactivity was accounted for.

Radiocarbon content in various tissues were highest in liver followed by kidney, fat and muscle while in milk radioactive residues were low, being lower than those observed in muscle. Following dosing equivalent to 10 ppm in the diet radioactivity was 0.45–0.64 mg/kg in liver, 0.2–0.3 mg/kg in kidney, 0.04 mg/g in fat, 0.01–0.02 mg/kg in muscle and 0.01–0.02 mg/kg in milk. Fluopicolide was the major component of the extracted radioactivity identified in muscle (5.1%), fat (64–78%) and milk (37%) samples and was also present in liver (0.9–2.9%) and kidney (0.7–1.8%). A large number of metabolites were present in extracts of liver and kidney, each accounting for less than 10% of the TRR, most notably mono- and di-hydroxy-glucuronides of fluopicolide as well as mono- and dihydroxy-sulphate conjugates of fluopicolide (M-18, M-19).

Investigations into polar metabolites in liver and kidney demonstrated that they were associated with amino acids, peptides and proteins. There was no significant association of the radioactive residues of fluopicolide with RNA or DNA.

Laying hens were orally dosed with [pyridyl-2,6-^{14}C]- or [phenyl-U-^{14}C]-fluopicolide at doses equivalent to approximately 1 or 10 ppm in the feed for 14 days. The majority of the administered radioactivity was excreted (82–95% over the 14 day dosing period), with 0.6–2.8% recovered from cage wash and approximately 0.08–0.13% in eggs (white and yolks). In tissues from the 10 ppm dose groups, the highest concentrations of radioactivity were in liver (0.28–0.98 mg/kg), followed by fat (0.03–0.06 mg/kg) and muscle (0.01–0.04 mg/kg). Fluopicolide represented 11% of the radioactivity in yolks and 0–2.5% in egg whites. The major component of the radioactivity in egg whites (51%) was tentatively assigned to a methylsulphone conjugate of fluopicolide; the conjugate was also present in fat (38% TRR). A large number of degradates were present in the eggs and tissues, most notably M-01 (37% liver TRR), M-06 in liver (5.4% TRR) and skin plus fat (38% TRR), M-07 in egg white (41% TRR), egg yolk (9.6–16% TRR), liver (5.9% TRR) and fat (47% TRR). Monohydroxy-sulphate (M-18 10% TRR in yolk and liver) and dihydroxy-sulphate conjugates (M-19 23% egg white TRR, 15–34% yolk TRR) were also observed but no mono- and dihydroxy-glucuronides.

As with lactating cows, investigations into polar metabolites in liver demonstrated that they were associated with amino acids, peptides and proteins and that there was no significant association of the radioactive residues of fluopicolide with RNA or DNA.

In summary, in livestock the majority of the administered radioactivity was recovered in the excreta (75–95% of dose) leaving only low levels of radioactivity in the tissues (0.06–0.78%), milk

(0.08–0.14%) and eggs (0.08–0.13%). The highest tissue concentrations were consistently observed in the liver of cow and hen at both dose levels. There was no evidence of any accumulation of radioactivity in milk, eggs or edible tissues.

The identified metabolites of fluopicolide in the cow and hen are thought to be formed by hydroxylation of the chlorophenyl ring in the meta- and para- positions to give metabolites M-07 and M-06, respectively. Each of these metabolites is conjugated with sulphate or hydroxylated in a second position to give a proposed dihydroxy intermediate, which is further metabolised to a sulphate conjugate. In the cow, conjugation with glucuronic acid was also observed. Additionally a methyl sulphone conjugate of fluopicolide and M-01 have been observed in the hen.

Plant Metabolism

The Meeting received information on the fate of [^{14}C]fluopicolide after foliar application to grapes, lettuce and potato and also as a soil drench to lettuce.

Metabolism studies in grapes, lettuce and potato demonstrated that following foliar application, fluopicolide was not metabolised to any great extent. With up to three consecutive foliar applications of fluopicolide to grapes, lettuce and potato, parent compound was the major component of the radioactive residues at 87–95%, 96% and 51–70% of the TRR respectively for grapes (berries), lettuce (leaves) and potato (tubers). When applied as a soil drench to lettuce parent compound was the major component of the TRR in lettuce at harvest (72% TRR). Minor metabolites (< 0.035 mg/kg) identified in the studies were M-01 (1.3–25% TRR), M-02 (0.6–26% TRR) and M-06 (0.1–2.8% TRR) with the higher levels of metabolites resulting from uptake from soil (lettuce following a soil drench or in potato tubers following foliar sprays). Surface washes of samples removed the majority of the residue, decreasing with time after spraying.

Metabolism of fluopicolide is proposed to occur through hydrolysis of the amide bond of fluopicolide to form metabolites M-01 and M-02 and hydroxylation in position 3 of the phenyl ring to form metabolite M-06.

Environmental fate

Photolytic degradation of fluopicolide occurs to some extent and may contribute to its degradation. Fluopicolide is considered stable to hydrolysis.

The aerobic degradation of fluopicolide in soil is primarily via oxidative cleavage to produce, M-01 and M-02. Ultimately mineralisation to $^{14}CO_2$ occurs. The half-life for disappearance of parent fluopicolide in soil is estimated to be > 200 days. Fluopicolide is considered to be persistent.

Residues in succeeding crops

The log K_{ow} of fluopicolide (log K_{ow} 2.9) and the results of the lettuce and potato metabolism studies suggest fluopicolide may be translocated in plants. In confined and field rotational crop studies, residues of fluopicolide were found in leafy and brassica vegetables, root vegetables, and cereal and pulse grain at harvest. In confined rotational crop studies with radiolabelled fluopicolide metabolites M-01, M-02 and M-04 occurred at levels higher than fluopicolide in some matrices, principally wheat grain and forage. In lettuce and radish (root and tops), the main residues were fluopicolide and M-01. Residues of M-06, M-08 and M-09 were also detected but the levels were lower than for fluopicolide. The levels of fluopicolide and metabolites in field rotational crop studies on wheat were < 0.01–0.12 mg/kg for fluopicolide, < 0.01–0.06 mg/kg for M-01, < 0.01–0.02 mg/kg for M-02, < 0.01–0.09 mg/kg for M-04 and < 0.01–0.08 mg/kg for M-05 in forage, straw and grain. For cabbage, faba beans (shoots, pods and dried seed) and radish (root and tops) residues were < 0.01–0.03 mg/kg for fluopicolide, < 0.01–0.10 mg/kg for M-01 and < 0.01–0.02 mg/kg for M-02. It is concluded that rotational crops may contain low levels of residues of fluopicolide and metabolites.

Analytical methods

Several different analytical methods have been reported for the analysis of fluopicolide and selected metabolites/degradates in plant material (M-01, M-02) and fluopicolide in animal commodities. The basic approach employs extraction by homogenisation with acetonitrile:water, and column clean-up using SPE. Residues are determined by liquid chromatography with mass spectra detection. The methods for fluopicolide and selected metabolites have been validated with for a range of substrates with LOQs of 0.01 mg/kg for each analyte. Studies on extraction efficiency indicated greater than 80% of the residue is able to be extracted with acetone:water.

The official German multi-residue method (DFG-S19) with LC-MS/MS detection was validated for fluopicolide; M-01, M-02 in plant, and fluopicolide in animal commodities. LOQs were also 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. Fluopicolide, M-01 and M-02 residues are stable in grapes, potatoes, cabbages and wheat grain for at least 30 months frozen storage. Fluopicolide, M-01, M-04 and M-05 are stable in wheat straw for at least 18 months frozen storage. Data on freezer storage stability showed that fluopicolide, M-01 and M-02 residues are stable in milk for at least 2 months, in fat and muscle for at least 4 months and in liver and kidney for at least 9 months.

Definition of the residue

The metabolism of fluopicolide in a range of crops has been studied following both foliar and soil drench application. Studies were conducted with leafy vegetables (lettuce), root vegetables (potatoes) and fruit crops (grape vine). Each was conducted with both phenyl- and pyridyl-radiolabelled fluopicolide. The rate of degradation on plants is low and the parent compound was always the major component (51–96% TRR). Metabolites M-01 and M-02 were present at 1.3–25% and 0.6–26% respectively. Minor metabolites M-04, M-05, M-08 and M-09 were found in plant matrices at low levels (≤ 2.8% TRR) but not in rat metabolism studies.

In rotational crop studies fluopicolide and M-01 were generally the main components of the residue. The Meeting considered the acute and long term toxicity of M-01 is higher than fluopicolide while the available data show that the metabolites M-02, M-04 and M-05 are less toxic than the parent compound. The Meeting decided to include M-01 in the residue definition for risk assessment. However, the metabolite M-01 is not unique to fluopicolide, e.g. M-01 is also a metabolite of dichlobenil. Therefore, it was proposed not to include M-01 in the residue definition for compliance. The Meeting considered the majority of dietary exposure to residues of toxicological concern would be accounted for when measuring residues of fluopicolide and M-01.

In the lactating cow metabolism study, fluopicolide is the major component of the residue in muscle (5.1%), fat (64–78%) and milk (37%) and was also present in liver (0.9–2.9%) and kidney (0.7–1.8%) and in the laying hen study represented 11% of the radioactivity in yolks and 0–2.5% in egg whites. Parent fluopicolide is present in most tissues and considered a good indicator compound for enforcement purposes.

The Meeting recommended that the residue definition for plant and animal commodities for compliance with MRLs should be fluopicolide.

The Meeting recommended that the residue definition for plant and animal commodities for dietary risk assessment should be fluopicolide and M-01.

The log K_{ow} of fluopicolide (log K_{ow} 2.9, pH 7) suggests that fluopicolide might be borderline fat soluble. The ratio of fluopicolide residues in muscle and fat observed in the livestock metabolism studies (lactating cow 1:32–1:49) support the conclusion that fluopicolide is fat soluble.

Proposed definition of the residue (for compliance with MRL for plant and animal commodities): *fluopicolide.*

Proposed definition of the residue (for estimation of dietary intake for plant and animal commodities): *fluopicolide and 2,6-dichlorobenzamide measured separately*.

The residue is fat soluble.

Results of supervised trials on crops

Dietary risk assessment requires separate STMR and HR values for fluopicolide and M-01. Supervised trials were available for the use of fluopicolide on: grapes, onions, leeks, Brassica vegetables (broccoli, Brussels sprouts, cabbage and cauliflower), cucumber, melon and summer squash including zucchini, chilli peppers, sweet peppers, tomatoes, lettuce, spinach, carrots, radish, and celery. Residue trial data was made available from Brazil, Canada, member states of the European Union and the USA.

The NAFTA calculator was used as a tool in the estimation of the maximum residue levels from the selected residue data sets obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level with the calculator using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value than that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Grapes

Data were available from supervised trials on grapes in member states of the European Union, Canada and the USA.

The GAPs of Italy and Slovenia are similar at one to three sprays at 133 g ai/ha and a PHI of 28 days. Residues in grapes from trials in southern Europe matching GAP of Italy and Slovenia were (n=20): 0.11, 0.11, 0.15, 0.16, 0.20, 0.21, 0.21, 0.21, 0.27, 0.35, 0.38, 0.39, 0.40, 0.46, 0.54, 0.60, 0.69, 0.97, 1.1 and 1.2 mg/kg. M-01 residues were < 0.01 (12), 0.014, 0.015, 0.02 (2), 0.026, 0.03, 0.037 and 0.04 mg/kg. Residues in grapes from trials in northern Europe matching GAP of Italy and Slovenia were (n=19): 0.18, 0.20, 0.21, 0.24, 0.27 (0.013), 0.32, 0.32, 0.33, 0.33, 0.38, 0.44, 0.48 (0.01), 0.50, 0.51 (0.01), 0.52, 0.56, 0.66, 0.83 and 0.96 mg/kg. Residues of M-01 were: < 0.01 (16), 0.01 (2) and 0.013 mg/kg. The residue populations for trials conducted in northern and southern Europe were similar (Mann-Whitney U test) and the Meeting decided to combine the data for the purposes of estimating a maximum residue level (n=39) 0.11, 0.11, 0.15, 0.16, 0.18, 0.2, 0.2, 0.21, 0.21, 0.21, 0.21, 0.24, 0.27, 0.27, 0.32, 0.32, 0.33, 0.33, 0.35, 0.38, 0.38, 0.39, 0.4, 0.44, 0.46, 0.48, 0.5, 0.51, 0.52, 0.54, 0.56, 0.6, 0.66, 0.69, 0.83, 0.96, 0.97, 1.1 and 1.2 mg/kg. Residues of M-01 were: < 0.01 (28), 0.01 (2), 0.013, 0.014, 0.015, 0.02 (2), 0.026, 0.03, 0.037 and 0.04 mg/kg.

The GAP of the USA was used to evaluate trials on grapes from Canada and the USA (USA GAP: 140 g ai/ha, PHI 21 days with a maximum seasonal application of 420 g ai/ha). The intervals between sprays in the trials were 4 to 5 days compared with the minimum specified for GAP of 7 days. The meeting noted the DT_{50} for residues in grapes from trials in Europe were approximately 21 days and concluded the shorter interval between sprays would have minimal impact on observed residues at harvest. Residues of fluopicolide in grapes from 16 trials in Canada and the USA approximating GAP of the USA, in rank order, were: 0.07, 0.10, 0.10, 0.13, 0.13, 0.14, 0.19, 0.21, 0.25, 0.26, 0.32, 0.44, 0.53, 0.56, 0.99 and 1.1 mg/kg. No residues of M-01 were detected, LOQ = 0.01 mg/kg.

Residues according to the GAP of Canada and the USA were similar to those for Italy and Slovenia and the larger dataset of trials conducted in Europe was used to estimate residue values. The

Meeting considered a value of 2 mg/kg appropriate as a maximum residue using a mixture of expert judgement and information on initial residue deposits. Use of the NAFTA calculator yielded a value of 1.4 mg/kg which agreed with the estimate of 2 mg/kg made by the Meeting (after rounding up to one figure). The Meeting estimated a maximum residue level for fluopicolide in grapes of 2 mg/kg. The corresponding HR values are 1.2 mg/kg for fluopicolide and 0.04 mg/kg for M-01, and STMRs are 0.38 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

Bulb vegetables

Data were available from supervised trials on onions in member states of the European Union and the USA. Details of GAP for countries from the European Union were not available and the data from these trials were not further evaluated.

The GAP of the USA is foliar application at a maximum rate of 140 g ai/ha, PHI 2 days with a maximum seasonal application of 420 g ai/ha and a minimum interval between sprays of 7 days. In trials conducted in the USA the interval between sprays was lower (4–6 days) than the minimum; however, the meeting noted that the DT_{50} for residues in decline trials from Europe was of the order of 4 days and therefore it is the last spray that has the greatest influence on residues. Residues of fluopicolide in onions from seven trials in the USA complying with GAP were (in rank order, median underlined): 0.01, 0.05, 0.05, 0.07, 0.08, 0.11 and 0.58 mg/kg. No residues of M-01 were detected, < 0.01 (7) mg/kg.

The Meeting suggested a value of 1 mg/kg would be appropriate noting the size of the dataset and variability in residues. Using the NAFTA calculator a proposal of 0.51 mg/kg was derived assuming a lognormal distribution however, inspection of plots indicated the data did not follow this distribution type. The Meeting estimated maximum residue level for fluopicolide in onions of 1 mg/kg. The corresponding HR values are 0.58 mg/kg (fluopicolide) and 0.01 mg/kg (M-01) and STMR values of 0.07 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

Additionally three trials were available on bunching onions (Welsh onions). Residues according to the GAP of the USA for bulb vegetables were: 1.7, 2.1 and 4.5 g/kg. Corresponding residues of M-01 were < 0.01, ≤ 0.01 and 0.01 mg/kg respectively. The Meeting noted the small dataset and suggested a value of 10 mg/kg would be suitable as a maximum residue level. The value derived from use of the the NAFTA calculator was 8.3 mg/kg. The Meeting considered the uncertainty of estimates based on very small datasets and considered the higher estimate more appropriate.

The Meeting estimated maximum residue level for fluopicolide in Welsh onions of 10 mg/kg, HR values of 4.5 mg/kg (fluopicolide) and 0.01 mg/kg (M-01) and STMRs of 2.1 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

Residue trials were provided from Europe for use of fluopicolide on leeks but no GAP was available.

Brassica vegetables

In Estonia and Lithuania, fluopicolide is registered for use on cabbage at a maximum of three sprays of 100 g ai/ha with a PHI of 14 days. Residues in head cabbage from northern Europe complying with GAP were: < 0.01, < 0.01, 0.01, 0.01, 0.03, 0.03, 0.08 and 0.18 mg/kg. Residues of M-01 were not detected. Residues in head cabbage from southern Europe complying with GAP were: 0.01, 0.01, 0.02, and 0.03 mg/kg. Residues of M-01 were not detected. The residue populations for trials conducted in northern and southern Europe were similar (Mann-Whitney U test) and the Meeting decided to combine the data for the purposes of estimating a maximum residue level (n=12): < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.01, 0.02, 0.03, 0.03, 0.03, 0.08 and 0.18 mg/kg.

Fluopicolide is registered in the USA for use on cabbage (Brassica vegetables) at 140 g ai/ha, PHI 2 days with a maximum seasonal application of 420 g ai/ha. Trials were available from the USA

in which crops were treated three times at four to six day intervals at 133 g ai/ha with harvest 2 days after the last spray. Residues in head cabbage (with wrapper leaves) were: 0.31, 0.36, 0.61, 1.2, 1.9, 2.3 and 3.9 mg/kg. Residues of M-01 were < 0.01 (6) and 0.02 mg/kg.

The Meeting noted the data from the US for head cabbage had the higher residues and decided to use this dataset to estimate a maximum residue level. The Meeting considered a value of 7 mg/kg appropriate as a maximum residue using a mixture of expert judgement and initial residue deposits. Use of the NAFTA calculator yielded a value of 8.85 mg/kg. The Meeting estimated a maximum residue value for fluopicolide in head cabbages of 7 mg/kg. The corresponding HR values are 4.0 and 0.02 mg/kg respectively for fluopicolide and M-01. The STMRs are 1.2 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

Trials reported from Europe on Brussels sprouts were assessed according to the GAP of Estonia (maximum of three sprays of 100 g ai/ha with a PHI of 14 days). Residues that approximated GAP of Estonia were (n=8): 0.01, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05 and 0.13 mg/kg. Residues of M-01 were < 0.01 (8) mg/kg.

The Meeting considered a value of 0.2 mg/kg appropriate as a maximum residue noting the distribution of residue values. The value derived from use of the the NAFTA calculator was also 0.2 mg/kg. The Meeting estimated maximum residue level for fluopicolide in Brussels sprouts of 0.2 mg/kg, HR values of 0.13 and 0.01 mg/kg for fluopicolide and M-01 respectively, and STMRs of 0.04 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

In Estonia and Lithuania, fluopicolide is registered for use on cauliflower and broccoli at a maximum of three sprays of 100 g ai/ha with a PHI of 14 days. Residues in broccoli from northern Europe trials complying with GAP were: < 0.01, 0.01, 0.02, and 0.10 mg/kg. Corresponding residues of M-01 were all < 0.01 mg/kg. Residues in broccoli from southern Europe trials complying with GAP were: < 0.01, 0.04, 0.06 and 0.11 mg/kg. Corresponding residues of M-01 were all < 0.01 mg/kg.

In Estonia and Lithuania, fluopicolide is registered for use on cauliflower at a maximum of three sprays of 100 g ai/ha with a PHI of 14 days. Residues in cauliflower from northern Europe trials complying with GAP were: < 0.01, < 0.01, < 0.01, and 0.01 mg/kg. Corresponding residues of M-01 were all < 0.01 (4) mg/kg. Residues in cauliflower from southern Europe trials complying with GAP were: < 0.01, < 0.01, 0.01 and 0.06 mg/kg. Corresponding residues of M-01 were all < 0.01 (4) mg/kg.

Fluopicolide is registered in the USA for use on broccoli (Brassica vegetables) at 140 g ai/ha, PHI 2 days with a maximum seasonal application of 420 g ai/ha. Trials were available from the USA in which crops were treated three times at four to six day intervals at 133 g ai/ha with harvest 2 days after the last spray. Residues in broccoli were: 0.18, 0.21, 0.32, 0.45, 0.50 and 0.69 mg/kg. Residues of M-01 were not detected (< 0.01 (6) mg/kg).

The Meeting agreed to extrapolate the USA data for broccoli to establish a maximum residue level for Flowerhead brassicas. The Meeting considered a value of 2 mg/kg appropriate as a maximum residue. The value derived from use of the NAFTA calculator agreed with the estimate of 2 mg/kg made by the present Meeting (after rounding up to one figure (NAFTA = 1.2 mg/kg). The Meeting estimated a maximum residue level, HR and an STMR value of 2 mg/kg for fluopicolide in Flowerhead brassicas. The corresponding HR values are 0.69 mg/kg for fluopicolide and 0.01 mg/kg for M-01. The STMRs are 0.385 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

Fruiting vegetables, Cucurbits

Fluopicolide is registered in Estonia for use on cucumbers at 100 g ai/ha or 10 g ai/hL, PHI 3 days for field use. Trials were available from northern Europe that complied with GAP of Estonia. Residues in field grown cucumbers were: 0.02, 0.02, 0.03 and 0.08 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg).

In Lithuania, fluopicolide is registered for use on cucumbers grown under protected cover at a maximum of three sprays at 8.8 g ai/hL with a PHI of 1 day. Trials were available from Europe that complied with GAP of Lithuania with residues of: 0.02, 0.02, 0.03, 0.03, 0.04, 0.04, 0.08 and 0.09 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg).

Trials on cucumber were reported from the USA (USA GAP for cucurbits: 140 g ai/ha, PHI of 2 days and a maximum application per season of 420 g ai/ha). Fluopicolide residues on cucumbers in six trials from the USA matching GAP in rank order were: 0.01, 0.02, 0.03, 0.03, 0.03 and 0.06 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg).

Residue trials were provided from Europe for use of fluopicolide on melons but no GAP was available.

Residues on melons (cantaloupe) in nine trials from the USA matching GAP in rank order were: < 0.01, 0.05, 0.06, 0.06, 0.07, 0.07, 0.10, 0.26 and 0.30 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg).

Trials were available from Greece, Italy and Spain on zucchini but did not match GAP.

Fluopicolide residues on summer squash (including zucchini) in six trials from the USA matching GAP in rank order were: 0.01, 0.03, 0.04, 0.04, 0.05 and 0.06 mg/kg. Residues of M-01 were not detected (< 0.01 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 considered a value of 0.5 mg/kg appropriate as a maximum residue using a mixture of expert judgement and initial residue deposit data. The value derived from use of the NAFTA calculator was 0.5 mg/kg, which agreed with the estimate of the Meeting. The Meeting estimated a maximum residue level for fluopicolide in fruiting vegetables, cucurbits of 0.5 mg/kg.

The commodity group encompasses fruit with both edible and inedible peel. For fruit with edible peel the HR and STMRs listed above should be used. Data on residues in the edible portion for melons in trials complying with USA GAP were not available; however, in trials from Europe with similar residues in melons, no residues of fluopicolide or M-01 were detected in the edible portion (LOQ 0.01 mg/kg). For fruit with inedible peel the HR and STMRs are all 0.01 mg/kg and for fruit with edible peel the HR and STMRs are 0.3, 0.07 (fluopicolide) and 0.01, 0.01 (M-01) mg/kg respectively. This is consistent with fluopicolide being a surface residue on crops if applied by foliar application.

Fruiting vegetables, other than Cucurbits

Trials on tomatoes were made available from Brazil but did not match GAP for that country. Fluopicolide is registered in Italy for use on tomatoes at 100 g ai/ha or 10 g ai/hL, PHI 3 days for field use, and 125 g ai/ha or 10 g ai/hL, PHI 3 days for crops grown under protected cover. Trials were available from Europe that complied with GAP of Italy. Residues in field grown tomatoes from trials conducted in northern Europe were: 0.015, 0.14, 0.22, and 0.23 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg). Residues in field grown tomatoes from trials conducted in southern Europe were: 0.019, 0.046, 0.05, 0.055, 0.09, 0.10, 0.14 and 0.28 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg). The residue populations for trials conducted in northern and southern Europe were similar (Mann-Whitney U test) and the Meeting decided to combine the data for the purposes of estimating a maximum residue level (n=12): 0.015, 0.019, 0.046, 0.05, 0.055, 0.09, 0.10, 0.14, 0.14, 0.22, 0.23 and 0.28 mg/kg.

In Lithuania, fluopicolide is registered for use on tomatoes grown under protected cover at a maximum of three sprays at 8.8 g ai/hL with a PHI of 1 day. Trials were available from Europe that complied with GAP of Lithuania with residues of: 0.063, 0.08, 0.085, 0.093, 0.14, 0.18, 0.20 and 0.21 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg).

Trials on tomatoes (including cherry tomatoes) were reported from the USA (USA GAP: 140 g ai/ha, PHI of 2 days and a maximum application per season of 420 g ai/ha). Fluopicolide residues in twelve trials from the USA matching GAP in rank order were: 0.05, 0.06, 0.08, 0.10, 0.15, 0.15[c], 0.17[c], 0.17, 0.19, 0.19, 0.28 and 0.42[c] mg/kg ([c] = cherry tomatoes). Residues of M-01 were not detected (< 0.01 mg/kg).

Trials on sweet peppers were reported from the USA (GAP: 140 g ai/ha, PHI of 2 days and a maximum application per season of 420 g ai/ha). Fluopicolide residues in seven trials on sweet peppers (including Bell peppers) from the USA matching GAP in rank order were: 0.04, 0.05, 0.09, 0.15, 0.17, 0.19 and 0.57 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg).

Fluopicolide residues in chilli peppers in three trials from the USA matching GAP in rank order were: 0.10, 0.36 and 0.58 mg/kg. Residues of M-01 were not detected (< 0.01 mg/kg).

The Meeting decided that the trials in tomatoes, sweet and chilli peppers could be used to support a 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 (sweet and chilli peppers) to estimate a maximum residue level for the group (fluopicolide residues: 0.04, 0.05, 0.09, 0.10, 0.15, 0.17, 0.19, 0.36, 0.57 and 0.58 mg/kg; M-01 residues < 0.01 (10) mg/kg).

The Meeting considered a value of 1 mg/kg appropriate as a maximum residue using a mixture of expert judgement and initial residue deposit data. Use of the NAFTA calculator yielded a value of 0.8 mg/kg. The Meeting estimated a maximum residue level for fluopicolide in fruiting vegetables other than cucurbits (except mushrooms and sweet corn) of 1 mg/kg. The HR values are 0.58 mg/kg for fluopicolide and 0.01 mg/kg for M-01. The STMRs are 0.16 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

Leafy vegetables

In Romania, fluopicolide is registered for use on lettuce grown under protected cover at a maximum of two sprays at 7 day intervals and at 8.8 g ai/hL (88 g ai/ha) with a PHI of 14 days. Noting that growth dilution would ensure a spray made 28 days before harvest would make a negligible contribution to the final residues; the Meeting agreed that the trials from Europe with three sprays at 7 day intervals could be evaluated against the GAP of Romania. Trials were available from Europe that complied with GAP of Romania with residues of: 0.40, 0.40, 0.63, 0.68, 1.5, 2.7, 4.0 and 4.9 mg/kg. Corresponding residues of M-01 were: < 0.01, 0.018, 0.017, 0.017, 0.022, 0.014, 0.020 and 0.011 mg/kg).

Trials on lettuce and spinach were reported from the USA (GAP: 140 g ai/ha, PHI of 2 days and a maximum application per season of 420 g ai/ha). Fluopicolide residues in seven trials on head lettuce from the USA matching GAP in rank order were: 0.62, 2.3, 2.3, 2.4, 4.2, 4.3 and 7.2 mg/kg. Corresponding residues of M-01 were: < 0.01 (5) and 0.01 (2) mg/kg.

Residues of fluopicolide in seven trials on leaf lettuce from the USA matching GAP were higher than in head lettuce and were (in rank order): 4.3, 5.0, 5.3, 7.6, 7.6, 10 and 12 mg/kg. Corresponding residues of M-01 were: 0.01, 0.01, < 0.01, 0.02, 0.04, < 0.01 and 0.02 mg/kg.

Residue trials were provided from Europe for use of fluopicolide on spinach but no GAP was available.

Fluopicolide residues in seven trials on spinach from the USA matching GAP in rank order were: 6.8, 6.8, 6.9, 8.6, 12, 16 and 17 mg/kg. Corresponding residues of M-01 in rank order were: 0.02, 0.03, 0.06, 0.07, 0.07, 0.09 and 0.19 mg/kg.

The Meeting noted that the registered use of fluopicolide 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

considered a value of 30 mg/kg appropriate as a maximum residue using a mixture of expert judgement and initial residue deposit data. Use of the NAFTA calculator yielded a value of 25.3 mg/kg which, on rounding, also leads to a value of 30 mg/kg. The Meeting estimated a maximum residue level for fluopicolide in leafy vegetables of 30 mg/kg. The HR values are 17 mg/kg for fluopicolide and 0.19 mg/kg for M-01, while the STMRs are 8.6 mg/kg for fluopicolide and 0.07 mg/kg for M-01.

Root and tuber vegetables

Trials on carrot and radish were made available from the USA. No carrot trials matched GAP (no GAP available) and one trial on radish matched GAP in the USA (GAP: 140 g ai/ha, PHI of 2 days and a maximum application per season of 420 g ai/ha) with residues of 0.11 mg/kg (M-01 < 0.01 mg/kg). The Meeting decided that a single trial constitutes an insufficient dataset to estimate a maximum residue level.

Celery

Fluopicolide residues in seven trials on celery from the USA matching GAP (the USA crop group 'leafy vegetables' includes celery) in rank order were (median underlined): 0.16, 0.76, 1.0, 1.4, 5.2, 6.7 and 14 mg/kg. Residues of M-01 were < 0.01 (4), 0.01, 0.03 and 0.04 mg/kg. The Meeting considered a value of 20 mg/kg appropriate as a maximum residue using a mixture of expert judgement. Use of the NAFTA calculator yielded a value of 10.15 mg/kg, which is less than the highest observed residues. The Meeting estimated a maximum residue level for fluopicolide in celery of 20 mg/kg. The HR values are 14 mg/kg for fluopicolide and 0.04 mg/kg for M-01, and STMRs 1.4 mg/kg for fluopicolide and 0.01 mg/kg for M-01.

Rotational crops

Residues of fluopicolide are persistent in soil and may be taken up by succeeding crops. In the USA the total seasonal application rate for crops is 420 g ai/ha. Studies of residues in rotational crops were made available to the meeting where in confined rotational crop studies bare soil was treated at 400 g ai/ha, and in field studies preceding potato crops were treated four times at 100 g ai/ha (400 g ai/ha). It is likely that soil residues would require several years to reach plateau levels and residues in succeeding crops could be higher than those observed in the rotational crop following a single season of applications.

Residues in brassica vegetables grown as a rotational crop were < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (0.02) and < 0.01 (0.04) mg/kg in cabbage (figures in brackets are for M-01). The levels in brassica vegetables from rotational crops are adequately covered by the recommendations for Head cabbages (5 mg/kg), Flowerhead brassicas (2 mg/kg) and Brussels sprouts (0.2 mg/kg). In addition, if the levels found in cabbage are representative of those taken up by leafy vegetables, considering the magnitude of the maximum residue level recommended for leafy vegetables, it is concluded that residues taken up from soil are a minor contribution for leafy vegetables and adequately covered by the recommendation for leafy vegetables.

Residues in follow-crop cereal grains were < 0.01 mg/kg in 17 trials on wheat. No residues of M-01 were detected. As the residues were all below the LOQ, the Meeting decided it is not necessary to recommend a maximum residue level for cereals grown as rotational crops.

Corresponding residues in cereal forage (wheat) were: < 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.02, 0.03, 0.04 and 0.04 mg/kg. The Meeting decided to recommend STMR and highest residue values of 0.015 and 0.04 mg/kg respectively for forage of cereals (or 0.06 and 0.16 mg/kg on a dry weight basis respectively and assuming 25% dry matter content).

Corresponding residues in cereal straw (wheat) were: < 0.01, 0.01, 0.02, 0.02, 0.03, 0.04, 0.05, 0.05, 0.06, 0.06, 0.06, 0.07, 0.07, 0.07, 0.08, 0.09 and 0.12 mg/kg. The estimated STMR and highest residue values for straw of cereals are 0.06 (or 0.07 mg/kg on a dry weight basis) and 0.12 (or 0.14 mg/kg on a dry weight basis assuming 88% dry matter content) mg/kg respectively. The Meeting recommended a maximum residue level for straw and hay of cereals of 0.2 mg/kg.

Eight trials on residues in pulses (faba bean) grown as rotational crops were available with residues in seed of < 0.01(8) mg/kg. No residues of M-01 were detected. The Meeting decided it is not necessary to recommend a maximum residue level for pulses grown as rotational crops. Residues in forage were < 0.01 (5), 0.01, 0.02 and 0.03 mg/kg. The Meeting also estimated STMR and highest residue values of 0.01 and 0.03 mg/kg respectively for legume animal feeds, or 0.04 and 0.12 mg/kg on a dry weight basis respectively, assuming 25% dry matter content.

Metabolism studies on rotational crops suggested residues of fluopicolide and metabolites would be present in root and tuber crops; however, no field studies were available. The Meeting did not have sufficient information to evaluate residue levels in root and tuber crops or other rotational crops not mentioned above.

Fate of residues during processing

The effect of processing on the nature of residues was investigated in buffer solutions under conditions simulating pasteurisation, boiling and sterilisation. Fluopicolide was shown to be stable under these conditions.

The fate of fluopicolide residues has been examined in grapes and tomato processing studies. Processing of tomatoes into purée and paste showed an increase of fluopicolide residues in the processed commodities compared to the raw commodity, whilst there was a decrease in residues found in the corresponding juice and ketchup. Grapes showed a decrease in residues found in wine, but an increase in pomace. Estimated processing factors and STMR-Ps are summarised below.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	PF (Mean, median or best estimate)	Fluopicolide RAC-STMR (mg/kg)	Fluopicolide STMR-P (mg/kg)	M-01 STMR-P (mg/kg)[a]
Grape	Pomace wet	1.6 1.8 2.3 5.0 6.3 6.6	3.65 (median)	0.38	1.387	0.01
	Raisin	2.2, 6.5	6.5 (highest)		2.47	0.045
	White wine (np)	0.40 0.43 0.61	0.43 (median)		0.1634	0.01
	Red wine	0.28 0.31 0.38	0.31 (median)		0.1178	0.01
Tomato	Preserve	0.1 0.1 0.1 0.1 0.1	0.1 (median)	0.16[c]	0.016	0.01
	Juice	0.2 0.2 0.3 0.3 0.3	0.3 (median)		0.048	0.01
	Purée[b]	(0.3 0.3 0.4 0.5 0.5) 1.5 1.8 2.2	1.8 (median US)		0.288	0.01
	Paste	1.9 2.2 3.5	2.2 (median)		0.352	0.01

np = non-pasteurised

[a] values in brackets are for 2,6-dichlorobenzamide residues observed in processed commodities from processing trials. Residues were scaled to the application rate for GAP for the crop from which the RAC was derived.

[b] higher tomato values are from US study

[c] STMR for USA tomato trials

On processing tomatoes, fluopicolide concentrated in tomato purée and paste. For grapes, residues concentrated in raisins and pomace. The Meeting decided to estimate a maximum residue level for dried grapes of 10 mg/kg based on a highest residue for grapes of 1.2 mg/kg and a processing factor of 6.5 (1.2 mg/kg × 6.5 = 7.8 mg/kg). The highest residue observed for M-01 in

grapes from vines treated according to GAP and processed was 0.06 mg/kg. The STMR-P for residues of fluopicolide in dried grapes is 2.47 mg/kg while that for M-01 is 0.045 mg/kg (average of the two residue values for M-01 observed in the trials that processed grapes into raisins).

Residues in grape pomace were estimated to be 0.785 mg/kg on a wet weight basis and 5.2 mg/kg (assuming a default 15% dry matter content) when expressed on a dry weight basis. The Meeting decided to recommend a maximum residue level for grape pomace (dry) of 7 mg/kg.

The Meeting also decided to estimate a maximum residue for chilli pepper (dried) of 7 mg/kg following application of a default dehydration factor of 7 to the estimated maximum residue level of 1 mg/kg for chilli pepper (7 × 1 mg/kg = 7 mg/kg). The STMR for residues of fluopicolide in chilli peppers (dry) is estimated to be 7 × 0.13 mg/kg = 0.91 mg/kg. As residues of M-01 were < 0.01 in peppers, the HR and STMR for chilli pepper (dried) is also estimated to be 0.01 mg/kg.

Residues in animal commodities

Farm animal dietary burden

The Meeting estimated the dietary burden of fluopicolide in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Residues of M-01 are extremely low and considered unlikely to transfer from feed to tissues, milk and eggs. 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, fluopicolide, ppm of dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	0.08	5.1[a]	2.0
	mean	0.03	1.1	1.9[c]
Dairy cattle	max	0.09	5.1[b]	2.0
	mean	0.05	1.1	1.9[d]
Poultry – broiler	max	0.01	1.3[e]	0.01
	mean	0.01	0.28[f]	0.01
Poultry – layer	max	0.01	0.03[g]	0.01
	mean	0.01	0.02[h]	0.01

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

[b] Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

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

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

[g] Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

[h] Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

The fluopicolide dietary burdens for animal commodity MRL and STMR estimation (residue levels in animal feeds expressed on dry weight) are: beef cattle 5.1 and 1.1 ppm, dairy cattle 5.1 and 1.9 ppm and poultry 1.3 and 0.28 ppm (for eggs 0.03 and 0.02 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 fluopicolide for 28 days at the equivalent of 0.5, 1.7 and 5.7 ppm in the diet. Average residues of fluopicolide in milk for the 5.7 ppm dose group were < 0.01 mg/kg. Residues of fluopicolide in milk were detected for one sample at day 4 and one at day 28 of dosing; levels were 0.01 and 0.02 mg/kg respectively. No residues of the metabolites M-01 and M-02 were detected in milk (LOQ 0.01 mg/kg). No residues of fluopicolide or the metabolites M-01 and M-02 were detected in tissues (LOQ 0.02 mg/kg).

The Meeting also received information on the residue levels arising in tissues and eggs when laying hens were dosed with [^{14}C]fluopicolide for 14 days at levels equivalent to 1 and 10 ppm in the diet. At the high dose residues of fluopicolide in eggs and tissues were below the LOQ (0.01 mg/kg) for the analytical method.

Animal commodity maximum residue levels

The maximum dietary burden for beef and dairy cattle is 5.1 ppm, so the levels of residues in tissues can be obtained directly from the 5.7 ppm feeding level. Maximum residues expected in tissues are: fat, muscle, liver and kidney are 0 mg/kg and the mean residue for milk 0 mg/kg. The Meeting estimated maximum residue levels for meat (from mammals other than marine mammals) 0.01(*) mg/kg; edible offal (mammalian) 0.01(*) mg/kg and milks 0.02 mg/kg. Estimated HRs for short term intake estimations for fluopicolide are all 0 mg/kg for tissues. No residues of M-01 are expected, HR values are 0 mg/kg.

No residues are expected to be detected on exposure to the mean dietary burden and estimated STMRs for fluopicolide and M-01 are 0 mg/kg for meat (from mammals other than marine mammals), fat (from mammals other than marine mammals), edible offal (mammalian) and milk.

The maximum dietary burden for broiler poultry is 1.3 ppm. No residues above the LOQ of the analytical method are expected for fluopicolide or M-01.

The Meeting estimated maximum residue levels for poultry meat 0.01(*) mg/kg; poultry offal 0.01(*) and eggs 0.01* mg/kg. The mean dietary burden for poultry is 0.28 ppm. No residues are expected in poultry tissues and eggs of birds at the mean dietary burden. HRs and STMRs for fluopicolide and M-01 in poultry meat, skin/fat, edible offal and eggs are all 0 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intake (IEDI) for fluopicolide was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 3.

The International Estimated Daily Intakes of fluopicolide and 2,6-dichlorobenzamide for the 13 GEMS/Food Consumption Cluster Diets, based on estimated STMRs were 1–10% of the maximum ADI of 0.08 mg/kg bw for fluopicolide and 0–1% of the maximum ADI of 0.02 mg/kg bw for 2,6-dichlorobenzamide (Annex 3). The Meeting concluded that the long-term intake of residues of fluopicolide from uses that have been considered by the JMPR is unlikely to present a public health concern.

Long-term intake

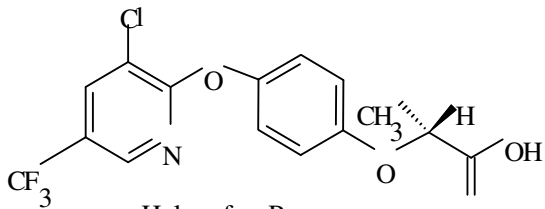
The International Estimated Short-term Intake (IESTI) for fluopicolide was calculated for the food commodities for which STMRs or HRs were estimated and for which consumption data were available. The results are shown in Annex 4 of the 2009 Report of the JMPR.

For fluopicolide the IESTI varied from 0–70% of the ARfD (0.6 mg/kg bw) for women of child bearing age when using intake figures for the general population. An ARfD was unnecessary for the other groups of the population. For 2,6-dichlorobenzamide the IESTI varies from 0–1% of the ARfD (0.6 mg/kg bw) for the general population and 0–2% for children. The Meeting concluded that the short-term intake of residues of fluopicolide from uses considered by the Meeting is unlikely to present a public health concern.

5.13 HALOXYFOP (194) AND HALOXYFOP-P

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of haloxyfop were evaluated by the JMPR in 1995, 1996 and 2001. The compound was listed in the Periodic Re-Evaluation Program at the Thirty-ninth Session of the CCPR (2007) for periodic review by the 2009 JMPR. The most recent toxicological review by JMPR was in 2006 when a group ADI of 0–0.0007 mg/kg bw and a group ARfD of 0.08 mg/kg bw were established for racemic haloxyfop, haloxyfop-R and their methyl esters. For the residue evaluation, the primary manufacturer provided a full residue data package. GAP information was also provided by Australia and The Netherlands.



Haloxyfop-P

Haloxyfop was originally produced as a racemic mixture for use as a herbicide for controlling grassy weeds. The compound is now available as the R-isomer, which is the herbicidally active one and is produced commercially as the methyl ester. The ISO name for the R isomer is haloxyfop-P. The ISO name for the unresolved isomeric mixture is haloxyfop.

Animal metabolism

The 2006 JMPR evaluated laboratory animal (mice, rats, dogs and monkeys) metabolism studies of orally administered haloxyfop esters and salts and reported that the different isomers, esters and salts of haloxyfop end up as the de-esterified R enantiomer. This suggests that studies on haloxyfop or haloxyfop-P are mutually supportive.

When two lactating goats were dosed with phenyl ring labelled haloxyfop via gelatin capsule twice daily for 10 consecutive days at the equivalent of 16 ppm haloxyfop in the feed, most of the administered dose (92% and 84%) was excreted in urine, with 1.9% and 1.5% in faeces. Milk accounted for 1.9% and 3.2% of the dose, and tissues less than 0.5% of the dose. Residues in milk reached a plateau very quickly, within 24 hours of the first dose. Monitoring on one goat for 10 hours did not detect [^{14}C] volatiles or $^{14}CO_2$.

Radiolabel, expressed as haloxyfop, was higher in the kidney (1.45 and 1.07 mg/kg) and liver (0.45 and 0.31 mg/kg) than in fat or muscle. The residues in kidney and liver consisted mostly of parent haloxyfop, but some may have been present as labile conjugates.

Radiolabel levels in milk were 0.25 and 0.20 mg/kg. The ^{14}C residues in milk fat were nonpolar and were susceptible to alkaline hydrolysis or lipase hydrolysis releasing haloxyfop. The behaviour was consistent with haloxyfop conjugated as triacylglycerides. Residues in body fat were of the same nature as the residues in milk fat.

When four laying hens were dosed with phenyl ring labelled haloxyfop via gelatin capsule for 11 consecutive days at the equivalent of 12 ppm haloxyfop in the feed, most of the administered dose (82–90%) was excreted in the droppings or present as gut contents (5.8–8.6%). Eggs accounted for an average of 1.6% of the label, and tissues approximately 2%.

Radiolabel, as haloxyfop, was higher in the liver (1.2–2.5 mg/kg) than in the muscle (0.02–0.35 mg/kg) or fat (0.46–2.0 mg/kg). Alkaline hydrolysis of solvent extracts from liver, kidney and

fat converted the residues almost quantitatively to a single product, haloxyfop. Most likely, parent haloxyfop was largely incorporated into lipids from which it could be readily released by hydrolysis.

Radio-labelled residue levels were much higher in the yolk (2.0–4.0 mg/kg) than in the whites (0.12–0.37 mg/kg) of eggs (day 10) and reached a plateau in yolks on approximately the 7th day of dosing. Almost the entire residue in the yolks was present as triacylglycerides. Mild alkaline hydrolysis or lipase hydrolysis produced haloxyfop as the single product.

In summary, the metabolism of haloxyfop in goats and hens is similar and also similar to metabolism in laboratory animals in the respect that the esters are de-esterified with little further breakdown of the parent compound. Haloxyfop is readily conjugated and incorporated into fats or secreted in the lipid of milk or eggs. The intact haloxyfop may be released from its conjugates by mild alkaline or enzymatic hydrolysis.

Plant metabolism

The Meeting received plant metabolism studies with haloxyfop-butyl in cotton; haloxyfop-methyl, haloxyfop-butyl and haloxyfop-ethoxyethyl in soya beans; and haloxyfop-P-methyl in sugar beet and lettuce.

The distribution of radiolabel in cotton seed, oil, lint and field trash was reported for cotton that had been foliar treated with phenyl ring labelled haloxyfop butyl ester at a rate equivalent to 0.56 kg ai/ha and sampled 78 and 105 days after treatment. Concentrations of radiolabel on day 78, expressed as haloxyfop, were: cotton seed 0.78 mg/kg, oil 1.1 mg/kg and lint 0.19 mg/kg. By day 105, radiolabel concentrations had become: cotton seed 0.20 mg/kg, oil 0.38 mg/kg, lint 0.04 mg/kg and field trash 1.1 mg/kg.

None of the residue in any component was identified as haloxyfop butyl ester. In the cotton seed, almost all of the ^{14}C was accounted for as haloxyfop free acid (32% at day 105) and haloxyfop conjugates (66% at day 105). In the oil, 100% of the ^{14}C was present as haloxyfop conjugates. In the field trash, the radiolabel was present as free acid (39%) and conjugates (55%).

The ^{14}C in the oil was associated with the triglycerides. Lipase hydrolysis and alkali hydrolysis released 91–99.8% of the ^{14}C as haloxyfop, suggesting that the non-polar residues were triglyceride esters of haloxyfop.

In a soya bean metabolism study, the mature second and developing third trifoliate leaves of 20 day old soya bean plants were treated with [^{14}C]labelled haloxyfop in the form of an ester (methyl, butyl and ethoxyethyl) at a dose equivalent to 0.2 mg per plant. Labelling was in the phenyl ring or the pyridyl ring. Treated leaves and the remainder of the plant were sampled 2, 4 and 8 days after treatment.

The distribution of radiolabel was very similar in plants treated with haloxyfop-methyl phenyl label and pyridyl label, suggesting that the haloxyfop molecule had remained intact.

The esters hydrolysed rapidly. Even after 2 days, little of the applied ester remained in the treated leaves. After 8 days, polar metabolites and haloxyfop accounted for 58–65% and 34–40% of the label respectively in the treated leaves. The nature of the applied ester seemed to have little influence on the nature and distribution of the residue.

Applied ester did not appear in untreated portions of the plant. After 8 days, polar metabolites and haloxyfop accounted for 35–39% and 61–65% of the label respectively in the untreated parts of the plant, i.e., unconjugated haloxyfop was the major component of the residue. Mild alkaline hydrolysis of the polar translocated residue released haloxyfop, demonstrating that at least part of the polar fraction consisted of haloxyfop conjugates.

In a second soya bean metabolism study, plants were treated once with [^{14}C]haloxyfop-butyl at two plant growth stages, 89 and 61 days before harvest and at two application rates, 0.28 and 0.56 kg ai/ha. Two labels were used: a phenyl ring label and a pyridyl label.

The parallel behaviour of the phenyl ring and the pyridyl labelled haloxyfop showed that the haloxyfop molecule remained intact and essentially the entire residue contained both the phenyl and pyridyl rings.

Radiolabelled residue levels, expressed as haloxyfop, in the beans for the two treatment rates were 3.1–5.8 mg/kg 61 days after treatment and 0.8–1.3 mg/kg 89 days after treatment. The composition of the residue was essentially the same after both treatments, i.e., unconjugated haloxyfop 57–59%, polar conjugates 17–20% and non-polar conjugates 17–18%. Alkaline and lipase hydrolysis of the non-polar residue from the beans suggested that haloxyfop was incorporated into the oil triglycerides. Most of the polar conjugates also produced haloxyfop on hydrolysis.

Polar conjugates (65–66%) were the main component of the residues in treated soya bean forage 15 days after treatment, with unconjugated haloxyfop (27–30%) accounting for most of the remainder. In new-growth forage sampled at the same time, unconjugated haloxyfop and polar conjugates accounted for 42% and 57% of the residue respectively. In soya bean straw, unconjugated haloxyfop accounted for the majority of the residue (60–66%) with polar conjugates (24–32%) making up most of the remainder.

In a sugar-beet metabolism study, young plants in field plots were foliar sprayed at 0.22 kg ai/ha with pyridyl-labelled haloxyfop-P-methyl formulated as an EC. At maturity, 92 days after application, ^{14}C residues expressed as haloxyfop-P-methyl were much lower in the roots (0.019 mg/kg) than in the shoots (0.079 mg/kg).

The composition of the residue in sugar beet roots at maturity was: 31% haloxyfop-P acid, 19% conjugate 1, 20% haloxyfop-P glycoside conjugate 1 and 20% unextracted. The composition of the residue in sugar beet shoots at maturity was: 33% haloxyfop-P acid, 24% conjugate 1, 14% haloxyfop-P glycoside conjugate 1 and 12% unextracted.

In summary, haloxyfop-P readily translocated to the roots of treated sugar beet. The majority of the residue was present as polar conjugates.

In a lettuce metabolism study, plants in field plots were foliar sprayed at 0.11 kg ai/ha with pyridyl-labelled haloxyfop-P-methyl formulated as an EC. By day 14, haloxyfop-P-methyl had disappeared and haloxyfop-P acid was the major component of the residue. At maturity, 29 days after treatment, ^{14}C residues expressed as haloxyfop-P-methyl were at higher levels in the outer leaves (0.16 mg/kg) than in the inner leaves (0.048 mg/kg).

The main residue component in lettuce inner leaves at maturity was haloxyfop-P acid at 93% of the ^{14}C, with 5.4% accounted for by various conjugates. The ^{14}C residue in lettuce outer leaves consisted of: 38% haloxyfop-P acid, 24% conjugate 1, 23% glycoside conjugate 2, 10% unextracted and 6.9% glycoside conjugate 1.

Summary of haloxyfop in plant metabolism—when applied to a plant, the esters of haloxyfop or haloxyfop-P are broken down quickly to release free acid which is readily translocated throughout the plant. The haloxyfop (or haloxyfop-P) becomes conjugated, typically as glycosides (polar metabolites) or as triglycerides (non-polar metabolites), the conjugates often accounting for the major part of the residue.

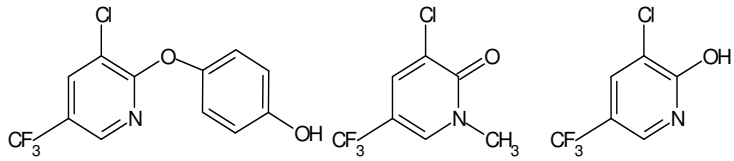
Environmental fate in soil

The Meeting received information on soil aerobic metabolism and soil photolysis properties of [^{14}C]haloxyfop-P-methyl. Studies were also received on the behaviour of [^{14}C]labelled haloxyfop-butyl in a rotational crop situation and haloxyfop-methyl in an unconfined rotational crop situation.

Haloxyfop residues are generally not persistent in soils. Haloxyfop residues in soils resulting from recommended uses should not contribute to the residues in root vegetables or to residues in succeeding crops.

In soil incubation studies under aerobic conditions at 20 °C, parent haloxyfop-P-methyl disappeared with a half-life of approximately 0.5 days. Haloxyfop-P-methyl was hydrolysed just as quickly in a sterile soil as in a fresh soil, demonstrating that the methyl ester is chemically labile. Haloxyfop-P acid was persistent in the sterile soil.

Under aerobic soil incubation, the first metabolite was haloxyfop-P acid, which mostly disappeared with half-lives in the range of 9–21 days (n=8), but in subsoils with low organic carbon its disappearance half-lives were 28 and 129 days. After approximately 9 months, 6–33% of the dose (haloxyfop-P-methyl labelled in the pyridyl ring) had been mineralized and 28–46% was unextracted.



The metabolites 'phenol metab', 'pyridinone metab' and 'pyridinol metab' were consistently produced, with the 'pyridinone metab' apparently the most persistent.

In a soil photolysis study with labelled haloxyfop-P-methyl on the surface of a sandy clay loam, degradation rates in the dark controls and the photolysis samples were similar, suggesting that photolysis had negligible effect compared with hydrolysis and metabolism.

In a confined rotational crop study with wheat, soya beans, leaf lettuce, carrots and turnips, a plot of sandy loam soil was treated with [^{14}C]phenyl ring labelled haloxyfop-butyl at the equivalent of 0.56 kg ai/ha and the crops were sown 30 days later. Crops were harvested at various intervals after sowing: lettuce 49 days, soya bean forage 56 days, turnips 64 days, carrots 124 days, wheat 110 days and soya beans 145 days.

The ^{14}C contents of the plant tissues, expressed as haloxyfop on fresh weight, were: lettuce 0.01 mg/kg, turnip foliage < 0.01 mg/kg, turnip root < 0.01 mg/kg, wheat grain 0.01 mg/kg, wheat straw 0.02 mg/kg, soya bean forage 0.07 mg/kg, soya bean grain < 0.01 mg/kg, soya bean straw 0.01 mg/kg, carrot foliage < 0.01 mg/kg and carrot root < 0.01 mg/kg. The levels were all too low for identification of the residue.

In an unconfined rotational crop study haloxyfop-methyl was applied to soya beans (0.28 kg ai/ha) and to cotton (0.56 kg ai/ha) as the first crops. Approximately 30 and 120 days after treatment, rotational crops of lettuce, sugar beets and wheat were sown into the plots and grown to maturity. Haloxyfop residues generally did not occur in the rotational crops at levels exceeding LOQs (0.01 and 0.02 mg/kg). Residues were detected in wheat green forage, but detection in a sample from the control plot suggested possible contamination.

Summary of haloxyfop in soil metabolism–haloxyfop esters are quickly hydrolysed and the acid becomes the major residue in the short term, but also disappears readily with typical half-lives of 9–21 days. Three soil metabolites were identified. Soil photolysis has little effect on haloxyfop residues compared with soil metabolism. Haloxyfop residues in soil should contribute very little to residue levels in root crops or rotational crops.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for residues of haloxyfop in animal and plant matrices.

Analytical methods must take account of the nature of the residue as observed in metabolism studies–much of the residue occurs as polar and non-polar conjugates.

Haloxyfop residue methods rely on an initial extraction and hydrolysis step, usually with methanolic NaOH to release haloxyfop from conjugates. After solvent partition cleanup, the haloxyfop is methylated or butylated ready for GC analysis or further cleanup before the GC analysis. Typically, haloxyfop residues can be measured in most matrices to an LOQ of 0.01–0.05 mg/kg.

For various substrates, the extraction and hydrolysis step ranges from a simple methanolic NaOH extraction to a period of shaking homogenised sample with extractant (2 hours or overnight) to a more vigorous hydrolysis at elevated temperature for 2 hours.

The completeness of extraction of haloxyfop and its conjugates and of their conversion to parent acid was tested on soya bean samples available from the previous metabolism study. Overnight shaking of substrate with 0.1 M NaOH in 98% methanol + 2% water extracted 93% of the ^{14}C from the soya beans. HPLC produced a single peak matching haloxyfop which accounted for 95% of the ^{14}C in the extract.

The completeness of extraction of haloxyfop, esters and conjugates from goat milk was tested on a sample from a goat dosed with [^{14}C]haloxyfop-butyl. The method relied on an initial diethyl ether extraction from milk, followed by hydrolysis of the extracted residue in benzene-KOH-ethanol at 50 °C to release conjugates. A high percentage of the ^{14}C (91%) was extracted and released as haloxyfop acid by this procedure.

Little information is available on the completeness of extraction by briefer contact of the substrate with the alkaline extractant. Most of the validations have not included a check on this step. However, some validations have used a haloxyfop ester such as haloxyfop-ethoxyethyl as the spiked analyte, which does check that the extraction conditions quantitatively hydrolyse the spiked ester. Haloxyfop esters are readily hydrolysed, so the release of conjugates by the alkaline extractant with the conditions of the analytical methods would be generally expected.

None of the methods separates the haloxyfop enantiomers. The methods effectively measure 'total' haloxyfop present as acid, salts, esters and conjugates (esters with natural compounds).

Haloxyfop residues are not suitable for analysis by multi-residue methods because the extraction step is typically also a base-hydrolysis step designed to release haloxyfop from non-polar and polar conjugates found in animal and plant tissues. Such an extraction-hydrolysis step is not suitable for many other pesticides.

Stability of residues in stored analytical samples

The Meeting received information on the stability, during frozen storage, of residues in samples of green peas, cabbage, rice, soya beans and cotton seed. The analytical methods for haloxyfop measure haloxyfop present as acid, salts, esters and conjugates, so changes among these different forms during storage would not be detected.

Haloxyfop residues fortified in homogenized green peas and chopped cabbage were stable for 16 months (the test interval) storage at -16 °C.

Haloxyfop residues fortified in rice were stable in freezer storage for 7 months, the test interval.

Haloxyfop residues in soya beans matrix were stable for 17 months (the test interval) storage at -20 °C.

In another study, haloxyfop residues in soya beans were reported to be stable under frozen conditions for 43 months, the period of the test.

Haloxyfop residues fortified in cotton seed matrix were stable in freezer storage at -20 °C for 17 months, the test interval.

No data are available on the freezer storage stability of haloxyfop residues in animal commodities, but from haloxyfop stability in animal metabolism and during storage as residues in various plant matrices, no storage stability problems would be expected.

Definition of the residue

The current residue definition for haloxyfop is: Haloxyfop esters, haloxyfop and its conjugates expressed as haloxyfop.

The question of fat solubility requires careful consideration because some components of the residue are clearly fat-soluble, but unconjugated haloxyfop and its salts are not:

- Goat metabolism study: the ^{14}C residue concentrations (mg/kg) in fat were higher than in muscle: fat/muscle = 0.06/0.02 and 0.11/< 0.01.
- Hen metabolism study: the ^{14}C residue concentration (mg/kg) in fat was higher than in muscle: fat/muscle = 0.99/0.12. Also residue levels in egg yolks were much higher than in egg whites.
- Beef cattle feeding study: total haloxyfop residue concentrations (mg/kg) in fat were higher than in muscle: fat/muscle = 0.057/0.01 and 0.27/0.03.
- Dairy cattle feeding study: the total haloxyfop residue concentrations (mg/kg) in cream were higher than in milk: cream/milk = 0.12/0.01 and 0.29/0.034.
- Laying hen feeding study: the total haloxyfop residue concentrations (mg/kg) in fat were higher than in muscle: fat/muscle = 0.045/0.014 and 0.26/0.063.

The evidence is that the residue in animal commodities is fat-soluble.

The definition should also recognize the inclusion of haloxyfop-P.

The Meeting recommended a revised residue definition for haloxyfop.

Definition of the residue for plants and animals (for compliance with the MRL and for estimation of dietary intake): *sum of haloxyfop (including haloxyfop-P), its esters and its conjugates expressed as haloxyfop.*

The residue is fat-soluble.

Results of supervised trials on crops

The Meeting received information on the use patterns and labels for haloxyfop-P-methyl from many countries. On many of the labels, the application rates are given for the weeds to be controlled. It is not always absolutely clear which rates apply to which crops without knowing which are the likely weeds for each crop.

Application rates for a herbicide should be understood in a different way from application rates for an insecticide or fungicide because the target is different. For an insecticide or fungicide the aim is for a high percentage of the applied pesticide to reach the crop. Whereas for a herbicide, the target is the weed(s) to be controlled.

Particularly in the early growth stages of a crop, only a small percentage of applied herbicide is likely to reach the crop. For the same application rate, expressed in kg ai/ha, the amount of herbicides actually applied to the crop will depend on the crop growth stage and the degree of area coverage by the crop.

The Meeting received supervised trials data for the uses of haloxyfop-P-methyl, haloxyfop-methyl and haloxyfop-ethoxyethyl.

Current GAP relies on haloxyfop-P-methyl. Because the esters hydrolyse reasonably quickly when exposed to the environment, the behaviour of the residue should be little influenced by the

nature of the ester and the Meeting decided to make use of residue data from other esters where application rates and timing were comparable to the GAP conditions.

Supervised trials were available on the following crops: oranges, grapefruit, lemons, apples, peaches, grapes, bananas, onions, field beans, peas, pigeon peas, beans, chickpeas, peas (pulses), sugar beet, rice, cotton, oilseed rape, peanuts, soya beans, sunflowers, coffee and alfalfa.

No residue data were available for potatoes. The meeting withdrew the previous haloxyfop maximum residue level recommendation of 0.1 mg/kg for potatoes.

For present purposes, haloxyfop or haloxyfop-P are considered as the active ingredient. Application rates and residue concentrations are expressed in terms of haloxyfop acid equivalent.

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided. Some common factors that may lead to rejection of the statistical estimate include those situations where the number of data points is less than 15 or where there are too many values below LOQ.

Fruit and vine crops

Haloxyfop is used for weed control in orchards, vineyards and plantations. It is applied as a directed spray on the weeds, not on the trees or vines. In this situation, residues are not expected to occur in the fruit and this is confirmed by the residue trials. LOQs for haloxyfop in the trials from the 1980s until more recent times ranged from 0.01 mg/kg to 0.1 mg/kg, with many trials at 0.02 and 0.05 mg/kg.

Although different LOQs were used in the fruit and vine crop trials, the Meeting decided to use a consistent value for recommending MRLs for fruits where no residue is expected, i.e., 0.02 mg/kg.

Citrus fruits

Supervised trials on citrus were available from Australia, Brazil, Italy and New Zealand.

Haloxyfop-P-methyl is registered in Australia for weed control in orchards, vines and plantations at 0.42 kg ai/ha. In two Australian trials on lemons with directed applications of haloxyfop-ethoxyethyl (0.42 and 0.83 kg ai/ha, PHI 28 days), haloxyfop residues were below LOQ (0.05 mg/kg).

In Uruguay, haloxyfop-P-methyl is registered for control of weeds around fruit trees at an application rate of 0.15 kg ai/ha. In six trials in Brazil (compare with Uruguay GAP), haloxyfop-methyl was used as a directed spray around orange trees at 0.24, 0.48, 0.72, 0.96, 1.4 and 1.9 kg ai/ha and fruit were harvested 67 days after treatment. In another six trials with the same application rates, fruit were harvested 206 days after treatment. Haloxyfop residues were all below LOQ (0.1 mg/kg).

Haloxyfop-P-methyl is registered in New Zealand for weed control around citrus trees at 0.15 kg ai/ha. In two NZ trials on grapefruit with directed applications of haloxyfop-ethoxyethyl (0.21 and 0.42 kg ai/ha, PHI 29 days) and six trials on lemons also with haloxyfop-ethoxyethyl (0.21–0.83 kg ai/ha, PHI 28 days), haloxyfop residues were all below LOQ (0.05 mg/kg).

The Syrian label allows the use of haloxyfop-P-methyl for weed control in fruit trees and vines at 0.13 kg ai/ha. In two Italian trials (compare with Syrian GAP) on oranges with a directed application (0.16 kg ai/ha, PHI 56 days), haloxyfop residues were below LOQ (0.02 mg/kg).

Residues in fruits are not expected with this directed use on the weeds because haloxyfop breaks down reasonably quickly in soils and its residues are not readily taken up from the soil (evidence from the rotational crop studies).

The trials data, many at exaggerated rates, support that expectation that residues would be essentially zero.

The Meeting estimated a maximum residue level of 0.02(*) mg/kg and STMR and HR values of 0 mg/kg for citrus fruits. The previous recommendation of 0.05(*) mg/kg is withdrawn.

Pome fruits

Supervised trials on apples were available from Australia, Italy, New Zealand and the USA.

Haloxyfop-P-methyl is registered in Australia for weed control in orchards, vines and plantations at 0.42 kg ai/ha. In two Australian trials on apples with directed applications of haloxyfop-ethoxyethyl (0.42 and 0.83 kg ai/ha, PHI 24 days), haloxyfop residues were below LOQ (0.05 mg/kg).

The Syrian label allows the use of haloxyfop-P-methyl for weed control in fruit trees and vines at 0.13 kg ai/ha. In six Italian trials (compare with Syrian GAP) on apples with directed applications of haloxyfop-ethoxyethyl (0.16 kg ai/ha, PHI 126–132 days), haloxyfop residues were below LOQ (0.02 mg/kg).

Haloxyfop-P-methyl is registered in New Zealand for weed control around pome fruit trees at 0.15 kg ai/ha. In two NZ trials on apples with directed applications of haloxyfop-ethoxyethyl (0.21 kg ai/ha, PHI 29 days), haloxyfop residues were below LOQ (0.01 mg/kg).

In eight US trials on apples with directed applications of haloxyfop-methyl (0.28 and 0.56 kg ai/ha, PHI 59–60 days), haloxyfop residues were below LOQ (0.05 mg/kg). No GAP is available to evaluate the US trials, but they provide supporting evidence that the directed use around fruit trees is essentially a zero residue situation.

The Meeting estimated a maximum residue level of 0.02(*) mg/kg and STMR and HR values of 0 mg/kg for pome fruits. The previous recommendation of 0.05(*) mg/kg is withdrawn.

Stone fruits

Supervised trials on peaches were available from Australia.

Haloxyfop-P-methyl is registered in Australia for weed control in orchards, vines and plantations at 0.42 kg ai/ha. In two Australian trials on peaches with directed applications of haloxyfop-ethoxyethyl (0.42 and 0.83 kg ai/ha, PHI 24 days), haloxyfop residues were below LOQ (0.05 mg/kg).

Because of the nature of this use, i.e., the pesticide is not applied to the crop, and the expectation of a zero residue, the Meeting agreed to extrapolate from the results on citrus and pome fruits to stone fruits.

The Meeting estimated a maximum residue level of 0.02(*) mg/kg and STMR and HR values of 0 mg/kg for stone fruits.

Grapes

Supervised trials on grapes were available from Australia, France and Italy.

Haloxyfop-P-methyl is registered in Australia for weed control in orchards, vines and plantations at 0.42 kg ai/ha. In six Australian trials on grapes with directed application of haloxyfop-ethoxyethyl (0.21, 0.42 and 0.83 kg ai/ha, PHI 21 and 29 days), haloxyfop residues were below LOQ (0.05 mg/kg).

The Swiss label allows the use of haloxyfop-P-methyl for weed control in grapevines at 0.16 kg ai/ha. In 11 French trials (compare with Swiss GAP) on grapes with directed applications of haloxyfop-ethoxyethyl (0.10, 0.21, 0.42, 0.83 and 1.7 kg ai/ha, PHI 86-115 days), haloxyfop residues were below LOQ (0.01 mg/kg).

The directed use in vineyards is directly comparable with the use in orchards with also the expectation of a zero residue.

The Meeting estimated a maximum residue level of 0.02(*) mg/kg and STMR and HR values of 0 mg/kg for grapes. The previous recommendation of 0.05(*) mg/kg is withdrawn.

Bananas

Supervised trials on bananas were available from Australia.

Haloxyfop-P-methyl is registered in Australia for weed control in orchards, vines and plantations at 0.42 kg ai/ha. In two Australian trials on bananas with directed applications of haloxyfop-P-methyl and haloxyfop-ethoxyethyl (0.42 and 0.83 kg ai/ha respectively, PHI 14 days), haloxyfop residues were below LOQ (0.05 mg/kg).

Because of the nature of this use, i.e., the pesticide is not applied to the crop, and the expectation of a zero residue, the Meeting agreed to extrapolate from the results on orchards and vineyards to banana plantations.

The Meeting estimated a maximum residue level of 0.02(*) mg/kg and STMR and HR values of 0 mg/kg for bananas. The previous recommendation of 0.05(*) mg/kg is withdrawn.

Onions

Supervised trials on onions were available from Belgium, France, Germany and New Zealand.

The Moldovan label allows the use of haloxyfop-P-methyl for weed control in onions at 0.10 kg ai/ha. In two Belgian trials matching Moldovan GAP on onions, haloxyfop residues in the onions (whole plant) were 0.06 and 0.12 mg/kg, 28 days after treatment. In four German trials matching Moldovan GAP on onions, haloxyfop residues in the onions were 0.02, 0.03, 0.04, and 0.09 mg/kg, 26–28 days after treatment.

The Tunisian label allows the use of haloxyfop-P-methyl for weed control in onions at 0.10 kg ai/ha. In two French trials matching Tunisian GAP on onions, haloxyfop residues in the onions (whole plant) were < 0.02 and 0.03 mg/kg 28 days after treatment.

Haloxyfop-P-methyl is registered in New Zealand for weed control in onions at 0.15 kg ai/ha, with harvest permitted 35 days later. The six trials on onions did not match GAP and could not be evaluated.

Plant metabolism studies have shown that haloxyfop is systemic and is quickly distributed throughout a treated plant. The European data on samples described as 'onions' and 'onions (whole plant)' may be combined.

Haloxyfop residues from the eight onion trials in rank order, median underlined were: < 0.02, 0.02, 0.03, <u>0.03</u>, <u>0.04</u>, 0.06, 0.09 and 0.12 mg/kg.

The Meeting estimated an STMR value of 0.035 mg/kg and a maximum residue level of 0.2 mg/kg for onions. The HR was 0.12 mg/kg.

The value derived from use of the NAFTA Calculator (after MLE[34]) was 0.24 mg/kg. The calculated value is in good agreement with the Meeting's estimate. However, the MRL calculation is sensitive to the lowest value.

Beans

Supervised trials on field beans were available from Belgium, France, Germany, Greece and Spain.

The Tunisian label allows the use of haloxyfop-P-methyl for weed control in field beans at 0.10 kg ai/ha. In eight French trials matching Tunisian GAP on field beans, haloxyfop residues in the beans (whole pods) were: < 0.02, < 0.02, 0.03, 0.06, 0.07, 0.10, 0.19 and 0.26 mg/kg, 25–29 days after treatment.

In a Greek trial and a Spanish trial with conditions also matching Tunisian GAP, haloxyfop residues in the beans (whole pods) were 0.18 and 0.22 mg/kg respectively 28 days after treatment.

No suitable GAP was available to evaluate the trials in Belgium and Germany.

In summary, haloxyfop residues in beans (whole pods) from the 10 trials in rank order (median underlined) were: < 0.02, < 0.02, 0.03, 0.06, <u>0.07</u>, <u>0.10</u>, 0.18, 0.19, 0.22 and 0.26 mg/kg.

The Meeting noted that the lowest residues (< 0.02 mg/kg) were associated with applications at growth stage BBCH 14 (fourth true leaf unfolded) and the highest residues (0.19, 0.22 and 0.26 mg/kg) were associated with applications at BBCH 59 (first petals visible) and BBCH 65 (full flowering).

The growth stage timing for application clearly influences the residue level. Application at full flowering may occur while still observing the 28 days PHI. If all the trials were conducted with applications at BBCH 59–65, it is likely that most of the residues would be closer to the upper end of the distribution (0.19–0.26 mg/kg).

The Meeting estimated an STMR value of 0.085 mg/kg and a maximum residue level of 0.5 mg/kg for beans. The HR was 0.26 mg/kg.

The value derived from use of the NAFTA Calculator (after MLE) was 0.54 mg/kg. The calculated value is in good agreement with the Meeting's estimate. However, the lognormal plot extrapolation apparently diverges from the trend of the four highest residues. The calculated value is sensitive to the lowest value of the dataset.

Peas

Supervised trials on peas were available from Belgium, France, Italy and Spain.

The Tunisian label allows the use of haloxyfop-P-methyl for weed control in peas at 0.10 kg ai/ha. In eight French trials matching Tunisian GAP on peas, haloxyfop residues in the peas in pods were: 0.07, 0.08, 0.08, 0.14, 0.21, 0.32, 0.32 and 0.43 mg/kg, 22–60 days after treatment.

In three Italian trials matching Tunisian GAP on peas, haloxyfop residues in the peas in pods were: < 0.05, 0.05 and 0.07 mg/kg, 28–36 days after treatment.

In two Spanish trials matching Tunisian GAP on peas, haloxyfop residues in the peas in pods were: 0.12 and 0.53 mg/kg, 28 days after treatment.

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[34] <u>Note</u>: MLE (Maximum Likelihood Estimate) is the NAFTA process that adjusts the data below LOQ to a lognormal distribution, by applying the distribution based on values at or above the LOQ.

The Belarus label allows the use of haloxyfop-P-methyl for weed control in peas at 0.10 kg ai/ha. In two Belgian trials matching Belarus GAP on peas, haloxyfop residues in the peas in pods were: 0.07 and 0.11 mg/kg, 31–34 days after treatment.

In summary, haloxyfop residues in peas in pods from the 15 trials in rank order (median underlined) were: < 0.05, 0.05, 0.07, 0.07, 0.07, 0.08, 0.08, <u>0.11</u>, 0.12, 0.14, 0.21, 0.32, 0.32, 0.43 and 0.53 mg/kg.

All crops were treated between growth stages BBCH 50–51 (first flower buds visible) and BBCH 65 (full flowering), i.e., a limited growth stage range.

The Meeting estimated an STMR value of 0.11 mg/kg and a maximum residue level of 0.7 mg/kg for peas in pods. The latter replaces the previous recommendation (0.2 mg/kg). The HR was 0.53 mg/kg.

The value derived from use of the NAFTA Calculator was 0.9 mg/kg. The calculated value appears to be higher than necessary and is influenced by the lowest value in the dataset.

The Tunisian label allows the use of haloxyfop-P-methyl for weed control in peas at 0.10 kg ai/ha. In nine French trials matching Tunisian GAP on peas, haloxyfop residues in shelled peas were: < 0.01, < 0.05, 0.07, 0.07, 0.15, 0.26, 0.29, 0.32 and 0.44 mg/kg, 22–60 days after treatment.

In three Italian trials matching Tunisian GAP on peas, haloxyfop residues in shelled peas were: < 0.05, 0.05 and 0.05 mg/kg, 28–36 days after treatment.

In two Spanish trials matching Tunisian GAP on peas, haloxyfop residues in shelled peas were: 0.12 and 0.75 mg/kg, 28 days after treatment.

The Belarus label allows the use of haloxyfop-P-methyl for weed control in peas at 0.10 kg ai/ha. In two Belgian trials matching Belarus GAP on peas, haloxyfop residues in shelled peas were: 0.04 and 0.09 mg/kg, 31–34 days after treatment.

In summary, haloxyfop residues in shelled peas from the 16 trials in rank order (median underlined) were: < 0.01, 0.04, < 0.05, < 0.05, 0.05, 0.05, 0.07, <u>0.07</u>, <u>0.09</u>, 0.12, 0.15, 0.26, 0.29, 0.32, 0.44 and 0.75 mg/kg.

The Meeting estimated an STMR value of 0.08 mg/kg and a maximum residue level of 1 mg/kg for shelled peas. The HR was 0.75 mg/kg.

The value derived from use of the NAFTA Calculator (after MLE) was 1.8 mg/kg. This calculation appears to be higher than necessary and is influenced by the lowest value in the dataset. Different LOQs in the one dataset were probably not considered in the design of the NAFTA Calculator.

Pigeon peas

Supervised trials on pigeon peas were available from Australia, but no suitable GAP was available for evaluation.

Dry beans (pulses)

Supervised trials on beans (pulses) were available from Argentina, Brazil, Costa Rica and Germany.

No suitable GAPs were available for evaluating the data from Costa Rica and Germany.

In Argentina, haloxyfop-P-methyl may be used for weed control in beans at 0.15 kg ai/ha, with a PHI of 65 days. In seven trials in Argentina with an application matching GAP with a ± 25% tolerance (0.11–0.19 kg ai/ha and PHI range 50–80 days), haloxyfop residues in beans were: 0.21, 0.39, 0.86, 1.5, 1.5, 1.8 and 2.0 mg/kg.

In seven trials in Brazil with an application matching Argentinean GAP with a ± 25% tolerance (0.11–0.19 kg ai/ha and PHI range 50–80 days), haloxyfop residues in beans were: 0.01, 0.06, 0.07, 0.08, 0.08, 0.32 and 0.42 mg/kg.

In Brazil, haloxyfop-P-methyl may be used for weed control in beans at 0.048 kg ai/ha, with a PHI of 66 days. In 10 trials in Brazil with an application matching GAP with a ± 25% tolerance (0.036–0.060 kg ai/ha and PHI range 50–80 days), haloxyfop residues in beans were: < 0.01, 0.03, 0.03, 0.04, 0.04, 0.06, 0.06, 0.08, 0.23 and 0.49 mg/kg.

In seven trials in Argentina with an application matching Brazilian GAP with a ± 25% tolerance (0.036–0.060 kg ai/ha and PHI range 61–70 days), haloxyfop residues in beans were: 0.08, 0.26, 0.27, 0.41, 0.70, 0.80 and 1.2 mg/kg.

The data based on the Argentine GAP produced the higher residues and were selected for maximum residue estimation.

In summary, the residues from the 14 trials in line with Argentine GAP, in rank order, median underlined, were: 0.01, 0.06, 0.07, 0.08, 0.08, 0.21, <u>0.32</u>, <u>0.39</u>, 0.42, 0.86, 1.5, 1.5, 1.8 and 2.0 mg/kg.

The Meeting estimated an STMR value of 0.335 mg/kg and a maximum residue level of 3 mg/kg for beans (dry).

The previous recommendation of a group haloxyfop maximum residue level for pulses (0.2 mg/kg) is withdrawn. Insufficient data are available for a group maximum residue level. The group value is replaced by individual commodity recommendations where data are available.

The value derived from use of the NAFTA Calculator was 2.5 mg/kg. The calculated value is in good agreement with the Meeting's estimate.

Chickpeas

Supervised trials on chickpeas were available from Australia.

In Australia, haloxyfop-P-methyl may be used for weed control in chickpeas at 0.052 kg ai/ha from second leaf stage until prior to flowering.

In two trials in Australia with conditions in line with Australian GAP, haloxyfop residues in the chickpea grain were < 0.02 and 0.02 mg/kg. In two trials at double the GAP rate the residues were < 0.02 and 0.04 mg/kg.

The number of chickpea trials is very limited. However, the Australian use pattern for chickpeas is the same as for peas. In six trials matching GAP (see below), and four trials at 0.10 kg ai/ha, haloxyfop residues in peas (pulses) were < 0.01 mg/kg. The meeting used the pea data to support a chickpea maximum residue level.

The Meeting estimated an STMR value of 0.02 mg/kg and a maximum residue level of 0.05 mg/kg for chickpeas.

Peas (pulses)

Supervised trials on peas grown for dry pea production were available from Australia and France.

In Australia, haloxyfop-P-methyl may be used for weed control in peas at 0.052 kg ai/ha from second leaf stage until prior to flowering. In six trials in Australia matching GAP, haloxyfop residues in pea grain were: < 0.01 mg/kg (6). In four trials with the same timing but an application rate of 0.10 kg ai/ha, haloxyfop residues were also all below LOQ (0.01 mg/kg). In six trials with haloxyfop-ethoxyethyl at application rates of 0.10 and 0.21 kg ai/ha, but with the same timing, haloxyfop residues were also below LOQ (0.01 mg/kg).

The Tunisian label allows the use of haloxyfop-P-methyl for weed control in peas at 0.10 kg ai/ha. In eight French trials matching Tunisian GAP on peas, haloxyfop residues in the dry peas were: 0.02, 0.02, 0.04, < 0.05, 0.05, 0.06, 0.06 and 0.10 mg/kg. In nine French trials matching the Tunisian application rate (0.10 kg ai/ha), but using haloxyfop-ethoxyethyl, haloxyfop residues in dry peas were: < 0.02, < 0.02, < 0.02, 0.03, 0.04, 0.04, < 0.05, 0.05 and 0.07 mg/kg.

Residues from the Tunisian GAP were higher than those from Australian GAP and so were chosen for maximum residue evaluation.

In summary, the haloxyfop residues on dry peas from the Tunisian GAP (17 French trials) in rank order, median underlined, were: < 0.02, < 0.02, < 0.02, 0.02, 0.02, 0.03, 0.04, 0.04, <u>0.04</u>, < 0.05, < 0.05, 0.05, 0.05, 0.06, 0.06, 0.07 and 0.10 mg/kg.

The Meeting estimated an STMR value of 0.04 mg/kg and a maximum residue level of 0.2 mg/kg for peas (dry).

The value derived from use of the NAFTA Calculator (after MLE) was 0.17 mg/kg. The calculated value is in good agreement with the Meeting's estimate. The NAFTA Calculator is little influenced by the low values. However, the number of < LOQ values (5 in 17 trials, i.e., 29%) reduces the reliability of the calculated result. Different LOQs in the one dataset were probably not considered in the design of the NAFTA Calculator.

Soya beans

Supervised trials on soya beans were available from Argentina, Brazil, France, Germany, Hungary, Italy, Spain and the USA.

In Argentina, haloxyfop-P-methyl may be used for weed control in soya beans at 0.15 kg ai/ha. In two trials in Argentina with an application rate of 0.18 kg ai/ha (within 25% of 0.15 kg ai/ha), haloxyfop residues in soya beans were 0.03 and 0.11 mg/kg.

In 16 trials in Brazil with an application rate of 0.12 kg ai/ha (within 25% of the Argentinean GAP rate, 0.15 kg ai/ha), haloxyfop residues in soya beans were < 0.01 (4), 0.02, 0.02, 0.03, < 0.05, 0.06, 0.06, 0.08, 0.15, 0.19, 0.45, 0.90 and 1.8 mg/kg.

In Brazil, haloxyfop-P-methyl may be used for weed control in soya beans at 0.060 kg ai/ha with a PHI of 98 days. In five trials in Brazil in line with Brazilian GAP (accept tolerance on PHI of 90–110 days), haloxyfop residues in soya beans were < 0.01 (3), 0.01 and 0.06 mg/kg.

Haloxyfop-P-methyl is registered for use for weed control in soya beans in Moldova and Russian Federation at 0.10 kg ai/ha. No restraints on timing or crop growth stage are available.

In France, four trials with haloxyfop-P-methyl at 0.10 kg ai/ha (compare with Moldovan GAP) produced haloxyfop residues in soya beans of < 0.05 (2), 0.31 and 0.99 mg/kg.

In Germany, two trials with haloxyfop-P-methyl at 0.11 kg ai/ha (compare with Moldovan GAP) produced haloxyfop residues in soya beans of < 0.05 and 0.23 mg/kg.

In Hungary, two trials with haloxyfop-P-methyl at 0.10 kg ai/ha (compare with Moldovan GAP) produced haloxyfop residues in soya beans of < 0.05 and 0.11 mg/kg.

No suitable GAP was available to evaluate the US trials on soya beans.

Trials matching the conditions of Argentinean GAP produced the higher residues, so were used for maximum residue evaluation.

Summarising, 18 trials matching Argentinean GAP produced haloxyfop residues in soya beans (rank order, underlined median): < 0.01 (4), 0.02, 0.02, 0.03, 0.03, < <u>0.05</u>, <u>0.06</u>, 0.06, 0.08, 0.11, 0.15, 0.19, 0.45, 0.90 and 1.8 mg/kg.

The Meeting estimated an STMR value of 0.055 mg/kg and a maximum residue level of 2 mg/kg for soya beans.

The value derived from use of the NAFTA Calculator (after MLE) was 2.7 mg/kg. The number of < LOQ values (five in 18 trials, i.e., 28%) reduces the reliability of the calculated result. Different LOQs in the one dataset were probably not considered in the design of the NAFTA Calculator.

Sugar beet

Supervised trials on sugar beet were available from Belgium, France, Germany, Italy and Spain

Haloxyfop-P-methyl is registered for weed control in sugar beet in Belarus, Moldova, the Russian Federation and the Ukraine at 0.10 kg ai/ha.

In Belgium, a trial at 0.10 kg ai/ha of haloxyfop-P-methyl (compare with Belarus GAP) produced haloxyfop residues in sugar beet roots of 0.03 mg/kg.

In France, three trials with haloxyfop-P-methyl at 0.10 kg ai/ha (compare with Belarus GAP) produced haloxyfop residues in sugar beet roots of < 0.02, < 0.02 and < 0.02 mg/kg.

In France, three trials with haloxyfop-ethoxyethyl at 0.10 kg ai/ha (compare with Belarus GAP) produced haloxyfop residues in sugar beet roots of < 0.02, < 0.02 and < 0.02 mg/kg.

In Germany, five trials with haloxyfop-P-methyl at 0.10 kg ai/ha (compare with Belarus GAP) produced haloxyfop residues in sugar beet roots of 0.02, 0.04, 0.09, 0.11 and 0.30 mg/kg.

In summary, haloxyfop residues in sugar beet roots from 12 trials matching Belarus, Moldovan, Russian Federation and Ukrainian GAP were, in rank order, median underlined: < 0.02 (6), <u>0.02</u>, 0.03, 0.04, 0.09, 0.11 and 0.30 mg/kg.

The Meeting estimated an STMR value of 0.02 mg/kg, an HR value of 0.30 mg/kg and a maximum residue level of 0.4 mg/kg for sugar beet. The latter replaces the previous recommendation (0.3 mg/kg).

The value derived from use of the NAFTA Calculator (after MLE) was 0.11 mg/kg. The number of < LOQ values (6 in 12 trials, i.e., 50%) reduces the reliability of the calculated result.

Rice

Supervised trials with haloxyfop-methyl on rice were available from the USA.

No suitable GAP was available, so the trials could not be evaluated for estimation of a maximum residue level.

The Meeting withdrew its recommendations for polished rice of 0.02(*) mg/kg, husked rice of 0.02(*) mg/kg) and unprocessed rice bran of 0.02(*) mg/kg.

Cotton seed

Supervised trials on cotton, generating haloxyfop residue data on cotton seed, were available from Brazil, Greece, Spain and the USA.

In Brazil, haloxyfop-P-methyl may be used for weed control in cotton at 0.060 kg ai/ha, with a PHI of 123 days. In three trials in Brazil with an application matching GAP, haloxyfop residues in cotton seed were: < 0.01, < 0.01 and 0.08 mg/kg.

In Argentina, haloxyfop-P-methyl may be used for weed control in cotton at 0.15 kg ai/ha. In five trials in Brazil with an application of haloxyfop-P-methyl matching Argentinean GAP (± 25%), haloxyfop residues in cotton seed were: < 0.01, 0.02, 0.03, 0.09 and 0.52 mg/kg. In four trials in Brazil with an application of haloxyfop-methyl at 0.12 kg ai/ha, haloxyfop residues in cotton seed were < 0.1 (3) and 0.15 mg/kg.

No suitable GAP was available for evaluating cotton trials in Greece, Spain and the USA.

The Brazilian trials in line with Argentinean GAP were used for the maximum residue level estimation.

In summary, haloxyfop residues in cotton seed from the nine residue trials matching Argentinean GAP, in rank order, median underlined were: < 0.01, 0.02, 0.03, 0.09, < 0.1 (3), 0.15 and 0.52 mg/kg.

The Meeting estimated an STMR value of 0.1 mg/kg and a maximum residue level of 0.7 mg/kg for cotton seed. The latter replaces the previous recommendation (0.2 mg/kg).

The value derived from use of the NAFTA Calculator (after MLE) was 0.20 mg/kg. The lognormal plot extrapolation apparently diverges from the trend of the five highest residues. The number of < LOQ values (four in nine trials, i.e., 44%) reduces the reliability of the calculated result. Different LOQs in the one dataset were probably not considered in the design of the NAFTA Calculator.

Oilseed rape (canola)

Supervised trials on oilseed rape were available from Australia, France, Germany, Greece, Italy, Poland and Spain.

The Australian label allows application of haloxyfop-P-methyl for weed control in canola at 0.052 kg ai/ha at growth stages from second leaf to prior to bud formation and stem elongation. In two trials in Australia matching GAP, haloxyfop residues in canola grain were: 0.22 and 0.86 mg/kg.

Haloxyfop-P-methyl is registered for weed control in oilseed rape in Belarus, Moldova, Russian Federation and Ukraine at 0.10 kg ai/ha. No restraints on timing or crop growth stage are available, so all the European trials that have an application rate of 0.10 kg ai/ha (± 25%) are included.

In France, eight trials with haloxyfop-P-methyl at 0.10 kg ai/ha produced haloxyfop residues in rapeseed of < 0.01 (2), < 0.05 (3), 1.1, 1.5 and 1.9 mg/kg.

In France, three trials with haloxyfop-ethoxyethyl at 0.10 kg ai/ha produced haloxyfop residues in rapeseed of < 0.05 mg/kg (3).

In Germany, eight trials with haloxyfop-P-methyl at 0.10 kg ai/ha produced haloxyfop residues in rapeseed of < 0.01, < 0.05, 0.07, 0.10, 0.11, 0.37, 0.43 and 0.57 mg/kg.

In Poland, three trials with haloxyfop-P-methyl at 0.10 kg ai/ha produced haloxyfop residues in rapeseed of 0.33, 0.42 and 0.62 mg/kg.

Summarising, 22 European trials with haloxyfop-P-methyl at 0.10 kg ai/ha produced haloxyfop residues in rapeseed (rank order, underlined median): < 0.01 (3), < 0.05 (7), 0.07, 0.10, 0.11, 0.33, 0.37, 0.42, 0.43, 0.57, 0.62, 1.1, 1.5 and 1.9 mg/kg.

The Meeting estimated an STMR value of 0.07 mg/kg and a maximum residue level of 3 mg/kg for rape seed. The latter replaces the previous recommendation (2 mg/kg).

The value derived from use of the NAFTA Calculator (after MLE) was 5.9 mg/kg. The number of < LOQ values (10 in 22 trials, i.e., 45%) reduces the reliability of the calculated result. Different LOQs in the one dataset were probably not considered in the design of the NAFTA Calculator.

Peanuts

Supervised trials on peanuts were available from Argentina and Australia.

In Argentina, haloxyfop-P-methyl may be used for weed control in peanuts at 0.15 kg ai/ha. The application rates in the trials were 0.045 and 0.090 kg ai/ha, so Argentine GAP could not be used for evaluation of the trials.

The Australian label allows application of haloxyfop-P-methyl for weed control in peanuts at 0.078 kg ai/ha at crop growth stages from second leaf to pegging. In four trials in Australia matching GAP, haloxyfop residues in peanuts were: < 0.02, < 0.02, 0.02 and 0.02 mg/kg.

The number of trials was too few to support a recommendation.

The Meeting agreed to withdraw its previous recommendations for peanuts (0.05 mg/kg).

Sunflowers

Supervised trials on sunflowers were available from Argentina, France, Germany, Greece and Spain.

In Argentina, haloxyfop-P-methyl may be used for weed control in sunflowers at 0.15 kg ai/ha. In one trial at 0.18 kg ai/ha, haloxyfop residues in sunflower seed were 0.14 mg/kg.

The Tunisian label allows the use of haloxyfop-P-methyl for weed control in sunflowers at 0.10 kg ai/ha. In five French trials matching Tunisian GAP on sunflowers, haloxyfop residues in the sunflower seed were: < 0.05 (2), 0.06, 0.07 and 0.10 mg/kg.

In three French trials with haloxyfop-ethoxyethyl, but matching the Tunisian GAP application rate on sunflowers, haloxyfop residues in the sunflower seed were: < 0.05 (2) and 0.05 mg/kg.

Summary of European sunflower seed data from eight trials matching Tunisian GAP: < 0.05 (4), 0.05, 0.06, 0.07 and 0.10 mg/kg.

The Serbian label allows the use of haloxyfop-P-methyl for weed control in sunflowers at 0.16 kg ai/ha. In three French trials matching Serbian GAP (0.16 ± 25%, 0.12–0.20 kg ai/ha) (all 3 done at 0.15 kg ai/ha) on sunflowers, haloxyfop residues in the sunflower seed were: < 0.05, 0.05 and 0.14 mg/kg.

In three French trials with haloxyfop-ethoxyethyl, but matching Serbian GAP (0.16 ± 25%, 0.12–0.20 kg ai/ha) (all 3 done at 0.20 kg ai/ha) on sunflowers, haloxyfop residues in the sunflower seed were: 0.07, 0.09 and 0.16 mg/kg.

In two Greek trials matching Serbian GAP on sunflowers, haloxyfop residues in the sunflower seed were: < 0.05 mg/kg (2).

In three Spanish trials matching Serbian GAP on sunflowers, haloxyfop residues in the sunflower seed were: < 0.05 (2) and 0.17 mg/kg.

Summary of European sunflower seed data from 11 trials matching Serbian GAP: < 0.05 (5), 0.05, 0.07, 0.09, 0.14, 0.16 and 0.17 mg/kg.

The Meeting relied on the data from the higher application rate, i.e., the second set, for estimating the maximum residue level.

The Meeting estimated an STMR value of 0.05 mg/kg and a maximum residue level of 0.3 mg/kg for sunflower seed. The latter replaces the previous recommendation (0.2 mg/kg).

The value derived from use of the NAFTA Calculator (after MLE) was 0.31 mg/kg. The calculated MRL is in good agreement with the Meeting's estimate. The MLE process converted the distribution from non-lognormal to one where the lognormal presumption was not rejected. The number of < LOQ values (5 in 11 trials, i.e., 44%) reduces the reliability of the calculated result.

Coffee

Supervised trials on coffee were available from Brazil and Colombia.

In Colombia, haloxyfop-P-methyl is allowed as a directed application for control of weeds in coffee at a maximum rate of 0.36 kg ai/ha.

In two trials on coffee in Colombia with directed applications of haloxyfop-methyl at 0.18 and 0.36 kg ai/ha, haloxyfop residues in coffee beans did not exceed the LOQ (0.02 mg/kg).

In 13 trials on coffee in Brazil with directed applications of haloxyfop-methyl at 0.12 to 0.96 kg ai/ha, haloxyfop residues in coffee beans did not exceed the LOQ (0.02 mg/kg).

Residues in coffee beans are not expected from such a use where the trees are not sprayed. The trials data, some at exaggerated rates, support that expectation that residues would be essentially zero.

The Meeting estimated an STMR value of 0 mg/kg and a maximum residue level of 0.02(*) mg/kg for coffee beans. The HR was 0 mg/kg.

Legume animal feeds—alfalfa

Supervised trials on alfalfa were available from Australia, France, Germany and Poland.

In Australia, haloxyfop-P-methyl is registered for weed control uses on alfalfa at 0.078 kg ai/ha. The label allows use from the second trifoliate leaf onwards and imposes a 28 days interval between application and grazing or cutting for livestock.

In five Australian trials matching GAP (0.078 ± 25%, 0.059–0.10 kg ai/ha, PHI 28–32 days) on alfalfa, haloxyfop residues in the alfalfa forage (fresh weight) were: 0.10, 0.76, 1.0, 1.9 and 3.1 mg/kg.

In two Australian trials with haloxyfop-ethoxyethyl matching the GAP application rate and PHI (0.078 ± 25%, 0.059–0.10 kg ai/ha, PHI 28–32 days) on alfalfa, haloxyfop residues in the alfalfa forage (fresh weight) were: 1.1 and 1.9 mg/kg.

No suitable GAP was available to evaluate the alfalfa trials from France, Germany and Poland.

In summary, haloxyfop residues in alfalfa forage, fresh weight, from the seven Australian trials in rank order, median underlined, were: 0.10, 0.76, 1.0, <u>1.1</u>, 1.9, 1.9 and 3.1 mg/kg.

The Meeting estimated STMR and high residue values for alfalfa forage (fresh weight) of 1.1 and 3.1 mg/kg, respectively.

The previous maximum residue level recommendation (5 mg/kg) for alfalfa forage is withdrawn because the policy is now to use information on forage in dietary burden calculations, but not to propose maximum residue levels for fresh forage commodities, which are understood not to be traded internationally.

Legume animal feeds—chickpea forage and straw

Supervised trials on chickpeas were available from Australia with data on forage and straw.

In Australia, haloxyfop-P-methyl may be applied for weed control in chickpeas at 0.052 kg ai/ha from second leaf stage until prior to flowering. The label imposes a 28 days interval between application and grazing or cutting for livestock.

In two trials in Australia with conditions in line with Australian GAP, haloxyfop residues in the chickpea forage (dry weight) were 2.9 and 4.3 mg/kg. In two trials at double the GAP rate the residues were 6.7 and 10.2 mg/kg.

Haloxyfop residues in chickpea straw (dry weight) from the four Australian trials were 0.13 and < 0.05 mg/kg for the label rate and 0.28 and < 0.05 mg/kg for the double rate.

The data were insufficient to support a recommendation.

Legume animal feeds—peanut forage and fodder

Supervised trials on peanuts were available from Australia with data on forage and fodder.

The Australian label allows application of haloxyfop-P-methyl for weed control in peanuts at 0.078 kg ai/ha at crop growth stages from second leaf to pegging. The label imposes a 28 days interval between application and grazing or cutting for livestock.

In four trials in Australia matching GAP, haloxyfop residues in peanut forage, dry weight, were: < 0.02, 0.13, 0.28 and 1.1 mg/kg. Haloxyfop residues in peanut straw (dry weight) from the same four Australian trials were: 0.42, 1.2, 2.9 and 3.0 mg/kg. Peanut forage data are not currently used in dietary burden calculations.

In four trials in Australia at 0.16 kg ai/ha (double the GAP application rate) but matching GAP for timing of application, haloxyfop residues in peanut straw (dry weight) were: 1.1, 1.9, 3.8 and 5.4 mg/kg, i.e., double the application rate produced approximately double the residue level. The data from the double rate trials provide support for the GAP trials.

The Meeting estimated an STMR of 2.1 mg/kg and a maximum residue level of 5 mg/kg for peanut fodder. The high residue was 3.0 mg/kg.

Legume animal feeds—soya bean forage

Supervised trials on soya beans were available from France, Germany, Hungary, Italy and Spain with data on forage.

Haloxyfop-P-methyl is registered for use for weed control in soya beans in Moldova and the Russian Federation at 0.10 kg ai/ha. No restraints on timing or crop growth stage are available.

In France, four trials with haloxyfop-P-methyl at 0.10 kg ai/ha (compare with Moldovan GAP) produced haloxyfop residues in soya bean plants, i.e., forage, of < 0.05 (2), 0.12 and 0.13 mg/kg.

In Germany, two trials with haloxyfop-P-methyl at 0.11 kg ai/ha (compare with Moldovan GAP) produced haloxyfop residues in soya bean plants, i.e., forage, of < 0.05 and 0.10 mg/kg.

In Hungary, two trials with haloxyfop-P-methyl at 0.10 kg ai/ha (compare with Moldovan GAP) produced haloxyfop residues in soya bean plants, i.e., forage, of < 0.05 and 0.18 mg/kg.

Summarising soya bean forage data—eight trials from Europe matching Moldova and Russian Federation GAP produced haloxyfop residues in soya bean forage (rank order, underlined median): < <u>0.05</u> (4), <u>0.10</u>, 0.12, 0.13 and 0.18 mg/kg.

The Meeting estimated STMR and high residue values for soya bean forage (fresh weight) of 0.075 and 0.18 mg/kg, respectively.

Sugar beet leaves or tops

Supervised trials on sugar beets were available from Germany, Italy and Spain with data on leaves and tops.

Haloxyfop-P-methyl is registered for weed control in sugar beet in Belarus, Moldova, the Russian Federation and the Ukraine at 0.10 kg ai/ha.

In Belgium, a trial at 0.10 kg ai/ha of haloxyfop-P-methyl (compare with Belarus GAP) produced haloxyfop residues in sugar beet tops of 0.07 mg/kg.

In Germany, five trials with haloxyfop-P-methyl at 0.10 kg ai/ha (compare with Belarus GAP) produced haloxyfop residues in sugar beet leaves of 0.10, 0.17 and 0.38 mg/kg and residues of 0.08 and 0.12 mg/kg in beet tops.

In summary, haloxyfop residues in sugar beet leaves or tops from six trials matching Belarus, Moldovan, Russian Federation and Ukrainian GAP were, in rank order median underlined: 0.07, 0.08, 0.10, 0.12, 0.17 and 0.38 mg/kg.

The Meeting estimated STMR and HR values of 0.11 and 0.38 mg/kg for sugar beet leaves or tops.

The previous maximum residue level recommendations (0.3 mg/kg) for sugar beet leaves or tops and fodder beet leaves or tops are withdrawn because the policy is now to use information on forage in dietary burden calculations, but not to propose maximum residue levels for fresh forage commodities, which are understood not to be traded internationally.

Fodder beet

Haloxyfop-P-methyl is registered for weed control in beets in Iraq at 0.12 kg ai/ha. Therefore, the data on sugar beet at 0.10 kg ai/ha can be used to support a fodder beet recommendation.

The Meeting extrapolated the estimate for sugar beet to fodder beet: an STMR value of 0.02 mg/kg, an HR value of 0.30 mg/kg and a maximum residue level of 0.4 mg/kg for fodder beet. The latter replaces the previous recommendation (0.3 mg/kg).

Rapeseed forage

Supervised trials on oilseed rape were available from Australia, France, Germany, Greece, Italy, Poland and Spain with data on forage.

The Australian label allows application of haloxyfop-P-methyl for weed control in canola (oilseed rape) at 0.052 kg ai/ha at growth stages from second leaf to prior to bud formation and stem elongation. The label imposes a 28 days interval between application and grazing or cutting for livestock.

In three trials in Australia matching GAP, haloxyfop residues in canola forage, expressed on dry weight, were: 0.32, 1.3 and 5.0 mg/kg.

In two trials in Australia matching GAP, haloxyfop residues in canola fodder were: 0.06 and 0.22 mg/kg.

The Meeting estimated STMR and high residue values for oilseed rape forage (dry weight) of 1.3 and 5.0 mg/kg, respectively for Australian uses.

Haloxyfop-P-methyl is registered for weed control in oilseed rape in Belarus, Moldova, the Russian Federation and the Ukraine at 0.10 kg ai/ha. No restraints on timing or crop growth stage are available, so all the European trials that have an application rate of 0.10 kg ai/ha (± 25%) could be included.

However, residues in forage decline quickly and some time limits are needed to produce a residue population suitable for STMR estimation. In practice, forage could be grazed or cut immediately after treatment. The Meeting decided to use forage data from samples taken on the same day as the treatment or 1 day later.

In three trials in France with haloxyfop-P-methyl application at 0.10 kg ai/ha (± 25%), haloxyfop residues in oilseed rape plants harvested on the day of application were: 1.5, 3.1 and 5.4 mg/kg.

In six trials in Germany with haloxyfop-P-methyl application at 0.10 kg ai/ha (± 25%), haloxyfop residues in oilseed rape plants harvested on the day of application or one day later were: 1.6, 3.9, 4.3, 5.6, 5.7 and 6.8 mg/kg.

In two trials in Poland with haloxyfop-P-methyl application at 0.10 kg ai/ha (± 25%), haloxyfop residues in oilseed rape plants harvested on the day of application were: 2.2 and 3.4 mg/kg.

In summary, 11 trials from Europe with the application rate 0.10 kg ai/ha (GAP of Belarus, Moldova, the Russian Federation and the Ukraine) produced haloxyfop residues in oilseed rape plant 0 or 1 day after treatment (rank order, median underlined): 1.5, 1.6, 2.2, 3.1, 3.4, 3.9, 4.3, 5.4, 5.6, 5.7 and 6.8 mg/kg

The Meeting estimated STMR and high residue values for oilseed rape forage (fresh weight) of 3.9 and 6.8 mg/kg, respectively for European uses.

Fate of residues during processing

The Meeting received information on the fate of haloxyfop residues during the processing of oilseed rape for oil and meal, soya beans for oil and meal and sugar beet for sugar.

No information was available on the fate of haloxyfop residues during the processing of cotton seed. The Meeting withdrew the previous recommendation of 0.5 mg/kg for a haloxyfop maximum residue level in crude cotton seed oil.

A processing study was also received for apples, but haloxyfop uses as a directed spray on weeds around apple trees did not produce detectable residues in the apples or processed commodities. No processing factors could be calculated.

In a series of trials in France, haloxyfop-ethoxyethyl was applied to oilseed rape at 0.10, 0.21 and 0.63 kg ai/ha at one of two growth stages, 5–6 leaves and beginning of flowering. The harvested rapeseed was processed at laboratory scale to crude oil, refined and deodorized oil and meal. Haloxyfop residues in the rapeseed were below LOQ (0.05 mg/kg) for low application rates and early growth-stage treatments and were not included in the processing factor calculations.

The laboratory process was designed to simulate the commercial process. Rapeseed was coarsely ground and extracted with hot hexane. The extracted solid material was the meal. Crude oil was degummed, alkali was added and the soap was allowed to settle. The oil was decanted and filtered and then bleached with a Fuller's earth treatment and deodorized by steam distillation at 240 ºC under reduced pressure.

The processing factors for haloxyfop residues for rapeseed → crude oil were: 1.1, 1.2, 1.4, 1.7, 1.8 and 2.0—median 1.6.

The processing factors for haloxyfop residues for rapeseed → refined and deodorized oil were: 0.93, 1.1, 1.3, 1.7, 1.9 and 2.2—median 1.5.

The processing factors for haloxyfop residues for rapeseed → meal were: 0.73, 0.88, 0.89, 0.92, 0.93 and 1.7—median 0.91.

The processing factors for crude rape seed oil (1.6), refined rape seed oil (1.5) and meal (0.91) were applied to the estimated STMR for rape seed (0.07 mg/kg) to produce STMR-P values for crude rape seed oil (0.17 mg/kg), refined rape seed oil (0.16 mg/kg) and rapeseed meal (0.10 mg/kg). These concentrations fall below the estimated maximum residue level for rape seed (3 mg/kg), so maximum residue levels for the oils and meal are not needed.

The maximum residue level recommendations for crude rape seed oil (5 mg/kg) and refined rape seed oil (5 mg/kg) are withdrawn.

In soya bean trials in the USA, haloxyfop-methyl was applied at 0.28 kg ai/ha to soya beans in bloom or haloxyfop-P-methyl at 0.70 kg ai/ha was applied to soya beans at the 5th trifoliate leaf stage. The soya beans were processed in a laboratory-scale system to produce hulls, meal, crude oil, refined oil and soapstock and haloxyfop residue levels were measured on the products.

The processing factors for haloxyfop residues for soya beans → crude oil were: 0.40, 0.79 and 1.3—median 0.79.

The processing factors for haloxyfop residues for soya beans → refined oil were: 0.33, 0.75 and 1.2—median 0.75.

The processing factors for haloxyfop residues for soya beans → meal were: 1.19, 1.25 and 1.29—median 1.25.

The processing factors for crude soya bean oil (0.79), refined soya bean oil (0.75) and soya bean meal (1.25) were applied to the estimated STMR for soya beans (0.055 mg/kg) to produce STMR-P values for crude soya bean oil (0.044 mg/kg), refined soya bean oil (0.041 mg/kg) and soya bean meal (0.069 mg/kg). These concentrations fall below the estimated maximum residue level for soya beans (2 mg/kg), so maximum residue levels for the oils and meal are not needed.

The maximum residue level recommendations for crude soya bean oil (0.2 mg/kg) and refined soya bean oil (0.2 mg/kg) are withdrawn.

In UK trials, sugar beet were treated with haloxyfop-ethoxyethyl at 0.25 or 0.50 kg ai/ha at the 6–8 leaf growth stage. After harvest, beets were processed to juice, pressed pulp, refined sugar and green syrup. The process was pilot scale and consisted of washing, slicing, water extraction, pressing, filtration, calcium carbonate precipitation-filtration, boiling and centrifuging.

Haloxyfop residue levels in the refined sugar did not exceed the analytical method LOQ (0.01 mg/kg). Processing factors were calculated for the refined sugar, the green syrup and the pressed pulp. Green syrup is the liquor from the second last crystallizer, comparable with molasses, the liquor from the final crystallizer.

The processing factors for haloxyfop residues for sugar beet → refined sugar were: < 0.09 and 0.15—best estimate < 0.09.

The processing factors for haloxyfop residues for sugar beet → green syrup were: 2.95 and 3.31—mean 3.1.

The processing factors for haloxyfop residues for sugar beet → pressed pulp were: 0.36 and 0.46—mean 0.41.

The processing factor for refined sugar (< 0.09) was applied to the estimated STMR for sugar beet (0.02 mg/kg) to produce an STMR-P value for refined sugar (0.002 mg/kg). This concentration falls below the estimated maximum residue level for sugar beet (0.4 mg/kg), so a maximum residue level for haloxyfop residues in raw sugar is not needed.

The processing factor for green syrup (3.1) was applied to the estimated STMR for sugar beet (0.02 mg/kg) to produce an STMR-P value for green syrup (0.063 mg/kg).

The processing factor for pressed pulp (0.41) was applied to the estimated STMR for sugar beet (0.02 mg/kg) to produce an STMR-P value for pressed pulp (0.008 mg/kg).

Residues in animal commodities

The meeting received beef cattle feeding studies with haloxyfop and haloxyfop-P, dairy cattle studies with haloxyfop and haloxyfop-P and a laying hen study with haloxyfop. These livestock feeding studies provided information on likely haloxyfop residues resulting in bovine tissues and milk and poultry tissues and eggs from haloxyfop residues in the livestock diets.

Beef calves were dosed with haloxyfop via gelatin capsule at rates equivalent to 0.25, 0.5, 1, 5 and 10 ppm in the dry-weight diet for 28 consecutive days. Animals were slaughtered 18 to 21 hours after the final dose for tissue collection. Additional groups of animals at the highest dose were kept for 7 and 14 days after the final dose to observe declines in residue levels.

Mean haloxyfop residues in the muscle from the fivr dose rates (equivalent to 0.25, 0.5, 1, 5 and 10 ppm of dry weight diet) were: < 0.01, < 0.01, < 0.01, 0.01, and 0.03 mg/kg, respectively.

Similarly for liver: 0.02, 0.02, 0.05, 0.13 and 0.54 mg/kg, respectively; kidney: 0.06, 0.07, 0.14, 0.39 and 1.3 mg/kg, respectively; and fat: 0.02, 0.01, 0.01, 0.057, and 0.27 mg/kg, respectively.

After 7 and 14 days on a residue-free diet, residues had declined, but residue levels were widely variable between animals.

For animals dosed at 5 and 10 ppm, residues in muscle equalled or exceeded LOQ and ratios between residue levels in fat and muscle were calculated: mean = 7.8, range 3.6–18.5, n = 5, suggesting a fat-soluble residue.

Beef cattle were dosed with haloxyfop-P via gelatin capsule at rates equivalent 10, 20 and 30 ppm in the dry-weight diet for 28 consecutive days and were slaughtered on day 28 for tissue collection. Additional animals at the highest dose were kept for 7, 14, 21 and 28 days after the final dose to observe declines in residue levels. The analytical method did not include a hydrolysis step, so the residue data for fat were unlikely to include haloxyfop triacylglyceride conjugates and could not be used.

Mean haloxyfop residues in the muscle from the three dose rates (equivalent to 10, 20 and 30 ppm of dry weight diet) were: 0.03, 0.05 and 0.04 mg/kg, respectively. Similarly for liver: 0.25, 0.38 and 0.28 mg/kg, respectively; and kidney: 0.58, 1.0 and 1.2 mg/kg, respectively.

After 7 days on a residue-free diet, haloxyfop residues in muscle had fallen below LOQ (0.01 mg/kg) while residues in liver and kidney had fallen by approximately 70% and 90% respectively. Residues continued to decline during the next 21 days, but at a slower rate.

Holstein dairy cows were dosed through the feed with haloxyfop at nominal concentrations of 0.25, 0.75 and 2.5 ppm in the dry-weight diet for 28 consecutive days. Milk was collected twice daily. Milk from morning milking was put through a separator to produce cream.

Haloxyfop residues in milk from the low-dose (0.25 ppm) cows did not exceed the LOQ (0.01 mg/kg) except for one case (0.01 mg/kg). Residues in the milk from the middle dose group (0.75 ppm) were in the range < 0.01 to 0.026 mg/kg from days 5 to 28. Residues in the milk from the high dose group (2.5 ppm) were in the range < 0.01 to 0.055 mg/kg (mean 0.033 mg/kg) from days 5 to 28, the approximate plateau of residue levels.

The range of haloxyfop residue levels in cream from days 10 and 17 were 0.043–0.051 mg/kg for the low dose (0.25 ppm), 0.11–0.22 mg/kg for the middle dose group (0.75 ppm) and 0.28–0.42 mg/kg the high dose group (2.5 ppm).

Residue data were available for cream and milk on an individual animal basis for days 3 and 10. Average (and range) of haloxyfop residue levels were: cream 0.316 mg/kg (0.24–0.42 mg/kg) and milk 0.019 (0.01–0.11 mg/kg). The average for 'milk residues ÷ cream residues' was 0.059.

Friesian dairy cows were dosed with haloxyfop-P via gelatin capsule at rates equivalent to 10, 20 and 30 ppm in the dry-weight diet for 28 consecutive days. Milk was collected twice daily. Milk was analysed for haloxyfop by a method that does not include a hydrolysis step and therefore may not have recovered haloxyfop residues quantitatively from triacylglyceride conjugates. Residues appeared to plateau at or before 10 days. The average concentrations of haloxyfop measured in the milk from days 10 to 26 were 0.317, 0.558 and 0.804 mg/kg for dosing levels equivalent to 10, 20 and 30 ppm, respectively.

White Leghorn laying hens were dosed through the feed with haloxyfop at nominal concentrations of 0.25, 0.75, and 2.5 ppm in the diet, for 28 consecutive days. Eggs were collected twice daily. Birds were slaughtered approximately 24 hours after the final dose for tissue collection. Additional groups of birds at the highest dose were kept for 7 and 14 days after the final dose to observe declines in residue levels.

Mean haloxyfop residues in the muscle + skin from the three dose rates (equivalent to 0.25, 0.75 and 2.5 ppm of dry weight diet) were: < 0.01, 0.014 and 0.063 mg/kg, respectively. Similarly for

liver: 0.033, 0.12 and 0.36 mg/kg, respectively; fat: 0.013, 0.045 and 0.26 mg/kg, respectively; and eggs (day 4 to day 28, 11 sampling days): < 0.01, 0.014 and 0.036 mg/kg, respectively.

Residues depleted quickly in muscle and liver for birds placed on a haloxyfop residue-free diet, but were quite persistent in fat. Mean haloxyfop residues in the fat (dose rate equivalent to 2.5 ppm of the dry weight diet) were 0.26 mg/kg (day 28, final dose), 0.17 mg/kg (day 35, 7 days later) and 0.16 mg/kg (day 42, 14 days after the final dose).

Haloxyfop residue levels in fat were approximately 4–5 times as high as in the muscle for the 2.5 ppm dosing group on day 28 and an average 14 times on day 35 for cases where residues in muscle exceeded the LOQ (0.01 mg/kg).

Livestock dietary burden

The Meeting estimated the dietary burden of haloxyfop 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.

Some processed and forage commodities do not appear in the Recommendations Table (because no maximum residue level is needed) but they are used in estimating livestock dietary burdens. Those commodities are listed here. Also, the terminology for commodities in the OECD feed tables is not always identical to descriptions in the original studies or Codex descriptions and some clarification is needed.

Commodity	STMR or STMR-P, mg/kg	High residue, mg/kg
Alfalfa forage = Alfalfa forage (Australia)	1.1	3.1
Fodder beet = Beet, mangel, fodder	see Recommendations Table	
Oilseed rape forage = Rape forage (Europe)	3.9	6.8
Oilseed rape forage = Rape forage (Australia)	1.3 dry wt	5.0 dry wt
Peanut fodder = Peanut hay	see Recommendations Table	
Rape seed meal = Canola meal	0.10	
Soya bean forage (green) = Soya bean forage (Europe)	0.075	0.18
Soya bean meal	0.069	
Sugar beet green syrup = Beet sugar, molasses	0.063	
Sugar beet leaves or tops = Beet, sugar tops (Europe)	0.11	0.38
Sugar beet pressed pulp = Beet, sugar, dried pulp	0.008	

Estimated maximum and mean dietary burdens of livestock

Tier 1

In a Tier 1 assessment, livestock from US-Canada, EU and Australia are assumed to be exposed to residues on all feed commodities irrespective of where they are produced.

Tier 1 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 Appendix IX of the 2009 FAO Manual.

	Livestock dietary burden, haloxyfop, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean

	Livestock dietary burden, haloxyfop, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	9.91	4.55	8.87	3.59	22.7[a]	13.0[b]
Dairy cattle	8.16	3.94	6.53	2.70	14.4[c]	7.09[d]
Poultry-broiler	0.11	0.11	0.11	0.11	0.29	0.29
Poultry-layer	0.11	0.11	2.40[e]	1.41[f]	0.29	0.29

[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.

Tier 2

A Tier 2 refinement was considered because the estimated IEDI exceeded the ADI for some diets (see below).

In a Tier 2 assessment, livestock from US-Canada, EU and Australia are assumed to be exposed to residues on all feed commodities that are traded internationally. Fresh forages are not traded internationally, so the dietary burden from fresh forage arises only where the relevant GAP produces residues on that fresh forage.

For example, a registered haloxyfop use in Australia produces residues on fresh alfalfa forage. In a Tier 2 assessment, the residues on fresh alfalfa forage would add to the dietary burden of Australian livestock, but not to livestock in US-Canada and EU.

Tier 2 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 Appendix IX of the 2009 FAO Manual.

	Livestock dietary burden, haloxyfop, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	0.98	0.71	3.12	1.51	8.86[a]	3.14[b]
Dairy cattle	0.80	0.59	3.03	1.47	7.31[c]	2.41[d]
Poultry—broiler	0.11	0.11	0.11	0.11	0.29	0.29
Poultry—layer	0.11	0.11	2.40[e]	1.41[f]	0.29	0.29

[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 commodities, maximum residue level estimation

Cattle

Tier 1

Residue levels in milk appeared to be critical for chronic dietary exposure.

The STMR for milk was calculated from the STMR dairy cow dietary burden (7.09 ppm) by interpolating between the 0 and the 10 ppm feeding levels of the Friesian dairy cow study.

The Meeting estimated an STMR value of 0.22 mg/kg for milks.

With milk STMR of 0.22 mg/kg, the IEDI for haloxyfop in the 13 diets was 60–190% of the ADI. In an IEDI calculation for milk only, the intake was estimated as 15–63 μg/person for the 13 diets, which exceeded the ADI (equivalent to 42 μg/person) in some diets.

The Meeting examined how the assessment may be refined in a Tier 2 assessment.

Tier 2

Fresh forages are not traded internationally, so the livestock dietary burdens were recalculated assuming that fresh forages (with locally generated residues) are consumed only by livestock where the relevant GAP produces residues on that fresh forage.

For MRL estimation, the high residues in the tissues were calculated by interpolating the maximum beef cattle dietary burden (8.86 ppm) between the relevant feeding levels (5 and 10 ppm) from the beef calf 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 beef cattle dietary burden (3.14 ppm) between the relevant feeding levels (1 and 5 ppm) from the haloxyfop beef calf feeding study and using the mean tissue concentrations from those feeding groups. For muscle, residues were below LOQ at the 1 ppm feeding level, so the STMR for muscle was calculated by taking the dietary burden (3.14 ppm) as a proportion of the 5 ppm feeding level.

For milk, the high residues were calculated from the maximum dairy cow dietary burden (7.31 ppm) as a proportion of the 10 ppm feeding level and using the mean milk residues from the Friesian dairy cow feeding study. The STMR for milk was calculated from the STMR dairy cow dietary burden (2.41 ppm) by interpolating between the 0.75 and 2.5 ppm feeding levels of the Holstein dairy cow study.

The Holstein dairy cow study provided some information on the relative concentrations of haloxyfop residues in milk and cream. The ratio between residue concentrations in milk and in cream was quite variable.

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 (8.86 ppm) [5, 10 ppm]		0.041 mg/kg [0.01, 0.05]	0.53 mg/kg [0.14, 0.65]	1.42 mg/kg [0.46, 1.7]	0.33 mg/kg [0.068, 0.41]
MRL dairy cattle (7.31 ppm) [0, 10 ppm]	0.23 mg/kg [0, 0.317]				

Dietary burden (ppm)					
Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
	mean	mean	mean	mean	mean
STMR beef cattle (3.14 ppm) [0, 1, 5 ppm]		0.006 mg/kg [0, < 0.01, 0.01]	0.093 mg/kg [0, 0.05, 0.13]	0.27 mg/kg [0, 0.14, 0.39]	0.035 mg/kg [0, 0.01, 0.057]
STMR dairy cattle (2.41 ppm) [0.75, 2.5 ppm]	0.033 mg/kg [0.01, 0.034]				

The data from the cattle feeding studies were used to support the estimation of maximum residue levels for haloxyfop in mammalian meat, edible offal and milk based on the residues in liver and kidney.

The Meeting estimated an STMR value of 0.27 mg/kg and a maximum residue level of 2 mg/kg for mammalian edible offal, based on liver and kidney data. The HR was 1.42 mg/kg.

The Meeting estimated an STMR value of 0.033 mg/kg and a maximum residue level of 0.3 mg/kg for milks.

The average for 'milk residues ÷ cream residues' for the 2.5 ppm dosing group (day 10 data) was 0.076. The STMR and high residue for milk fat may be calculated from the values for milk (HR = 0.23 mg/kg, STMR = 0.033 mg/kg), the 'milk residues ÷ cream residues' factor and taking cream as 50% milk fat.

The Meeting estimated an STMR value of 0.87 mg/kg and a high residue level of 6.1 mg/kg for milk fat. The Meeting estimated a maximum residue level of 7 mg/kg for milk fat.

The Meeting estimated STMR values of 0.006 mg/kg for mammalian muscle and 0.035 mg/kg for mammalian fat, and a maximum residue level of 0.5 (fat) for mammalian meat. The HRs were 0.041 and 0.33 mg/kg for muscle and fat respectively.

Previous recommendations for cattle meat (0.05 mg/kg), cattle liver (0.5 mg/kg), cattle kidney (1 mg/kg) and cattle milk (0.3 mg/kg) are withdrawn.

Poultry

For MRL estimation, the high residues in the tissues and eggs were calculated by interpolating the maximum dietary burden (2.4 ppm) between the relevant feeding levels (0.75 and 2.5 ppm) from the haloxyfop laying hen feeding study and using the highest tissue concentrations of the group.

The STMR values for the poultry tissues and eggs were calculated by interpolating the STMR dietary burden (1.41 ppm) between the relevant feeding levels (0.75 and 2.5 ppm) from the haloxyfop laying hen feeding study and using the mean tissue and egg 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]	Eggs	Muscle + skin	Liver	Fat
MRL	highest	highest	highest	highest
MRL broilers and layers (2.4 ppm) [0.75, 2.5 ppm]	0.050 mg/kg [0.02, 0.052 mg/kg]	0.105 mg/kg [0.02, 0.11 mg/kg]	0.61 mg/kg [0.19, 0.64 mg/kg]	0.52 mg/kg [0.11, 0.54 mg/kg]
STMR	mean	mean	mean	mean

Dietary burden (ppm)				
Feeding level [ppm]	Eggs	Muscle + skin	Liver	Fat
STMR broilers and layers (1.41 ppm) [0.75, 2.5 ppm]	0.022 mg/kg [0.014, 0.036 mg/kg]	0.032 mg/kg [0.014, 0.063]	0.21 mg/kg [0.12, 0.36 mg/kg]	0.13 mg/kg [0.045, 0.26 mg/kg]

The data from the laying hen feeding studies were used to support the estimation of maximum residue levels for haloxyfop in poultry tissues and eggs.

The Meeting estimated a maximum residue level for poultry meat (fat) of 0.7 mg/kg. The STMR values were: 0.13 mg/kg (fat) and 0.032 mg/kg (muscle). The recommendation for chicken meat (0.01(*) mg/kg) is withdrawn. The HR values were: 0.52 mg/kg (fat) and 0.11 mg/kg (muscle).

The Meeting estimated an STMR value of 0.21 mg/kg and a maximum residue level of 0.7 mg/kg for edible offal of poultry. The recommendation for edible offal of chicken (0.05 mg/kg) is withdrawn. The HR for poultry edible offal was 0.61 mg/kg.

The Meeting estimated an STMR value of 0.022 mg/kg and a maximum residue level of 0.1 mg/kg for eggs. The recommendation for chicken eggs (0.01(*) mg/kg) is withdrawn. The HR for eggs was 0.05 mg/kg.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes of haloxyfop, based on the STMRs estimated for 22 commodities, for the GEMS/Food Consumption Cluster Diets were in the range of 20 to 80% of the maximum ADI (0.0007 mg/kg bw/day)(Annex 3). The Meeting concluded that the long-term intake of residues of haloxyfop resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for haloxyfop was calculated for food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4.

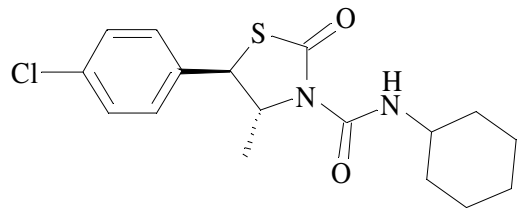
The IESTI represented 0–10% of the ARfD for the general population and 0–10% of the ARfD for children. The Meeting concluded that the short-term intake of residues of haloxyfop, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.

5.14 HEXYTHIAZOX (176)

RESIDUE AND ANALYTICAL ASPECTS

Hexythiazox is a non-systemic insecticide and miticide first evaluated by the 1991 JMPR and a number of times subsequently. It was recently reviewed for toxicology by the 2008 JMPR within the periodic review program of the CCPR. An ADI of 0–0.03 mg/kg bw was established. An ARfD was not considered necessary by the Meeting. In the 2009 JMPR hexythiazox is scheduled for periodic review for the residue section.

The Fortieth Session of the CCPR scheduled this compound for periodic evaluation by the 2009 JMPR (ALINORM 08/40/24, Appendix X). Information on GAPs was also provided by the Netherlands.



The following abbreviations are used for the metabolites discussed below:

hexythiazox	trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxo-3-thiazolidine-carboxamide
PT-1-2	tran-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-3-carboxamide
PT-1-3	trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine
PT-1-4	trans-5-(4-chlorophenyl)-N-(cis/trans-3-hydroxycyclohexyl)-4-methyl-2-oxothiazolidine-3-carboxamide
PT-1-8	rans-5-(4-chlorophenyl)-N-(cis/trans-4-hydroxycyclohexyl)-4-methyl-2-oxothiazolidine-3-carboxamide
PT-1-10	trans-5-(4-chlorophenyl)-N-(3,4-dihydroxycyclohexyl)-4-methyl-2-oxothiazolidine-3-carboxamide

Animal metabolism

The Meeting received animal metabolism studies with ^{14}C-hexythiazox in rats, lactating goats and laying hens. Parent substance labelled in the 5-position of the thiazolidine ring was used in all of these studies. In general the metabolism of hexythiazox in animals is relatively limited. In all species the hydroxylation of the cyclohexane ring was the dominating biotransformation, resulting in the metabolites PT-1-4, PT-1-8 and PT-1-10. The cleavage of the amide bond was observed in rats only.

In the 2008 Evaluation for toxicology it was reported that in rats most of the administered radioactivity (60–90%) was excreted via the faeces. Depending on the dose level 10–20% (at 10 mg/kg bw dose) up to 65–70% (880 mg/kg bw dose) of the radioactivity was identified as unchanged parent substance. The highest concentrations of tissue residues were found in fat, adrenals, liver and ovaries; the main component in fat was hexythiazox. Metabolism of the absorbed dose 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. The main identified metabolite was PT-1-8 (cis) representing approximately 10% of the administered radioactivity.

For lactating goats one animal was dosed with 46 mg per day (approx. 26 ppm or 1.16 mg/kg bw) for seven consecutive days. Most of the excretion of radioactivity was observed via faeces (56.2%) and urine (18.1%). In milk 0.3% of the administered dose (corresponding to approximately 0.1 mg/kg) was found. For the tissues liver was found with the highest TRR levels of 2.2 mg/kg. Kidney and fat contained 0.44 and 0.55 mg/kg, respectively. In muscle the lowest TRR levels of 0.11 mg/kg at maximum were measured. Identification of the radioactivity revealed unchanged parent hexythiazox as dominant residue in fat tissue and milk (61% TRR and 31% TRR, respectively). In liver, muscle and kidney hexythiazox was found at levels of 10% of the TRR or less. Most of the TRR was identified as PT-1-4 (cis) or PT-1-10 at levels up to 23% TRR and 36% TRR, respectively.

The metabolism of hexythiazox in laying hens was investigated using doses of 0.6 or 6 mg per animal per day for 6 consecutive days. In this case the highest residues were found in the eggs of the animals at levels of 0.5 mg/kg for the low dose group and 2.1 mg/kg for the high dosed animals. The highest residues in all tissues were detected in the liver, ranging from 0.14 mg/kg (low dose) up to 1.6 mg/kg (high dose). Kidney and fat tissues were in the same range of 0.06–0.07 mg/kg for the low dose group and 0.5 mg/kg for the high dose group. In muscle very low residues of 0.01 to 0.08 mg/kg were found. Identification of the radioactivity was conducted for eggs, liver and fat only. Eggs and liver gave very high unextracted residues in the range of 50% of the TRR. In the extracts the results were comparable to rats and lactating goats. In fat tissue most of the residue consisted of unchanged hexythiazox (48% of the TRR while in eggs and liver mainly hydroxylated metabolites (PT-1-8 and PT-1-10) were identified.

Plant metabolism

The Meeting received plant metabolism studies with [^{14}C]hexythiazox in apples, citrus, grapes, pears and tea. Parent substance labelled in the 5-position of the thiazolidine ring was used in all of these studies.

In general the biotransformation of hexythiazox is relatively slow. In most of the studies unchanged hexythiazox was the dominating residue found mainly on the surface. Following a period of three week a minor translocation into the plants of PT-1-2 and PT-1-3, the remaining cleavage products after removal of the cyclohexane ring, can be observed whereas parent hexythiazox remained nearly immobile.

In the study on apples, leaves and fruits were treated by micro pipette at a rate equivalent to a concentration of 5 g ai/hL. Leaf samples were taken 0, 10, 21, 30, 60 and 91 days after the application and single fruit samples 10, 20, 30 and 59 days after the application. In the surface wash as well as in the extracts of the samples unchanged parent compound was the dominant residue accounting for 73.7–94.9% of the TRR. The leaf extracts contained additional metabolites at rates of 0.4–0.7% of TRR for PT-1-2, 0.5–2.5% TRR for cis-PT-1-8 (including conjugates) and 1.8–6.8% TRR for trans-PT-1-8 (including conjugates). In apple fruits traces of PT-1-2 and PT-1-8 (trans) were found in levels of less than 1.2% of the TRR.

For citrus fruits a similar methodology as for apples was used. The application rate was at a comparable concentration of 5.3 g ai/hL. Samples of treated and untreated citrus leaves and fruits were taken 7, 14, 30, 60 or 62 and 90 or 91 days after the application. In the surface wash and the peel extract the concentration of hexythiazox decreased from 98.1% down to 30.5% of the applied dose after 91 days. The only metabolite identified in the surface wash was PT-1-2 (up to 1.0% TRR), which was also found in the peel extract at higher amounts (up to 3.3% TRR). In the peel extract free and conjugated PT-1-4 (trans-2), PT-1-6 (trans-2), PT-1-8 (cis) and PT-1-8 (trans) were found. The conjugated form was always present in at least 2-fold higher amounts. In total PT-1-4 (trans-2), PT-1-6 (trans-2), PT-1-8 (cis) and PT-1-8 (trans) including conjugates were found in concentrations of up to 7.0%, 4.3% and 13.7% of the TRR, respectively.

Grapes were treated twice with an amount of 0.1 kg ai/ha of labelled hexythiazox each. Sampling of the leaves and fruits was conducted 21 days after the final application, but only the fruits were analysed for radioactive residues. In the fruits TRR of 0.233 mg/kg could be found. 62.9% of the TRR was located in the surface of the fruits and was released with the surface wash. Nearly all of the radioactivity coeluated with the parent reference compound. The fruit extract contained about 31.4% of the TRR in total. Hexythiazox was detected in all phases (5.0–6.3% TRR), but unidentified peaks were present in higher concentrations (up to 12.1% of the TRR). In the remainings, hydrolysed using NaOH 11.2%, the TRR were identified as PT-1-3. In this study no confirmation of the identity of metabolites via mass spectrometric methods was conducted.

In pears the leaves and fruits of the trees were also treated by micro pipette at a rate equivalent to a concentration of 5 g ai/hL. Leaf samples were taken 0, 5, 10, 20, 30, 60 and 90 days after the application and fruit samples 0, 5, 10, 20, 30 and 60 days after the application. In the surface wash as well as in the peel extract of the fruits hexythiazox was identified as the dominant residue amounting 64.6–95.0% of the TRR. The metabolites PT-1-2, PT-1-4 (trans-2) and the cis and trans isomers of PT-1-8 were identified in the fruits, but none at levels of more than 2.3% of the TRR.

In the leaves a comparable distribution of the radioactive residues was observed. Unchanged hexythiazox was dominant in the surface extract (93.1–44.6% of the TRR). In leaf tissue higher amounts of metabolites were found in comparison to the fruits. The metabolite PT-1-2 was found at low levels of 1.2% of the TRR. Most of the radioactivity found was identified as PT-1-8 (cis) and PT-1-8 (trans) in their conjugated forms at amounts of up to 4.3% and 9.2% of the TRR, respectively.

For tea the plants were treated once at a rate of 0.2 kg ai/ha. Leaf specimens were collected at 0, 7, 14 and 21 days after the treatment. The TRR in the tea leaves did not change with increasing PHI. In all of the samples TRR levels of 8.17 to 9.03 mg/kg, calculated as parent equivalents, were found. In comparison to the 0 day PHI results, more of the radioactivity was found in the extracts rather than the surface wash in the later samples (93.2% surface wash at PHI 0 down to 55.3% at PHI 21). The identification of the radioactivity revealed very limited degradation of the parent substance. In all samples hexythiazox was the dominant residue found at levels of at least 84.5% of the TRR. The only metabolites identified were PT-1-2 and PT-1-8 (trans), each at levels of less than 0.3% of the TRR.

Environmental fate in soil

Hexythiazox is degraded in soil quite rapidly with half-life rates of about one month. The main metabolites found in soil consisted of cleavage products of the parent molecule (PT-1-3 and PT-1-2). Under consideration of a rotational crop study using unlabelled material a significant uptake by follow crops is not expected.

For the environmental fate of hexythiazox in soil one study on the aerobic metabolism is available. Estimated aerobic soil metabolism half-lives for hexythiazox at 20 °C ranged from 32.1 to 35.2 days. After 153 days mineralisation and unextracted residues were in the range of 10–12.2% and 19.7–23% of the radioactivity, respectively.

The metabolite PT-1-9 was formed in the early stage of the study, reaching its maximum concentration of 10.1–14.4% of the applied radioactivity after 31 days. PT-1-2 and PT-1-3 were found in the later samples reaching a plateau after 90 days at individual amounts of 34.2–39.5% and 7.5–9.2% of the applied dose.

In addition to soil metabolism a field rotational crop study was submitted to the Meeting. Bare soil was treated at rates of 0.21 kg ai/ha and incorporated into the soil before planting. After 30, 120 and 240 days lettuce, mustard, radish, sorghum and wheat were planted as follow crops. Except for one sample each of radish tops (0.046 mg/kg) and sorghum stover (0.014 mg/kg) no hexythiazox residues above the LOQ of 0.01 mg/kg were found (sum of hexythiazox and all metabolites hydrolysable to PT-1-3, expressed as hexythiazox).

No confined study on rotational crops was submitted to the Meeting. Given that cleavage of the molecule is the only significant transformation step observed in soil metabolism studies and the results of the analysis of all residues hydrolysable to PT-1-3 in the unlabelled study, the Meeting considered the residue situation in rotational crops to have been investigated sufficiently.

Methods of residue analysis

The Meeting received information on analytical methods for the determination of hexythiazox in plant and animal matrices.

In the methods hexythiazox is extracted with methanol and the partitioned into n-hexane. After partition between n-hexane and acetonitrile, the acetonitrile layer is concentrated to dryness. The residue is cleaned-up by Florisil PR Column chromatography and a C18 solid phase extraction column. Hexythiazox is determined by HPLC-UV at 225 nm. The LOQ was 0.05 mg/kg for all plant matrices. Analytical recovery data were satisfactory for hexythiazox in plant commodities. Residue methods were tested by independent laboratories unfamiliar with the analysis and were found to have satisfactory recoveries and no background interferences.

In supervised field trials an additional method was described measuring the total residue of hexythiazox including metabolites after hydrolysis with 0.1N NaOH into PT-1-3. The separation and detection of PT-1-3 is achieved via HPLC-UV. This method is applicable to plant and animal matrices, but no studies including validation data for animal material were submitted. In the corresponding field trials LOQs of 0.02 mg/kg were achieved.

For animal matrices the samples are extracted with methanol (muscle, kidney, liver and eggs) or acetone (milk and fat). The extract was then liquid/liquid partitioned, evaporated to dryness and hydrolysed with sodium hydroxide solution. After further cleaned up on a silica gel column PT-1-3 was determined by reversed phase HPLC and UV detection at 225 nm. The LOQ achieved in the validations was 0.05 mg/kg for all matrices.

Although no data on analytical multi-residue method for plant commodities were submitted to Meeting it is noted that hexythiazox parent substance is validated within the QuEChERS-Multimethod.

Stability of residues in stored analytical samples

Information was received on the freezer storage stability of hexythiazox residues in plant commodities.

The storage stability of hexythiazox was investigated in one study including homogenated samples with a fortification level of 0.5 or 1.0 mg/kg (strawberry, cucumber, water melon, grape, green pepper, mandarin orange pulp and whole fruits, pears and apples) as well as treated field samples, which were chopped instead of macerated (cucumber, strawberry, tea, Chinese citron peel and pulp and mandarin orange peel and pulp). All samples were stored at –30 °C for a period of one month up to 13 months, analysed for hexythiazox and compared to the nominal level of fortification. Expect for homogenised grapes (63% recovery) all samples were stable and gave recoveries of at least 70% of the initial dose.

For the storage stability of hexythiazox in animal commodities no data on the storage stability was submitted to the Meeting. Under consideration of a residue definition for hexythiazox involving all metabolites containing the PT-1-3-moiety, it was concluded by the Meeting that theoretical breakdown products of hexythiazox are also measured by the analytical method. In view of this estimation of the “total residue” further data on the storage stability of hexythiazox residues is not considered necessary.

Definition of the residue

The residue following use of hexythiazox on crops is predominantly unchanged hexythiazox. After 30 days at least 70% of the radioactivity was identified as parent substance mainly located on the plant surface. At higher PHI of 60 to 90 days 30% to 60% of the radioactivity was still present as hexythiazox. Metabolites identified were mainly hydroxylated at the cyclohexane ring (PT-1-4, PT-1-8 and PT-1-10), followed by cleavage and removal of the cyclohexane-ring forming PT-1-2 in amounts of less than 4% of the TRR after up to 90 days. The combined quantities of PT-1-4, PT-1-8 and PT-1-10 were at levels of less than 10% of the hexythiazox levels in all samples analysed. In summary at all sampling dates most of the residue was identified as unchanged hexythiazox parent located on the surface.

The hydroxyl-metabolites (PT-1-4 and PT-1-8) are not mutagenic in bacteria and are of low acute toxicity (oral LD_{50} > 5000 mg/kg bw). These metabolites, together with PT-1-10 are formed in rats. Although there are no repeat dose toxicity studies on these compounds, it is considered realistic to assume them to have similar toxicity to hexythiazox.

In soil, degradation of hexythiazox is dominated by a cleavage resulting mainly in PT-1-2. The uptake from the soil observed in field rotation studies is very limited, showing most residues below 0.01 mg/kg (measured as PT-1-3 after hydrolytic extraction). Only in radish tops (0.046 mg/kg) and sorghum stover (0.012 mg/kg) total hexythiazox residues, determined as PT-1-3 for analysis, were found above the LOQ of 0.01 mg/kg after 30 days.

Metabolite PT-1-3 is of greater acute toxicity than hexythiazox, while it is not mutagenic in bacteria there are no data on its toxicity after repeat dosing.

Following normal solvent extraction no PT-1-3 was identified in metabolism studies.

The Meeting was aware that according to the hydrolysis study, using aqueous buffer solutions parent hexythiazox in sterilised food commodities might be subject to a transformation into PT-1-3 to a certain extent. Quantitative data representing realistic processing conditions are not available, since all information is based on residues converted to PT-1-3 for analysis. In general the Meeting expects the contribution to dietary intake to be small in comparison to the overall intake.

The Meeting concluded parent hexythiazox is a representative marker for hexythiazox residues in all plant commodities and decided to set the residue definition for enforcement purposes in plant commodities to be parent hexythiazox only.

For dietary intake assessment the toxicological significant metabolites PT-1-4, PT-1-8 and PT-1-10, also identified in the rat, amounted in sum less than 10% of the TRR according to the results of metabolism studies using radiolabelled material. No data on the ratio between hexythiazox and all residues converted to PT-1-3 under field conditions were submitted. The plant specific metabolite PT-1-3 was not identified in any sample in plant metabolism studies and the Meeting considered it to be an analytical artefact. Although the low share of PT-1-4, PT-1-8 and PT-1-10 would not suggest an inclusion into the residue definition for risk assessment purposes of plant commodities normally, the Meeting acknowledged that no data besides metabolism studies are available to confirm this assumption. Taking into account a possible deviations in the rate of metabolisation under field conditions, the Meeting agreed to define the residue definition for intake purposes as “sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox” to cover all of the residue of toxicological concern.

In animals hexythiazox is also hydroxylated at various positions of the cyclohexane ring. A cleavage into PT-1-3 was not observed. In fatty tissues, milk and eggs hexythiazox was the dominant residue. Watery matrices like liver, kidney and muscle mainly contained a mixture of hydroxylated metabolites. Residues found in fatty tissues of goats and laying hens were by a factor of 5 to 8 times higher in comparison to muscle. For milk (skim milk ↔ cream) and eggs (egg white ↔ egg yolk)

higher residues of total PT-1-3 were found in the fat, based on the livestock feeding studies submitted. Due to overall low residues a ratio could not be estimated.

For animal matrices the metabolism results in a higher percentage of hydrolysed metabolites with hexythiazox being found at very low levels or even below the LOQ. In addition, no analytical methods for the parent substance alone are available, as well as livestock feeding studies analysed for single substances instead of the total residues determined as PT-1-3. In view of these factors the Meeting concluded that the residue definition (for risk assessment and enforcement) for hexythiazox in animal matrices is sum of hexythiazox including all metabolites hydrolysable to PT-1-3, expressed as hexythiazox. The residue is considered as fat soluble.

Definition of the residue (for compliance with MRLs) for plant commodities: *hexythiazox*

Definition of the residue (for estimation of dietary intake) for plant commodities: *sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox*

Definition of the residue (for compliance with MRLs and for estimation of dietary intake) for animal commodities: *sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox*

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trials data for hexythiazox on citrus (grapefruit, lemons, mandarins and oranges), almonds, pecan, apples, pears, stone fruit (cherries, nectarines, peaches and plums), blackberries, grapes, raspberries, strawberries, dates, tomatoes, cucumbers, melons, sweet corn, fresh beans, succulent beans, dry beans, cotton, hops and corn.

In trials where duplicate field samples from replicated or unreplicated plots were taken at each sampling time and analysed separately, the sample with higher residues was taken as the best estimate of the residue from the plot. Supervised field trials conducted with different formulations at identical varieties, locations and dates were not considered as independent. The highest result according to the corresponding GAP was selected in these cases.

Labels (or translation of labels) were available from the Netherlands and USA describing the registered uses of hexythiazox.

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Citrus fruits

Hexythiazox is registered in the USA for use on citrus fruits at a rate of 1 × 0.2 kg ai/ha with a PHI of 28 days. Supervised residue trials conducted in the US on grapefruits, lemons and oranges according to this GAP were submitted.

For whole grapefruits residues were (n=6): < 0.05, < 0.05, 0.05, 0.06, 0.16 and 0.18 mg/kg. The distribution between pulp and whole fruits was not measured.

In whole lemons fruits residues were (n=5): 0.06, 0.1, 0.15, 0.2 and 0.29 mg/kg. The distribution between pulp and whole fruits was not measured.

For whole oranges residues were (n=6): < 0.05, 0.06, 0.11, 0.11, 0.12 and 0.2 mg/kg. The distribution between pulp and whole fruits was not measured.

For mandarins and oranges additional field trials conducted in Southern Europe were submitted, but no corresponding GAP is available. Since these trials contained analytical results for whole fruits and pulp, the data from day 14 is used to estimate the residue ratio between both matrices. Individual ratios were (n=5) < 0.56, < 0.63, < 0.71, < 0.83 and < 0.83. Additional trials are available, but no residues above the LOQ were found in whole fruits as well as in citrus pulp. The Meeting estimated a factor of 0.7 for the ratio of residues between whole citrus fruits and citrus pulp.

The Kruskal-Wallis-Test for grapefruits, lemons and oranges (residues below the LOQ were treated as residues at the LOQ) indicated that the residue populations were not significantly different and may be combined.

The Meeting decided to combine the US data for grapefruits, lemons and oranges for the whole group of citrus fruits, resulting in residues of < 0.05(3), 0.05, 0.06(3), 0.1, 0.11, 0.11, 0.12, 0.15, 0.16, 0.18, 0.2, 0.2 and 0.29 mg/kg for the whole fruits (n=17). Under consideration of the ratio of 0.7 between the residues in whole fruits and citrus pulp an STMR value of 0.077 mg/kg was estimated by the Meeting.

The Meeting confirmed the previous recommendation on a maximum residue level for hexythiazox in citrus fruits of 0.5 mg/kg (whole fruit) and estimated an STMR value for hexythiazox in citrus fruit of 0.077 mg/kg (pulp).

The value derived from use of the NAFTA calculator of 0.45 mg/kg (95/99 95th percentile) was in good agreement with the estimate of 0.5 mg/kg made by the Meeting (after rounding up to one significant figure).

Pome fruit

For pome fruit hexythiazox is registered in the USA at rates of 1 × 0.2 kg ai/ha with a PHI of 28 days. Supervised residue trials conducted in the US on apples and pears according to this GAP were submitted.

For apples residues were (n=15): 0.05, 0.05, 0.08, 0.08, 0.09(3), 0.11, 0.11, 0.12, 0.15, 0.16, 0.2, 0.21 and 0.21 mg/kg.

In pears residues were (n=6): 0.06, 0.06, 0.1, 0.11 and 0.16 mg/kg.

Based on the results for apples the Meeting estimated a maximum residue level and an STMR value for hexythiazox in pome fruits of 0.4 and 0.11 mg/kg, respectively.

The value derived from use of the NAFTA calculator of 0.35 mg/kg was in good agreement with the estimate of 0.4 mg/kg made by the Meeting (after rounding up to one figure (NAFTA 95/99 95th percentile)).

The Meeting withdraws its previous recommendations of maximum residue levels of 0.5 mg/kg for hexythiazox in apples and pears.

Stone fruit

Hexythiazox is registered on stone fruit in the USA with an application rate of 1 × 0.2 kg ai/ha with a PHI of 28 days. Supervised residue trials conducted in the US on cherries, nectarines and peaches according to this GAP were submitted.

For cherries residues were (n=4): 0.04, 0.06, 0.08 and 0.12 mg/kg.

For nectarines residues were (n=3): 0.05, 0.05 and 0.09 mg/kg.

For peaches residues were (n=3): 0.09, 0.09 and 0.18 mg/kg.

Additional trials on plums and other stone fruit were submitted, but the PHI of 7 days was below the registered GAP in the US.

The Meeting decided to combine the data for nectarines and peaches treated according to US GAP , resulting in residues of 0.05, 0.05, 0.09(3) and 0.18 mg/kg (n=6).

Considering the supportive data for cherries the Meeting estimated a maximum residue level and an STMR value for hexythiazox in stone fruits of 0.3 and 0.09 mg/kg, respectively.

The value derived from use of the NAFTA calculator was 0.3 mg/kg, which agreed with the maximum residue level of 0.3 mg/kg estimated by the current Meeting.

The Meeting withdraws its previous recommendations of maximum residue levels for hexythiazox of 1 mg/kg in cherries, 1 mg/kg in peaches and 0.2 mg/kg in plums (including prunes).

Currants (red, white)

Hexythiazox is registered in the USA on currants at a rate of 0.21 kg ai/ha with a PHI of 3 days. Supervised residue trials submitted on blackberries and raspberries were conducted with an application rate of 0.42 kg ai/ha with a PHI of 21 days.

The Meeting noted that the data from USA does not match GAP and can not be used for a maximum residue level estimation. The Meeting withdraws its previous recommendations for currants (red, white) of 0.2 mg/kg.

Grapes

For grapes hexythiazox is registered in the USA at a rate of 1 × 0.2 kg ai/ha with a PHI of 28 days. Corresponding supervised residues trials were conducted according to the maximum GAP with two formulations in the US.

For grapes residues were (n=12): 0.04, 0.04, 0.05, 0.13, 0.13, 0.19, 0.21, 0.22, 0.24, 0.31, 0.31 and 0.48 mg/kg.

Additional supervised field trials were submitted for Europe, but no corresponding GAPs are available.

The Meeting confirms its previous recommendation of a maximum residue level of 1 mg/kg and estimated an STMR value for hexythiazox in grapes of 0.2 mg/kg.

An estimate of 1 mg/kg, derived from the use of the NAFTA calculator, was in agreement with the maximum residue level estimated by the current Meeting.

Strawberries

Hexythiazox is registered in the USA on strawberries at a rate of 0.21 kg ai/ha with a PHI of 3 days. Corresponding supervised residues trials were conducted according to the maximum GAP with two formulations in the US. Residues found in strawberries were (n=3): 0.13, 0.17 and 0.3 mg/kg.

The Meeting noted that the data from USA for strawberries, representing a major crop, were not sufficient for a maximum residue level estimation. The Meeting withdraws its previous recommendation for strawberries of 0.5 mg/kg.

Dates

In dates hexythiazox is used according to US GAP with an application rate of 0.21 kg ai/ha and a PHI of 90 days. Corresponding supervised residues trials were conducted according to the maximum GAP in the US. Residues found in dates were (n=3): 0.11, 0.26 and 0.63 mg/kg.

The Meeting estimated a maximum residue level and an STMR value for hexythiazox in dates of 2 and 0.26 mg/kg, respectively.

An estimate of 2 mg/kg, derived from the use of the NAFTA calculator, was in agreement with the maximum residue level estimated by the current Meeting.

Tomatoes

For protected tomatoes hexythiazox is registered in the Netherlands with an application rate of 1 × 0.08 kg ai/ha (0.005 kg ai/hL) with a PHI of 3 days. Supervised residue trials on protected tomatoes corresponding to the maximum GAP are available from France and Italy. Residues found in the fruits were (n=8): < 0.05(6), 0.05 and 0.05 mg/kg.

The Meeting confirmed the maximum residue level for hexythiazox in tomatoes of 0.1 mg/kg and estimated an STMR value of 0.05 mg/kg.

Statistical calculations were not conducted, as the majority of reported residue levels were below the LOQ.

Egg plant

Hexythiazox is registered in the Netherlands for protected eggplants with an application rate of 1 × 0.08 kg ai/ha (0.005 kg ai/hL) with a PHI of 3 days. No supervised residue trials on eggplants were submitted to the Meeting.

The Meeting decided that tomatoes can be extrapolated to eggplants. Based on the residue data for tomatoes the Meeting estimated a maximum residue level and an STMR value for hexythiazox in eggplants of 0.1 and 0.05 mg/kg, respectively.

Sweet corn

For sweet corn supervised residue trials were submitted to the Meeting although no corresponding GAP is available.

The Meeting concluded that maximum residue levels on sweet corn could not be estimated without a corresponding GAP.

Fruiting vegetables, Cucurbits (except watermelon)

For cucumbers hexythiazox is registered in the Netherlands for field and glasshouse use with an application rate of 1 × 0.08 kg ai/ha (0.005 kg ai/hL) with a PHI of 3 days. Supervised residue trials on protected cucumbers corresponding to the maximum GAP are available from Italy, Spain and the Netherlands. Residues found in the fruits were (n=8): < 0.05(8) mg/kg.

Hexythiazox is registered in the Netherlands for protected melons (except water melons) with an application rate of 1 × 0.08 kg ai/ha (0.005 kg ai/hL) with a PHI of 3 days. Supervised residue trials on protected melons corresponding to the maximum GAP are available from France, Spain and the Netherlands.

Residues found in melon whole fruits were (n=8): < 0.05(8) mg/kg.

Residues found in melon pulp were (n=8): < 0.05(8) mg/kg.

Hexythiazox is registered in the Netherlands for protected summer squash with an application rate of 1 × 0.08 kg ai/ha (0.005 kg ai/hL) with a PHI of 3 days. No supervised residue trials on squashes were submitted to the Meeting.

Hexythiazox is registered in the Netherlands for protected winter squash with an application rate of 1 × 0.08 kg ai/ha (0.005 kg ai/hL) with a PHI of 3 days. No supervised residue trials on squashes were submitted to the Meeting.

The Meeting decided that data for cucumbers can be extrapolated to summer squash and data for melons to winter squash. Based on the identical residue data for protected cucumbers and melons the Meeting estimated a maximum residue level and an STMR value for hexythiazox in fruiting vegetables, cucurbits expect water melons of 0.05 and 0.05 mg/kg, respectively.

Statistical calculations were not possible, since all reported residue levels were below the LOQ.

The Meeting withdraws its previous recommendation of maximum residue levels of 0.1 mg/kg for hexythiazox in cucumbers.

Common beans (pods and/or immature seeds)

For common beans (pods and/or immature seeds) supervised residue trials were submitted to the Meeting although no corresponding GAP is available.

The Meeting withdraws its previous recommendation of maximum residue levels of 0.5 mg/kg for hexythiazox in common beans (pods and/or immature seeds).

Pulses

For pulses supervised residue trials were submitted to the Meeting although no corresponding GAP is available.

The Meeting concluded that maximum residue levels on pulses could not be estimated without corresponding GAP.

Maize

Hexythiazox is registered in maize in the USA with an application rate of 1 × 0.2 kg ai/ha with a PHI of 45 days. Supervised residue trials conducted in the US were available using one application at rates of 0.21 or 1.1 kg ai/ha and PHIs of 79 up to 110 days, which did not match the US GAP.

The Meeting noted that the data from USA did not match GAP for maize and could not be used to estimate a maximum residue level.

Tree nuts

In tree nuts hexythiazox is registered in the USA at a rate of 1 × 0.2 kg ai/ha with a PHI of 28 days. Supervised field trials were conducted in the US at rates of 0.25 kg ai/ha up to 0.42 kg ai/ha on almonds and pecan with a PHI of 28 and 29 days. For almonds residues were (n=2): < 0.02 and < 0.02 mg/kg. In pecans residues of < 0.02(5) mg/kg were found.

The Meeting estimated a maximum residue level based on the LOQ of the analytical method for hexythiazox parent of 0.05(*) mg/kg. Under consideration of the non-systemic properties the Meeting estimated an STMR value of 0 mg/kg for hexythiazox in tree nuts.

Statistical calculations were not possible, as all reported residue levels were below the LOQ.

Cotton

For cotton hexythiazox is registered in the USA (California only) at a rate 1 × 0.17 kg ai/ha with a PHI of 35 days. Supervised field trials from the US were submitted involving two applications in an

2–3 months interval with 0.17 to 0.21 kg ai/ha each and a PHI of 28–35 days. Residues found in the ginned seeds were (n=3): 0.07, 0.1 and 0.1 mg/kg.

The Meeting noted that the data from USA for cotton were not sufficient for a maximum residue level estimation.

Hops

Hexythiazox is registered in the USA for hops with an application rate of 1 × 0.21 kg ai/ha without a specified PHI. In one supervised field trials according to GAP residues in hops were (n=1): 1.9 mg/kg

The Meeting noted that the data for hops from USA was insufficient for a maximum residue level estimation and withdraws its previous recommendation of 2 mg/kg for hexythiazox in dry hops.

Almond hulls

In almonds hexythiazox is registered in the USA at a rate of 1 × 0.2 kg ai/ha with a PHI of 28 days. Supervised field trials were conducted in the US at rates of 0.25 kg ai/ha on almonds with a PHI of 28 days. For almond hulls residues were (n=2): 1.2 and 1.4 mg/kg.

The Meeting noted that the data for almond hulls from USA was insufficient for a maximum residue level estimation.

Cotton gin trash

For cotton hexythiazox is registered in the USA at a rate 1 × 0.17 kg ai/ha with a PHI of 35 days. Supervised field trials from the US were submitted involving two applications in an 2–3 months interval with 0.17 to 0.21 kg ai/ha each and a PHI of 28 days. Residues found in gin trash were (n=3): 1.5, 1.6 and 2.3 mg/kg.

The Meeting noted that the data from USA for cotton gin trash was insufficient to give any recommendation.

Maize forage

Hexythiazox is registered for use in maize in the USA with an application rate of 1 × 0.2 kg ai/ha and a PHI of 45 days. Supervised residue trials conducted in the US were available using one application at a rate of 0.21 kg ai/ha with a PHI of 44 to 49 days. Residues found in maize forage were (n=5): 0.13, 0.58, 0.91, 1.1 and 1.7 mg/kg.

The Meeting estimated an STMR value and a highest residue value for hexythiazox in maize forage of 0.91 and 1.7 mg/kg, respectively.

Maize stover

For maize stover, hexythiazox is registered in the USA with an application rate of 1 × 0.2 kg ai/ha with a PHI of 45 days. Supervised residue trials conducted in the US, using one application at rates of 0.21 kg ai/ha with a PHI of 79 up to 110 days, did not match the US GAP.

The Meeting noted that as the data from the USA did not match GAP for maize it could not be used for a recommendation.

Fate of residues during processing

The Meeting received information on the fate of hexythiazox residues during processing of oranges, grapes, plums and cotton seeds. Also information was provided on hydrolysis studies with hexythiazox to assist with identification of the nature of the residue during processing. Processing

factors presented below have been calculated for hexythiazox 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.

Hexythiazox was stable at pH4, 80 °C for 20 minutes and pH5, 100 °C for 60 minutes, simulating pasteurisation and cooking of commodities. Under simulated sterilisation conditions (pH6, 120 °C for 20 minutes) hexythiazox degraded into PT-1-3, leaving only half of the initial concentration in the test solutions.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate [a]
Oranges	Juice	< 0.05, < 0.07, 0.22, 0.26, 0.3	0.22
	Marmalade	0.11, 0.14, 0.27	0.14
	Pulp, dry	1.8, 2.7	2.3
Grapes	Wine, red	< 0.02, < 0.1	< 0.06
	Wine, white	< 0.02, < 0.09	< 0.06
	Juice, red	0.08, 0.75	0.42
	Juice, white	< 0.02, 0.14	0.08
	Raisins	0.52, 1.4, 1.7, 3.3	1.6
	Pomace, wet	3.4, 16.6	10
Plums	Prunes, dried	4.8, 5	4.9

[a] processing factors presented are based on the total residue hydrolysable to PT1-3

Oranges were processed into juice, marmalade and dry pulp. Processing factors were 0.22, 0.14 and 2.3, respectively. Based on the median residue of 0.11 mg/kg for whole citrus fruits, STMR-P values for hexythiazox residues were 0.024 mg/kg in orange juice, 0.015 mg/kg in marmalade and 0.25 mg/kg in dry pulp.

Grapes were processed into red and white wine, red and white juice, raisins and wet pomace. Processing factors were < 0.06 for wine (red and white combined), 0.42 for juice (based on red juice), 1.6 for raisins and 10 for wet grape pomace. Based on the STMR value of 0.2 mg/kg for grapes STMR-P values for hexythiazox were 0.01 mg/kg for wine (red and white), 0.084 mg/kg for grape juice, 0.32 mg/kg for raisins and 2 mg/kg for wet pomace.

Based on the average dry-matter content of grape pomace, wet of 15% the Meeting estimated a maximum residue level of 15 mg/kg for grape pomace, dry.

Plums were processed into prunes, resulting in a processing factor of 4.9. Based on the STMR of 0.09 mg/kg for stone fruit a STMR-P value of 0.44 mg/kg for dried prunes was estimated.

Based on the highest residue of 0.18 mg/kg for stone fruit and the processing factor of 4.9 for dried prunes, the Meeting estimated a maximum residue level of 1 mg/kg and an STMR-P value of 0.44 mg/kg for hexythiazox in dried prunes.

Residues in animal commodities

Livestock dietary burden

The Meeting received lactating dairy cow and laying hens feeding studies which provided information on likely residues resulting in animal commodities, milk and eggs from hexythiazox residues in the animal diet.

Lactating dairy cows

In a study two lactating cows were dosed over a period of 14 consecutive days with hexythiazox at rates of 12 mg or 120 mg per animal and day. Milk was collected over the whole study period. After the dosage period the animals were kept 8 days for withdrawal before being sacrificed. Samples of fat, muscle, kidney and liver were taken for analysis. All samples were analysed for the sum of hexythiazox and its metabolites, determined as PT-1-3. In none of the samples residues above the limit of quantification of 0.05 mg/kg were found.

In a second study twelve lactating Holstein cows were divided into four groups receiving doses of 0, 5, 15 or 50 ppm hexythiazox for a period of 28 consecutive days. One animal of each dose group was kept for an additional withdrawal period of 7 days. During the whole period of time samples of milk were collected. After the withdrawal period the animals were sacrificed and samples of fat, liver, kidney and muscle were taken. All samples were analysed for the sum of hexythiazox and its metabolites, determined as PT-1-3. In the groups receiving doses of 0, 5 or 15 ppm per day, no residues above the LOQ of 0.01 mg/kg were found in any sample expect liver (0.06 mg/kg), kidney (0.01 mg/kg) and renal/omental fat (0.01 mg/kg). For the dose group 50 ppm residues in milk were slightly above the LOQ (< 0.01–0.02 mg/kg). The separation into skim milk and cream revealed that most of the residue is found in the fat fraction. No residues above the LOQ of 0.01 mg/kg were found in skim milk, while in cream levels ranging from 0.02 to 0.1 mg/kg were found. Highest residues were found in the liver, going up to 0.186 mg/kg in the 50 ppm dose group.

Laying hens

For laying hens the animals were separated into four groups receiving doses of 0, 5, 15 or 50 ppm hexythiazox for 28 consecutive days. Each group consisted of four subgroups with four animals each. For each dose group one subgroup was kept 7 additional days for withdrawal. During the whole period of time eggs were collected. At the end of the dose period the animals were sacrificed and samples of fat, muscle, liver and kidney were taken. All samples were analysed for the sum of hexythiazox and its metabolites, determined as PT-1-3. In eggs residues were found in all dose groups ranging from < 0.01 to 0.058 mg/kg for the 5 ppm group up to 0.03 to 0.36 mg/kg for the 50 ppm group. A separate analysis of egg white and egg yolk on day 20 reveals higher residues in the yolk by a factor of 1.7 to 2.5. In muscle no residues above the LOQ of 0.01 mg/kg could be detected. Highest residues in the tissues were found in liver and fat. Residues were 0.03 mg/kg and 0.05 mg/kg for the 5ppm group, 0.07 mg/kg and 0.08 mg/kg for the 15ppm group and 0.12 mg/kg and 0.17 mg/kg for the 50 ppm group, respectively.

Estimated maximum and mean dietary burdens of livestock

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, hexythiazox, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Beef cattle	1.7	0.9	3.5	1.9	6.1[a]	4.5[b]
Dairy cattle	2.2	1.2	3.0	1.4	6.1	4.5
Poultry—broiler	0	0	0	0	0	0

	Livestock dietary burden, hexythiazox, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max.	mean	max.	mean	max.	mean
Poultry—layer	0	0	0.4[c]	0.2[d]	0	0

[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 broiler or layer poultry burden suitable for MRL estimates for poultry meat and eggs

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

Animal commodities, MRL estimation

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/Eggs	Muscle	Liver	Kidney	Fat
HR	mean	highest	highest	highest	highest
HR beef or dairy cattle (6.1) [5, 15]	Milk 0.01 [< 0.01, < 0.01]	0 [< 0.01, < 0.01]	0.03 [< 0.01, 0.09]	0.02 [0.02, 0.02]	0.01 [< 0.01, 0.01]
HR laying hens (0.4) [5]	Eggs 0.004 [0.05]	0 [< 0.01]	0.002 [0.03]	0.01 [< 0.01]	0.004 [0.05]
STMR	mean	mean	mean	mean	mean
STMR beef or dairy cattle (4.5) [5, 15]	Milk 0.01 [< 0.01, < 0.01]	0 [< 0.01, < 0.01]	0.01 [< 0.01, 0.06]	0.01 [0.01, 0.01]	0.01 [< 0.01, 0.01]
STMR laying hens (0.2) [5]	Eggs 0.002 [0.05]	0 [< 0.01]	0.001 [0.02]	0.01 [< 0.01]	0.002 [0.05]

In lactating cows as well as in laying hens no residues above the LOQ of 0.05 mg/kg for the analytical method for enforcement purposes were estimated. The Meeting estimated maximum residue levels for mammalian meat (fat), eggs, milk, milk fat, edible offal (mammalian) and poultry edible offal of 0.05 mg/kg. For poultry meat (fat) the Meeting estimated a maximum residue level of 0.05(*) mg/kg.

The Meeting estimated an STMR value for hexythiazox in whole milk of 0.01 mg/kg. The separation of skim milk and cream was conducted for the 50ppm dose group revealing residues up to 0.1 mg/kg in the fat. Under consideration of the maximum dietary burden of 5.7 ppm the Meeting also estimated an STMR value of 0.01 mg/kg for hexythiazox in milk fat.

The residue arising from a dietary burden of 5.7 ppm was 0.01 mg/kg in the fat. Since the target tissue for hexythiazox residues in animal tissues is fat, the Meeting estimated an STMR value of 0.01 mg/kg for mammalian meat (fat basis). For mammalian meat (muscle) the Meeting estimated an STMR value of 0 mg/kg.

In kidney and liver the Meeting estimated STMR values 0.01 mg/kg, respectively.

For eggs the Meeting estimated an STMR value of 0.002 mg/kg. In poultry tissues STMR values were estimated at levels of 0.01 mg/kg for poultry edible offal of, 0.002 mg/kg for poultry meat (fat) and 0 mg/kg for poultry meat (muscle).

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of hexythiazox resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3.

The IEDIs in the thirteen Cluster Diets, based on the estimated STMRs were 0–2% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intake of residues of hexythiazox 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 hexythiazox residues is unlikely to present a public health concern.

5.15 INDOXACARB (216)

RESIDUE AND ANALYTICAL ASPECTS

Indoxacarb is an indeno-oxadiazine insecticide that is used for control of lepidoptera and other insect pests. It was first evaluated by the 2005 JMPR. The 2007 JMPR then re-evaluated data for head cabbage, due to short-term dietary intake concerns for children. The present Meeting received information on the residue analysis, storage stability, use pattern, supervised field trials, fate of residues during processing of plum and mint and a laying hen feeding study. The supervised trial information included data on stone fruit (cherry, peach and plum), cranberry, fruiting vegetables – cucurbits (cucumber, melons and summer squash), cowpea (dry), and mints.

Methods of analysis

The Meeting received information on an analytical method (AMR 12739) for indoxacarb, its R enantiomer and five metabolites, which was used in the laying hen feeding study for the analysis of poultry muscle, fat, skin (with fat), liver and eggs. The metabolites included compound IN-JT333 (methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno-[1,2-e][1,3,4] oxadiazine-4a(3H)-carboxylate), which is part of the residue definition for estimation of dietary intake of indoxacarb in animal commodities. The method is based on extraction with acidified acetonitrile, de-fatting with hexane, solid-phase extraction clean-up and LC-MS/MS analysis. The method validation and concurrent recoveries were typically ranging between 70–120%. The method LOQ was 0.01 mg/kg (LOD of 0.003 mg/kg) for all target poultry matrices.

For plant commodities, two single-residue methods and one multiresidue method (modified DFG S19) for the determination of indoxacarb residues (sum of indoxacarb and its R enantiomer) were reported to the JMPR in 2005. The 2005 Meeting concluded that these methods were adequate for gathering data in supervised trials and other studies and for monitoring and enforcing indoxacarb MRLs in samples of plant origin. These three methods were also used for the analysis of indoxacarb residues in supervised trials submitted to the present Meeting. The method validation and concurrent recoveries were typically ranging between 70–120%. The typical LOQ was 0.01 mg/kg, except for cranberry and mint tops (0.05 mg/kg), and mint oil (0.10 mg/kg).

Stability of pesticide residues in stored analytical samples

Freezer storage stability data for indoxacarb residues were available for the hen feeding study results, e.g., eggs, poultry fat, liver, meat and skin, and all commodities, for which supervised trial data were made available to the present Meeting, e.g., cherry, cowpea, cranberry, cucumber, melons, mint tops and oil, peach, plum, prune, and summer squash. Indoxacarb residues (sum of indoxacarb and its R enantiomer) were stable (less than 30% disappearance) during the storage stability study with the storage intervals generally covering the actual duration of sample storage in the supervised trials. The only exception was cranberry trials, in which samples were held in freezer storage for up to 125 days, whereas the duration of the stability study was only 45 days. Based on the stability data in other plant commodities (storage intervals significantly longer than 125 days) evaluated by this and the 2005 JMPR, the Meeting concluded that indoxacarb residues in the evaluated cranberry trials can be considered stable.

Results of supervised trials on crops

The Meeting received supervised trials data for indoxacarb on stone fruits (cherry, peach and plum), cranberry, fruiting vegetables – cucurbits (cucumber, melons and summer squash), cowpea (dry), and mints. All trials were conducted using a 30 WG formulation containing 300 g/kg of indoxacarb (S enantiomer) and 100 g/kg inactive R enantiomer ("indoxacarb 3S+1R").

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors, that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Stone fruits

The GAP on stone fruit in the USA is 4 × 0.12 kg ai/ha (maximum seasonal application rate of 0.49 kg ai/ha) and a PHI of 14 days.

The Meeting received supervised trial data on cherries, peach and plum from Canada and the USA. Results from supervised trials on cherries and plum in Italy and France were also submitted, however the Meeting received no GAP information for southern Europe to support the trials.

Twelve trials on cherries were conducted in Canada and the USA at the US GAP rate with a PHI of 12–14 days. Indoxacarb residues in cherries, in ranked order (n=12), were: 0.07 (2), 0.13, 0.15 (3), 0.19, 0.22, 0.26, 0.32, 0.51, and 0.64 mg/kg.

Fifteen trials on peaches were conducted in Canada and the USA at the US GAP rate with a PHI of 13–15 days. Indoxacarb residues in peaches, in ranked order (n=15), were: 0.04 (2), 0.07, 0.09 (2), 0.10 (3), 0.13, 0.16, 0.20, 0.29, 0.30, 0.50, and 0.59 mg/kg.

Eleven trials on plums were conducted in Canada and the USA at the US GAP rate with a PHI of 13–15 days. Indoxacarb residues in plums, in ranked order (n=11), were: < 0.01, 0.01, 0.02 (4), 0.03, 0.04, 0.07 (2), and 0.19 mg/kg.

The 2005 JMPR received results from supervised trials on peaches from southern Europe (France, Greece and Italy) and on apricot, nectarine and peaches from Australia. The Australian data was insufficient to support a recommendation. The results from trials on peaches in Greece, matching Greek GAP (0.1 kg ai/ha, 3 applications, and a PHI of 7 days), and in France and Italy, matching Italian GAP (0.075 kg ai/ha, 4 applications, and a PHI of 7 days), were used as a basis for estimation of a maximum residue level, STMR and HR values for peach by the 2005 JMPR. Based on the highest values from replicate field samples, indoxacarb residues in peach from European trials, in ranked order (n=9), were: 0.05, 0.07, 0.08, 0.11, 0.13 (2), 0.15, 0.16, and 0.18 mg/kg.

The Meeting agreed that the data on cherries, peaches and plums obtained in Canada and the USA, matching the US GAP for stone fruit, could be used to support a commodity group maximum residue level estimate. Based on the residues obtained on cherries, the Meeting estimated a maximum residue level for indoxacarb in stone fruit of 1 mg/kg and STMR and HR values of 0.17 and 0.64 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.94 mg/kg. The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. With rounding up the value derived from use of the calculator was in good agreement with the Meeting's estimate.

The Meeting agreed to withdraw its previous recommendation of a maximum residue level of 0.3 mg/kg for indoxacarb in peach.

Cranberry

Supervised trials were available inform the USA. The GAP of the USA specifies 0.12 kg ai/ha per application with maximum seasonal rate of 0.49 kg ai/ha and a PHI of 30 days.

Six trials on cranberry were conducted matching the US GAP rate with a PHI of 28–30 days. Indoxacarb residues in cranberry, in ranked order (n=6), were: 0.11, 0.13, 0.15 (2), 0.19, and 0.69 mg/kg.

The Meeting estimated a maximum residue level for indoxacarb in cranberry of 1 mg/kg and STMR and HR values of 0.15 and 0.69 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.91 mg/kg, which when rounded up corresponded to the Meeting's estimation.

Fruiting vegetables, Cucurbits

The Meeting received results from supervised trials on cucumber, melons and summer squash in Canada and the USA. The GAP of the USA for cucurbits specifies 0.12 kg ai/ha with maximum seasonal application rate of 0.49 kg ai/ha and a PHI of 3 days.

Ten trials on cucumber were conducted according to the US GAP. Indoxacarb residues in cucumber, in ranked order (n=10), were: < 0.01, 0.01, 0.02 (4), 0.03 (3), and 0.07 mg/kg.

Eleven trials on cantaloupe melons were conducted according to the US GAP. Indoxacarb residues in whole melons, in ranked order (n=11), were: 0.02, 0.03, 0.04, 0.05, 0.06 (2), 0.09, 0.14, 0.17, 0.25, and 0.39 mg/kg.

Twelve trials on summer squash were conducted according to the US GAP with a PHI of 2–4 days. Indoxacarb residues in summer squash, in ranked order (n=12), were: < 0.01 (3), 0.01 (2), 0.02, and 0.03 (2), 0.04 (2), 0.11, and 0.12 mg/kg.

The 2005 JMPR received results from supervised trials on cucumber, melons, and summer squash from southern Europe (France, Greece, Italy and Spain). The summer squash data was considered insufficient to support a recommendation.

Results from greenhouse trials on cucumber matching Hungarian GAP for greenhouse use (0.051 kg ai/ha and a PHI of 1 day) were used as a basis for estimation of a maximum residue level and STMR and HR values for cucumber by the 2005 JMPR. Based on the highest values from replicate field samples, indoxacarb residues in cucumber from European greenhouse trials, in ranked order (n=13), were: < 0.02 (6), 0.02 (2), 0.03 (3), 0.05, and 0.10 mg/kg.

Results from field and greenhouse trials on melons matching Spanish GAP (0.038 kg ai/ha and a PHI of 1 day) were used as a basis for estimation of a maximum residue level and STMR and HR values for melons by the 2005 JMPR. Indoxacarb residues in melons (whole fruit) from European trials (n=18), in ranked order, were: 0.02 (4), 0.03 (8), 0.04 (4), 0.05, and 0.09 mg/kg. Indoxacarb residues were below LOQ of 0.02 mg/kg in every sample of pulp in all trials (PHI 0–7 days). The 2005 JMPR concluded that indoxacarb residues are unlikely to occur in melon pulp.

The Meeting agreed that the data on cucumber, melons and summer squash obtained in Canada and the USA according to the US GAP for cucurbits could be used to support a commodity group maximum residue level estimate. Based on the residues obtained on whole melons, the Meeting estimated a maximum residue level for indoxacarb in fruiting vegetables, cucurbits of 0.5 mg/kg and STMR and HR values of 0.06 and 0.39 mg/kg, respectively.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.37 mg/kg. This was below the HR value of 0.39 mg/kg. As noted by the Meeting, the number of data points was insufficient to minimize the errors of the statistical extrapolation to the required high percentile values.

Based on the pulp data for melon from the European trials, the Meeting estimated STMR and HR values of 0.02 mg/kg for indoxacarb in cucurbits with inedible peel.

The Meeting agreed to withdraw its previous recommendations of indoxacarb maximum residue levels of 0.2 mg/kg in cucumber and 0.1 mg/kg in melon, except watermelon.

Cowpea, dry

The Meeting received results from supervised trials data on dry cowpea (southern pea, dry) in the USA. The GAP of the USA for southern pea, dry (including cowpea and other similar kinds of southern peas) specifies an application rate of 0.073 kg ai/ha with maximum seasonal rate of 0.29 kg ai/ha with a PHI of 7 days.

Six trials on cowpeas were conducted at the US GAP rate with PHIs of 6–7 days. Indoxacarb residues in dry cowpea, in ranked order (n=6), were: < 0.01 (2), 0.01, 0.03 (2), and 0.07 mg/kg.

The Meeting estimated a maximum residue level for indoxacarb in cowpea, dry of 0.1 mg/kg and an STMR value of 0.02 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.13 mg/kg, which when rounded down corresponded to the Meeting's estimation.

Mints

The Meeting received results from supervised trials on mint in the USA. The GAP of the USA for mint specifies an application rate of 0.073 kg ai/ha with seasonal maximum of 0.29 kg ai/ha and a PHI of 7 days.

Six trials on mint were conducted at the US GAP rate with PHIs of 7–8 days. Indoxacarb residues in mints, in ranked order (n=6), were: 2.2, 2.7, 3.4, 3.6, and 6.8 (2) mg/kg.

The Meeting estimated a maximum residue level for indoxacarb in mint of 15 mg/kg and STMR and HR values of 3.5 and 6.8 mg/kg, respectively.

The normal JMPR procedure is to round up the value to the nearest 5 for maximum residue levels between 10 and 30 mg/kg. The maximum residue level estimate derived from use of the NAFTA statistical calculator was 11.6 mg/kg. With rounding up, the value derived from use of the calculator corresponded to the Meeting's recommendation.

Fate of residues during processing

The Meeting received information on the fate of incurred residues of indoxacarb during commercial-type processing of plums and mints. The processing factors and STMR-P and HR-P values are summarized in the table below.

Processing (Transfer) factors from the processing of Raw Agricultural Commodities (RACs) with field-incurred residues from foliar treatment with indoxacarb

RAC			Processed commodity					
					Processing factor			
Name	STMR (mg/kg)	HR (mg/kg)	CCN	Name	Calculated values	Median or best estimate	STMR-P (mg/kg)	HR-P (mg/kg)
Plum [a]	0.17	0.64	DF 0014	Prunes	2.7, 4.0, 8.5	4.0	0.68	2.6
				Plum juice	0.31, 0.43	0.37	0.06	
				Plum pomace, wet	0.58, 1.1	0.84	0.14	
				Canned plums	0.50, 0.77	0.64	0.11	
				Plum jam	0.75, 1.2	0.98	0.17	
				Plum puree	1.1, 1.5	1.3	0.22	
Mints	3.5	6.8		Mint oil	< 0.015, < 0.037	< 0.015	0.052	

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

Based on the HR-P value of 2.6 mg/kg, the Meeting estimated a maximum residue level of 3 mg/kg for indoxacarb in prunes.

Farm animal dietary burden

The Meeting estimated the dietary burden of indoxacarb in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops), using previously estimated highest residues and STMR/STMR-P values for feed commodities and an STMR value for cowpea (dry) estimated by the present Meeting. Calculation from the highest residue and STMR/STMR-P (some bulk commodities) 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.

		Indoxacarb, Animal dietary burden (ppm of dry matter diet)		
		US-Canada	EU	Australia
Beef cattle	Maximum	30	23	41[a]
	Mean	12	13	17[b]
Dairy cattle	Maximum	20	20	33[c]
	Mean	8.1	8.0	14[d]
Poultry - broiler	Maximum	0.047	0.027	0.024
	Mean	0.047	0.027	0.024
Poultry - layer	Maximum	0.027	1.5[e]	0.024
	Mean	0.027	0.80[f]	0.024

[a] Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian meat.

[b] Highest mean beef 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.

Farm animal feeding studies

The Meeting received information on a laying hen feeding study. Sixty laying White Leghorn hens were randomized into six groups. Each group was fed for 28 consecutive days with a nominal dose rate of 0, 1.75, 7, 21, 70 and 70 ppm of indoxacarb (3S+1R) in the dry-weight diet. The second 70 ppm treatment group was used to evaluate depuration of residues after 29 consecutive days of dosing. This group was slaughtered 28 days after withdrawal. The other birds were slaughtered on Day 29. In each case, muscle, liver, abdominal fat pad and skin with fat samples were collected for the analysis of indoxacarb, its R enantiomer and metabolites, including metabolite IN-JT333.

Eggs were collected twice daily. Residues of indoxacarb and its R enantiomer in eggs reached a plateau at about 7 days (and declined < LOQ of 0.01 mg/kg within 10 days after withdrawal of the 70 ppm dose). Residues of IN-JT333 reached a plateau at about 14 days (and declined < 0.01 mg/kg within 17 days after withdrawal of the 70 ppm dose). Residue levels were approximately proportional to the dose. The highest residues obtained during the dosing period for indoxacarb and its enantiomer in whole eggs were 0.01 mg/kg (1.75 ppm), 0.05 mg/kg (7 ppm), 0.12 mg/kg (21 ppm), and 0.40 mg/kg (70 ppm). For metabolite IN-JT333, these values were 0.01, 0.02, 0.07, and 0.21 mg/kg, respectively.

Residue levels in egg yolk and white were similar for indoxacarb and its enantiomer, whereas metabolite IN-JT333 concentrated in egg yolk (0.45 mg/kg vs. 0.005 mg/kg in egg yolk and white, respectively, at 70 ppm dosing level).

As concluded by the 2005 JMPR, the indoxacarb residue is fat soluble. For indoxacarb and its R enantiomer, residues above LOQ were found only in fat or skin with fat, at higher dosing levels. The highest residues in abdominal fat (higher residues than in skin with fat) were < 0.01 (1.75 ppm), 0.05 mg/kg (7 ppm), 0.16 mg/kg (21 ppm), and 0.76 mg/kg (70 ppm).

Metabolite IN-JT333 gave generally higher residues in the tissues than indoxacarb and its enantiomer. The highest residues of IN-JT333 in fat were 0.05 (1.75 ppm), 0.21 mg/kg (7 ppm), 0.81 mg/kg (21 ppm), and 2.0 mg/kg (70 ppm). The corresponding highest IN-JT333 residues in muscle were < 0.01, < 0.01, 0.02, and 0.02 mg/kg, respectively; and in liver: < 0.01, < 0.01, 0.02, and 0.09 mg/kg, respectively.

No detectable residues (< 0.003 mg/kg) of indoxacarb and its R enantiomer were found in the tissues after 28 days of withdrawal of the 70 ppm daily dose. In the same tissues, metabolite IN-JT333 was detected only in fat at 0.006 mg/kg, which is below the method LOQ.

The 2005 Meeting received information on a lactating dairy cattle feeding study, which was conducted at the equivalent of 7.5, 22.5, and 75 ppm of indoxacarb in the dry-weight diet for 28 consecutive days. Indoxacarb, its R enantiomer and metabolite IN-JT333 were analysed in milk, cream and tissues (muscle, liver, kidney and fat).

Animal commodity maximum residue levels

The dietary burdens for the estimation of maximum residue levels for indoxacarb in animal commodities are 41 ppm for beef cattle, 33 ppm for dairy cattle and 1.5 ppm for poultry. The dietary burdens for the estimation of STMR values for animal commodities are 17 ppm for beef cattle, 14 ppm for dairy cattle and 0.80 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 (interpolated) indoxacarb concentration related to the dietary burdens are shown without brackets. The MRL estimations are based on sum of indoxacarb and its R enantiomer. For STMR and HR estimation, the concentrations of metabolite IN-JT333 were expressed as indoxacarb and added to the concentration of indoxacarb and its R enantiomer, which caused a slight change in concentrations in cream and fat, but not in milk or the other tissues. Therefore, the residue concentrations listed below include the IN-JT333 metabolite unless noted otherwise.

Summary of residues corresponding to the estimated dietary burden

Dietary burden (ppm) Feeding level [mg/kg]	Milk	Cream	Muscle	Liver	Kidney	Fat
MRL Beef Cattle			highest	highest	highest	highest
(41)						1.02[a]
			0.039	0.015	0.030	1.07[b]
[22.5, 75]			[< 0.01, 0.093]	[0.013, 0.019]	[0.020, 0.049]	[0.54, 1.9][a] [0.57, 2.0][b]
MRL Dairy Cattle	mean	mean				
(33)		0.92[a]				
	0.084	0.96[b]				
[22.5, 75]		[0.60, 2.2][a]				
	[0.058, 0.19]	[0.62, 2.3][b]				
STMR Beef Cattle			mean	mean	mean	mean
(17)			< 0.01	0.01	0.014	0.38

Dietary burden (ppm) Feeding level [mg/kg]	Milk	Cream	Muscle	Liver	Kidney	Fat
[7.5, 22.5]			[< 0.01, < 0.01]	[< 0.01, 0.01]	[< 0.01, 0.017]	[0.22, 0.48]
STMR Dairy Cattle	mean	mean				
(14)	0.037	0.39				
[7.5, 22.5]	[0.021, 0.058]	[0.21, 0.62]				

[a] Indoxacarb residue for MRL estimation: sum of indoxacarb and its R enantiomer.

[b] Indoxacarb residue for HR estimation: sum of indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb.

Based on the highest indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 22.5 and 75 ppm, the interpolated (estimated) highest residues for the maximum beef cattle dietary burden of 41 ppm were 0.039 mg/kg in muscle, 0.015 mg/kg in liver, 0.030 mg/kg in kidney, and 1.07 mg/kg in fat. Estimated highest residue concentration of indoxacarb and its R metabolite in fat was 1.02 mg/kg.

On the fat basis, the Meeting estimated a maximum residue level of 2 mg/kg for indoxacarb in meat (fat) from mammals (other than marine mammals) to replace the previous recommendation of 1 mg/kg. The Meeting estimated a maximum residue level of 0.05 mg/kg for indoxacarb in edible offal (mammalian), which confirms the previous recommendation made by the 2005 JMPR.

Based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 7.5 and 22.5 ppm, the interpolated (estimated) mean residues for the mean beef cattle dietary burden of 17 ppm were < 0.01 mg/kg in muscle, 0.01 mg/kg in liver, 0.014 mg/kg in kidney, and 0.38 mg/kg in fat.

The Meeting estimated STMR values for indoxacarb in mammalian meat, fat and edible offal of 0.01, 0.38 and 0.014 mg/kg, respectively, with corresponding HR values of 0.039, 1.07 and 0.030 mg/kg, respectively.

Based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 22.5 and 75 ppm, the interpolated (estimated) highest residues for the maximum dairy cattle dietary burden of 33 ppm were 0.084 mg/kg in milk and 0.96 mg/kg in cream. Estimated highest residue concentration of indoxacarb and its R metabolite in cream was 0.92 mg/kg. Similarly, based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing levels of 7.5 and 22.5 ppm, the interpolated (estimated) mean residues for the mean dairy cattle dietary burden of 14 ppm were 0.037 mg/kg in milk and 0.39 mg/kg in cream. On the assumption of 50% milk fat in cream, the highest and mean residues in milk fat were 1.92 and 0.78 mg/kg, respectively. For indoxacarb and its R metabolite, the estimated highest residue concentration of in milk fat was 1.84 mg/kg.

The Meeting estimated maximum residue levels of 0.1 and 2 mg/kg for indoxacarb in milk and milk fat, respectively, which confirms the previous maximum residue level recommendations made by the 2005 JMPR.

The Meeting estimated STMR values of 0.037 and 0.78 mg/kg for indoxacarb in milk and milk fat, respectively.

For poultry, the maximum dietary burden of 1.5 ppm is close to the dose level of 1.75 ppm in the hen feeding study. At 1.75 ppm, residues of indoxacarb and its R enantiomer were < 0.01 mg/kg in muscle, liver and fat (only one sample of fat had detectable residues above the LOD of 0.003 mg/kg). In eggs, the highest residue at 1.75 ppm dose was 0.012 mg/kg, which by estimation gives 0.010 mg/kg at 1.5 ppm.

The Meeting estimated maximum residue level of 0.01(*) mg/kg for indoxacarb in poultry meat (fat) and poultry offal, which confirms the previous recommendation made by the 2005 JMPR.

The Meeting estimated maximum residue level of 0.02 mg/kg for indoxacarb in eggs to replace the previous recommendation of 0.01(*) mg/kg.

Based on the highest indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing level of 1.75 ppm and maximum poultry dietary burden of 1.5 ppm, the Meeting estimated HR values of 0, 0.05, 0 and 0.02 for indoxacarb in poultry meat, fat, offal and eggs, respectively.

Based on the mean indoxacarb residues (sum indoxacarb, its R enantiomer and metabolite IN-JT333, expressed as indoxacarb) at the dosing level of 1.75 ppm and mean poultry dietary burden of 0.8 ppm, the Meeting estimated STMR values of 0, 0.025, 0 and 0.01 for indoxacarb in poultry meat, fat, offal and eggs, respectively.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of indoxacarb based on STMR and STMR-P values estimated by the 2005 JMPR and the present Meeting for 46 commodities and commodity groups for the thirteen GEMS/Food Consumption Cluster Diets were 1–30% of the maximum ADI (0.01 mg/kg bw). The results are shown in Annex 3 of the Report. The Meeting concluded that the long-term dietary intake of indoxacarb residues resulting 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 indoxacarb calculated on the basis of the recommendations made by the present Meeting represented for the general population 0–10% and for children 0–20% of the ARfD (0.1 mg/kg bw). The results are shown in Annex 4 of the Report.

The 2005 Meeting was not able to calculate the IESTI for leaf lettuce at the time because unit weight data were not available for leaf lettuce. Based on the new consumption data, the current Meeting calculated the IESTI for leaf lettuce and obtained 60% and 150% of the ARfD for the general population and for children, respectively.

The Meeting concluded that the short-term intake of residues of indoxacarb resulting from uses that have been considered by the JMPR, except the use on leaf lettuce, is unlikely to present a public health concern.

The Meeting also considered ways in which the short-term dietary intake for leaf lettuce could be refined. The Meeting noted that leaf lettuce is consumed as a raw commodity and that there was no alternative GAP available. Furthermore, the basis upon which the ARfD was set, a single-dose study, by the JMPR in 2005 meant that refinement was not possible. Consequently, the Meeting concluded that the information provided to the JMPR precludes an estimate that the dietary intake would be below ARfD for consumption of leaf lettuce by children.

5.16 METAFLUMIZONE (236)

TOXICOLOGY

Metaflumizone is the ISO approved common name for (EZ)-2´-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-4-(trifluoromethoxy)carbanilohydrazide (CAS No. 139968-49-3), which is a mixture of E and Z isomers (ratio, approximately 9: 1). Metaflumizone is a novel insecticide of the semicarbazone class, which acts by blocking voltage-dependent sodium channels of the nervous system, causing paralysis of the insect. Metaflumizone was evaluated at the request of CCPR and was not evaluated previously by JMPR.

All pivotal studies were certified as complying with GLP or an approved quality-assurance programme.

Biochemical aspects

In rats given [^{14}C]benzonitrile-ring (B)-labelled or [^{14}C]trifluoromethoxyphenyl-ring (T)-labelled metaflumizone orally by gavage, absorption was up to 17% of the administered dose after a single dose at 6 mg/kg bw, and up to 7% after a single dose at 30 or 1000 mg/kg bw. Absorption may be higher by dietary administration (23% at 0.76 mg/kg bw) or by gavage in Cremophor, an emulsifying agent (33% at 6 mg/kg bw). The maximum plasma concentrations were reached after 10–48 h, depending on the dose and the radiolabel tested. Increasing the dose by a factor of 33 resulted in an increase in AUC of about 10-fold, correlating with the lower absorption of metaflumizone at the higher dose. Radiolabel was widely distributed throughout the body. Residues in tissues at 168 h after a single dose at 6 or 30 mg/kg bw accounted for approximately 15% or approximately 2–3% of the administered dose, respectively, with fat, liver, kidney, muscle and blood containing the highest concentrations of residues. The major route of excretion of radiolabel was via the faeces (mainly unabsorbed substance; < 5% in bile) while only < 3% of the administered dose was excreted via the urine. The elimination half-lives depended on the position of the radiolabel, ranging from 27–48 h to 139–402 h for the B-labelled and the T-labelled metaflumizone, respectively.

Metaflumizone was metabolized via hydroxylation of the aniline or benzonitrile ring, hydrolysis of the central hydrazine carboxamide group and conjugation with sulfate, glucuronic acid, glycine or glutathione. Unchanged parent compound was the major component of the residues extracted in tissues and plasma, while no parent was found in the urine and bile.

Toxicological data

Metaflumizone was of low toxicity in rats exposed orally or dermally (LD_{50} > 5000 mg/kg bw) and caused neither mortality nor systemic toxicity at this limit dose. Metaflumizone was also of low toxicity in rats exposed by inhalation (LC_{50} > 5.2 mg/L).

Metaflumizone was not a skin irritant in rabbits, was non-to-slightly irritating to rabbits' eyes, and was not a skin sensitizer in the guinea-pig maximization test.

After repeated administration of metaflumizone, decreased food consumption, decreased body-weight gain or body-weight loss and subsequent poor general state of health at higher doses were observed in all species tested. These effects were observed regardless the route of administration, i.e., after oral, dermal or inhalation exposure. Data also indicated that females, both rats and dogs, are relatively more sensitive to intoxication than are males.

The poor palatability of the test substance at dietary concentrations of ≥ 50 ppm was considered to significantly affect food consumption in short-term feeding studies, and consequently in all further studies (including short-term studies of toxicity, long-term studies of toxicity and carcinogenicity, two-generation study of reproductive toxicity) the test substance was administered

via gavage (rats) or in capsules (dogs). However, similar effects (such as decreased food consumption and body-weight gain) were observed with all methods of administration, but occurred at markedly lower doses with dietary administration.

A clear mode of action for the toxicity of metaflumizone in mammals has not been identified. Many of the effects observed after repeated dosing were consistent with decreased food consumption and body-weight loss but do not appear to be induced by the insecticidal mode of action (i.e.,specific receptor affinity, blocking of sodium channels).

The short-term toxicity of metaflumizone was investigated in mice, rats and dogs. In two 28-day range-finding feeding studies in mice, the NOAEL was 40 ppm, equal to 8.2 mg/kg bw per day, on the basis of decreased food consumption and body-weight gain at dietary concentrations of 200 ppm and above. Effects at higher doses included body-weight loss, clinical signs of toxicity (ataxia, convulsions) and mortality.

In 28-day and 3-month feeding studies in rats, the NOAEL was 20 ppm, equal to 2.2 mg/kg bw per day, on the basis of decreased food consumption and body-weight gain at 40 ppm, equal to 4.3 mg/kg bw per day, and above. Effects at higher doses (≥ 1000 ppm, equal to 83 mg/kg bw per day) included body-weight loss and poor general state (emaciation, hair loss, pallor, hunched posture). In subsequent 28-day and 3-month studies in rats treated by gavage, the NOAEL was 60 mg/kg bw per day on the basis of reduced food consumption and body-weight gain in females at 300/200 mg/kg bw per day.

In a combined 3-month/1-year study of toxicity in dogs given metaflumizone in capsules, the NOAEL was 12 mg/kg bw per day on the basis of clinical signs of poor general state of health and premature sacrifice, decreased food consumption, reduced body-weight gain and body-weight loss and changes in haematological parameters at doses of 30 mg/kg bw per day and above.

Metaflumizone was tested in an adequate battery of assays for genotoxicity in vitro and in vivo. Negative results were obtained in the tests in vitro, except for a positive result in a test for chromosomal aberration in the absence of metabolic activation. In vivo, an assay for micronucleus formation in mice and a test for unscheduled DNA synthesis in rats gave negative results.

The Meeting concluded that metaflumizone was unlikely to be genotoxic.

Long-term studies of toxicity and carcinogenicity were conducted in mice and rats. In an 18-month study of carcinogenicity in mice treated by gavage, the NOAEL was 250 mg/kg bw per day on the basis of decreased body weight/body-weight gain and increased incidences of brown pigment in the spleen at 1000 mg/kg bw per day, the highest dose tested. There was no evidence for carcinogenicity with metaflumizone in this study.

In a 2-year study of toxicity and carcinogenicity in rats treated by gavage, the NOAEL was 30 mg/kg bw per day on the basis of increased incidences of centrilobular hepatocellular hypertrophy and hepatocellular basophilic alteration in males at 60 mg/kg bw per day. There was no evidence for carcinogenicity up to the highest doses tested (300 or 200 mg/kg bw per day for males or females, respectively).

On the basis of the absence of carcinogenicity in mice and rats and the absence of genotoxicity, the Meeting concluded that metaflumizone is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats treated by gavage, the highest dose tested (75 mg/kg bw per day) induced excessive parental toxicity, resulting in reduced fertility and high pup mortality. Consequently, the highest dose was reduced from 75 to 50 mg/kg bw per day and the intermediate dose from 30 to 20 mg/kg bw per day for the next two successive parental generations. The NOAEL for parental toxicity was 20 mg/kg bw per day on the basis of increased incidences of poor general state of health of females at doses of 30 mg/kg bw per day and above. The NOAEL for offspring toxicity was 20 mg/kg bw per day on the basis of increased incidences of stillborn pups and increased pup mortality at doses of 50 mg/kg bw per day and above. The NOAEL

for effects on fertility was 50 mg/kg bw per day on the basis of a reduction in the male and female fertility index at 75 mg/kg bw per day.

In a study of prenatal developmental toxicity in rats, the NOAEL for maternal toxicity was 40 mg/kg bw per day on the basis of reduced food consumption and decreased body-weight gain at 120 mg/kg bw per day. The NOAEL for developmental toxicity was 120 mg/kg bw per day, the highest dose tested.

In a study of prenatal developmental toxicity in rabbits, the NOAEL for maternal toxicity was 100 mg/kg bw per day on the basis of clinical signs of toxicity (poor general state, including ataxia) and abortion at 300 mg/kg bw per day. The NOAEL for developmental toxicity was 100 mg/kg bw per day on the basis of decreased fetal body weights and an increased rate of incomplete ossification of the sternebrae at 300 mg/kg bw per day.

The Meeting concluded that metaflumizone caused developmental toxicity only at doses that were maternally toxic but that it was not teratogenic.

In a study of acute neurotoxicity in rats, metaflumizone did not induce signs of systemic toxicity or neurotoxicity at up to the highest dose tested (2000 mg/kg bw). In a short-term study of neurotoxicity in rats treated by gavage, the NOAEL for neurotoxicity was 300 and 150 mg/kg bw per day in males and females, respectively, the highest doses tested. The NOAEL for systemic toxicity was 36 mg/kg bw per day on the basis of poor general state, including mortality and impairment of food consumption and body-weight gain at 150 mg/kg bw per day.

In a range-finding study of developmental neurotoxicity in rats treated by gavage, the NOAEL for systemic toxicity and reproductive performance was 80 mg/kg bw per day on the basis of clinical signs of poor general state and litter loss at 120 mg/kg bw per day. The concentrations of metaflumizone in milk and pup plasma were up to 15 mg/kg and up to 4 mg/kg, respectively. A full study of developmental neurotoxicity was not performed since young rats were not more sensitive than adults to the effects of metaflumizone and no evidence of neurotoxicity was seen in standard studies of toxicity or in studies of acute or subchronic neurotoxicity.

The Z-isomer of metaflumizone (M320I02) was of low acute oral toxicity in rats (LD_{50} > 5000 mg/kg bw) and was not mutagenic in an assay for reverse mutation in bacteria. In a short-term study of toxicity in rats treated by gavage, the NOAEL was 100 mg/kg bw per day on the basis of decreased body-weight gain, reduced motor activity and histopathological findings in mesenteric lymph nodes and adrenal cortex in females at doses of 300 mg/kg bw per day and above.

The main plant and soil metabolite of metaflumizone (Reg. No. 4984051; M320I23), was of low acute oral toxicity in rats (LD_{50} > 2000 mg/kg bw). It was not genotoxic in assays for gene mutation in vitro, but induced chromosomal aberrations in the presence of metabolic activation in vitro. A test for micronucleus formation in mice gave negative results. In a short-term study of toxicity in rats treated by gavage, the NOAEL was 200 mg/kg bw per day on the basis of increased salivation in both sexes and increased relative liver weights and centrilobular hepatocellular hypertrophy in females at 1000 mg/kg bw per day.

An additional soil metabolite of metaflumizone (Reg. No. 43455; M320I29), was not genotoxic in assays for gene mutation and chromosomal aberration in vitro.

There were no reports of adverse health effects in manufacturing-plant personnel. Also, there were no reports of poisonings with metaflumizone.

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

Toxicological evaluation

The Meeting established an ADI for metaflumizone of 0–0.1 mg/kg bw based on a NOAEL of 12 mg/kg bw per day for clinical signs of poor general state of health, decreased food consumption,

reduced body-weight gain and body-weight loss, and changes in haematological parameters at 30 mg/kg bw per day and above in a 1-year study in dogs, and using a 100-fold safety factor.

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

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month study of carcinogenicity[a]	Toxicity	250 mg/kg bw per day	1000 mg/kg bw per day
		Carcinogenicity	1000 mg/kg bw per day[c]	—
Rat	Three-month study of toxicity[a]	Toxicity	60 mg/kg bw per day	200 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	30 mg/kg bw per day	60 mg/kg bw per day
		Carcinogenicity	200 mg/kg bw per day[c]	—
	Multigeneration study of reproductive toxicity[a]	Fertility	50 mg/kg bw per day	75 mg/kg bw per day
		Parental toxicity	20 mg/kg bw per day	30 mg/kg bw per day
		Offspring toxicity	20 mg/kg bw per day	50 mg/kg bw per day
	Developmental toxicity[a]	Maternal toxicity	40 mg/kg bw per day	120 mg/kg bw per day
		Embryo- and fetotoxicity	120 mg/kg bw per day[c]	—
	Acute neurotoxicity[a]	Neurotoxicity	2000 mg/kg bw per day[c]	—
	Subchronic neurotoxicity[a]	Neurotoxicity	150 mg/kg bw per day[c]	—
	Developmental neurotoxicity[a]	Maternal toxicity	80 mg/kg bw per day	120 mg/kg bw per day
		Offspring toxicity	80 mg/kg bw per day	120 mg/kg bw per day
Rabbit	Developmental toxicity[a]	Maternal toxicity	100 mg/kg bw per day	300 mg/kg bw per day
		Embryo- and fetotoxicity	100 mg/kg bw per day	300 mg/kg bw per day
Dog	One-year study of toxicity[b]	Toxicity	12 mg/kg bw per day	30 mg/kg bw per day

[a] Gavage administration.

[b] Capsule administration.

[c] Highest dose tested.

Estimate of acceptable daily intake for humans

0–0.1 mg/kg bw

Estimate of acute reference dose

Unnecessary

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

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

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

Absorption, distribution, excretion and metabolism in animals	
Rate and extent of oral absorption	≤ 17% at 6 mg/kg bw; ≤ 7% at 30 or 1000 mg/kg bw
Distribution	Widely; highest concentrations in fat, liver, kidney, muscle and blood
Rate and extent of excretion	≥ 90% within 168 h for a single dose of ≥ 30 mg/kg bw, mainly via faeces (< 5% in bile), < 3% via urine; elimination half-life, 27–48 h or 139–402 h, depending on position of radiolabel
Potential for accumulation	Evidence of accumulation in fat after repeated exposure (steady state after 21–28 days; terminal half-life, 15–17 days)
Metabolism in mammals	Extensive; hydroxylation (aniline and benzonitrile rings), hydrolysis (hydrazine carboxamide group), conjugation (sulfate, glucuronic acid, glycine, glutathione); in tissues, mainly unchanged parent.
Toxicologically significant compounds (animals, plants and the environment)	Parent compound
Acute toxicity	
Rat, LD_{50}, oral	> 5000 mg/kg bw
Rat, LD_{50}, dermal	> 5000 mg/kg bw
LC_{50} inhalation	> 5.2 mg/L air (4-h, nose-only exposure)
Rabbit, dermal irritation	Not an irritant
Rabbit; ocular irritation	Not or slightly irritating
Guinea-pig, dermal sensitization	Not sensitizing (Magnussen & Kligman test)
Short-term studies of toxicity	
Target/critical effect	Decreased food consumption and body-weight gain; clinical signs of poor general state, mortality or premature sacrifice; changes in haematological parameters
Lowest relevant oral NOAEL	12 mg/kg bw per day (1-year study in dogs)
Lowest relevant dermal NOAEL	100 mg/kg bw per day (3-month study in rats)
Lowest relevant inhalation NOAEC	0.03 mg/L air (28-day study in rats)
Genotoxicity	
	No genotoxic potential
Long-term studies of toxicity and carcinogenicity	

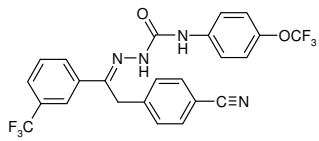
Target/critical effect	Liver (hepatocellular hypertrophy, basophilic alteration) in rats;, spleen (pigment deposition), decreased body-weight gain in mice
Lowest relevant NOAEL	30 mg/kg bw per day (2-year study in rats)
Carcinogenicity	No evidence for carcinogenicity in rats and mice
Reproductive toxicity	
Reproductive target/critical effect	Reduced male & female fertility in the presence of severe systemic toxicity
	Increased incidences of stillborn pups and pup mortality at parentally toxic dose
Lowest relevant reproductive NOAEL	50 mg/kg bw per day for effects on fertility (two-generation study in rats)
	20 mg/kg bw per day for systemic toxicity in parents and offspring
Developmental target/critical effect	No developmental toxic effects at maternally toxic dose in rats; decreased fetal weights, incomplete ossification of sternebrae at maternally toxic dose in rabbits
Lowest relevant developmental NOAEL	100 mg/kg bw per day (rabbits)
Neurotoxicity	
Acute neurotoxicity	No evidence of neurotoxicity; NOAEL: 2000 mg/kg bw (highest dose tested)
Subchronic neurotoxicity	No evidence of neurotoxicity; NOAEL: 300/150 mg/kg bw per day (highest dose tested; 90-day study in rats)
Other toxicological studies	
Studies on Z-isomer (M320I02)	Rat, oral LD_{50}, > 5000 mg/kg bw;
	Rat, 90-day study, NOAEL: 100 mg/kg bw per day (reduced body-weight gain, histopathological changes in lymph nodes and adrenal cortex);
	No genotoxic potential
Studies on metabolites:	
Reg. No. 4984051 (M320I23, plant & soil metabolite)	Rat, oral LD_{50}, > 5000 mg/kg bw;
	Rat, 90-day study: NOAEL 200 mg/kg bw per day (salivation, increased relative liver weight, hepatocellular hypertrophy);
	No genotoxic potential
Reg. No. 43455 (M320I29, soil metabolite)	No genotoxic potential
Medical data	Limited data; no adverse health effects reported in manufacturing plant personnel

Summary

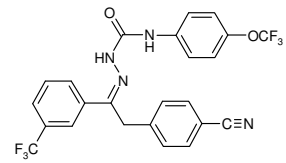
	Value	**Study**	**Safety factor**
ADI	0–0.1 mg/kg bw	Dog; 1-year study	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

The insecticide metaflumizone is a broad-spectrum semicarbazone composed of two optical isomers in the ratio E:Z of 90:10 and was considered for the first time by the JMPR.



E-isomer



Z-isomer

The manufacturer submitted studies on physical and chemical properties, animal and plant metabolism, environmental fate in soil, rotational crops, analytical methods, freezer storage stability, use patterns, supervised field trials on plants, processing and residues in animal commodities.

List of metabolites and degradation products

M3210I04	4-{2-oxo-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile
M3210I05	trifluoromethoxy aniline
M3210I06	4-cyanobenzoic acid
M3210I07	(EZ)-2-{2-(4-cyanophenyl)-2-hydroxy-1-[3-(trifluoromethylphenyl]ethylidene}-N-[4-(trifluoromethoxy)- phenyl]hydrazinecarboxamide
M3210I08	N-[4-(trifluoromethoxy) phenyl]hydrazinecarboxamide
M3210I09	4-{(2E)-2-hydrazono-2-[3-(trifluoromethyl)phenyl]ethyl} benzonitrile
M3210I10	(2S,3S,4S,5R,6R)-6-[2-(4-cyano-phenyl)-1-(3-trifluoromethyl-phenyl)-ethoxy]-3,4,5-trihydroxy-tetrahydro-pyran-2-carboxylic acid
M3210I13	glycine conjugate of M3210I06
M3210I22	metaflumizone hydroxylated at the 3-fluoromethoxyphenyl ring
M3210I23	4-{5-hydroxy-3-oxo-4-[4-(trifluoromethoxy)phenyl]-6-[3-(trifluoromethyl)phenyl]-2,3,4,5-tetrahydro-1,2,4-triazin-5-yl}benzonitrile
M3210I24	glucuronic acid conjugate of M3210I22
M3210I25	4-{2-hydroxy-2-[3-(trifluoromethyl) phenyl]ethyl}benzonitrile
M3210I26	2-amino-pentanedioic acid 1-[2-(4-cyano-phenyl)-1-(3-trifluoromethyl-phenyl)-ethyl]ester
M3210I27	metaflumizone hydroxylated at the 3-fluoromethylphenyl ring
M3210I28	N-[4-(trifluoromethoxy) phenyl]acetamide
M3210I29	m-trifluoromethyl benzoic acid

Animal metabolism

The Meeting received animal metabolism studies with metaflumizone in rats, lactating goats and laying hens. The metabolism and distribution of metaflumizone in animals was investigated using the trifluoromethoxyphenyl-U-[^{14}C] and benzonitrile-U-[^{14}C]-labelled compound, referred as T- and B-label.

Metaflumizone was found to be metabolised in the rat via hydroxylation of the aniline ring or benzonitrile ring and hydrolysis of the central hydrazine carboxamide group to yield the aniline and phenacylbenzoylnitrile derivatives. The trifluoromethoxyaniline group was shown to conjugate with malonic and oxalic acids. Ring hydroxylated derivatives of metaflumizone were readily conjugated with sulphate or glucuronic acid. Glycine conjugation occurred at the carboxyl group of the cyanobenzoic acid, whereas glutathione conjugation occurred by displacement of one of the fluorine atoms of the trifluoromethyl or trifluoromethoxy groups. Analysis of tissues after a single oral dose revealed that the major residue was unchanged metaflumizone. Evaluation of residues in adipose tissue following repeated dosing demonstrated that unchanged metaflumizone was the only significant residue.

When lactating goats received a nominal oral dose of 12 ppm of [^{14}C]metaflumizone for 14 consecutive days in the feed, most of the absorbed radioactive material was excreted through the faeces (66–79%). About 2.5–5% of the initial dose was excreted via urine. Milk accounted for 0.87–1.47% of the initial radioactive dose, though the radioactive concentration in milk increased throughout the application period. TRR were 0.2 mg/kg in milk, 1.3 mg/kg in liver, 0.21 mg/kg in kidney, 0.068 mg/kg in muscle, and 0.73 mg/kg in fat from goats dosed orally with T-label [^{14}C]metaflumizone. TRR were 0.53 mg/kg in milk, 2.8 mg/kg in liver, 0.38 mg/kg in kidney, 0.18 mg/kg in muscle, and 2.9 mg/kg in fat from goats dosed orally with B-label [^{14}C]metaflumizone. Metaflumizone (sum of E- and Z-isomers) were found to be the major residue in all matrices, with 31–108% TRR (highest level at 3.1 mg/kg in fat). The metabolites M320I04, M320I07, M320I13, M320I23, M320I24, M320I25 and M320I26 were identified in liver. Furthermore, the non-extracted residues of liver (T-label) could be converted into the hydrolysis product M320I28 after mixing with acetonitrile and acetic acid and treated by micro-wave for 30 minutes at 150 °C. M320I24 was identified in kidney.

Metabolism of metaflumizone in goats followed two different paths. One route was cleavage of the molecule at the imine-bridge resulting in the formation of M320I04 and the trifluoromethoxyaniline (M320I05). M320I04 was cleaved, oxidized and conjugated with glycine to M320I13 or reduced and conjugated with glucuronic acid (M320I10) or glutamic acid (M320I26). The main route involved hydroxylation of the parent compound at the trifluoromethoxyaniline ring, followed by conjugation to glucuronic acid. The hydroxylation at the benzyl-position of the molecule was followed by oxidation and ring formation to M320I23. In extracts of edible portions of the goat the parent compound is the main residue.

After 14 consecutive daily oral administrations of [^{14}C]metaflumizone at nominal dose level of 12 ppm feed to laying hens, considerable retention in organs and tissues, especially in adipose tissue, was measured. Depending on the label used, radioactivity in eggs amounted to 5.75–6.35% of the total radioactivity administered. The relevant residue in organic extracts of egg, liver, muscle and fat was the parent compound with 56–106% TRR (highest level at 28 mg/kg in fat) in extractable fractions. The metabolite M320I04 was found at low levels (1.5% TRR, 0.042 mg/kg) in extracts of egg and excreta (B-label). Additionally, considerable amounts of the hydroxylated metabolite M320I27 were detected in excreta. The metabolites M320I25 and M320I26 were identified in liver.

Furthermore, the non-extracted residues of liver could be converted into the detectable hydrolysis products M320I28 for T-label and M320I04 for B-label after mixing with acetonitrile and acetic acid and treated by micro-wave for 30 minutes at 150 °C.

The active substance was metabolized in hens via two routes: the cleavage of the molecule at the imine-bridge resulted in the formation of M320I04, which was further converted to M320I25 and M320I26. The hydroxylation of the parent compound at the 3-trifluoro-methylphenyl moiety resulted in the formation of the metabolite M320I27. In edible portions of poultry the parent compound is the main residue.

In summary, the metabolic pathways in rats, goats and poultry were generally similar. Metaflumizone is metabolized in livestock via the following reactions:

- hydroxylation at the 3-trifluoromethylphenyl ring forming M320I27
- hydroxylation at the trifluoromethoxyaniline ring forming M320I22 followed by conjugation to glucuronic acid to form M320I24
- hydroxylation of metaflumizone at the benzyl position to form M320I07 followed by oxidation and ring formation yielding M320I23
- cleavage at the imine bridge, resulting in the formation of M320I04 and a metabolite containing the trifluoromethoxyaniline moiety
- cleavage of M320I04 to form M320I06 which is conjugated with glycine to form M320I13; and/or reduction of M320I04 to form M320I25 which is conjugated with glucuronic acid to form M320I10 or conjugated with glutamic acid to form M320I26.

In edible portions the parent compound is the main residue.

Plant metabolism

Plant metabolism studies were performed on white cabbage (sampling at 0, 3 and 7 days PHI), tomato (sampling at 0 and 7 days PHI) and cotton (sampling at 21 days PHI) using the benzonitrile- and trifluoromethoxyphenyl-U-[^{14}C]labelled metaflumizone (B- and T-label). The cabbage study was conducted at 4 × 0.28 kg ai/ha. The rates of application for the cotton and the tomato study (under both field and glasshouse conditions) were 6 × 0.34 kg ai/ha.

In cabbage, TRR were 11.7, 11.2, and 10.0 mg/kg in cabbage leaves harvested 0, 3, and 7 days, respectively, following application of B-label metaflumizone, and 12.4, 11.8, and 11.3 mg/kg in cabbage leaves harvested 0, 3, and 7 days, respectively, following application of T-label metaflumizone. The E- and Z-isomers of metaflumizone were the major identified residues in both B- and T-label cabbage. The E-isomer constituted 60–81% TRR and the Z-isomer 6–18% TRR at 3 or 7 days PHI. The E:Z isomer ratio decreased from the 3 to the 7 day sampling interval. Metabolite M320I04 was also a significant residue identified in B-label cabbage (up to 16% TRR, 2.1 mg/kg). Two additional metabolites, M320I07 and M320I23, were identified as minor residues in cabbage (both labels, maximum of 3.2% TRR).

In tomatoes, TRR were found at up to 0.6 mg/kg for the field (0 day PHI) and 0.78 mg/kg for the glasshouse (0 day PHI). At day 7, residues up to 0.52 mg/kg were found. In field-grown tomatoes, the E- and Z-isomers of metaflumizone were the major identified residues in tomatoes from both labels and both sampling intervals.

In field grown B-label tomatoes, the E- and Z-isomers of metaflumizone, respectively, accounted for 29% TRR (0.17 mg/kg) and 34% TRR (0.20 mg/kg) in the 0 day PHI samples, and in samples from a 7 day PHI 25% TRR (0.083 mg/kg) and 35% TRR (0.12 mg/kg). In T-label tomatoes, the E- and Z-isomers, respectively, accounted for 35% TRR (0.14 mg/kg) and 44% TRR (0.18 mg/kg) from 0 days PHI samples, and 32% TRR (0.096 mg/kg) and 49% TRR (0.15 mg/kg) from 7 day PHI samples. Metabolite M320I04 was also a residue in B-label tomatoes at 12% TRR (0.04–0.08 mg/kg). Two additional metabolites were identified: M320I23 at 2.7–3.6% TRR (0.01–0.02 mg/kg) in B- and T-label samples, and M320I06 at < 1% TRR (0.003–0.004 mg/kg) in B-label samples.

The E- and Z-isomers of metaflumizone were also the major identified residues in tomatoes grown under protected cropping conditions (green-house) from both labels and both sampling intervals. In B-label tomatoes, the E- and Z-isomers, respectively, accounted for 44% TRR (0.35 mg/kg) and 29% TRR (0.22 mg/kg) in samples from a 0 day PHI, and 32% TRR (0.17 mg/kg) and 40% TRR (0.21mg/kg) in 7 day PHI samples. In T-label tomatoes, the E- and Z-isomers, respectively, accounted for 47%TRR (0.18 mg/kg) and 37% TRR (0.14 mg/kg) in samples from the 0 day PHI, and 38% TRR (0.11 mg/kg) and 45% TRR (0.13 mg/kg) from the 7 day PHI. Metabolite M320I04 was also a residue in B-label tomatoes at 11.5–15.7% TRR (0.06–0.12 mg/kg). Two

additional metabolites were identified: M320I23 at 1–3% TRR (0.007–0.011 mg/kg) in B- and T-label samples, and M320I06 at < 1% TRR (0.003–0.005 mg/kg) in B-label samples.

In cotton seed, TRR were up to 0.37 mg/kg of which 56–64% of them were identified. The E- and Z-isomers of metaflumizone and metabolite M320I04 were the major identified residues, with the E- and Z-isomers accounting for 16.8% TRR (0.063 mg/kg) and 16.9% TRR (0.063 mg/kg), respectively, in B-label cotton seed, and 20.8% TRR (0.029 mg/kg) and 25.6% TRR (0.036 mg/kg), respectively, in T-label cotton seed; metabolite M320I04 was identified at 16.6% TRR (0.059 mg/kg) in B-label cotton seed. Three additional metabolites were identified in cotton seed: M320I23 at 7.1% TRR (0.026 mg/kg) and 8.4% TRR (0.011 mg/kg) in B- and T-label cotton seed, M320I06 at 6.4% TRR (0.024 mg/kg) in B-label cotton seed, and M320I05 at 1.5% TRR (0.002 mg/kg) in T-label cotton seed.

Total radioactive residues were up to 29 mg/kg in cotton gin by-products. The E- and Z-isomers of metaflumizone were the major identified residues, accounting for 19% TRR (5.58 mg/kg) and 29% TRR (8.50 mg/kg), respectively, in B-label gin by-products, and for 26% TRR (4.97 mg/kg) and 38.9% TRR (7.49 mg/kg), respectively, in T-label gin by-products. Three additional metabolites were identified in cotton gin by-products: M320I23 at 6.4% TRR (1.9 mg/kg) and 8.3% TRR (1.6 mg/kg) in B- and T-label samples, and M320I04 and M320I06 at 13.1% TRR (3.83 mg/kg) and 7.2% TRR (2.11 mg/kg) in B-label samples.

In the plant metabolism studies on cabbage, tomato and cotton, the same metabolic pathway was observed. In all plant metabolism studies the parent compound metaflumizone was identified as the most prominent component (E- and Z-isomers; 34–98% TRR; E:Z ratio of about 1:1 to 12:1). The major degradation product is M320I04, accounting for 12–17% of TRR. The cyclic derivative M320I23, arising from M320I07 by ring closure, was detected in concentrations < 10% of TRR in all three plant metabolism studies. M320I07 was only found at low leves in cabbage samples (2–3% of TRR). Metabolite M320I05 also formed by cleavage of the parent compound was only found in cotton seed and in low amounts, accounting for 1.5% of TRR. Metabolite M320I06 is formed by cleavage of M320I04. This metabolite accounted for 7% of the TRR in cotton seed and < 1% in tomato samples. Based on these data, it appears that metaflumizone is metabolized in plants via the following reactions:

- isomerisation of the metaflumizone E-isomer to the Z-isomer,
- cleavage of the parent molecule to form M320I04,
- ring closure to form metabolite M320I23,
- cleavage of M320I23 to form M320I05
- cleavage of M320I23 and/or M320I04 to form M320I06.

Environmental fate in soil

Aerobic degradation

Two studies were carried out to investigate the degradation of metaflumizone under aerobic conditions. In the first study benzonitrile- and trifluoromethoxyphenyl-U-[^{14}C]labelled metaflumizone (B- and T-label) was used. Metaflumizone degraded and mineralized in soil with a DT_{50} of 186–209 days. CO_2 (8–29% of total applied radioactivity) and non extracted residues (21–38% of total applied radioactivity) were the major degradation products. Several metabolites were observed, but only metabolite M320I23 exceeded 5% of total applied radioactivity, showing maximum amounts of 7–8% of total applied radioactivity during the incubation period.

In the second study the [^{14}C]trifluoromethylphenyl-labelled compound was used to get information on the fate of the third ring system of the metaflumizone molecule. The results show that the parent is slowly degraded in soil with half-lives of 202, 328, and 423 days for the three tested soils, respectively. In all three soils numerous minor metabolites appeared during the course to the study. However, all metabolites detected were formed only in very small amounts and none exceeded 3.8% of the applied radioactivity. The mineralization rate reached 2–15% of the applied radioactivity after 122 days of incubation, whereas the non-extracted residues amounted to 6–13% of the applied radioactivity at the end of the study.

The degradation of metaflumizone in soil is characterized by a breakdown of the molecule leading to several intermediate products representing the various aromatic ring moieties of the parent compound. In all tested soils, in principle the same routes of degradation are followed. Metaflumizone can be oxidized at the benzyl group between the trifluoromethylphenyl ring and the benzonitrile ring (M320I07), which further leads to the cyclic product (M320I23). Metaflumizone can also split up into two moieties, one representing the trifluoromethoxyphenyl ring (M320I08 or M320I05), the other one still consisting of benzonitrile and trifluoromethylphenyl ring (M320I09 or M320I04). The two aromatic rings in metabolites M320I09 and M320I04 can be split up forming the single ring structures M320I29 (trifluoromethyl benzoic acid) and M320I06 (cyano benzoic acid). All intermediates are further degradable to finally form CO_2 and non-extracted residues.

Rotational crops

A field-based rotational crop study was not conducted. Two confined rotational crop metabolism studies were undertaken to consider the uptake of residues in rotational crops. Both studies were conducted using B- and T-label [^{14}C]metaflumizone applied to bare soil. The first study involved considering a range of replanting intervals, where rotational lettuce, radish, and spring wheat were planted 30, 60/62, 120, and 365 days after treatment. The application rate of the first study was 2 × 0.56 kg ai/ha/application (20 days between applications). The second study involved a 30 days replant interval only, and a single application of 1.2 kg ai/ha, and again lettuce, radish and spring wheat were planted.

For all plant back intervals (PBI) of the first study, the residue levels in lettuce leaf were very low and remained at the same level (≤ 0.01 mg/kg). The concentration of TRR in radish leaves and roots were only slightly higher (max. 0.036 mg/kg) than in lettuce and declined with subsequent plant back periods. In the wheat matrices hay and grain the initial TRR values were clearly higher, with highest values in wheat hay of 0.67 mg/kg and in grain of 0.17 mg/kg, but they also declined with longer PBI. In wheat straw, the initial TRR (0.11–0.14 mg/kg) were higher than in lettuce, radish and wheat forage at a PBI of 30 days. The TRR in straw increased in the 60 day PBI (0.24–0.27 mg/kg) and declined again in the samples at 120 (0.11–0.12 mg/kg) and 365 PBI (0.04–0.05 mg/kg).There were no major differences in radioactivity levels between the two labels.

In the second rotational crop metabolism study, TRR were comparable in both labels, with the exception of wheat straw and grain, where the B-label showed higher residues. The TRR in lettuce leaf were low (0.02 mg/kg) and had a range similar to radish roots (0.01 mg/kg), but were slightly higher in radish leaves (0.04 mg/kg). In wheat matrices, residues were generally higher than in other matrices with highest values in wheat hay (0.8 mg/kg). In grain and straw, TRR of 0.04 and 0.1 mg/kg were found. The extractability of the different matrices (with the exception of grain) had a range of 54–95% TRR. In grain samples only 11–15% of TRR was extractable.

In the second study, HPLC analysis of the methanol extracts showed that the unchanged parent compound was present in all matrices (with the exception of wheat grain) as a minor component of the radioactive residue with levels of < 0.001–0.015 mg/kg. In radish roots and wheat grain, the radioactivity was mainly in the polar region. In all other matrices, the metabolite patterns of the methanol extracts were quantitatively comparable. The radioactivity was divided into a range of peaks, mainly in the polar and medium polar fraction. M320I04 and M320I06 could be identified as minor components in the radioactive residues. HPLC analysis of all other extractable radioactive

residues showed that these split up in a variety of polar and medium polar peaks that can all be considered as minor. Bound residues that could be released by treatments with aqueous ammonia solution, NaOH and different enzymes also split up in various fractions with TRR at a maximum level of 0.014 mg/kg.

The data submitted on rotational crop metabolism suggest there are no residues of significance that are expected to arise in crops planted in the rotation following primary crop use of metaflumizone according to GAP. Besides the parent, two other metabolites, M320I04 and M320I06, could be detected in low levels (< 5% TRR).

Environmental fate in water-sediment systems

Hydrolysis

In the hydrolysis study with [^{14}C]metaflumizone conducted using sterile buffer solutions at 25 °C, the hydrolytic half-lives were found to be about 6 days at pH 4 and about 27–31 days at pH 5. No degradation of metaflumizone occurred in the pH 7 and pH 9 buffer solutions. At pH 4 and pH 5, the hydrolysis products M320I04 and M320I08 were identified, reaching maximum amounts of up to 90% and 68% TAR, respectively. A number of minor unidentified components were also detected (individually mostly < 5%).

Photolysis

The results showed that metaflumizone is extensively degraded in water under photolytic conditions. A DT_{50} value of 2–3 days of continuous irradiation was calculated. Isomerisation of the metaflumizone E-isomer to the Z-isomer occurred. There were several major and minor photoproducts appearing in the water phase identified as M320I04, M320I06, M320I09, and M320I08, representing the different ring moieties of the parent after cleavage of the molecule. One degradation product, M320I05, proved to be volatile and was trapped in the ethylene glycol trapping solution. Additionally, numerous minor non-identified photoproducts (n > 50) were formed. With both B- and T-label it was shown that even under sterile conditions, metaflumizone was completely degraded forming finally CO_2.

Methods of analysis

Metaflumizone and its metabolites M320I04 and M320I23 are extracted from the following plant matrices; white cabbage, tomato, cotton seed, lettuce, potato tuber, lemon, gin trash, wheat grain and potato crisps using a mixture of methanol and water. For clean-up a liquid/liquid partition against dichloromethane was used. The final determination of metaflumizone, M320I04 and M320I23 was performed by HPLC-MS/MS. For cotton seed no clean-up was done.

The LC-MS/MS method of analysis for a range of plant products was acceptably validated as method 531/0 over the concentration range of 0.01 to 0.1 mg/kg. Independent laboratory validation (ILV) data were available as method 531/1 and the individual recoveries were all within a good range.

The LC-MS/MS method of analysis of metaflumizone (E- and Z-isomer) for animal products as muscle (bovine, hen), liver (bovine, hen), kidney (bovine) and fat (bovine) together with intra-laboratory validation was acceptably validated as method 528/0 over the concentration range 0.01 to 0.20 mg/kg. The methods for the determination of metaflumizone (E- and Z-isomer) in bovine milk and hen eggs were validated over the concentration range 0.005 to 0.10 mg/kg.

In general, for residues methods of analyses in plants and animal products, the following criteria were fulfilled:

- adequate limit of quantification

- mean recovery 70–110%
- relative standard deviation of recovery rates < 20%
- interfering blanks lower than 30% of the limit of quantification

The GC-MS multiresidue method DFG method S19 was tested for both the E- and the Z-isomer and was found not to be applicable to the analysis of metaflumizone.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of residues in extracts available from metabolism studies, in fortified samples and incurred residues.

Extracts available from metabolism studies in lactating goats, laying hens, white cabbage and tomatoes were used to estimate the stability of [^{14}C]metaflumizone residues in stored analytical samples. It was shown, that the chromatographic pattern of the stored extract was comparable with the pattern of the first extract. It can be concluded that residues are stable in methanol extracts of animal matrices (eggs, milk, liver, kidney, muscle and fat) and in plant matrices (methanol extracts of white cabbage, acetonitrile extracts of tomato) for at least 18 and 12 months, respectively.

The Meeting received information on the stability of metaflumizone E- and Z-isomer, M320I04 and M320I23 in fortification experiments on tomato, cotton seed, potato, white cabbage and lettuce at –20 °C in the dark.

Both isomers of the parent were stable for up to two years in potato tuber, white cabbage and lettuce. Storage stability for one year was demonstrated for the metaflumizone E-isomer in tomato and the E- and Z-isomer in cotton seed. The metaflumizone Z-isomer was unstable in tomatoes stored for greater than 28 days.

For the metabolite M320I04, freezer storage stability was adequately demonstrated in tomato and cotton seed but not in potato, white cabbage and lettuce. The calculation of the 70% stability for potato, white cabbage and lettuce gave results of 23, 15 and 2 days respectively.

For the metabolite M320I23, freezer storage stability was adequately demonstrated in tomato, cotton seed, potato, white cabbage and lettuce for one year.

Incurred residues of the E-isomer of metaflumizone were stable at –20 °C in the dark in tomatoes, cabbage, broccoli, lettuce, celery and mustard greens for at least one year. The metaflumizone Z-isomer was stable in cabbage, broccoli, lettuce, celery and mustard greens for at least 290 days. In tomatoes there was a loss of the parent Z-isomer, but an increase in concentration of M320I04 was noted, indicating a possible degradation of parent to M320I04.

Definition of the residue

Plants

The main residues found in the crop metabolism studies are the E- and Z-isomers of metaflumizone. In tomatoes, the metabolite M320I04 constituted up to 16%TRR in the fruit. This metabolite was also found in cotton seed and cabbage at up to 17% of TRR. Other metabolites were found in lower amounts, e.g., M320I23 was found at up to 8% TRR in the cotton study, up to 4% TRR in tomatoes, and up to 1% TRR in cabbage.

In metabolism studies and residues trials, where positive residues were found, evidence of isomerisation from the E- to the Z-isomer was shown. As a consequence both isomers should be included into the residue definition.

The metabolite M320I23 was not identified in the rat metabolism study done with metaflumizone. A separate toxicity study of metabolite M320I23 shows that it is of lower toxicity than the parent. Residues of M320I23 were consistently absent in supervised residue trials but were found in the outer leaves of cabbage at 0.02 to 0.06 mg/kg. This was about 0.5% of the applied concentration of metaflumizone. Because of its general absence, it was concluded that this component does not need to be accommodated in the residue definition.

The metabolite M320I04 was identified in the rat metabolism study done with metaflumizone and its toxicity is covered by the derived ADI. Storage stability studies with incurred metaflumizone residues indicate that the concentration of M320I04 may increase during freezer storage, but the concentrations were at low levels. M320I04 was not detected in most of the supervised residue trials. However, in processing studies on tomatoes it was found in juice, purée, paste and wet pomace in equal or higher concentrations than the parent. Based on the very low or non-detectable residues of M320I04 in samples of supervised residue trials, this component does not need to be taken into account in the residue definition for enforcement and dietary risk assessment. However, the Meeting was aware, that the metabolite M320I04 may arise in processed products from acidic raw agricultural commodities in concentrations that may be of interest for dietary intake estimation. This should be taken into account for future uses.

Animals

The main residues found in the farm animal metabolism studies are the E- and Z-isomers of metaflumizone. Both isomers should be included into the residue definition.

The component that was identified in liver hydrolysates in the highest amount was M320I28 at 9% TRR (0.11 mg/kg) for goat and 18% TRR (0.66 mg/kg) for hen. As this component was only built under strong hydrolysis its inclusion in the residue definition was considered unnecessary.

The octanol/water coefficient (log P_{ow}) of 4.4 for the Z-isomer and 5.1 for the E-isomer, and the distribution of residues between muscle and fat in metabolism studies indicate that the residue is fat soluble.

The Meeting recommended the following residue definition:

Definition of the residue for compliance with MRLs and estimation of dietary intake for plants and animals: *Metaflumizone, sum of E-isomer and Z-isomer*.

The residue is fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trials data for the foliar application of metaflumizone as a suspension concentrate formulation (SC) to a variety of fruit, and vegetable crops. The Meeting also received supervised trials data for the application of a granular bait (GB) formulation to the soil of citrus orchards, grape vineyards, and tree nut orchards.

The NAFTA calculator was used as a tool in the estimation of maximum residue levels from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Citrus

Trials from the USA on grapefruit, lemons, and oranges were reported for soil treatment using a granular formulation to control fire ants. However, the GAP/label had not been approved by the national authority as of the time of the current Meeting. As there was no GAP provided to support the trials, the Meeting could not estimate a maximum residue level for citrus.

Berries and othersmall fruits

Trials from the USA on grapes were reported for the application to the soil of a granular formulation. However, the GAP/label had not been approved by the national authority as at the time of the current Meeting. As there was no approved GAP provided to support the trials, the Meeting could not estimate a maximum residue level for berries and other small fruits.

Brassica vegetables

Trials for the foliar application of an SC formulation of metaflumizone to head cabbage were reported for the USA, Japan, Germany, Denmark, Spain, France, United Kingdom, Greece, Sweden, and China. The proposed GAP has been withdrawn in the USA.

No label was presented for Japan, and the trials are evaluated against the GAP of Taiwan (3 × 0.029 kg as/hL, SC, 9 day PHI). The ranked order of residues from the Japan trials (n=4) were: 0.19, 0.20, 0.21, 0.25 mg/kg.

The GAP was made available for use on cabbage for Italy (2 × 0.24 kg ai/ha or 2 × 0.024 kg as/hL, SC, 3 day PHI) and Macedonia (4 × 0.24 kg ai/ha or 4× 0.06 kg as/hL, SC, PHI not specified). Using the GAP of Italy, the ranked order of residues in the southern European trials (n=4) were: < 0.02 (2), 0.05, 0.06 mg/kg. The ranked order of residues in the northern European trials (n=8) were: < 0.02 (2), 0.04, 0.06, 0.08, 0.15, 0.39, 0.48 mg/kg. The trials from the North and the South do not appear to be from the same populations and should not be combined. Four trial results (from the South and under the GAP of Italy) were not considered sufficient to estimate a maximum residue level for cabbage.

The GAP for use on cabbage in China is 3 × 0.29 kg ai/ha or 3 × 0.048 kg as/hL, SC, 3 day PHI. The residue values in ranked order (n=4) were: 4.5, 4.7, 4.9, 5.5 mg/kg. Four trial results were not considered sufficient to estimate a maximum residue level for cabbage.

Trials were reported from the USA for the foliar application of an SC formulation to broccoli. However, the proposed GAP/label has been withdrawn in the USA. Trials were also presented from Belgium, United Kingdom, France, Germany, Italy, and Spain. No label/GAP was available for a European country.

Trials were reported from Taiwan for Chinese Broccoli. The ranked order of trial results for trials conducted according to the maximum GAP of Taiwan, China (3 × 0.20 kg as/hL, SC, 9 day PHI) is: 1.2, 1.3 mg/kg. The Meeting considered two trials insufficient for the estimation of a maximum residue level and STMR.

Trials were reported for Brussels sprouts from Germany, Spain, France, Sweden, Italy, the United Kingdom, and the Netherlands. A label was available for Italy (2 × 0.24 kg ai/ha, SC, 3 day PHI). Four trials were conducted in the southern Europe (0.10, 0.12, 0.35, 0.39) mg/kg), and eight trials were conducted in the northern Europe (0.07 (2), 0.10, 0.11, 0.13, 0.16, 0.22, 0.60 mg//kg). The data sets are not from different populations and could be combined for evaluation against the GAP of Italy. The residue values (n=12) in ranked order were: 0.07 (2), 0.10 (2), 0.11, 0.12, 0.13, 0.16, 0.22, 0.35, 0.39, 0.60 mg/kg.

The Meeting estimated an STMR of 0.125 mg/kg. The Meeting estimated a maximum residue level of 0.8 mg/kg. The maximum residue level estimate derived from use of the NAFTA calculator was 0.76 mg/kg. The normal JMPR procedure is to use one significant figure for maximum residue

levels below 10 mg/kg. With rounding the value derived from use of the calculator corresponded to the Meeting's recommendation, i.e., 0.8 mg/kg rounded.

Fruiting vegetables, Cucurbits

Melon field trials were reported from Greece and Spain. No label/GAP is available for melons or cucurbits. As there was no GAP provided to support the trials, the Meeting could not estimate a maximum residue level for melons.

Fruiting vegetables other than Cucurbits

Chilli pepper field trials were reported from South Korea and the USA. However, the proposed label in the USA has been withdrawn. The ranked order of trials from South Korea that approximate the maximum GAP of South Korea (3 × 0.016 kg as/hL, SC, 2 day PHI) was: 0.10 and 0.12 mg/kg. The Meeting noted that two trials were insufficient to estimate a maximum residue level, HR, and STMR.

Field trial studies for peppers (bell or sweet) were reported from the USA. However, the proposed label in the USA was withdrawn.

Glasshouse trial studies on peppers were reported from Germany, the Netherlands, France, Italy, Spain, and Greece. Relevant labels were available for Germany, Italy, and Austria. The labels specify 2 × 0.024 kg as/hL, 3 day PHI in Germany and Italy, 1 day PHI in Austria. Residue data for a 1 day PHI were not supplied. The GAPs of Germany and Italy were utilized, and the residue values in ranked order (n=15) were: 0.10 (2), 0.16, 0.18 (5), 0.24 (2), 0.30, 0.34 (2), 0.35 (2) mg/kg.

The Meeting estimated a STMR of 0.18 mg/kg. The Meeting estimated a maximum residue level of 0.6 mg/kg. The maximum residue level estimate derived from use of the NAFTA calculator was 0.56 mg/kg. The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. With rounding, the value derived from use of the calculator corresponded to the Meeting's recommendation, i.e., 0.6 mg/kg rounded.

Tomato field trial studies were reported from the USA. However, the proposed label in the USA has been withdrawn.

Tomato field trial studies were reported from Spain and Italy. The GAP/label of Italy specifies 2 × 0.24 kg ai/ha, SC, and a 3 day PHI. The ranked order of trial results (n=10) were: 0.03 (4), 0.04 (2), 0.07, 0.10 (2), 0.14 mg/kg.

Tomato glasshouse studies were reported from Germany, the Netherlands, Spain, France, Italy, and Greece. Labels for use in glasshouses were available from Austria, Germany, and Italy. All specify 2 × 0.24 kg ai/ha. There is a 1 day PHI in Austria and a 3 day PHI in Germany and Italy. Residue data were not available for a 1 day PHI. The labels for Germany and Italy were utilized to arrive at the ranked order of residue values (n=10) of: < 0.02, 0.08, 0.09, 0.10, 0.11, 0.13 (2), 0.17, 0.25, 0.36 mg/kg. The Meeting noted that the tomatoes from glasshouses generated a higher residue value set than those from field trials in Europe.

Using the glasshouse trials from Europe, the Meeting estimated an STMR of 0.18 mg/kg. Noting the similarity of the residue populations for peppers and tomatoes, the Meeting estimated a maximum residue level of 0.6 mg/kg was appropriate for tomatoes.

The maximum residue level estimate derived from use of the NAFTA calculator was 0.69 mg/kg. The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. With rounding the value derived from use of the calculator was 0.7 mg/kg rounded. The Meeting noted the similarity of the tomato and pepper data sets and the 0.6 mg/kg estimate for peppers was selected for tomatoes

The Meeting agreed to use the tomato and pepper data as support for egg plant (aubergine) and estimated a STMR and a maximum residue level of 0.18, and 0.6 mg/kg, respectively, for egg plant.

Using the default dehydration factor of 10, the meeting estimated an STMR of 1.8 and a maximum residue level of 6 mg/kg for dried chilli peppers.

Leafy vegetables

Chinese cabbage field trials were reported from Japan, South Korea, and Taiwan, China. No label was available for Japan, and the Japanese trials were evaluated against the label of Taiwan (3 × 0.029 kg as/hL, SC, 18 day PHI). Results in ranked order are: < 0.10 (2), 0.76, 0.77 mg/kg. Two trials from Taiwan match the Taiwan label: 1.4, 1.6 mg/kg. One trial from South Koreas matches the South Korea label (2 × 0.016 kg as/hL, 7 day PHI): 2.1 mg/kg. The trials matching Taiwan GAP were combined: < 0.10 (2), 0.76, 0.77, 1.4, 1.6 mg/kg. The Meeting utilized the trials from Japan and Taiwan to estimate an STMR of 0.765. The Meeting estimated a maximum residue level of 6 mg/kg appropriate.

The maximum residue level estimate derived from use of the NAFTA calculator was 5.97 mg/kg. With rounding the value derived from use of the calculator corresponded to the Meeting's recommendation, i.e., 6 mg/kg.

Field trial studies were reported from the USA for lettuce, spinach, and mustard greens. However, the proposed labels in the USA had been withdrawn.

Trials for head lettuce were reported from the Netherlands, Spain, Germany, France, Greece, Denmark, and Italy. A label was available for Italy (3 × 0.24 kg ai/ha, SC, 3 day PHI). The residue values in ranked order (n=8) for the trials from southern Europe were: 0.76, 1.8, 2.7, 2.8, 3.0 (2), 3.6, 5.0 mg/kg. The residue values in ranked order (n=8) for trials from northern Europe were: 1.0, 1.2, 1.4, 1.5, 1.7, 2.0 (3). The Meeting agreed that the data from the northern and southern European trials appear to be from similar populations and could be combined (n=16): 0.76, 1.0, 1.2, 1.4, 1.5, 1.7, 1.8, 2.0 (3), 2.7, 2.8, 3.0 (2), 3.6, 5.0 mg/kg.

Trials for head lettuce grown in glasshouses were reported from Germany, France, the Netherlands, Italy, Greece and Spain. However, the only available approved label, from Italy, specified field use only.

The Meeting estimated an STMR of 2.0 mg/kg for head lettuce based on the field trials in Europe. The Meeting estimated a maximum residue level of 7 mg/kg. The maximum residue level estimate derived from use of the NAFTA calculator was 6.24 mg/kg. With rounding the value derived from use of the calculator was 7 mg/kg.

Legume vegetables

The Meeting received a field trial study report for soya beans from Taiwan, China. However, only two trials were reported (0.30, 0.45 mg/kg) conducted at the maximum GAP of Taiwan (0.033 kg as/hL, 15 day PHI). The Meeting considered two trials an insufficient number for the estimation of a maximum residue level, HR, and STMR.

Root and tuber vegetables

Potato field trial studies were reported from the USA. However, the pending label has been withdrawn.

Potato field trial studies were reported from the United Kingdom, the Netherlands, Spain, Germany, France and Italy. Relevant labels were provided for Austria, Croatia, Germany, Hungary, Italy, Macedonia, Romania and Serbia. The application rate is 0.06 kg ai/ha (except in Macedonia at 0.072 kg ai/ha) and 2 treatments (except 3 in Italy and 4 in Macedonia), and a PHI of 14 days (except

3 days in Romania and not specified in Hungary and Germany). Using the GAP of Italy, the residue values in ranked order were: < 0.02 (11) mg/kg. One trial conducted at an exaggerated rate (3 × 1 kg ai/ha) also yielded < 0.02 mg/kg. It was also noted that in thirty-three trials conducted in the USA at 4 × 0.3 kg ai/ha, PHI 7 days, all residue values were < 0.02 mg/kg. Samples from four of these trials were < 0.02 mg/kg at a 1 day PHI. Four trials were conducted in the USA at a total seasonal rate of 5.8 kg ai/ha (4 × 1.45 kg ai/ha). Two of the trials revealed the E and/or Z isomer at 0.01 mg/kg each.

The Meeting estimated an STMR of 0 and a maximum residue level of 0.02(*) mg/kg for potato.

The use of the NAFTA statistical calculation spreadsheet was not considered applicable as all data points were below the LOQ.

Stalk and stem vegetables

A report on celery field trials was received from the USA. However, the proposed label in the USA has been withdrawn. As there was no GAP provided to support the trials, the Meeting could not estimate a maximum residue level for celery.

Tree nuts

A report on almond and pecan field trials was received from the USA, for the application of a granular formulation to the soil. However, the label is pending in the USA at the time of this Meeting. As there was no approved GAP available to support the trials, the Meeting could not estimate a maximum residue level for tree nuts.

Cotton seed

Study report on cotton field trials in the USA, Spain and Greece were available. However, the relevant pending label in the USA has been withdrawn and no additional approved labels were made available. As there was no GAP information available to support the trials, the Meeting could not estimate a maximum residue level for cotton seed.

Fate of residues during processing

A nature of the residue under simulated processing conditions study was received. Hydrolyses of benzonitrile ring-U-[^{14}C]metaflumizone and trifluromethoxyphenyl ring-U-[^{14}C]metaflumizone were conducted at 90 °C in pH 4 aqueous buffer for 20 minutes (pasteurization simulation), at 100 °C in pH 5 aqueous buffer for 60 minutes (baking, brewing, boiling simulation), and at 120 °C in pH 6 aqueous buffer for 20 minutes (sterilization simulation). Metaflumizone was not stable at pH 4 and pH 5 (90 °C–100 °C). Metaflumizone loss was as much as 40%. The hydrolysis products were M320I04 and M320I08.

Processing studies were provided for tomato, cabbage, lettuce, potato, and cotton seed. The potato processing studies could not be used to derive processing factors, as the RAC contained no residues above LOQ and all processed fraction residues were below the LOQ.

The processing factors and the derived STMR-P and HR-P values relevant to proposed maximum residue levels are summarized as follows:

RAC	Processed Commodity	Processing Factor [a, b]	RAC maximum residue level	RAC STMR	Processed Commodity STMR-P
Tomato	Juice	< 0.33 < 0.14	0.6	0.125	0.020

RAC	Processed Commodity	Processing Factor [a, b]	RAC maximum residue level	RAC STMR	Processed Commodity STMR-P
		< 0.19			
		< 0.046			
		Median			
		0.16			
	Wet pomace	1.5	0.6	0.125	0.25
		2.4			
		3.1			
		1.1			
		Median			
		2.0			
	Puree	0.48	0.6	0.125	0.040
		0.20			
		0.42			
		0.23			
		Median			
		0.32			
	Paste	1.5	0.6	0.125	0.10
		0.80			
		0.89			
		0.54			
		Median			
		0.84			
	Canned	< 0.33	0.6	0.125	0.020
		< 0.14			
		< 0.19			
		< 0.046			
		Median			
		0.16			

[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 metaflumizone (E isomer + Z isomer).

[b] Processing studies were conducted for potatoes. However, RAC samples were at or below the LOQ (0.04 mg/kg), and no residues were found in any processed commodity (< 0.04 mg/kg).

Residues in animal commodities

The Meeting received reports of lactating cow and laying hen feeding studies.

Laying hens

Hens were dosed orally for 55 days at levels of 0.1, 0.3, and 1 ppm based on feed consumption. Residues reached a plateau in eggs between day 21 and day 25. For the 0.1 ppm feeding regime, total residues of metaflumizone in eggs, muscle, liver, and fat at day 55 were 0.038–0.061 mg/kg, < 0.02–0.021 mg/kg, 0.029–0.033 mg/kg, and 0.30–0.34 mg/kg, respectively. Residue levels were approximately linear with dose.

Lactating dairy cattle

Holstein cows were dosed orally for 45 days at levels of 0.2, 1.0, 5.5, and 16.2 ppm in the feed. Total metaflumizone residues were below the LOQ (< 0.01) in whole milk at the 0.2 and 1.0 ppm feeding levels. Cream (Day 40) from the 1.0 ppm level contained 0.047–0.052 mg/kg metaflumizone (E + Z).

At the 5.5 ppm feeding level, metaflumizone in milk reached a plateau of 0.02–0.03 mg/kg between day 21 and day 25. Liver, kidney, and muscle contained no residue (< 0.02 mg/kg) at the 0.2, 1.0, and 5.5 ppm levels; fat contained residue at the LOQ (0.02 mg/kg) at the 1.0 ppm level. At the 5.5 ppm feeding level, residues were 0.12–0.18 mg/kg in fat.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculation results for beef cattle and dairy cattle are provided below. The calculations are in Annex 6 and 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).

There are no potential poultry feed items. Potential cattle feed items include: potato culls and pulp and waste, and tomato pomace.

Animal dietary burden, metaflumizone total residue, ppm of dry matter diet				
		US-Canada	EU	Australia
Beef cattle	max	0.00	0.00	0.13[a]
	mean	0.00	0.00	0.13[b]
Dairy cattle	max	0.00	0.00	0.13[a]
	mean	0.00	0.00	0.13[b]

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

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat and milk.

Animal commodity maximum residue levels

Cattle

In the table below, 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]	Cream	Milk	Muscle	Liver	Kidney	Fat
MRL	Mean	Mean	Highest	Highest	Highest	Highest
MRL beef cattle (0.13) [0.2]			0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]
MRL dairy cattle (0.13) [0.2]	0.0065 [< 0.01]	0.0065 [< 0.01]	0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]
STMR	Mean	Mean	Mean	Mean	Mean	Mean
STMR beef cattle (0.13) [0.2]			0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]
STMR dairy Cattle (0.13) [0.2]	0.0065 [< 0.01]	0.0065 [< 0.01]	0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]	0.013 [< 0.02]

The data from the lactating dairy cow feeding study was used to support mammalian (except marine) milk and meat maximum residue levels.

The Meeting estimated the following STMR values: milk 0.007; milk fat 0.013; muscle 0.013; edible offal 0.013; fat 0.013 mg/kg. Cream was assumed to contain 50% fat.

The Meeting estimated the following maximum residue levels for mammalian commodities (except marine): milk 0.01(*); milk fat 0.02; meat (fat) 0.02(*); edible offal 0.02(*).

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes of metaflumizone, based on the STMRs estimated for the 12 commodities, for the 13 GEMS/Food Consumption Cluster Diets, were in the range 0–1% of the maximum ADI of 0.1 mg/kg bw (Annex 3). The Meeting concluded that the long-term intake of residues of metaflumizone from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The 2009 JMPR decided that an ARfD was unnecessary. The Meeting therefore concluded that the short-term intake of metaflumizone residues is unlikely to present a public health concern.

5.17 METHOXYFENOZIDE (209)

RESIDUE AND ANALYTICAL ASPECTS

Methoxyfenozide was evaluated by the JMPR for residues and toxicology in 2003, when an ADI of 0-0.1 mg/kg bw and an ARfD of 0.9 mg/kg bw were established and maximum residue levels, supervised trial median residues and highest residues were recommended for a number of commodities. The residue was defined as methoxyfenozide for compliance with MRLs and for dietary intake estimation in both plant and animal commodities. The residue is fat-soluble, but is not classed as fat-soluble with respect to its distribution in milk.

Additional residue data and information on use patterns as well as residue analytical methods were submitted for evaluation by the present meeting on citrus fruits, small fruits and berries, tropical fruits with inedible peel, cucurbits, legume vegetables, pulses, and root and tuber vegetables.

Methods of Analysis

The fully validated analytical methods used in the supervised trials were based on LC/MS/MS detection. The average recovery values reported at various fortification levels were between 76 and 107%. The LOQ values ranged from 0.01 mg/kg to 0.07mg/kg.

The tests for stability of residues under deep-frozen conditions were performed in oranges, orange processed fractions, peas, radishes, sugar beets, sweet potatoes and peanuts. They indicated that the residues were stable during the deep-frozen storage intervals.

Results of supervised trials on crops

Most of the supervised trials were conducted within the programme of IR-4 in the USA where the maximum total seasonal application rate is 1.12 kg ai/ha. Some trials were from Europe and residue data on soybean was obtained from trials carried out by Dow AgroScience in the USA.

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at the best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculator spreadsheet suggested a different value from that recommended by JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Citrus fruit

Supervised trials were conducted on oranges (2) lemons (2) and grapefruit (2) in California and Texas during the 2005 and 2006 growing seasons that complied with the registered use patterns in the USA (dosage rate 0.134–0.28 kg ai/ha with 4 applications at 14–17 days intervals and PHI of 1 day.) The residues in whole fruits were: grapefruit: 0.12, 0.28 mg/kg; orange: 0.17, 1.7 mg/kg; lemon: 0.41, 0.93 mg/kg.

Nine supervised trials were performed on oranges in Greece, Italy, Portugal and Spain. The use pattern is 0.144–0.192 kg ai/ha with 2 applications at 10-day intervals and PHI of 14 days in Greece, Portugal and Spain. The Italian trials were also evaluated according to the use pattern in the other South European countries. The residues in whole orange were in rank order: 0.06, 0.13, 0.14, 0.16, 0.18, 0.19, 0.21, and 0.34 mg/kg.

Eight residue trials were performed on mandarins in South Europe, which were evaluated according to the GAP in Greece, Portugal and Spain (dosage of 0.144–0.192 kg ai/ha with 2 applications at 10 day interval, PHI of 14 days) taking into account the dosage at the last application. The residues in whole mandarin were in rank order: 0.11, 0.16, 0.21, 0.24, 0.27, 0.30, 0.35 and 0.45 mg/kg.

The Mann-Whitney U-test indicated that residue distributions in orange and mandarin were not significantly different and they can be combined: 0.06, 0.11, 0.13, 0.14, 0.16, 0.16, 0.18, 0.19, 0.21, 0.21, 0.24, 0.27, 0.3, 0.34, 0.35, and 0.45 mg/kg.

In the same trials, the residues in 17 orange and mandarin pulp samples 14 days after the last application were: < 0.05 mg/kg. As the residue data from US trials are not sufficient for estimation of maximum residue levels for citrus fruits, and the US GAP is quite different from that in South Europe, the Meeting estimated the following residue levels in citrus fruits based on the European GAP and residue data: maximum residue level of 0.7 mg/kg, median residue and HR of 0.05 mg/kg. The value derived from use of the NAFTA calculator was 0.7 mg/kg which corresponds to the maximum residue level of 0.7 mg/kg estimated by the current Meeting.

Blueberry

Eight field trials were performed in USA with three foliar applications of the test substance 6–9 days apart at rates ranged from 0.27 to 0.30 kg ai/ha per application (US GAP: dosage rate 0.134–0.28 kg ai/ha with 3 applications at 7 day interval and PHI of 7 days.). Samples were collected 6–7 days after last application. The residues measured in six independent trials were in rank order: 0.54, 0.85, 1.1, 1.4, 1.8, and 2.0 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg, median residue of 1.25 mg/kg, HR of 2 mg/kg. The value derived from use of the NAFTA calculator was 3.5 mg/kg which, after rounding up to one figure, agrees with the maximum residue level of 4 mg/kg estimated by the current Meeting.

Cranberry

The trials evaluated by the 2006 JMPR were submitted again. The results were not evaluated by this meeting.

Strawberry

Eight field trials were conducted in USA with four or five foliar applications at a rate of approximately 0.28 kg ai/ha (1.33 times maximum US GAP: dosage 0.1/0.21 kg/ha at 14 day intervals, PHI of 3 days) amounting to a total seasonal rate of approximately 1.12 kg ai/ha. Samples were collected at 2–4 days after the final application. The residues were: 0.18, 0.20, 0.21, 0.24, 0.43, 0.49 and 1.2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, median residue of 0.24 mg/kg and HR of 1.2 mg/kg. The value derived from use of the NAFTA calculator was 1.7 mg/kg which, after rounding up to one significant figure, was in agreement with the maximum residue level of 2 mg/kg estimated by the current Meeting.

Avocado

Six trials were conducted in the USA with four applications corresponding to maximum US GAP (dosage rate 0.18–0.28 kg ai/ha with five applications at 6 day intervals, PHI of 2 days and total seasonal rate of 1.12 kg ai/ha.).

The residues in five independent trials were 0.06, 0.08, 0.13, 0.16 and 0.41 mg/kg.

The Meeting estimated maximum, HR and median residues of 0.7 mg/kg, 0.41 and 0.13 mg/kg. The value derived from use of the NAFTA calculator was 0.7 mg/kg which was in agreement with the maximum residue level estimated by the current Meeting.

Papaya

Four trials were conducted in the USA at maximum US label rate (GAP: dosage rate 0.21–0.28 kg ai/ha with maximum five applications at 10-day intervals, PHI is 3 days). Samples taken from independent trials 3–4 days after last application contained residues: 0.18, 0.31 and 0.33 mg/kg. The residue in samples taken from a replicate plot was 0.17 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, median residue of 0.31 and high residue of 0.33 mg/kg. The value derived from use of the NAFTA calculator was 0.6 mg/kg. However, the Meeting considered this value too low, as previously evaluated data sets indicate that two times the median value would cover only less than 70% of the residues derived from trials performed with various compounds at maximum GAP in commodities belonging to the Codex commodity group of 'Assorted tropical fruits – inedible peel' (FI).

Fruiting vegetables, Cucurbits

Cantaloupe

Seven trials were conducted in the USA with application rates of 1.55 times maximum US GAP (dosage rate 0.067–0.18 kg/ha, four applications at 7 day intervals, with a PHI of 3 days).

As the application rate did not match the GAP, the Meeting could not estimate a maximum residue level.

Cucumber

Eight trials were conducted in the USA with application rates of 1.55 maximum US GAP (dosage rate 0.067–0.18 kg/ha, four applications at 7 days intervals, PHI 3 days).

As the application rate did not match the GAP, the Meeting could not estimate a maximum residue level.

Squash, Summer

Six trials were conducted in the USA with application rates of 1.55 maximum US GAP (dosage rate 0.067–0.18 kg/ha, four applications at 7 days intervals, PHI 3 days).

As the application rate did not match the GAP, the Meeting could not estimate a maximum residue level.

Legume vegetables

Beans (in pods)

Six field trials were conducted in the USA with maximum US GAP (4 × 0.28 kg ai/ha, 7–14 days apart, PHI 7 days). The samples collected7–8 days after last application contained residues of: < 0.05, < 0.05, < 0.05, 0.079, 0.62 and 0.99 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg, median residue of 0.065 mg/kg and HR of 0.99 mg/kg. The value derived from use of the NAFTA calculator was 0.45 mg/kg. However, it was considered too low as 2 of 6 valid residue values were higher.

Beans and peas succulent shelled

Seven field trials were conducted on beans in the USA with four or five foliar applications corresponding to maximum US GAP (4 × 0.28 kg ai/ha at 7–14 days, PHI of 7 days). The Meeting considered that an early application did not have any influence on the residues in shelled beans and evaluated the residue data together. Two trials were performed at the same site using different varieties. The residues measured in shelled beans after 6–7 days PHI were: < 0.05 (4), 0.052, 0.086 and 0.14 mg/kg.

Eight field trials were conducted on peas according to maximum US GAP (4 × 0.28 kg ai/ha at 7–14 days, PHI of 7 days). Two field trials conducted on the same site were not considered independent and only the highest residue was used for evaluation. The residues found in the independent trial samples were: < 0.05 (3), 0.058, 0.12, 0.14, and 0.18 mg/kg.

The Meeting noted that the residue populations in shelled beans and peas were not significantly different and can be combined: < 0.05 (7), 0.052, 0.058, 0.086, 0.12, 0.14, 0.14 and 0.18 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, median residue of 0.05 mg/kg and HR of 0.18 mg/kg for shelled succulent beans and peas. The value derived from use of the NAFTA calculator was 0.3 mg/kg which was in agreement with the maximum residue level estimated by the present Meeting.

Pulses

Dry beans

Thirteen field trials were conducted in the USA according to maximum US GAP (4 × 0.28 kg ai/ha at 7–14 days, with a PHI of 7 days).

Several trials were conducted at the same site. The residues in independent trials were < 0.05 (9) and 0.22. No explanation as to the cause of the high detectable residue could be found in the trial report.

The Meeting noted that the residue distribution in succulent beans and peas support the residue distribution in dry beans and peas, and estimated a maximum residue level of 0.5 mg/kg, and median residue of 0.05 mg/kg. The NAFTA calculator was not used due to the large proportion of values below the LOQ.

Cowpea (Black eyed pea), dry

Six field trials were conducted in the USA according to maximum US GAP (4 × 0.28 kg ai/ha at 7–14 days, 7 day PHI). After harvest, the peas were dried for up to 11 days and shelled. Two trials were conducted at the same site approximately 20 days apart.

The residues in independent trials were 0.13, 0.17, 0.56, 0.67, and 3.4 mg/kg

The Meeting estimated a maximum residues level of 5 mg/kg, and median residue of 0.56 mg/kg. The value derived from use of the NAFTA calculator was 5 mg/kg which was in agreement with the maximum residue level estimated by the present Meeting.

Soya bean

Sixteen residue trials, including two decline and three bridging studies, were conducted in the USA with 4 applications over double the label rate each with a PHI of 14–15 days instead of the registered 7 days. In addition to the parent compound, the residues of OH-methoxyfenozide and the total sugar conjugates of methoxyfenozide (G-methoxyfenozide) were also determined.

As the trial conditions did not match the US label rate and PHI, the Meeting could not make and estimation or recommendation of a maximum residue level.

Root and tuber vegetables

Carrot

Seven field trials were conducted in the USA according to maximum US GAP (0.28 kg ai/ha, with a 14 day PHI). The residues measured were < 0.05, 0.057, 0.084, 0.13, 0.14, 0.16, and 0.31 mg/kg.

The Meeting estimated a maximum residues level of 0.5 mg/kg, median residue of 0.13 mg/kg and an HR of 0.31 mg/kg. The value derived from use of the NAFTA calculator was 0.5 mg/kg which was in agreement with the maximum residue level estimated by the present Meeting.

Radish

Five field trials were conducted in USA according to maximum US GAP (2 × 0.28 kg ai/ha, at 14 days, with a PHI of 14 days). The residues in radish were: < 0.05, <0.05, 0.08, 0.10 and 0.12 mg/kg

The Meeting estimated a maximum residues level of 0.4 mg/kg, median residue of 0.08 mg/kg and an HR of 0.12 mg/kg for radish. The value derived from use of the NAFTA calculator was 0.35 mg/kg which was comparable with the maximum residue level estimated by the present Meeting.

The residues in radish tops with leaves were: 0.33, 0.34, 0.75, 1.8, and 4.0 mg/kg.

The Meeting estimated a maximum residues level of 7 mg/kg, median residue of 0.75 mg/kg and an HR of 4.0 mg/kg for radish leaves including tops. The value derived from use of the NAFTA calculator was 7 mg/kg which was in agreement with the maximum residue level of 7 mg/kg estimated by the present Meeting.

Sugar beet

Eleven field trials were conducted in the USA according to maximum US GAP (0.28 kg ai/ha with a PHI of 7 days). The residues measured in roots were: < 0.05(3), 0.066, 0.092, 0.11, 0.13, 0.14, 0.14, 0.17, and 0.18 mg/kg.

The Meeting estimated a maximum residues level of 0.3 mg/kg, median residue of 0.11 mg/kg and an HR of 0.18 mg/kg. The value derived from use of the NAFTA calculator was 0.3 mg/kg which agreed with the maximum residue level of 0.3 mg/kg estimated by the current Meeting.

Sweet potato

Nine field trials were conducted in the USA according to maximum US GAP (3 × 0.18 kg ai/ha at 14 days, 7 days PHI). The residues measured in roots were < 0.01 (8) and 0.012 mg/kg.

The Meeting estimated a maximum residues level of 0.02 mg/kg, median residue of 0.01 mg/kg and an HR of 0.012 mg/kg for sweet potato. The NAFTA calculator was not used due to the large proportion of values below LOQ.

Peanut

Supervised field trials on peanut were conducted in Maryland, Colorado, Georgia (four trials at the same site), North Carolina (four trials at the same site), and Texas (two trials at the same site) according to maximum US GAP (3 × 0.10-0.18 at 7-day intervals, PHI of 7 days). The varieties were

also the same in the trials in Texas. The residues were below the LOQ in all trials except one where 0.011 and 0.016 mg/kg were measured in replicate samples of peanut meat.

The Meeting estimated a maximum residues level of 0.03 mg/kg, median residue of 0.01 mg/kg and an HR of 0.016 mg/kg. The NAFTA calculator was not used due to the large proportion of values below LOQ.

Fate of residues during processing

The fate of methoxyfenozide residues during processing was examined in oranges, peanut and sugar beet in processing studies simulating the industrial processing as far as possible. The marmalade was prepared according to household practice. Estimated processing factors and STMR-Ps are summarised below.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	PF (Mean, median or best estimate)	RAC-STMR (mg/kg)	STMR-P (mg/kg)
Orange	Orange peel	2.884, 4.201, 4.0	4.0		
	Orange pulp dry	< 0.253, < 0.223, < 0.385, 1.098	1.1	0.2	0.22
	Marmalade	0.505, 1.067, 0.769	0.77		
	Orange juice	0.253, 0.223	0.22	0.05	0.011
	Orange oil	42.5	42.5		
Peanuts	Peanut oil	2.89	2.89	0.01	0.0289
Sugar beet	Sugar beet molasses	1.143	1.14	0.11	0.126
	Refined sugar	0.071	0.071		

Based on the processing factors, the Meeting estimated STMR values of 0.22 mg/kg for dry orange pulp (based on median residue of 0.2 mg/kg in whole fruits), 0.011 mg/kg for citrus juice, 0.0289 for refined peanut oil, and 0.126 mg/kg for sugar beet molasses.

On processing peanuts, methoxyfenozide concentrated in the oil. The Meeting decided to estimate a maximum residue level for peanut oil refined of 0.1 mg/kg based on a highest residue for peanuts of 0.016 mg/kg and a processing factor of 2.89 (0.016 mg/kg × 2.89 = 0.05 mg/kg).

Residues in animal feed

The residues in animal feed were measured in crops derived from supervised trials conducted according to maximum US GAPs which are reported above under individual commodities.

Residues in/on bean foliage treated with methoxyfenozide at maximum GAP were: 3.4, 4.6, 5.3, 6.6, 16, and 32 mg/kg.

The Meeting estimated a highest residue of 32 mg/kg and a median residue of 5.95 mg/kg.

Residues in sugar beet tops were: 0.85, 0.85, 1.9, 2.6, 3.3, 3.6, 3.8, 4.7, 4.9, 9.5 and 10 mg/kg.

The Meeting estimated a highest residue of 10 mg/kg and a median residue of 3.8 mg/kg.

Residues in peanut hay were: 0.22, 0.3, 0.46, 1.1, 9.0, 13, 14, 17, 27, 29, 33, and 51 mg/kg

The Meeting estimated, respectively maximum, highest and median residue levels of 80mg/kg, 60 mg/kg and 16 mg/kg based on dry weight basis (85% dry matter) corresponding to 70 mg/kg on peanut hay, highest residue of 51 mg/kg and a median residue of 13.5 mg/kg for peanut fodder as received. (NAFTA calculator indicates 50 mg/kg maximum residue for commodity as received. However, it was considered too low as previously evaluated data sets indicate that 4 times the median value would cover only less than about 60% of the residues derived from trials performed

with various pesticides at maximum GAP in commodities belonging to the Codex commodity group of Legume animal feeds (AL)).

Residues were reported in soya bean forage and hay. As the application conditions did not match GAP, the residues were recorded in the monograph but not evaluated.

Residues in 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, methoxyfenozide [ppm] in dry matter diet		
		US-Canada	EU	Australia
Beef cattle	max	47.92	44.65	78.86
	mean	12.30	10.62	16.55
Dairy cattle	max	30.41	40.76	82.00[a]
	mean	9.61	9.74	16.66[b]

[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.

The 2003 JMPR estimated maximum dietary burdens of methoxyfenozide for beef cattle, dairy cattle, and poultry of 26 ppm, 31 ppm, and 0.07 ppm, and median dietary burdens of 7.5 ppm, 7.8 ppm, and 0.07 ppm, respectively. The maximum and mean dietary burdens for beef and dairy cattle based on the new OECD feed consumption figures and the residue levels estimated by the present Meeting are 82 ppm and 16.66 ppm, respectively.

Farm animal feeding studies

The 2003 JMPR reported feeding studies on cows, where three cows at each level were dosed orally with the equivalent of 16, 54, or 180 ppm in the diet for 28 consecutive days. Milk was collected daily and analysed on days 1, 2, 4, 7, 10, 14, 17, 21, 24, and 28. The cows were slaughtered within 24 h of the last dose, and tissues were collected and analysed for methoxyfenozide and the glucuronide conjugate of the A-ring phenol.

The residues [mg/kg] detected in various tissues at feeding levels given are summarised below:

Tissue	Residue level	16 ppm	54 ppm	180 ppm
Milk	Max	< 0.01	< 0.01	0.1
	Average	< 0.01	< 0.01	0.028
Muscle	Max	< 0.003	< 0.003	0.1
	Average	< 0.003	0.028	0.073
Fat	Max	0.011	0.082	0.44
	Average	< 0.01	0.041	0.28
Liver	Max	< 0.003	0.03	0.15
	Average		0.028	0.13
Kidney	Max	< 0.01	< 0.01	0.034
	Average	< 0.01	< 0.01	0.026

The Meeting interpolated the residues measured following feeding with 54 ppm and 180 ppm methoxyfenozide in the diet. The calculated maximum and average (in brackets) residues were: milk: 0.03 mg/kg, (0.014 mg/kg), muscle: 0.025 mg/kg (0.019 mg/kg), fat: 0.162 mg/kg (0.094 mg/kg), liver: 0.057 mg/kg (0.051 mg/kg), and kidney: 0.015 mg/kg (0.014 mg/kg)

The Meeting estimated a maximum residue level, HR and median residue, respectively, 0.1 mg/kg, 0.057 mg/kg, 0.051 mg/kg for edible offal; of 0.2 mg/kg, 0.162 mg/kg, 0.094 mg/kg for meat from mammals other than marine mammals (based on fat) and maximum residue level and median residues of 0.05 mg/kg, 0.03 mg/kg for whole milk. .

The new maximum or median level recommendations do not affect the dietary burden of poultry. The residue levels estimated by the 2003 JMPR remain the same.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for methoxyfenozide 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 methoxyfenozide in the 13 GEMS/Food Consumption Cluster Diets, based on the STMRs estimated by the 2003 and 2009 JMPR were in the range 0–8% of the maximum ADI of 0.1 mg/kg bw. The Meeting concluded that the long-term intake of residues of methoxyfenozide 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 methoxyfenozide was calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4.

The International Estimated Short Term Intake (IESTI) varied from 0–2% of the ARfD (0.9 mg/kg bw) for the general population. The IESTI varied from 0–6% of the ARfD for children 6 years and below. The Meeting concluded that the short-term intake of residues of methoxyfenozide from uses considered by the present Meeting is unlikely to present a public health concern.

5.18 PARAQUAT (057)

RESIDUE AND ANALYTICAL ASPECTS

Paraquat, a non-selective contact herbicide, was first evaluated in 1970 for toxicology and residues. The 2003 JMPR evaluated paraquat toxicologically under the Periodic Review Programme and recommended the current ADI of 0–0.005 mg paraquat cation/kg bw and ARfD of 0.006 mg paraquat cation/kg bw. The 2004 JMPR evaluated paraquat for residues under the Periodic Review Programme, concluded that the definition of residue for compliance with MRLs and for estimation of dietary intake was paraquat cation. It withdrew the previously recommended maximum residue levels for rice and polished rice due to insufficient data provided to the Meeting. The current Meeting received information on previously submitted and additional residue trials on rice and the US label.

Results of supervised trials on crops

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Rice

Paraquat is registered for weed control in rice production in the USA by pre-plant or pre-emergence broadcast application at a maximum rate of 1.12 kg ai/ha, with no PHI specified.

When used in a pre-plant or pre-emergence treatment, paraquat is not sprayed directly onto the crop, the time between the application and harvest is sufficiently long, and paraquat is strongly adsorbed to soil with negligible dissociation, with little paraquat cation expected to be found in rice grain or straw at harvest. As agreed by the 2004 JMPR, the Meeting evaluated data from trials of pre-plant and pre-emergence application against any GAP available to the Meeting, regardless of the country or region.

A total of 14 trials on rice conducted in Guatemala, Italy and the USA were provided to the current Meeting. Paraquat was applied prior to flooding in these trials. Rice grain and straw samples were collected at harvest.

Three trials were conducted in Guatemala in 1983 in which paraquat was applied as a pre-emergence treatment at rates of 0.60 and 1.0 kg ai/ha. The residues in de-husked rice in one trial conducted in accordance with US GAP were below the LOQ of 0.05 mg/kg. The residues in rice grain were not analysed.

Two trials were conducted in Italy in 1993, in which paraquat was applied at a rate of 0.92 kg ai/ha to the seed bed 5 days before rice was sown. Rice grain samples taken at harvest did not contain residues of paraquat at levels above the LOQ of 0.05 mg/kg (2).

Six residue trials were conducted in the USA in 1978 and 1982 in which paraquat was applied as a pre-emergence treatment at rates of 0.56 or 1.12 kg ai/ha. In trials conducted in compliance with the maximum US GAP, the residues were below the LOQ of 0.01 mg/kg (3).

Three new residue trials were conducted in the USA in 2007 in which paraquat was applied as a pre-emergence treatment at a rate of 1.12 kg ai/ha. The residues of paraquat in rice grain samples taken at harvest were < 0.01 mg/kg (2).

No trials were conducted at rates higher than the maximum allowed in US GAP for rice.

The residues in rice grain from trials in compliance with maximum US GAP in rank order were: < 0.01 (5), < 0.05 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.05(*) mg/kg and STMR of 0 mg/kg for rice grain, taking into consideration readily achievable LOQ of analytical methods used in enforcement of MRLs.

As the residues from all the trials matching GAP were below the LOQs, the NAFTA calculator was not used.

Rice straw

In two trials conducted in Italy in 1993, rice straw samples taken at harvest did not contain residues of paraquat at levels above the LOQ of 0.05 mg/kg (2).

In three residue trials conducted according to maximum US GAP in the USA in 1978 and 1982, the residues were < 0.02 mg/kg (2) and < 0.03 mg/kg. However, in one trial with the application rate of 0.56 kg ai/ha (one half of the maximum rate), the residues in duplicate straw samples were < 0.03 and 0.04 mg/kg. In comparison with the results of other trials, sample contamination was suspected but without any concrete evidence.

In three new residue trials in the USA in 2007, the residues of paraquat in rice straw samples taken at harvest were < 0.01 mg/kg (3).

The residues from trials in compliance with US GAP in rank order were: < 0.01 (3), < 0.02 (2), 0.04 and < 0.05 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg, STMR of 0.02 mg/kg and highest residue of 0.04 mg/kg for rice straw.

As the residues from seven out of eight trials matching GAP were below the LOQs, the NAFTA calculator was not used.

Residues in animal commodities

The addition of new maximum residue levels for rice grain and straw at 0.05 mg/kg would not affect the animal dietary burden calculated in 2004 in which much higher residue levels in cotton seed and maize forage were used in calculation. The Meeting concluded that there was no need to change the previous recommendations for animal commodities.

DIETARY RISK ASSESSMENT

Long-term intake

Since the STMR for rice is estimated by the current Meeting to be 0 mg/kg, no new IEDI calculation was conducted. The Meeting confirmed the previous conclusion that the IEDIs were 2–5% of the maximum ADI of 0.005 mg/kg bw and that the intake of residues of paraquat resulting from uses considered by the 2004 and the current JMPR was unlikely to present a public health concern.

Short-term intake

Since the STMR for rice is estimated by the current Meeting to be 0 mg/kg, IESTI was not calculated for rice (IESTI of 0 µg/kg bw/day). The Meeting concluded that the short-term intake of residues of paraquat from uses on rice was unlikely to present a public health concern.

5.19 PROCHLORAZ (142)

RESIDUE AND ANALYTICAL ASPECTS

Prochloraz is a broad-spectrum imidazole fungicide that is active against a range of diseases in field crops, fruit and vegetables and is also used on mushrooms, as a post-harvest treatment of fruit and as a seed treatment on cereals. It was evaluated initially in 1983 for residues and toxicology, and subsequently six additional reviews of residues were carried out between 1985 and 1992. Under the CCPR Periodic Review Programme the toxicology was re-evaluated in 2001, when an ADI of 0-0.01 mg/kg bw and an ARfD of 0.1 mg/kg bw were established. In 2004, a Periodic Review of the residue and -analytical aspects of prochloraz was conducted.

In the 2004 review the Meeting estimated a maximum residue level for mushrooms of 40 mg/kg and noted acute intake concerns relating to this level. As a consequence the CCPR at its Thirty-seventh and and Thirty-eighth Sessions did not advance this level as an MRL. In 2007, the Committee was informed that the manufacturer would provide alternative GAP information on mushroom and corresponding trial data for evaluation by the 2009 JMPR (ALINORM 07/30/24 – Rev. 1).

The Meeting received new data on supervised trials on mushrooms in several European countries, as well as current European labels on mushrooms.

Methods of analysis

The Meeting received descriptions and validation data for an analytical method for residues of prochloraz in mushrooms. Mushrooms were analysed for the total prochloraz derived residue by analytical method RESID/88/72 which was evaluated before in the 2004 JMPR. All results were expressed as a total prochloraz derived residue by correcting the measured 2,4,6-trichlorophenol concentration for the molecular weight factor of 1.9

The method performed satisfactorily, and was validated in the range of 0.05–50 mg/kg.

Results of supervised trials on crops

The 2004 JMPR noted two distinct patterns of use of prochloraz on mushrooms: one established in the United Kingdom, involving two to three casing sprays of 0.3–0.6 g ai/m^2, with a PHI of 2 days, and the other common in a number of other European countries, Australia and New Zealand, involving one or more treatments at 1.5 g ai/m^2 and a PHI of 10–14 days.

JMPR 2004 identified seven trials in The Netherlands, Switzerland and the United Kingdom matching GAP in Denmark, Italy, the Netherlands, New Zealand and Poland (one or two treatments at 1.5 g ai/m^2, 10-day PHI), the residue levels were: 0.21, 0.25, 0.48, 0.71 and 0.74 mg/kg.

As reported by JMPR 2004, the maximum GAP of two sprays of 0.6 g ai/m^2 (2 day PHI) in the United Kingdom was supported by the results of trials in Germany and the United Kingdom, with residue levels of: 0.81, 3.6, 6.2 and 37 mg/kg.

The 2004 Meeting noted that these two residue populations are different and, on the basis of the data supporting the United Kingdom GAP (with a PHI of 2 days), estimated a maximum residue level of 40 mg/kg for prochloraz in mushrooms, an STMR of 4.9 mg/kg and a highest residue level of 37 mg/kg.

The 2009 Meeting noted, that still two distinct patterns of use of prochloraz on mushrooms exist; one with a relatively low dose and a short (2–4 day) PHI, and one with a higher dose and a PHI of 10 days.

For this years evaluation another set of trials conducted in Germany, France, Ireland and Belgium was provided together with current GAP from Belgium, France, Ireland, Italy, the Netherlands, Poland, Spain and the UK. Trials agreeing with the 'alternative GAP' (for an explanation see the JMPR 2006 report, General considerations point 2.3) involving one or more treatments at 1.5 g ai/m^2 and a PHI of 10 days (GAP in Italy and Poland) yielded residues of 1.3, 1.4 mg/kg.

Together with the data set of 2004 matching the same GAP, the total data set was: 0.21, 0.25, 0.48, 0.71, 0.74, 1.3, 1.4 mg/kg; the Meeting estimated a maximum residue level of 3 mg/kg for prochloraz in mushroom, an STMR of 0.71 and a highest residue level of 1.4 mg/kg.

Use of the NAFTA calculator resulted in an estimated maximum residue level of 3.5 mg/kg. The Meeting noted that the trials yielding the high residues were exactly at GAP, and over-all the distribution was relatively uniform.

Farm animal dietary burden

This Meeting estimated a maximum residue level for mushrooms. As mushrooms are not a feed item the Meeting decided it was unnecessary to revisit the farm animal dietary burden.

DIETARY RISK ASSESSMENT

Long-term intake

Due to the low contribution of mushrooms to the total diet, no revision of the chronic dietary exposure assessment has been carried out.

In 2004 the Meeting concluded that the long term intake of residues of prochloraz from uses that have been considered by the JMPR is unlikely to present a public health concern. The IEDI in the five GEMS/Food Consumption Cluster Diets, on the basis of the estimated STMRs, represented 7-10% of the maximum ADI of 0.01 mg/kg bw.

Short-term intake

The International Estimated Short-term Intake (IESTI) was calculated for mushrooms. The short-term intake of mushrooms represented 10% of the ARfD for children ≤ 6 years and 7% of the ARfD for the general population. The Meeting concluded that the short-term intake of residues of prochloraz from its uses on mushroom was unlikely to present a public health concern.

5.20 PROTHIOCONAZOLE (232)

RESIDUE AND ANALYTICAL ASPECTS

Prothioconazole was evaluated for the first time by the 2008 JMPR which recommended maximum residue limits for barley, oats, rye, triticale and wheat grain and straw, peanut, rape seed and for meat, mammalian fats, edible offal and milks based on a residue definition of 'prothioconazole-desthio'.

At the Forty-first Session of the CCPR, the Delegation of the USA expressed a concern that because JMPR had adopted the above residue definition, all US field trial data which reported only 'total residue' (i.e., the sum of prothioconazole and desthio-prothioconazole) had been discarded, even though residues of the parent compound, prothioconazole were a very small part of the total residue.

The CCPR noted this concern and requested JMPR to review the existing US data (together with any additional residue information) on pulses, sugar beet, cereal grains (wheat and barley), canola (rape seed), soya bean, and cereal forages/straws.

The current Meeting was provided with information on residues of the sulfonic acid and desthio metabolites of prothioconazole that were analysed seperately in the above US/Canadian field trials (but initially summed and reported as 'total prothioconazole' residues).

Results of supervised trials on crops

The NAFTA statistical calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Pulses (beans (dry), peas (dry) and soya bean)

The 2008 JMPR reported that a total of 22 trials on peas (dry) and beans (dry) were carried out with 3 foliar application of a SC480 formulation at a target rate of 200 g/ha in Canada (9) and USA (13), but that the results of these trials could not be used to estimate residue levels as only total prothioconazole residues had been reported. The 2008 JMPR also reported that although 19 trials in USA on soya beans had been provided, these did not comply with the US GAP and also only reported total prothioconazole residues.

Additional information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in these trials were provided to the meeting.

In trials on beans conducted in the USA and Canada, matching the USA GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in beans (dry) were < 0.05 (7), 0.08, 0.12 and 0.22 mg/kg (n=10).

In trials conducted on field peas in USA and Canada, matching the North American GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in peas (dry) were < 0.05 (7), 0.06, 0.1, 0.11, 0.36, 0.49 and 0.57 mg/kg (n=13)

The Meeting considered that these results for peas (dry) and beans (dry) were from similar populations and based on the combined residue data set (< 0.05 (13), ≤ 0.05, 0.06, 0.08, 0.1, 0.11,

0.12, 0.22, 0.36, 0.49 and 0.57 mg/kg (n=23), estimated a maximum residue level of 1 mg/kg for prothioconazole in pulses (except soya beans, dry) and estimated an STMR of 0.05 mg/kg.

The value derived from use of the NAFTA calculator was 0.83 mg/kg, which differed from the estimate of 1 mg/kg made by the Meeting. With 60% of the values < LOQ, a higher level is required to accommodate the range of commodities in this commodity group.

While information on residues of desthio-proconazole in soya beans (dry) were provided from trials conducted on soya beans in USA, the Meeting confirmed that these trials, involving three foliar applications of about 0.15 kg ai/ha, were not supported by any matching GAP.

Sugar beet

The 2008 JMPR received reports of 12 residue trials on sugar beet from USA, complying with US GAP, but where only total residues were reported.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in sugar beet roots from these trials were provided to the meeting.

In trials on sugar beet conducted in the USA and Canada, matching the North American GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in sugar beet roots were < 0.05 (8), < 0.05, 0.11, 0.17 and 0.19 mg/kg (n=12).

The Meeting estimated a maximum residue level of 0.3 mg/kg for prothioconazole in sugar beet and estimated an STMR of 0.05 mg/kg.

The value derived from use of the NAFTA calculator was 0.18 mg/kg, which differed from the estimate of 0.3 mg/kg made by the Meeting. With 75% of the values < LOQ, the Meeting considered the calculator derived value may not be a reliable estimate of maximum expected residues in sugar beet.

Cereal grains

The 2008 JMPR reported that a total of 123 trials had been carried out on cereals (wheat, triticale and barley) with SC 480, EC250 and FS200 formulations in Canada, Europe and USA but that only 'total residues' had been reported from US and Canadian trials.

Based on the European data and GAP, the 2008 JMPR recommended a maximum residue of 0.05 mg/kg for barley, oat, rye, triticale and wheat, based on the combined data for barley and wheat following a seed treatment and 2–3 applications of 0.2 kg ai/ha, PHI 35–64 days. Results from these European trials were < 0.01 (10), 0.01, 0.01, 0.02 (4) mg/kg for barley grain and < 0.01 (16) for wheat grain.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in wheat and barley from the North American trials were provided to the present meeting.

Wheat

In trials on wheat conducted in the USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 30 days), residues of desthio-prothioconazole in wheat grain were < 0.02 (8), < 0.02, 0.02, 0.03, 0.04 and 0.05 mg/kg (n=13).

The Meeting estimated a maximum residue level of 0.1 mg/kg for prothioconazole in wheat (to replace the previous recommendation of 0.05 mg/kg) and estimated an STMR value of 0.02 mg/kg (to replace the previous estimate of 0.01 mg/kg).

The value derived from use of the NAFTA calculator was 0.07 mg/kg, which differed from the estimate of 0.1 mg/kg made by the Meeting. With 70% of the values < LOQ, the Meeting

considered the calculator derived value may not be a reliable estimate of maximum expected residues in wheat grain.

Barley

In trials on barley conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 32 days), residues of desthio-prothioconazole in barley grain were < 0.02, < 0.02, < 0.02, 0.03, 0.03, 0.04, 0.05, 0.07, 0.07 and 0.09 mg/kg (n=10).

The Meeting estimated a maximum residue level of 0.2 mg/kg for prothioconazole for barley (to replace the previous recommendation of 0.05 mg/kg) and estimated an STMR value of 0.035 mg/kg (to replace the previous estimate of 0.01 mg/kg).

The value derived from use of the NAFTA calculator of 0.2 mg/kg was in agreement with the estimate of 0.2 mg/kg made by the Meeting.

The Meeting also confirmed the 2008 JMPR recommendations for oat, rye and triticale, where maximum residue levels of 0.05 mg/kg and STMRs of 0.01 mg/kg were estimated, based on extrapolation from the European data on wheat and barley matching the European GAP for these cereal crops.

Oil seeds

The 2008 JMPR received a total of 34 trials on oil seed rape/canola carried out with either 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.

Based on data from the European trials matching the UK GAP (2 × 0.175 kg ai/ha, PHI 56 days), with reported prothioconazole-desthio residues of < 0.01 (7), 0.01 (3) and 0.02 mg/kg, the 2008 JMPR recommended a maximum residue level of 0.05 mg/kg for rape seed.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in the North American trials were provided to the meeting. GAP in USA is for two applications during early-mid flowering, prior to significant petal fall and at least 36 days before harvest.

In trials on oil seed rape (canola) conducted in USA and Canada, matching the USA GAP (2 × 0.2 kg ai/ha, 14 days apart, early-mid flowering, minimum 30 day PHI) residues of desthio-prothioconazole in rape seed sampled at earliest maturity, i.e., 36 to 71 days after a mid-late flowering treatment, and consistent with the US GAP) were < 0.02 (8), < 0.02, 0.03, 0.04 and 0.08 mg/kg (n=12)

The Meeting estimated a maximum residue level of 0.1 mg/kg for prothioconazole in rape seed based on the US GAP and data (to replace the previous recommendation of 0.05 mg/kg) and estimated an STMR of 0.02 mg/kg (to replace the previous value of 0.01 mg/kg).

The value derived from use of the NAFTA calculator of 0.08 mg/kg differed from the estimate of 0.1 mg/kg made by the Meeting. With 75% of the values < LOQ, the calculator value may not be a reliable estimate of maximum expected residues in wheat grain.

Peanut

Information on the residues of desthio-prothioconazole in peanut meat from the trials on peanuts conducted in the USA (and initally summarised by the 2008 JMPR) was provided to the meeting.

The present meeting agreed that the information, reporting desthio-prothioconazole residues of < 0.02 mg/kg in 12 trials matching the US GAP, confirmed the 2008 JMPR conclusion (based on the lack of measurable 'total residues' in these trials) that only low residues of desthio-prothioconazole would be expected in peanut meat.

The Meeting confirmed the previous recommendations for a maximum residue level of 0.02(*) mg/kg for prothioconazole in peanut and an STMR of 0.01 mg/kg.

Primary feed commodities

The 2008 JMPR evaluated prothioconazole residue information from North America on a number of primary feed commodities and concluded that the data from these trials could not be used for estimation of residue levels because only the total residue was reported.

The present meeting received information on the the individual residue components measured in these trials from Canada and USA.

Sugar beet leaves and tops

The 2008 JMPR received reports of 12 residue trials on sugar beet from USA, complying with US GAP, but where only total residues were reported. These studies were not evaluated by the 2008 Meeting.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in sugar beet tops from these trials were provided to the present meeting.

In trials on sugar beet conducted in USA and Canada, matching the North American GAP (3 × 0.2 kg ai/ha, PHI 7 days), residues of desthio-prothioconazole in sugar beet tops were 0.45, 0.48, 0.58, 0.61, 1.1, 1.5, 1.5, 1.8, 2.1, 2.2, 2.4 and 3.9 mg/kg (n=12)

The Meeting estimated an STMR of 1.5 mg/kg and a highest residue of 3.9 mg/kg for desthio-prothioconazole in sugar beet tops.

Soya bean forage and hay

While the present meeting received data on residues of desthio-prothioconazole in soya bean forage and hay from trials initially evaluated by the 2008 JMPR, none of these trials matched the US GAP and the meeting was unable to use these data to estimate residue levels.

Peanut hay

The present meeting received data on residues of desthio-prothioconazole in peanut hay from trials in USA, initially evaluated by the 2008 JMPR, but as noted by the 2008 JMPR, peanut hay from prothioconazole-treated peanuts cannot be used as an animal feed in USA, and the Meeting was unable to use these data to estimate residue levels.

Cereal forage, hay and straw

Cereal forage

The 2008 JMPR noted that forage samples in most of the North American trials and many European trials were taken 7 days after last application and since several countries labels do not contain any restriction on grazing, this 7-day sampling interval was considered the shortest under practical conditions, and residues measured in 7 day samples were used for estimation of animal burden. In the North European trials considered by the 2008 JMPR, the prothioconazole-desthio residues (fresh weight) 7 days after ther last 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 wheat forage and 0.6, 0.85, 1.0, 1.2, 1.7, 2.0 and 2.6 mg/kg in barley forage.

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in wheat forage from the North American trials were provided to the present meeting.

In trials conducted in the USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year), residues of desthio-prothioconazole in wheat forage sampled 7 days after the last application were 0.05, 0.09, 0.11, 0.23, 0.31, 0.37, 0.46, 0.66, 0.74, 0.89, 1.2, 1.2, 1.2, 1.3, 1.6, 1.6, 1.6, 1.6, 1.8, 1.8, 2.1, 2.4 and 5.4 mg/kg (n=23, fresh weight basis).

The meeting agreed that for purposes of calculating animal dietary burdens, the results of the North American trials on wheat could be used to calculate animal dietary burdens from both wheat and barley forage, and estimated STMRs of 1.2 mg/kg and highest residues of 5.4 mg/kg for wheat and barley forages (to replace the previous STMR estimates of 0.96 mg/kg and highest residue estimates of 2.6 mg/kg).

For other cereal forage commodities, the Meeting confirmed the STMRs of 0.96 mg/kg and highest residues of 2.6 mg/kg for oat, rye, and triticale forage, estimated by the 2008 JMPR based on the combined European data for wheat and barley.

Cereal fodders

Information on residues of desthio-prothioconazole and prothioconazole sulfonic acid in wheat and barley hay from the North American trials were provided to the present meeting.

In trials conducted in USA and Canada, matching the GAP of the USA (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year), residues of desthio-prothioconazole in wheat hay sampled 12–14 days after the last application were 0.21, 0.29, 0.32, 0.33, 0.41, 0.42, 0.45, 0.55, 0.61, 0.77, 0.83, 0.87, 0.87, 0.97, 1.1, 1.4, 1.4, 1.5, 1.6, 1.6, 1.6, 1.9, 1.9, 2.0, 2.0, 2.2, 2.3, 2.4, 2.6, 3.0 and 3.3 mg/kg (n=31, fresh weight basis).

In trials conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year) residues of desthio-prothioconazole in barley hay sampled 12–14 days after the last application were 0.3, 0.39, 0.53, 0.61, 0.63, 0.64, 0.69, 0.69, 0.71, 0.81, 1.1, 1.1, 1.3, 1.4, 1.4, 1.6, 1.9, 2.0, 2.3, 2.4, 2.8, 3.0, 3.3 and 4.2 mg/kg (n=24, fresh weight basis).

The Meeting agreed that because of the similarity of the data sets for wheat and barley hay the data sets for wheat and barley hays could be combined to recommend a maximum residue level for cereal hays.

Based on the combined data set of: 0.21, 0.29, 0.3, 0.32, 0.33, 0.39, 0.41, 0.42, 0.45, 0.53, 0.55, 0.61, 0.61, 0.63, 0.64, 0.69, 0.69, 0.71, 0.77, 0.81, 0.83, 0.87, 0.87, 0.97, 1.1, 1.1, 1.1, 1.3, 1.4, 1.4, 1.4, 1.4, 1.5, 1.6, 1.6, 1.6, 1.6, 1.9, 1.9, 1.9, 2.0, 2.0, 2.0, 2.2, 2.3, 2.3, 2.4, 2.4, 2.6, 2.8, 3.0, 3.0, 3.3, 3.3 and 4.2 mg/kg (n=55) and allowing for the common 88% dry matter content for most cereal hays, the meeting estimated a maximum residue level of 5 mg/kg, an STMR of 1.5 mg/kg and a highest residue of 4.8 mg/kg for desthio-prothioconazole for fodder (dry) of cereal grains

The value derived from use of the NAFTA calculator of 6 mg/kg, after adjusting for dry matter content and rounding, differed from the estimate of 5 mg/kg made by the Meeting. The Meeting considered the value derived from the NAFTA calculator to have been shaped by the lowest values in the dataset.

The 2008 JMPR evaluated data from European cereal trials and estimated an STMR of 0.3 mg/kg, a highest residue of 1.36 mg/kg and a maximum residue level of 2 mg/kg, for barley, oat, rye, triticale and wheat straw (dry weight), based on a combined data set for wheat and barley straw (fresh weight) of: 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, 0.2, 0.24, 0.25, 0.27, 0.3, 0.31, 0.38, 0.42, 0.47, 0.52, 0.53, 0.53, 0.72, 0.72, 0.72, 0.75, 0.77, 1.0, 1.1, 1.1, and 1.2 mg/kg.

In trials on wheat conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 30 days) residues of desthio-prothioconazole in wheat straw from 13 of these trials, sampled at grain harvest, close to 30 days after the last treatment,

residues (fresh weight basis) were 0.12, 0.15, 0.21, 0.23, 0.36, 0.41, 0.57, 0.67, 0.89, 0.89, 1.4, 1.4 and 1.7 mg/kg (n=13).

In trials on barley conducted in USA and Canada, matching the USA GAP (up to 2 × 0.2 kg ai/ha, maximum 0.33 kg ai/ha/year, PHI 32 days) residues of desthio-prothioconazole in barley straw from 10 of these trials, sampled at grain harvest, close to 32 days after the last treatment, residues (fresh weight basis) were: < 0.05, 0.17, 0.19, 0.22, 0.27, 0.61, 0.85, 0.92, 1.3 and 1.6 mg/kg (n=10).

The Meeting agreed that because of the similarity of the data sets for wheat and barley straw, the data sets for wheat and barley straws could be combined to recommend a maximum residue level for cereal straws.

Based on the combined data set of: < 0.05, 0.12, 0.15, 0.17, 0.19, 0.21, 0.22, 0.23, 0.27, 0.36, 0.41, 0.57, 0.61, 0.67, 0.85, 0.89, 0.89, 0.92, 1.3, 1.4, 1.4, 1.6 and 1.7 mg/kg (n=23) and allowing for the common 88% dry matter content for most cereal straws, the meeting estimated a maximum residue level of 4 mg/kg, an STMR of 0.65 mg/kg and a highest residue of 1.9 mg/kg for desthio-prothioconazole (dry weight basis) in straw and fodder (dry) of cereal grains and to withdraw the previous recommendations for maximum residue levels, STMRs and highest residues for barley straw, oat straw, rye straw, triticale straw and wheat straw.

The value derived from use of the NAFTA calculator of 5 mg/kg, after adjusting for dry matter content and rounding, differed from the estimate of 4 mg/kg made by the Meeting. The NAFTA calculator derived value appeared to be influenced by the lowest values in the dataset.

Fate of residues during processing

The 2008 JMPR evaluated a number of studies on the effects of processing on the fate of prothioconazole residues in wheat, rape seed, peanut and soya bean. Processing factors derived from these studies included:

raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors.
peanut	meal	1.8
peanut	peanut butter	0.6
peanut	peanut, roasted	0.5
peanut	refined oil	< 0.1
rape seed	meal	< 0.7
rape seed	refined oil	< 0.7
wheat	aspirated grain fraction	250
wheat	bran	2.4
wheat	flour	< 0.4
wheat	middling	0.6
wheat	shorts	1
wheat	wheat germ	2

The processing factor for peanut meal (1.8) was applied to the estimated STMR for peanut (0.01 mg/kg) to produce a STMR-P value of 0.018 mg/kg for peanut meal (for the purposes of livestock dietary burden estimation).

The processing factor for refined rape seed oil (< 0.7) was applied to the estimated STMR for rape seed (0.02 mg/kg) to produce a STMR-P value of 0.014 mg/kg for refined rape seed oil. This concentration falls below the estimated maximum residue level for rape seed, and the Meeting agreed that a maximum residue level for rape seed oils need not be recommended.

The processing factor for rape seed meal (< 0.7) was applied to the estimated STMR for rape seed (0.02 mg/kg) to produce a STMR-P value of 0.014 mg/kg for rape seed meal (for the purposes of livestock dietary burden estimation).

The processing factors for wheat bran (2.4), flour (< 0.4) and wheat germ (2) were applied to the estimated STMR for wheat (0.02 mg/kg) to produce STMR-P values for wheat bran (0.048 mg/kg), flour (0.008 mg/kg) and wheat germ (0.04 mg/kg). For the purposes of estimating livestock dietary burdens, the processing factor of 250 for aspirated grain fraction from wheat was applied to the wheat grain STMR (0.02 mg/kg) to produce a STMR-P of 5 mg/kg.

The Meeting agreed that it was not necessary to recommend a maximum residue level for wheat flour as residues did not concentrate during processing of wheat and also agreed to withdraw its previous maximum residue level recommendation of 0.05 mg/kg for wheat flour.

Residues in animal commodities

Farm animal dietary burden

The Meeting confirmed the conclusion of the 2008 JMPR that the feeding study conducted with parent prothioconazole does not represent the practical residue situations where the feed items contain the parent compound only up to 5% of the TRR and the major part of the residue was the prothioconazole-desthio and that the dietary burden should be calculated from the prothioconazole-desthio residues measured in feed commodities and compared to the residues found in animal commodities after the administration of prothioconazole-desthio.

Some processed and forage commodities do not appear in the Annex 1 Table as no maximum residue level estimate was required, but were used in estimating livestock dietary burdens. Those commodities are listed below.

Commodity	STMR or STMR-P (mg/kg)	High residue (mg/kg)
Barley forage (fresh)	1.2	5.4
Peanut meal	0.018	
Rape seed meal	0.014	
Sugar beet leaves or tops	1.5	3.9
Wheat aspirated fraction	5	
Wheat forage (fresh)	1.2	5.4

The 2008 JMPR reported the results of a 28 day prothioconazole-desthio feeding study in cattle where milk and tissue samples were analysed for residues of total prothioconazole-desthio (prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio and prothioconazole-desthio). Residues were observed in liver and kidney at all feeding levels, increasing in a linear fashion.

Total prothioconazole-desthio residues (mg/kg) in the edible tissues of dairy cattle after 28 days of dosing with prothioconazole-desthio.

Tissue	4 ppm dose		25 ppm dose		100 ppm dose	
	range	mean	range	mean	range	Mean
Liver	0.02–0.05	0.04	0.18–0.26	0.22	0.61–1.6	0.95
Kidney	0.01–0.04	0.02	0.11–0.17	0.14	0.41–1.1	0.65
Muscle	< 0.01	< 0.01	< 0.01	< 0.01	0.01–0.03	0.02
Fat	< 0.01	< 0.01	0.01–0.02	0.01	0.03–0.14	0.07

For poultry, the Meeting noted that the 2008 JMPR had concluded that the poultry feeding study designs did not reflect the residue composition in feed and that the results could not be used for estimating maximum residue limits or STMR values, and therefore the present Meeting did not estimate a dietary burden for poultry.

The Meeting revised the 2008 JMPR estimation of the dietary burden in farm animals on the basis of the above residue estimates in animal feeds and the animal 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.

	Livestock dietary burden, prothioconazole-desthio, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	7.81	1.72	6.21	2.68	21.6 [a]	4.8 [b]
Dairy cattle	10.57	2.16	7.1	3.33	12.97 [c]	3.84 [d]

[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.

Estimation of maximum residue and STMR values in animal commodities

For MRL estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden (21.6 ppm) between the relevant feeding levels (4 and 25 ppm) from the prothioconazole-desthio dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups and the STMR values were calculated by interpolating the STMR dietary burden (4.8 ppm) between the relevant feeding levels (4 and 25 ppm) and using the mean tissue concentrations from those feeding groups.

Dietary burden (ppm) Feeding level [ppm]	Muscle	Liver	Kidney	Fat
MRL	highest	highest	highest	Highest
MRL cattle (21.6) [4, 25]	< 0.01 [< 0.01, < 0.01]	0.23 [0.05, 026]	015 [0.04, 0.17]	0.02 [< 0.01, 0.02]
STMR	mean	mean	mean	Mean
STMR cattle (4.8) [4, 25]	< 0.01 [< 0.01, < 0.01]	0.05 [0.04, 0.22]	0.025 [0.02, 0.14]	0.01 [< 0.01, 0.01]

The data from the cattle feeding studies were used to support the estimation of maximum residue levels for mammalian meat and milk.

In milk the highest feeding dose (100 ppm) 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 13 ppm.

The Meeting estimated a maximum residue level of 0.5 mg/kg for edible offal (Mammalian) to replace the previous recommendations of 0.02 mg/kg and confirmed the previous recommended maximum residue levels for meat (0.01 mg/kg) and milk (0.004 (*) mg/kg).

The Meeting also agreed to recommend withdrawal of the 2008 JMPR recommendation for a maximum residue level of 0.02 mg/kg in mammalian fat.

The STMR values of 0.01 mg/kg for meat and fat, and the STMR value of 0.004 mg/kg for milk estimated by the 2008 JMPR were confirmed and the Meeting established STMRs of 0.05 mg/kg for liver, 0.025 mg/kg for kidney and established HRs of 0.23 mg/kg for liver, 0.15 mg/kg for kidney and 0.02 mg/kg in fat.

5.21 SPIRODICLOFEN (237)

TOXICOLOGY

Spirodiclofen is the ISO approved name for 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate (IUPAC) or 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutanoate (CAS), CAS No. 148477-71-8. Spirodiclofen is a selective, non-systemic foliar insecticide and acaricide belonging to the chemical class of ketoenols or tetronic acids, whose pesticidal mode of action is the inhibition of lipid synthesis.

Spirodiclofen is being reviewed for the first time by the present Meeting at the request of the CCPR.

All pivotal toxicological studies complied with GLP.

Biochemical aspects

The absorption, distribution, metabolism and excretion of spirodiclofen were investigated in rats. Orally administered ^{14}C-labelled spirodiclofen was rapidly absorbed and eliminated. Blood concentrations peaked at 3–4 h at low doses (1–2 mg/kg bw), and at ≥ 8 h at a higher dose (100 mg/kg bw). Decreased urinary excretion at the higher dose suggested saturation of absorption. Urine and faeces were the major routes of excretion. Retention in the carcass and organs was low (total body burden, < 1% of the administered dose within 48 h), and there was no evidence of bioaccumulation. Dietary pre-treatment with non-labelled compound did not have a significant impact on absorption or elimination.

After oral administration, ^{14}C-labelled spirodiclofen was extensively metabolized in rats. Spirodiclofen appears to be rapidly metabolized to the enol metabolite (BAJ 2510). No parent compound was detected in the urine or bile, and up to 11 metabolites were identified, representing 59–90% of the administered dose. Up to 16% of the parent compound was detected in the faeces. The profile of metabolites was generally similar qualitatively in males and females, but varied quantitatively. The major urinary metabolite in females was the enol metabolite, BAJ 2510, while the major urinary metabolite in males was the 3-hydroxy-enol metabolite. The metabolic profile in the bile was similar to that observed in the urine; however, a hydroxylated glucuronide metabolite was found to be unique to the bile.

Toxicological data

Spirodiclofen is of low acute toxicity when administered via the oral, dermal and inhalation routes. The oral and dermal LD_{50} values in rats were > 2500 and > 2000 mg/kg bw, respectively. The inhalation LC_{50} in rats was determined to be > 5.03 mg/L air. Spirodiclofen was not irritating to the eyes or skin of rabbits, but was found to be a dermal sensitizer under the conditions of the Magnussen & Kligman maximization test in guinea-pigs.

In short- and long-term studies of oral toxicity in mice, rats and dogs, the primary target organs of toxicity of spirodiclofen were the adrenal glands and testes. The predominant finding was vacuolation of the adrenal cortex, which was noted in the mouse, rat and dog, and was often accompanied by increased adrenal weight. With extended duration of dosing, adrenal vacuolation was associated with adrenal hypertrophy in rats, and adrenal enlargement and lymphocytic infiltration in mice. In rats, there were no adrenal findings after 28 days of dosing (NOAEL of 500 ppm, equal to 50 mg/kg bw per day, on the basis of changes in clinical chemistry parameters and induction of liver enzymes at 5000 ppm), and the overall NOAEL for adrenal effects from the 14-week and 2-year studies was 350 ppm, equal to 14.7 mg/kg bw per day from the 2-year study in rats. In mice, a NOAEL of 100 ppm, equal to 30 mg/kg bw per day, was identified in the short-term study on the basis of adrenal findings at 1000 ppm. After long-term dosing in mice, a NOAEL for adrenal findings

could not be identified as there was an increased incidence of adrenal pigmentation and vacuolation in females at the lowest dose tested (25 ppm, equal to 5.1 mg/kg bw per day). The incidence of pigmentation was only slightly above the reported range for historical controls, and the increase in vacuolation was not statistically significant. However, as the adrenal gland is clearly a target organ, these findings were considered to represent a marginal LOAEL for females at this dose. Compared with other species, the adrenal effects were observed at the lowest doses in dogs. Although a NOAEL could not be established for adrenal findings in the special 8-week study in dogs (LOAEL, 2.9 mg/kg bw per day) or for females in the 14-week study in dogs (LOAEL of 8.4 mg/kg bw per day), an overall NOAEL for adrenal histopathology in the dog was identified from the 1-year study in dogs (NOAEL of 1.4 mg/kg bw per day). Reversibility of the adrenal effects was observed in the short-term study in rats during a 28-day recovery period. The Meeting noted that these adrenal findings are a consequence of repeated dosing, which is supported by the lack of adrenal findings in the 28-day study in rats, and are potentially associated with prolonged perturbation of steroidogenesis.

Testicular effects in mice included Leydig-cell hypertrophy and vacuolation after short-term dosing, and increased weight, discoloration, degeneration, and interstitial-cell hyperplasia in the long-term study. In the long-term study, an increase in epididymal aspermia was also noted at the highets dose. In the dog, Leydig-cell vacuolation and hypertrophy, testicular immaturity, and degeneration of the germinal epithelium were noted in studies that ranged in duration from 28 days to 1 year. In the rat, Leydig-cell hyperplasia was observed in the 2-year study. The overall NOAEL for testicular effects was approximately 4 mg/kg bw per day from the 1-year study in dogs (150 ppm), 2-year study in rats (100 ppm), and 18-month study in mice (25 ppm), although it should be noted that increased testes weights were noted at this dose in the 1-year study in dogs. In dogs, the Meeting noted that when dosing began at a younger age, effects in reproductive tissues appeared to be more severe, and that the testicular effects were often accompanied by other effects, including immaturity of the prostate and oligo-/aspermia of the epididymides, which were noted in the 28-day (at 10 000 ppm) and 14-week studies (at ≥ 630 ppm). The Meeting also observed that there was evidence that effects in male reproductive tissues progressed, and that NOAELs decreased, with increasing duration of exposure, and that the nature of the findings indicated that they were potentially a result of prolonged perturbation of steroidogenesis.

Other effects observed following short- or long-term oral exposure to higher doses of spirodiclofen included effects on the liver, cholesterol levels, the thyroid, jejunum and thymus. Liver effects included hypertrophy, vacuolation and hepatocytomegaly in the mouse (at ≥ 1000 ppm, equal to 164 mg/kg bw per day); necrosis, cytoplasmic change, granulation and inflammatory infiltration in dogs (at ≥ 2000 ppm, equal to 84.7 mg/kg bw per day); and decreased concentrations of plasma proteins and tigroid basophilic focus in rats (at 2500 ppm, equal to 110.1 mg/kg bw per day). Increased liver weight and enzyme induction occurring in mice and dogs at lower doses were considered to be an adaptive response to the administration of spirodiclofen. Decreased cholesterol concentrations, which were consistent with the proposed pesticidal mode of action of this chemical, were observed in rats (at ≥ 110 mg/kg bw per day), dogs (at ≥ 4 mg/kg bw per day) and mice (at 1600 mg/kg bw per day), and were accompanied by decreased triglyceride concentrations in the rat. Vacuolization of the jejunum was observed in rats and dogs, and slight atrophy of the thymic cortex was also observed in dogs. Thyroid effects included decreased concentrations of thyroxin in dogs (at 2000 ppm in the 4-week study), and an increase in concentrations of thyroid-stimulating hormone (at ≥ 2500 ppm in the 14-week study) and colloidal alteration of the thyroid (at 2500 ppm in the 2-year study) in rats.

Spirodiclofen was tested for genotoxicity in vitro and in vivo in an adequate range of assays. It was not found to be genotoxic in mammalian or microbial systems.

The Meeting concluded that spirodiclofen was unlikely to be genotoxic.

In an 18-month study of carcinogenicity in mice, administration of spirodiclofen at dietary concentrations of 0, 25, 3500 or 7000 ppm resulted in the development of late-onset hepatocellular adenomas and carcinomas in males and females at doses of ≥ 3500 ppm. Systemic toxicity was noted

at the same doses, including changes in organ weights (liver, adrenal gland, testes, and kidney), and histopathological findings in the adrenal gland (vacuolation and pigmentation), liver (hepatocytomegaly), and testes (hypertrophy and hyperplasia). As discussed earlier, a NOAEL for systemic toxicity was not identified, on the basis of marginal effects on the adrenal gland in females at 25 ppm, equal to 5.1 mg/kg bw per day, the lowest dose tested. The NOAEL for carcinogenicity was 25 ppm, equal to 4.1 mg/kg bw per day, in this study. The Meeting noted that while pre-neoplastic lesions were not observed at lower doses than those at which the liver tumours were observed, this may have been due to the large dose-spacing. Additionally, the Meeting noted that these tumours were only observed at high doses (≥ 3500 ppm), which also produced hepatotoxicity, and that the dose–response relationship for these tumours was likely to exhibit a threshold.

The toxicity and carcinogenicity of spirodiclofen were investigated in a 2-year dietary study in rats. The incidence of late-onset Leydig-cell adenomas was increased in male rats at the highest dose tested (2500 ppm), preceded by an increased incidence of Leydig-cell hyperplasia at ≥ 350 ppm. An increased incidence of uterine adenocarcinomas and uterine nodules was also observed in female rats at the highest dose that had died or were sacrificed before study termination. These adenocarcinomas were noted to have metastasized into various organs of the abdominal cavity, as well as into the lung and bone marrow. Systemic toxicity was also noted at the highest dose, including increased mortality (females), decreased body weight (by 6–10%), increased levels of alkaline phosphatase, decreased concentrations of cholesterol and trigylerides, and histopathological findings in the adrenal gland (vacuolation and hypertrophy; males only), ovary (increased portion of stroma), vagina (possible increase in the number of animals in estrus based on morphology of vaginal epithelium), jejunum (vacuolation), thyroid (colloidal alteration), and olfactory epithelium (atrophy/degeneration; males only). The NOAEL for systemic toxicity was 100 ppm, equal to 4.1 mg/kg bw per day, on the basis of the increased incidence of Leydig-cell hyperplasia in males. The NOAEL for carcinogenicity was 350 ppm, equal to 14.7 mg/kg bw per day.

Several special studies were conducted with spirodiclofen and with three of the enol metabolites (BAJ 2510, 3-OH-enol and 4-OH-enol). Studies in vitro provided evidence that the enol metabolite (BAJ 2510) may contribute significantly to the effects observed with spirodiclofen via disruption of the metabolism of cholesterol, which is a precursor to a variety of hormones. Studies also confirmed that BAJ 2510 could inhibit the activity of malate dehydrogenase in tissue culture, resulting in a decrease in reducing equivalents required by various P450 monooxygenases involved in steroidogenesis, the downstream effect of which was ultimately predicted to reduce hormone production. Studies with BAJ 2510 in vitro, as well as special studies with spirodiclofen in vivo, provided some evidence of effects on steroid synthesis. The Meeting noted that the increased incidence of Leydig-cell and uterine tumours observed in rats was consistent with prolonged perturbations in steroidogensis, and the dose–response relationship for these effects would be anticipated to exhibit a threshold. However, a clear description of key events, with dose–response relationships and temporal associations, was not available, and the Meeting concluded that the data were not sufficient to develop a mode of action for formation of the observed tumours by spirodiclofen.

The Meeting concluded that the relevance of the tumorigenic responses in rats and mice to humans could not be discounted. However, the Meeting noted that spirodiclofen was not genotoxic, and that the dose–response relationship for the tumours would be anticipated to exhibit a threshold.

The effect of spirodiclofen on reproduction in rats was investigated in a two-generation study. Parental effects in both generations (F_0 and F_1) included vacuolation of the adrenal cortex and epithelium of the small intestine. Decreases in body weight and in concentrations of cholesterol, triglycerides and unesterified fatty acids were also observed in the F_1 generation (clinical chemistry evaluations were not performed for the F_0 generation). The NOAEL for parental toxicity was 70 ppm, equal to 5.2 mg/kg bw per day. Offspring toxicity included body-weight loss and decreased body-weight gain in the F_1 and F_2 pups at 350 ppm; the NOAEL for these findings in offspring was 70 ppm, equal to 5.2 mg/kg bw per day. Reproductive toxicity was observed in the F_1 generation only, at the highest dose tested (1750 ppm). Delayed sexual maturation was observed in male

offspring, and increased severity of ovarian vacuolation/degeneration, decreased testes, spermatid and epididymes sperm counts, reduced testes and epididymes size, as well as atrophy of the testes, epididymes and prostate were observed in some F_1 adults at the highest dose . The NOAEL for these findings in F_1 rats was 350 ppm, equal to 26.2 mg/kg bw per day. Although it is possible that the toxic effects on reproduction were associated with exposure in utero (as they were observed in the F_1 generation only), this remains uncertain, considering that F_1 rats began consuming treated diet at an earlier age, experienced a longer duration of dosing and were thus exposed to a higher overall average dose of spirodiclofen than the F_0 generation. The Meeting noted that this reproductive toxicity was potentially caused by sustained alteration of steroidogenesis.

The effect of spirodiclofen on developmental toxicity was investigated in rats and rabbits. In rats, no maternal toxicity was noted (the NOAEL was 1000 mg/kg bw per day, the highest dose tested), although the Meeting noted that investigation of target organs was not conducted in maternal animals. In the fetus, marginal increases in the incidences of slight renal pelvis dilatation and asymmetrical fourth sternebrae were observed at the highest dose tested. However, since these findings occurred at the highest dose tested (1000 mg/kg bw per day) and the incidences were within the range for historical controls, the Meeting considered that these effects represented a marginal LOAEL. The Meeting also noted that these findings would not be expected to occur after a single exposure (Solecki *et al.*, 2003; Makris *et al*., 2009).[35] The NOAEL for developmental toxicity in rats was 300 mg/kg bw per day on the basis of marginal findings at the highest dose tested. In the study in rabbits, maternal toxicity consisted of increased body-weight loss and decreased food consumption at 300 mg/kg bw per day. The NOAEL for maternal toxicity in rabbits was 100 mg/kg bw per day, and the NOAEL for developmental toxicity was 1000 mg/kg bw per day, the highest dose tested.

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

Neurotoxicity was investigated in studies of acute neurotoxicity, short-term studies of toxicity and studies of developmental neurotoxicity in rats. There was no evidence of neurotoxicity in the study of acute neurotoxicity, and the only evidence of neurotoxicity in the short-term study was decreased motor and locomotor activity in females at 12 500 ppm, equal to 1310 mg/kg bw per day, (the limit dose) during 1 week of treatment. Two studies of developmental neurotoxicity were conducted. The second was a modified study, intended to clarify potential findings related to brain morphometry and learning and memory parameters in offspring in the first study. Effects in parental animals were limited to small changes in body weight and/or food consumption at the highest dose tested, and these effects were not considered to be biologically relevant. The NOAEL for parental toxicity in both studies was 1500 ppm, equal to 119 mg/kg bw per day, the highest dose tested. In offspring, observed morphometric changes were small (3–7%), did not attain statistical significance in many cases, were not consistent between studies, and thus were not considered to be related to treatment. In tests of learning and memory, the findings were also inconsistent, and the considerable variability in the data limited their interpretation. Overall, the Meeting considered that these studies did not indicate any treatment-related findings on neurotoxicity parameters in offspring. The NOAEL was 350 ppm, equal to 28.6 mg/kg bw per day, on the basis of decreases in body weight and body-weight gain in offspring at 1500 ppm.

Studies of acute toxicity, short-term studies of toxicity and studies of genotoxicity were conducted with some of the metabolites of spirodiclofen, including BAJ 2740 ketohydroxy (a soil metabolite) and BAJ 2740-MA-3OH-cyclohexylester (a plant metabolite) – neither of which were detected in the studies of metabolism in rats – as well as the enol metabolite (BAJ 2510). BAJ 2740 ketohydroxy and BAJ 2740-MA-3OH-cyclohexylester were both of low acute toxicity when

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[35] (Solecki *et al*. Harmonization of rat fetal external and visceral terminology and classification Report of the Fourth Workshop on the Terminology in Developmental Toxicology, Berlin, 18–20 April 2002 ┌ Reproductive Toxicology 17 (2003) 625–637, Makris *et al*., Terminology of Developmental Abnormalities in Common Laboratory Mammals (Version 2) Birth Defects Research (Part B) 86:227–& 2009 Wiley-Liss, Inc. 327 (2009)

administered orally. BAJ 2510 was moderately toxic via the oral route (LD_{50}, 300–500 mg/kg bw per day), and was not irritating to the eyes and skin. A 6-week dietary study comparing the relative toxicity of spirodiclofen and the enol metabolite was conducted. Effects noted with both test substances included decreased body weight and food consumption, increased adrenal weights and enlargement and vacuolation of the adrenal gland. Both were also associated with decreased progesterone concentrations in females. In this short-term study, spirodiclofen and the enol metabolite were found to exert similar effects in rats given repeated doses, under the conditions of the study, and there was no indication that BAJ 2510 produced a different spectrum of toxic effects, or caused marked effects at lower doses than did spirodiclofen. Studies of reverse mutation in vitro were conducted with three metabolites of spirodiclofen (BAJ 2510, BAJ 2740 ketohydroxy and BAJ 2740-MA-3OH-cyclohexylester) to assess potential for inducing gene mutation in vitro. None of these metabolites of spirodiclofen were found to demonstrate any mutagenic potential under the conditions tested.

The following metabolites were identified only in plants: M05 (2,4-dichloro-mandelic acid hydroxy-cyclohexyl ester), M04 (2,4-dichloro-mandelic acid cyclohexyl ester glycosylpentoside) and M08 (2,4-dichloro-mandelic acid glucoside). The latter two metabolites are sugar conjugates of minor metabolites found in the rat. Limited toxicology data were provided for M05, and no toxicology data were provided for the other two plant metabolites. The Meeting therefore concluded that the information available was not sufficient to conduct a risk assessment for these metabolites. The enol metabolite was detected in plants and livestock matrices. As the enol metabolite was found to be of similar toxicity to the parent compound, the Meeting considered this metabolite to be toxicologically relevant for the dietary risk assessment.

There were no reports of adverse health effects in manufacturing-plant personnel or in operators and workers exposed to spirodiclofen formulations.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.01 mg/kg bw per day based on the NOAEL of 1.4 mg/kg bw per day identified on the basis of adrenal effects in males and females, and increased relative testes weights in males at 4.3 mg/kg bw per day in the 1-year study in dogs and with a safety factor of 100. This ADI provides adequate protection for the marginal adrenal effects noted in females at the lowest dose in the 18-month study in mice. The ADI provides a margin of at least 410-fold relative to the NOAEL for liver tumours in mice, and 1470-fold relative to the NOAEL for Leydig-cell and uterine tumours in rats, and thus the Meeting considered that spirodiclofen was not likely to pose a carcinogenic risk to humans at dietary levels of exposure.

The Meeting noted that spirodiclofen was not acutely toxic after short-term dosing, that there were no adverse findings in a study of acute neurotoxicity, and that there were no developmental toxicity findings that were expected to occur after a single dose in studies in rats or rabbits. The Meeting also noted that findings in the male reproductive system (observed in dogs, rats and mice) would not be caused by a single dose. Consequently, the Meeting determined that an ARfD was unnecessary.

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	—	25 ppm, equal to 5.1 mg/kg bw per day[f]

		Carcinogenicity	25 ppm, equal to 4.1 mg/kg bw per day	3500 ppm, equal to 610 mg/kg bw per day
Rat	Two-year studies[a]	Toxicity	100 ppm, equal to 4.1 mg/kg bw per day	350 ppm, equal to 14.7 mg/kg bw per day
		Carcinogenicity	350 ppm, equal to 14.7 mg/kg bw per day	2500 ppm, equal to 110.1 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Parental toxicity	70 ppm, equal to 5.2 mg/kg bw per day	350 ppm, equal to 26.2 mg/kg bw per day
		Offspring toxicity	350 ppm, equal to 26.2 mg/kg bw per day	1750 ppm, equal to 134.5 mg/kg bw per day
		Reproductive toxicity	70 ppm, equal to 5.2 mg/kg bw per day	350 ppm, equal to 26.2 mg/kg bw per day
	Developmental toxicity[b]	Maternal toxicity	1000 mg/kg bw per day[c]	—
		Embryo/fetotoxicity	300 mg/kg bw per day	1000 mg/kg bw per day
		Parental toxicity	1500 ppm, equal to 119 mg/kg bw per day[c]	—
	Developmental neurotoxicity[a,d]	Offspring toxicity	350 ppm, equal to 28.6 mg/kg bw per day	1500 ppm, equal to 119 mg/kg bw per day
Rabbit	Developmental toxicity[b]	Maternal toxicity	100 mg/kg bw per day	300 mg/kg bw per day
		Embryo/fetotoxicity	1000 mg/kg bw per day[c]	—
Dog	Eight-week study of toxicity[a, e]	Toxicity	—	100 ppm, equal to 2.9 mg/kg bw per day[f]
	Fourteen-week study of toxicity[a]	Toxicity in males	200 ppm, equal to 7.7 mg/kg bw per day	630 ppm, equal to 26.6 mg/kg bw per day
		Toxicity in females	—	200 ppm, equal to 8.4 mg/kg bw per day[f]
	One-year study of toxicity[a]	Toxicity	50 ppm, equal to 1.4 mg/kg bw per day	150 ppm, equal to 4.3 mg/kg bw per day

[a]Dietary administration.

[b]Gavage administration.

[c]Highest dose tested.

[d]Two studies combined.

[e]Study conducted with males only.

[f]Lowest dose tested.

Estimate of acceptable daily intake for humans

0–0.01 mg/kg bw

Estimate of acute reference dose

Unnecessary

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

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid (t_{max} of 3–4 h) and extensive (up to 76%; based on renal excretion data)
Distribution	Widely distributed; highest concentrations in liver and kidneys
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapidly excreted; 90% eliminated at 48 h
Metabolism in animals	Extensively metabolized; no parent compound detected in urine or bile. Quantitative differences in metabolic profile between sexes.
Toxicologically significant compounds (animals, plants, environment)	Parent compound and enol metabolite
Acute toxicity	
Rat, LD_{50} oral	> 2500 mg/kg bw
Rat, LD_{50} dermal	> 2000 mg/kg bw
Rat, LC_{50} inhalation	> 5.03 mg/L air
Guinea-pig, dermal sensitization (test method used)	Sensitizing (maximization test)
Short-term studies of toxicity	
Target/critical effect	Adrenal gland (cortical vacuolation and increased weight)
Lowest relevant oral NOAEL	50 ppm (equal to 1.4 mg/kg bw per day; 1-year study in dogs)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (28-day study in rats)
Genotoxicity	
	No genotoxic potential

Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Adrenal gland (cortical vacuolation and increased weight)
Lowest relevant NOAEL	50 ppm (equal to 1.4 mg/kg bw per day; 1-year study in dogs)
Carcinogenicity	Tumours in livers (mice), testes (rat) and uterus (rat) at doses that caused target organ and/or systemic toxicity. NOAELs identified; unlikely to pose a risk to humans at levels of dietary exposure.
Reproductive toxicity	
Reproduction target/critical effect	Delayed sexual maturation, decreased spermatid and sperm counts, atrophy of male sex organs, and ovarian vacuolation/degeneration in F_1 animals
Lowest relevant reproductive NOAEL	350 ppm (equal to 26.2 mg/kg bw per day)
Developmental target/critical effect	Renal pelvis dilatation and assymetric fourth sternebrae
Lowest relevant developmental NOAEL	300 mg/kg bw per day (rat)
Neurotoxicity/delayed neurotoxicity	
Acute neurotoxicity	No evidence of neurotoxicity; NOAEL: 1000 mg/kg bw per day
Subchronic neurotoxicity	Decreased motor and locomotor activity (females only); NOAEL: 87 mg/kg bw per day
Developmental neurotoxicity	No evidence of developmental neurotoxicity
Other toxicological studies	
Mechanism studies	Possible effect on steroidogenesis by the enol metabolite via effects on malate dehydrogenase
Studies with metabolites	
Acute toxicity	BAJ 2510 was moderately acutely toxic via the oral route (LD_{50} 300–500 mg/kg bw); BAJ 2740 ketohydroxy and BAJ 2740-3-OH-cyclohexylester were of low acute oral toxicity (LD_{50} > 2500 mg/kg bw)
Short-term toxicity	Similar results following short-term dosing with BAJ 2510 and spirodiclofen: decreased body weight and adrenal effects
Genotoxicity	BAJ 2510, BAJ 2740 ketohydroxy and BAJ 2740-3-OH-cyclohexylester were not mutagenic in vitro
Medical data	
	No occupational or accidental poisoning reported

Summary

	Value	**Study**	**Safety factor**
ADI	0–0.01	Dog, 1-year	100
ARfD	Unnecessary	—	—

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of spirodiclofen were considered for the first time by the present Meeting. The residue evaluation was scheduled for the 2009 JMPR by the Forty-first Session of the CCPR (ALINORM 09/32/24).

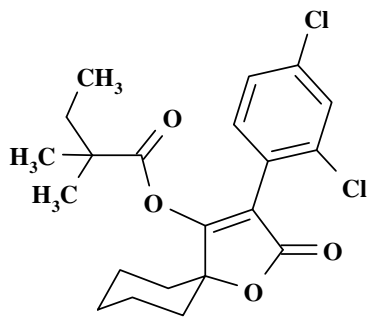
Spirodiclofen is an insecticide/acaricide belonging to the chemical class of ketoenols or tetronic acids and acts as inhibitor of lipid biosynthesis, mainly against mites. It has registered uses in many countries on fruits, fruiting vegetables, tree nuts, coffee and hops.

The Meeting received information from the manufacturer on identity, metabolism, storage stability, residues analyses, use patterns and residues resulting from supervised trials on grapefruit, lemons, mandarins, oranges, apples, pears, cherries, peaches, plums, blackberries, currants, grapes, raspberries, strawberries, papayas, cucumbers, gherkins, sweet peppers, tomatoes, almonds, coconuts, pecans, coffee, and hops, fates of residue during processing, processing, distribution in the edible portion and livestock feeding studies. In addition, the Meeting received information from the Netherlands, on use patterns.

Chemical name:

Spirodiclofen or 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate

Structural formula:



Metabolites referred to in the appraisal by codes:

M04: 2,4-dichloro-mandelic acid cyclohexyl ester glycosyl pentoside

M05: 2,4-dichloro-mandelic acid hydroxy-cyclohexyl ester

M08: 2,4-dichloro-mandelic acid glucoside

Animal metabolism

The Meeting received results of animal metabolism studies in a lactating goat. Experiments were carried out using spirodiclofen ^{14}C labelled in the 3-position of the dihydrofuranone ring.

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2009.

A lactating goat, orally treated once daily for 3 consecutive days with [^{14}C]spirodiclofen at a calculated dose rate of 252 ppm in the dry weight feed (equivalent to 10.7 mg ai/kg bw/d), was sacrificed 6 hours after the last dose. Of the administered dose 72% was recovered of which 28% was found in faeces, 17% in urine, while 54% remained in the gastro-intestinal tract. Tissues contained 0.29%, while milk contained 0.05% of the recovered radioactivity. The radioactivity in the tissues ranged from 2.9 mg/kg in kidney and 0.78 mg/kg in liver to 0.14 mg/kg in fat and 0.068 mg/kg

spirodiclofen equivalents in muscle. Radioactivity in milk increased until sacrifice to a level of 0.20 mg/L spirodiclofen equivalents. A plateau was not reached after three days of dosing.

Radioactivity was characterized in tissues and milk. No spirodiclofen (parent) was found in any of the tissues or in milk. The major metabolite was spirodiclofen-enol (M01) at 95% of the total radioactivity in kidney, 81% in liver, 85% in fat, 84% in muscle, and 82–86% in milk. 4-OH-enol spirodiclofen (M03) was identified as minor metabolite at levels up to 9% of the total radioactivity. A minor part of the extractable residue in tissues and milk remained unidentified (3.2–20% of the total radioactivity). Radiochromatograms showed that these residues did not occur in relevant amounts. Only up to 7% of the total radioactivity remained unextracted.

The absorbed dose was extensively metabolised as evidenced by full disappearance of the parent compound in tissues and milk.

One basic metabolic pathway of spirodiclofen in goat is proposed. The metabolic pathway consists of cleavage of the alkyl ester group resulting in spirodiclofen-enol (major metabolite) followed by hydroxylation of spirodiclofen-enol in the 4-position of the cyclohexyl ring, forming 4-OH-enol spirodiclofen (minor metabolite).

The metabolic pathway proposed for ruminants is consistent with that for rats, except that spirodiclofen is metabolised further in rats.

Plant metabolism

The Meeting received plant metabolism studies for spirodiclofen spray treatments on fruit (lemons, oranges, apples and grapes) and topical treatments on grapefruit leaves and hop leaves. Experiments were carried out using spirodiclofen ^{14}C labelled in the 3-position of the dihydrofuranone ring.

Greenhouse grown lemon trees were sprayed with [^{14}C]spirodiclofen once at a dose rate of 0.45 kg ai/ha. Total radioactive residues (TRR) in the lemon fruit harvested 21 days following the last application were 0.263 mg/kg spirodiclofen equivalents. The radioactivity was almost exclusively located in/on the peel (99.8% of the total radioactivity). Washing with acetonitrile removed 62% of the total radioactivity. The main component in the lemon peel was the parent compound, accounting for 75% of the total radioactivity. A total of 27 metabolites could be found, together amounting to 22% of the total radioactivity. None of these metabolites exceeded 3% of the total radioactivity or 0.01 mg/kg spirodiclofen equivalents.

Greenhouse grown orange trees were sprayed with [^{14}C]spirodiclofen once at a dose rate equivalent to 0.6 kg ai/ha. Total radioactive residues in the orange fruit harvested 160 days after the application were 0.072 mg/kg spirodiclofen equivalents. The radioactivity was almost exclusively located in/on the peel (92% of the total radioactivity). Washing with acetonitrile removed 56% of the total radioactivity. The main component in the orange peel was the parent compound, accounting for 34% of the total radioactivity. A total of 22 metabolites could be found, together amounting to 52% of the total radioactivity. None of these metabolites exceeded 10% of the total radioactivity or 0.01 mg/kg spirodiclofen equivalents. Of the total radioactivity 6% remained unextracted from the peel.

Field grown apple trees were sprayed with [^{14}C]spirodiclofen once at a dose rate of 1.1 kg ai/ha. Total radioactive residues in the apple fruit harvested 23 and 84 days following application were 0.85 and 0.39 mg/kg spirodiclofen equivalents. The vast majority of the total radioactivity could be removed by surface washing with dichloromethane and acetone: 98% and 83% for 23 and 84 day samples, respectively. The main component in apple fruit was the parent compound, accounting for 89–99% of the total radioactivity. A total of 10–11 metabolites could be found, together amounting to 0.5–10% of the total radioactivity. Only one metabolite was found in quantifiable amounts and was identified as M08 (4.5% of the total radioactivity).

Field grown grape vines were sprayed with [^{14}C]spirodiclofen once at a dose rate of 0.224 kg ai/ha. Total radioactive residues in the grape berries harvested 21 and 64 days following the

application were 1.9 and 1.1 mg/kg spirodiclofen equivalents. The majority of the total radioactivity could be removed by surface washing with dichloromethane: 96% and 57% for 21 and 64 day harvest samples, respectively. The main component in the grape berries was the parent compound, accounting for 58%–96% of the total radioactivity. In the 23 day harvest day samples, a total of 11 metabolites could be found, together amounting to 3.5% of the total radioactivity. In the 64 day harvest samples, a total of 17 metabolites could be found, together amounting to 41% of the total radioactivity. Four metabolites were found as quantifiable amounts and these were identified as M08 (12.2 % of the total radioactivity), M04 (7.9% of the total radioactivity), M05 (7.2% of the total radioactivity), and 3-OH-enol spirodiclofen (2.6% of the total radioactivity).

Grapefruit leaves from greenhouse grown trees were treated topically with [^{14}C]spirodiclofen at 0.45 kg ai/ha and adjacent fruits were harvested 85 days later. Sampled fruit contained only 0.09% of the applied dose and total radioactive residues in the fruit were less than 0.01 mg/kg spirodiclofen equivalents. This translocation study indicates that spirodiclofen does not move systemically through the plant, which is consistent with the approximate log K_{ow} of 5.8.

In each commodity tested, spirodiclofen was found to be the major residue (34%–99% of the total radioactivity). The radioactive residue primarily resided on the surface of the fruits. A total of 11–27 metabolites could be found which accounted for the remainder of the residue. In lemons and oranges none of these metabolites was present in quantifiable amounts. In apples, only one metabolite was found in quantifiable amounts and was identified as M08 (4.5% of the total radioactivity). In grapes, four metabolites were found in quantifiable amounts and these were identified as M08 (12% of the total radioactivity), M04 (7.9% of the total radioactivity), M05 (7.2% of the total radioactivity), and 3-OH-enol spirodiclofen (2.6% of the total radioactivity). The formation of these metabolites is time-dependent. Quantifiable amounts of these metabolites were only found in the apple and grape samples with long pre-harvest intervals (64–84 days).

The following metabolic pathway of spirodiclofen is proposed. The initial degradation reaction is cleavage of the ester bond forming the spirodiclofen-enol compound, followed by hydroxylation of spirodiclofen-enol in the 3- or 4- position of the cyclohexyl ring. Cleavage of the acid ring structure leads to a ring-open mandelic acid cyclohexyl ester intermediate which is further metabolised by derivatisation of this intermediate (hydroxylation, conjugation with carbohydrates) or by further degradation into the free 2,4-dichloro-mandelic acid, finally followed by glycosylation.

Plant metabolites identified were also found in rats, except for M05, M04 and M08. The latter two metabolites are sugar conjugates of minor metabolites found in rats. M05 is an intermediate in the degradation to 2,4-dichloro-mandelic acid, which is found in rats.

Environmental fate

The Meeting received information on the hydrolysis and photolysis of spirodiclofen in sterile water. Experiments were carried out using spirodiclofen ^{14}C labelled in the 3-position of the dihydrofuranone ring (hydrolysis, photolysis) or ^{14}C labelled at the cyclohexyl 1-position (photolysis).

Spirodiclofen is regarded as hydrolytically stable at pH 4 at ambient temperature, but is unstable at pH 7 and 9. The half-life for spirodiclofen at 20 °C was calculated as 119.6 days at pH 4, 52.1 days at pH 7 and 2.5 days at pH 9. Spirodiclofen is degraded by ester cleavage with the formation of spirodiclofen-enol.

A photolysis study was conducted with artificial sunlight, equivalent to 28.5 days of natural sunlight. Half life was 54 days for natural sunlight at summer. Since the pH during the experiment ranged from 4.4 to 5.6, part of the degradation might have been caused by hydrolysis. The half life must be considered an estimate. Spirodiclofen is degraded by ester cleavage with the formation of spirodiclofen-enol.

Methods of Analysis

The Meeting received description and validation data for analytical methods for enforcement-monitoring of spirodiclofen and some of its metabolites and residue analytical methods used in the various study reports for spirodiclofen and its metabolites.

Four analytical methods were proposed to the Meeting as post-registration monitoring and enforcement method for parent spirodiclofen in crops and animal commodities. Two of these methods also determined metabolite spirodiclofen-enol.

The Meeting considers the GC-ECD version of multi-residue method DFG S19 sufficiently validated for the determination of parent spirodiclofen in plant commodities with high water content, plant commodities with high acid content, plant commodities with high fat content, dry plant commodities, animal tissues, milk and eggs. The HPLC-MS-MS multi-residue method 109351 is considered sufficiently validated for the determination of parent spirodiclofen in plant commodities with high acid content, plant commodities with high water content and plant commodities with high fat content. The two HPLC-MS-MS single-residue methods 109720 and 00919 are considered sufficiently validated for the determination of parent and metabolite spirodiclofen-enol in animal tissues and milk. The use of deuterated standards in method 109720 makes the method very expensive and therefore less suitable as an enforcement-monitoring method for world-wide use.

The methods reported to the Meeting and used in the supervised residue trials, processing studies, storage stability studies and feeding studies determined parent spirodiclofen and in some cases also the metabolites spirodiclofen-enol, 3-OH-enol spirodiclofen and 4-OH-enol spirodiclofen. Macerated samples were extracted with acetone, acetonitrile/water (2:1), acetonitrile/water/20% cysteine HCl (200:100:1, v/v/v), acetonitrile/0.1% aqueous formic acid (4:1, v/v) or acetone/dichloromethane/petroleum ether (1:1:1, v/v/v). 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-ECD or HPLC-MS-MS. LOQs were in the 0.004–1.0 mg/kg range for spirodiclofen and its metabolites.

Extraction efficiencies for acetone and acetonitrile/water (2:1) were verified using samples with incurred radioactive residues from metabolism studies on oranges (180 day harvest sample), apples (84 day harvest sample) and grapes (21 day harvest sample). Extraction efficiency for acetone for spirodiclofen was 94–99% in apples. Extraction efficiency for acetonitrile/water (2:1) for spirodiclofen was 124%, 92%–100% and 96%, respectively in orange peel, apples and grapes. The Meeting considered the extraction efficiencies for the extraction solvents as used in the analytical methods sufficient.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of spirodiclofen in samples stored frozen.

Parent spirodiclofen was stable when stored frozen for at least 13 months in crops with high water content (peaches), at least 24 months in crops with high acid content (citrus and grapes), 16 months in crops with oil content (almond nutmeat, and dry hop cones), at least 8 months in fruit juice (apple juice and grape juice), and at least 10 months in dried fruit (dried apples, raisins and dried plums).

No storage stability studies were provided for animal commodities. Since the samples from the animal feeding study were analysed within 30 days after slaughter, there is no need to have storage stability studies on animal commodities.

Definition of the residue

In goats, the absorbed dose was extensively metabolised as evidenced by full disappearance of the parent compound in tissues and milk. The major metabolite was spirodiclofen-enol at 95% of the total radioactivity in kidney, 81% in liver, 85% in fat, 84% in muscle, and 82–86% in milk.

However, the Meeting noted that in a feeding study on lactating cows, which is described later, at a dose rate of 13 ppm dry feed, residues of up to 0.011 and 0.012 mg/kg spirodiclofen were found in milk fat (cream) and beef fat, respectively.

The metabolism study in goats was conducted at an exaggerated dose rate of 252 ppm and a feeding study on dairy cows was conducted at moderate levels of 1.3–13 ppm dry feed. Since anticipated livestock dietary burdens are below 1 ppm dry feed, no residues are expected in animal commodities. The feeding studies show that the first compound to be detected at exaggerated dose rates will be the parent compound in fat and spirodiclofen-enol in kidney. Since kidney is not an important commodity for enforcement, and fat is, the Meeting concluded that parent spirodiclofen is a suitable analyte in animal commodities for enforcement purposes. For dietary risk assessment spirodiclofen and spirodiclofen-enol are considered suitable analytes.

Based on the available comparative plant metabolism studies, parent spirodiclofen is the major component (34–99% of the total radioactivity TRR) of the crops tested. Quantifiable amounts of metabolites identified in plant commodities but not found in rat and livestock (goat), were M05 (7.2% TRR), M04 (7.9% TRR) and M08 (4.5–12% TRR). The latter two metabolites are sugar conjugates of minor metabolites found in the rat. Limited toxicology data were provided for M05, and no toxicology data were provided for the other two plant metabolites. The Meeting therefore concluded that sufficient information was not available to conduct a hazard assessment for these metabolites. Spirodiclofen-enol was detected in plants (2.1% TRR), livestock matrices (82–95% TRR) and rats. As spirodiclofen-enol was found to be of similar toxicity to the parent compound, it is considered to be toxicologically relevant for the dietary risk assessment.

Given the predominant presence of spirodiclofen in the fruit residues, none of these plant metabolites should be included in the residue definition, as none of these metabolites are expected to be present at levels above 0.01 mg/kg at the GAPs considered for the present evaluation. The Meeting concluded that parent spirodiclofen is a suitable analyte in plant commodities for enforcement purposes and for dietary risk assessment.

Fat solubility of spirodiclofen (parent) is shown in a feeding study on cows, where spirodiclofen was only found in milk fat and beef fat and not in any of the other tissues. The log K_{ow} for spirodiclofen of approximately 5.8 also suggests fat solubility. The Meeting considered the residue in animal commodities (spirodiclofen) to be fat-soluble.

The Meeting recommended the following as residue definitions for spirodiclofen:

Definition of the residue for compliance with the MRL or for estimation of the dietary intake for plant commodities: *spirodiclofen*

Definition of the residue for compliance with the MRL for animal commodities: *spirodiclofen.*

Definition of the residue for estimation of the dietary intake for animal commodities: *the sum of spirodiclofen and spirodiclofen-enol, expressed as spirodiclofen.*

The Meeting considers the residue in animal commodities to be fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for spirodiclofen on grapefruit, lemons, mandarins, oranges, apples, pears, cherries, peaches, plums, blackberries, currants, grapes,

raspberries, strawberries, papayas, cucumbers, gherkins, sweet peppers, tomatoes, almonds (nutmeat and hulls), coconuts, pecans, coffee and hops.

As an ARfD was considered unnecessary, no HR values are reported as an IESTI calculation was not needed.

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is < 15 or when there are a large number of values < LOQ.

Citrus fruits

Field trials involving grapefruit were performed in the USA. GAP for citrus in the USA is for one spray application at 0.35 kg ai/ha (PHI 7 days). In trials from the USA matching this GAP (1 × 0.343–0.387 kg ai/ha, PHI 7 days), spirodiclofen residues in grapefruit whole fruit were 0.032, 0.087, 0.088, 0.099, 0.12 and 0.31 mg/kg (n=6) from low volume spraying and 0.085, 0.090, 0.093, 0.13, 0.14 and 0.18 mg/kg (n=6) from normal (high or dilute) volume spraying on/under the same locations/conditions. In those cases where residues at a longer PHI were higher, these residues were selected for use in the estimation.

The Meeting noted that the residues corresponding to low volume spray and normal spray were from similar populations (Mann-Whitney U test) and because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for grapefruit whole fruit: 0.087, 0.09, 0.093, 0.13, 0.18 and 0.31 mg/kg (n=6).

Field trials involving lemons were performed in the USA. GAP for citrus in the USA is for one spray application at 0.35 kg ai/ha (PHI 7 days). In trials from the USA matching this GAP (1 × 0.340–0.376 kg ai/ha, PHI 7 days), spirodiclofen residues in lemon whole fruit were 0.041, 0.046, 0.16, 0.19 and 0.32 mg/kg (n=5) from low volume spraying and 0.026, 0.048, 0.13, 0.16 and 0.24 mg/kg (n=5) from normal spraying on/under the same locations/conditions. In those cases where residues at a longer PHI were higher, these residues were selected for use in the estimation.

The Meeting noted that the residues corresponding to low volume and normal spraying were from similar populations (Mann-Whitney U test) and because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for lemon whole fruit: 0.046, 0.048, 0.16, 0.19 and 0.32 mg/kg (n=5).

Field trials involving mandarins were performed in Spain, Portugal and Italy. GAP for citrus in Spain is for one spray application at 0.0048 kg ai/hL (PHI 14 days). In trials from Spain, Portugal and Italy matching this GAP (1 × 0.0048 kg ai/hL, PHI 14 days), spirodiclofen residues in mandarin whole fruit were: 0.021, 0.034, 0.042, 0.047, 0.050, 0.053, 0.059 and 0.076 mg/kg (n=8). In those cases where residues at a longer PHI were higher, these residues were selected for use in the estimation.

Field trials involving oranges were performed in Spain, Portugal, Italy, South Africa, Brazil and the USA. GAP for citrus in Spain is for one spray application at 0.0048 kg ai/hL (PHI 14 days). In trials from Spain, Portugal and Italy matching this GAP (1 × 0.0048 kg ai/hL, PHI 13–16 days), spirodiclofen residues in orange whole fruit were: < 0.02, 0.030, 0.034, 0.034, 0.047, 0.049, 0.053 and 0.055 mg/kg (n=8). In those cases where residues at a longer PHI were higher, these residues were selected for use in the estimation.

GAP for "citrus excluding lemon and kumquat" in South Africa is for one spray application at 0.0036 kg ai/hL (PHI 76 days). The Meeting considered trials with two applications (2 × 0.0036 kg ai/hL, interval 56–64 days, PHI 71–76 days) acceptable, since residue results from two applications at such long intervals are unlikely to differ from single applications. Spirodiclofen residues were: < 0.01 and 0.01 mg/kg (n=2).

GAP for citrus in Brazil is for one spray application at 0.0072 kg ai/hL (PHI 21 days). Field trials performed in Brazil did not match the GAP.

GAP for citrus in the USA is for one spray application at 0.35 kg ai/ha (PHI 7 days). In trials from the USA matching this GAP (1 × 0.340–0.395 kg ai/ha, PHI 7 days), spirodiclofen residues in orange whole fruit were 0.041, 0.051, 0.066, 0.11, 0.11, 0.12, 0.12, 0.13, 0.14, 0.14 and 0.15 mg/kg (n=11) from low volume spraying and 0.066, 0.081, 0.082, 0.098, 0.099, 0.12, 0.13, 0.13, 0.14, 0.14, 0.20 and 0.22 mg/kg from normal spraying (n=12) on/under the same locations/conditions. In those cases where residues at a longer PHI were higher, these residues were selected for use in the estimation.

The Meeting noted that the residues corresponding to low volume and normal spray applications were from similar populations (Mann-Whitney U test) and because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for orange whole fruit: 0.066, 0.082, 0.11, 0.11, 0.12, 0.13, 0.13, 0.14, 0.14, 0.14, 0.2 and 0.22 mg/kg (n=12).

The South African dataset was considered insufficient to support a recommendation. The Meeting noted that the residues based on the GAP for USA were higher than the residues based on the GAP for Spain (Mann-Whitney U test) and decided to use only the orange data corresponding to the USA GAP.

The Meeting noted that the Spanish dataset for mandarins had lower residues than the USA datasets for grapefruit, lemons or oranges (Kruskal-Wallis test) and agreed to use only the citrus data from the USA.

The Meeting noted that the USA datasets from grapefruit, lemon and orange were from similar populations (Kruskal-Wallis test). Since residue behaviour within the citrus group is expected to be similar, the Meeting agreed that the datasets could be combined. Spirodiclofen residues in citrus whole fruit were: 0.046, 0.048, 0.066, 0.082, 0.087, 0.09, 0.093, 0.11, 0.11, 0.12, 0.13, 0.13, 0.13, 0.14, 0.14, 0.14, 0.16, 0.18, 0.19, 0.2, 0.22, 0.31 and 0.32 mg/kg (n=23).

The Meeting agreed that the USA data on grapefruit, lemon and orange could be used to support a citrus fruit commodity group maximum residue level and estimated a maximum residue level of 0.4 mg/kg for spirodiclofen on citrus fruit and estimated an $STMR_{RAC}$ of 0.13 mg/kg for spirodiclofen in citrus whole fruit (for processing purposes).

The value derived from use of the NAFTA calculator (NAFTA 95/99 95th percentile) was 0.4 mg/kg, which was in agreement with the estimate of made by the Meeting.

Spirodiclofen residue data on the edible portion of citrus fruit at the relevant GAPs were not available. Residue trials on the distribution of peel and pulp in mandarins and orange at a longer PHI of 28 days showed that no residues are found in pulp (< 0.02 mg/kg). Metabolism studies in grapefruit and lemon confirm that spirodiclofen residues reside in the peel. The Meeting estimated an STMR of 0.02 mg/kg in the edible portion (pulp/flesh) of citrus fruit.

Pome fruits

Field trials involving apples were performed in Germany, Belgium, the United Kingdom, France, Spain, Italy, USA, Canada and Brazil.

GAP for pome fruit in Germany is for one spray application at 0.0096 kg ai/hL (PHI 14 days). In trials from Germany, Belgium, United Kingdom and France matching this GAP

(1 × 0.0096 kg ai/hL, PHI 14 days), spirodiclofen residues in apple, whole fruit, were 0.025, 0.035, 0.039, 0.043, 0.049, 0.049, 0.059 and 0.077 mg/kg (n=8). In those cases where residues at a longer PHI were higher, these residues were selected for use in the estimation.

GAP for apples in Italy is for one spray application at 0.14 kg ai/ha (PHI 14 days). In trials from Italy and Spain matching this GAP (1 × 0.120–0.144 kg ai/ha, PHI 14 days), spirodiclofen residues in apple whole fruit were < 0.02, 0.024, 0.046 and 0.055 mg/kg (n=4).

GAP for pome fruit in the USA is for one spray application at 0.32 kg ai/ha (PHI 7 days). In trials from the USA and Canada matching this GAP (1 × 0.297–0.356 kg ai/ha, PHI 7–8 days), spirodiclofen residues in apple whole fruit were < 0.01, 0.069, 0.070, 0.094, 0.099, 0.10, 0.11, 0.13, 0.13, 0.13, 0.18, 0.2, 0.22, 0.23, 0.24, 0.25, 0.34, 0.40 and 0.50 mg/kg (n=19) for low volume spray and 0.061, 0.080, 0.087, 0.091, 0.1, 0.11, 0.12, 0.13, 0.18, 0.18, 0.18, 0.21, 0.21, 0.22, 0.23, 0.26 and 0.28 mg/kg (n=17) for normal spray on/under the same locations/conditions. In addition on two of these locations comparisons were made between SC formulations (0.10, 0.13, 0.18 and 0.18 mg/kg) and WG formulations (0.1, 0.11, 0.11 and 0.13 mg/kg). In those cases where residues from a longer PHI were higher, these residues were selected for use in the estimation.

The Meeting noted that the residues corresponding to low volume spray and normal spray were from similar populations (Mann-Whitney U test) and that the residues corresponding to SC and WG formulations are from similar populations (Mann-Whitney U test). Because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for apple whole fruit: 0.07, 0.08, 0.087, 0.094, 0.099, 0.18, 0.18, 0.18, 0.20, 0.21, 0.22, 0.24, 0.25, 0.28, 0.34, 0.40 and 0.50 mg/kg (n=17).

GAP for apples in Brazil is for one spray application at 0.0048 kg ai/hL (PHI 7 days). In trials from Brazil matching this GAP (1 × 0.0048 kg ai/hL, PHI 7 days), spirodiclofen residues in apple whole fruit were 0.17, 0.18 and 0.18 mg/kg (n=3).

The Brazilian dataset was considered insufficient to support a maximum residue level recommendation. The Meeting noted that the dataset for apples from the USA gave higher residues than either the German or Italian datasets for apples (Kruskal-Wallis test) and agreed to use only the apple data from the USA.

Field trials involving pears were performed in Italy, France, the USA and Canada.

GAP for pears in Italy is for one spray application at 0.14 kg ai/ha (PHI 14 days). In trials from Italy and France matching this GAP (1 × 0.120–0.144 kg ai/ha, PHI 14 days), spirodiclofen residues in the whole fruit of pears were: 0.027, 0.035, 0.039 and 0.043 mg/kg (n=4).

GAP for pome fruit in the USA is for one spray application at 0.32 kg ai/ha (PHI 7 days). In trials from the USA and Canada matching this GAP (1 × 0.312–0.326 kg ai/ha, PHI 6–7 days), spirodiclofen residues in pears (whole fruit) were: 0.10, 0.11, 0.12, 0.14, 0.15, 0.19, 0.24, 0.31, 0.31, 0.45 and 0.70 mg/kg (n=11) for low volume spray and 0.10, 0.14, 0.17, 0.18, 0.18, 0.20, 0.20, 0.28 , 0.41 and 0.42 mg/kg (n=10) for dilute spray on/under the same locations/conditions. In addition, at one of the trial locations comparisons were made between SC formulations (0.14 and 0.31 mg/kg) and WG formulations (0.15 and 0.15 mg/kg). In those cases where residues at a longer PHI were higher, these residues were selected.

The Meeting noted that the residue populations corresponding to low volume spray and normal spray are from similar populations (Mann-Whitney U test) and that the residue populations corresponding to SC and WG formulations are from similar populations. Because only one residue could be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for pears (whole fruit): 0.10, 0.17, 0.18, 0.20, 0.20, 0.24, 0.31, 0.31, 0.45 and 0.70 mg/kg (n=10).

The Meeting noted that the dataset from the USA for pears had higher residues than that of the Italian dataset (Mann-Whitney U test) and decided to use only the pear data corresponding to the GAP of the USA.

The Meeting noted that the US datasets for apples and pears were from similar populations (Mann-Whitney U test). Since residue behaviour within the pome fruit group is expected to be similar, the Meeting agreed that they could be combined. Spirodiclofen residues in pome fruit (whole fruit) were: 0.070, 0.080, 0.087, 0.094, 0.099, 0.10, 0.17, 0.18, 0.18, 0.18, 0.18, 0.20, 0.20, 0.20, 0.21, 0.22, 0.24, 0.24, 0.25, 0.28, 0.31, 0.31, 0.34, 0.40, 0.45, 0.50 and 0.70 mg/kg (n=27).

The Meeting agreed that the US data for apples and pears could be used to support a pome fruit commodity group maximum residue level recommendation and estimated a maximum residue level of 0.8 mg/kg for spirodiclofen on pome fruit and estimated and STMR of 0.20 mg/kg for spirodiclofen in pome fruit.

The value derived from use of the NAFTA calculator (NAFTA 95/99 95th percentile) was 0.76 mg/kg, which was comparable with the estimate made by the Meeting (after rounding up to one figure).

Stone fruit

Field trials involving cherries were performed in Germany, Spain, Italy, and the USA.

For trials performed in Germany, Spain and Italy no GAP was available.

GAP for stone fruit in the USA is for one spray application at 0.32 kg ai/ha (PHI 7 days). In trials from the USA matching this GAP (1 × 0.309–0.325 kg ai/ha, PHI 7 days), spirodiclofen residues in cherry whole fruit were: 0.14, 0.14, 0.15, 0.16, 0.17, 0.17, 0.24, 0.27, 0.28, 0.29, 0.31, 0.35, 0.49, 0.50 and 0.62, mg/kg (n=15) from low volume spraying and 0.12, 0.17, 0.18, 0.19, 0.20, 0.21, 0.23, 0.24, 0.26, 0.29, 0.34, 0.35, 0.53, 0.66 and 0.73 mg/kg (n=15) from dilute spraying at/under the same locations or conditions. In addition at three of these locations comparisons were made between SC formulations (0.14, 0.17, 0.17, 0.19, 0.53 and 0.62 mg/kg) and WG formulations (0.12, 0.14, 0.15, 0.21, 0.24 and 0.49 mg/kg). In those cases where residues at a longer PHI were higher, these residues were selected.

The Meeting noted that the residues corresponding to low volume and dilute spraying were from similar populations (Mann-Whitney U test) and that the residues corresponding to the SC and WG formulations were from similar populations (Mann-Whitney U test). Because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in a dataset for cherry, whole fruit of: 0.18, 0.19, 0.20, 0.21, 0.27, 0.29, 0.34, 0.35, 0.35, 0.62, 0.66 and 0.73 mg/kg (n=12).

Field trials involving peaches were performed in Germany, France, Spain, Italy, and the USA.

German GAP for peaches is for one spray application at 0.0096 kg ai/hL (PHI 14 days). In a trial from Germany matching this GAP (1 × 0.0096 kg ai/hL, PHI 14 days), spirodiclofen residues in peach whole fruit were 0.12 mg/kg.

Italian GAP for peaches is for one spray application at 0.14 kg ai/ha (PHI 14 days). In trials from Italy, France and Spain matching this GAP (1 × 0.109–0.144 kg ai/ha, PHI 14 days), spirodiclofen residues in peach whole fruit were: < 0.02, < 0.02, 0.020, 0.027, 0.037, 0.047 and 0.096 mg/kg (n=7). In those cases where residues at a longer PHI were higher, these residues were selected.

GAP for stone fruit in the USA is for one spray application at 0.32 kg ai/ha (PHI 7 days). In trials from the USA matching this GAP (1 × 0.311–0.339 kg ai/ha, PHI 6–7 days), spirodiclofen residues in peach whole fruit were: 0.15, 0.18, 0.24, 0.25, 0.26, 0.29, 0.29, 0.32, 0.36, 0.41, 0.49, 0.50, 0.51 and 0.52 mg/kg (n=14) from low volume spraying and 0.14, 0.16, 0.18, 0.25, 0.27, 0.28,

0.28, 0.29, 0.29, 0.39, 0.52, 0.61, 0.77, 0.86 and 0.89 mg/kg (n=15) from dilute spraying at/under the same locations or conditions. In addition, at three locations comparisons were made between SC formulations (0.16, 0.26, 0.39, 0.49, 0.51 and 0.52 mg/kg) and WG formulations (0.14, 0.18, 0.27, 0.41, 0.52 and 0.86 mg/kg). In those cases where residues at a longer PHI were higher, these residues were selected.

The Meeting noted that the residues corresponding to low volume and dilute spraying were from similar populations (Mann-Whitney U test) and that the residues corresponding to SC and WG formulations were from similar populations (Mann-Whitney U test). Because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for peach whole fruit: 0.24, 0.25, 0.26, 0.28, 0.29, 0.29, 0.36, 0.51, 0.61, 0.77, 0.86 and 0.89 mg/kg (n=12).

The German dataset was considered insufficient to support a recommendation. The Meeting noted that the dataset from the USA for peaches had higher residues than the Italian dataset for peaches (Mann-Whitney U test) and decided to use only the peach data corresponding to the GAP of the USA.

Field trials involving plums were performed in Germany, the Netherlands, Belgium, Spain, Italy, the USA and Canada.

GAP for plums in Germany is for one spray application at 0.0096 kg ai/hL (PHI 21 days). In trials from Germany, the Netherlands, Belgium, Spain and Italy matching this GAP (1 × 0.0084–0.0096 kg ai/ha, PHI 21–22 days), spirodiclofen residues in plum whole fruit were: 0.016, 0.02, 0.023, 0.03, 0.03, 0.035 and 0.05 mg/kg (n=7) for northern European trials and 0.02 and 0.02 mg/kg (n=2) for southern European trials. In those cases where residues at a longer PHI were higher, these residues were selected.

The Meeting noted that the residue populations corresponding to northern and southern European trials were from similar populations and could be combined. This resulted in the following dataset: 0.016, 0.02, 0.02, 0.02, 0.023, 0.03, 0.03, 0.035 and 0.05 mg/kg (n=9)

The GAP for stone fruit in the USA is for one spray application at 0.32 kg ai/ha (PHI 7 days). In trials from the USA and Canada matching this GAP (1 × 0.307–0.326 kg ai/ha, PHI 6–7 days), spirodiclofen residues in plums, whole fruit, were: 0.014, 0.014, 0.017, 0.028, 0.036, 0.037, 0.053, 0.073, 0.090, 0.15 and 0.19 mg/kg (n=11) for low volume spray and < 0.01, 0.013, 0.024, 0.031, 0.044, 0.047, 0.066, 0.089, 0.11, 0.11 and 0.16 mg/kg (n=11) for normal or dilute spraying, on/under the same locations/conditions. In addition, on one of these locations comparisons were made between SC formulations (0.089 and 0.15 mg/kg) and WG formulations (0.073 and 0.11 mg/kg). In those cases where residues at a longer PHI were higher, these residues were selected instead.

The Meeting noted that the residue populations corresponding to low volume spray and normal spray are from similar populations (Mann-Whitney U test) and that the residue populations corresponding to SC and WG formulations are from similar populations. Because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for plum whole fruit: 0.014, 0.017, 0.028, 0.031, 0.044, 0.047, 0.066, 0.11, 0.15 and 0.19 mg/kg (n=10).

The Meeting noted that the GAP for USA resulted in a similar dataset when compared to the GAP for Germany (Mann-Whitney U test). However, as the GAPs are different the data cannot be combined. Since the highest residues are found in the US dataset, the Meeting decided to use only the plum data corresponding to the GAP of the USA.

The Meeting noted that the USA dataset for plums had lower residues than the USA datasets for cherries and peaches (Kruskal-Wallis test). The Meeting noted that the USA datasets from cherries and peaches were from similar populations (Mann-Whitney U test) and agreed that they could be combined. Spirodiclofen residues in whole fruit were: 0.18, 0.19, 0.20, 0.21, 0.24, 0.25,

0.26, 0.27, 0.28, 0.29, 0.29, 0.29, 0.34, 0.35, 0.35, 0.36, 0.51, 0.61, 0.62, 0.66, 0.73, 0.77, 0.86 and 0.89 mg/kg (n=24).

The Meeting agreed that the USA data on cherries and peaches could be used to support a stone fruit commodity group recommendation and estimated a maximum residue level of 2 mg/kg for spirodiclofen on stone fruit and estimated and STMR of 0.315 mg/kg for spirodiclofen in stone fruit.

The value derived from use of the NAFTA calculator (NAFTA 95/99 95th percentile) was 1.2 mg/kg, which was comparable with the estimate made by the Meeting after rounding up to one significant figure.

Berries and other small fruits

Field trials involving blackberries were performed in Germany. However, for trials performed in Germany no GAP was available.

The Meeting agreed that data were insufficient to estimate a maximum residue level for blackberries.

Field trials involving currants were performed in Germany. GAP for currants in Germany is for one spray application at 0.096 kg ai/ha (PHI 14 days). In trials from Germany matching this GAP (1 × 0.096 kg ai/ha, PHI 14 days), spirodiclofen residues in currants were 0.026, 0.040 and 0.44 mg/kg (n=3). In those cases where residues at a longer PHI were higher, these residues were selected instead.

The Meeting estimated a maximum residue level of 1 mg/kg for spirodiclofen on currants and estimated and STMR of 0.040 mg/kg for spirodiclofen in currants.

The value derived from use of the NAFTA calculator (NAFTA UCL median 95) of 0.64 mg/kg differed from the estimate of 1.0 mg/kg made by the Meeting. The recommendation of the Meeting was higher in recognition of the low number of data points (n=3) and the high variability within the data.

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

GAP for grapes in Germany is for one spray application at 0.0096 kg ai/hL (PHI 14 days). In trials from Germany matching this GAP (1 × 0.0096 kg ai/hL, PHI 14 days), spirodiclofen residues in grape bunches were: 0.044, 0.058, 0.067, 0.089, 0.10 mg/kg (n=5). In those cases where residues at a longer PHI were higher, these residues were selected instead. Spirodiclofen residues in berries were: 0.036, 0.060, 0.069, 0.074 and 0.084 mg/kg (n=5).

GAP for grapes in Italy is for one spray application at 0.096 kg ai/ha (PHI 14 days). In trials from France, Spain, Italy, Portugal and Greece matching this GAP (1 × 0.096 kg ai/ha, PHI 14 days), spirodiclofen residues in grape bunches were: 0.025, 0.030, 0.034, 0.037, 0.045, 0.052, 0.063, 0.064, 0.066, 0.069, 0.071, 0.072 and 0.11 mg/kg (n=13). In those cases where residues at a longer PHI were higher, these residues were selected. Spirodiclofen residues in berries were: 0.021, 0.023, 0.026, 0.041, 0.044, 0.049, 0.059, 0.061, 0.062, 0.062, 0.072, 0.075 and 0.077 mg/kg (n=13).

Trials performed in the USA and Canada did not match the available GAPs for the USA or Canada.

The Meeting noted that the datasets from Germany and Italy are from similar populations (Mann-Whitney U test). Since the GAPs are different, the datasets cannot be combined. Since the Italian dataset is larger than the German dataset, the Meeting agreed to use only the dataset from Italy. The Meeting estimated a maximum residue level of 0.2 mg/kg for spirodiclofen on grapes and estimated an STMR of 0.059 mg/kg for spirodiclofen in the edible portion of the grape bunches (berries). For purposes of calculating residues in processed grape commodities an $STMR_{RAC}$ of 0.063 mg/kg was estimated based on grape bunches (with stems).

The value derived from use of the NAFTA calculator (NAFTA 95/99 95th percentile) was 0.14 mg/kg, which agreed with the estimate made by the Meeting (after rounding up to one figure).

Field trials involving raspberries were performed in Germany. For trials performed in Germany no GAP was available.

The Meeting agreed that data were insufficient to estimate a maximum residue level for raspberries.

Field trials involving strawberries were performed in Germany, the United Kingdom, the Netherlands and France. Indoor trials involving strawberries were performed in Germany, Belgium, the Netherlands, France, Spain and Italy.

GAP for strawberries in the Netherlands is for two spray applications at 0.0096 kg ai/hL (PHI 3 days) in the field. In field trials from Germany, the United Kingdom, the Netherlands and France matching this GAP (2 × 0.0096 kg ai/hL, PHI 3 days), spirodiclofen residues in strawberry fruit were: 0.022, 0.041, 0.047, 0.06, 0.063, 0.12, 0.88 and 1.1, mg/kg (n=8). In those cases where residues at a longer PHI were higher, these residues were selected instead.

The GAP for strawberries in the Netherlands is for two spray applications at 0.0096 kg ai/hL (PHI 3 days) in a greenhouse. In indoor trials from Germany, Belgium, the Netherlands, the United Kingdom, France, Spain, Italy and Portugal matching this GAP (2 × 0.0096 kg ai/hL, PHI 3 days), spirodiclofen residues in strawberry fruit were: < 0.02, 0.041, 0.044, 0.056, 0.13, 0.16, 0.17 and 0.28 mg/kg (n=8). In those cases where residues at a longer PHI were higher, these residues were selected instead.

The Meeting noted that the Dutch datasets from field and indoor strawberries were from similar populations (Mann-Whitney U test) and agreed that they could be combined. Spirodiclofen residues in whole fruit were: < 0.02, 0.022, 0.041, 0.041, 0.044, 0.047, 0.056, 0.06, 0.063, 0.12, 0.13, 0.16, 0.17, 0.28, 0.88 and 1.1 mg/kg (n=16).

The Meeting estimated a maximum residue level of 2 mg/kg for spirodiclofen on strawberries and estimated and STMR of 0.0615 mg/kg for spirodiclofen in strawberries.

The value derived from use of the NAFTA calculator was 1.4 mg/kg (NAFTA 95/99 99th percentile), which was comparable with the estimate made by the Meeting (after rounding up to one figure).

Assorted tropical and sub-tropical fruits—inedible peel

Field trials involving papaya were performed in Brazil. GAP for papaya in Brazil is for one spray applications at 0.0072 kg ai/hL (PHI 7 days). Field trials performed in Brazil did not match this GAP. In field trials from Brazil with three applications at equal or higher application rates to GAP (3 × 0.0072 kg ai/hL, PHI 7 days or 3 × 0.014 kg ai/hL, PHI 7 days), spirodiclofen residues in papaya whole fruit could not be found: < 0.03 mg/kg (n=8).

The Meeting estimated a maximum residue level of 0.03(*) mg/kg for spirodiclofen in papaya whole fruit and estimated an STMR of 0.03 mg/kg for spirodiclofen in papaya (edible portion).

Statistical calculations were not possible, as all residues were below the LOQ.

Fruiting vegetables, Cucurbits

Indoor trials involving cucumbers were performed in Germany. GAP for cucumbers and gherkins in Germany is for two spray applications at 0.12 kg ai/ha (PHI 3 days) in a greenhouse. In indoor trials from Germany matching this GAP (2 × 0.115 kg ai/ha, PHI 3 days), spirodiclofen residues in cucumbers were: 0.02, 0.02, 0.03, 0.03, 0.03 mg/kg (n=5).

Indoor trials involving gherkins were performed in Germany. GAP for cucumbers and gherkins in Germany is for two spray applications at 0.12 kg ai/ha (PHI 3 days) in a greenhouse. In indoor trials from Germany matching this GAP (2 × 0.115 kg ai/ha, PHI 3 days), spirodiclofen residues in gherkins were 0.04, 0.04 mg/kg (n=2).

The dataset for gherkins was considered insufficient to support a recommendation, but the Meeting agreed that the dataset from gherkins could be combined with the dataset from cucumbers to mutually support a maximum residue level for each commodity. Spirodiclofen residues in whole fruit were: 0.02, 0.02, 0.03, 0.03, 0.03, 0.04 and 0.04, mg/kg (n=7).

The Meeting estimated a maximum residue level of 0.07 mg/kg for spirodiclofen on cucumbers and on gherkins and estimated and STMR of 0.03 mg/kg for spirodiclofen on cucumbers and on gherkins.

The value derived from use of the NAFTA calculator (NAFTA 95/99 99th percentile) of 0.056 mg/kg differed from the estimate of 0.07 mg/kg made by the Meeting. The level recommended by the Meeting was higher in recognition of the low number of data points (n=7).

Fruiting vegetables, other than Cucurbits

Indoor trials involving sweet peppers were performed in Germany. GAP for sweet peppers in Germany is for two spray applications at 0.0096 kg ai/hL (PHI 3 days) in a greenhouse. In indoor trials from Germany matching this GAP (2 × 0.0096 kg ai/hL, PHI 3 days), spirodiclofen residues in sweet peppers were: 0.03, 0.08, 0.08, 0.09 and 0.09 mg/kg (n=5).

The Meeting estimated a maximum residue level of 0.2 mg/kg for spirodiclofen in sweet pepper whole fruit and estimated an STMRRAC of 0.08 mg/kg for spirodiclofen in sweet pepper.

The value derived from use of the NAFTA calculator (NAFTA mean + 3SD) was 0.15 mg/kg, which was in agreement with the estimate made by the Meeting (after rounding up to one figure).

Field trials involving tomatoes were performed in Brazil. Indoor trials involving tomatoes were performed in Germany.

GAP for tomatoes in Brazil is for one spray application at 0.072 kg ai/ha (PHI 7 days). Field trials performed in Brazil did not match this GAP. In field trials from Brazil where three applications were made at equal or higher than GAP rates (3 × 0.072 kg ai/ha, PHI 7 days or 3 × 0.144 kg ai/ha, PHI 7 days), spirodiclofen residues in tomato fruit could not be found: < 0.03 mg/kg (n=8). The Meeting was not confident of the results, as no residues were detected 0 day samples and such an outcome was not consistent with results from other trials. Consequently, the Meeting agreed to disregard the residue values from the Brazilian trials.

GAP for tomatoes in Germany is for two spray applications at 0.12 kg ai/ha (PHI 3 days) in a greenhouse. In indoor trials from Germany on large tomato varieties matching this GAP (2 × 0.115 kg ai/ha, PHI 3 days), spirodiclofen residues in tomato fruit were: 0.03, 0.06, 0.07, 0.08, 0.08, 0.10, 0.10 and 0.24 mg/kg (n=8).

Based on the German dataset, The Meeting estimated a maximum residue level of 0.5 mg/kg for spirodiclofen on tomatoes and estimated and STMR of 0.08 mg/kg for spirodiclofen in tomatoes.

The value derived from use of the NAFTA calculator (NAFTA 95/99 99th percentile) of 0.31 mg/kg differed from the estimate of 0.5 mg/kg made by the Meeting. The level recommended by the Meeting was higher to accommodate smaller tomato varieties and in recognition of the small number of data points (n=8).

Tree nuts

Field trials involving almonds were performed in the USA. GAP for tree nuts in the USA is for one spray application at 0.60 kg ai/ha (PHI 7 days). In field trials from USA matching this GAP (1 × 0.593–0.617 kg ai/ha, PHI 6–7 days), spirodiclofen residues in almond nutmeat were < 0.01, < 0.01, 0.010, 0.014, 0.015 and 0.024 mg/kg (n=6) for low volume spraying and < 0.01, 0.013, 0.017, 0.023 and 0.023 mg/kg (n=5) for normal or dilute high volume spraying on/under the same locations/conditions. In addition, at two of the locations comparisons were made between SC formulations (0.013, 0.014, 0.015 and 0.017 mg/kg) and WG formulations (0.019, 0.023, 0.024 and 0.024 mg/kg). In those cases where residues at a longer PHI were higher, these residues were selected.

The Meeting noted that the residue populations corresponding to low volume spray and normal spray are from similar populations (Mann-Whitney U test) and that the residue populations corresponding to SC and WG formulations are from similar populations (Mann-Whitney U test). Because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprising of the highest residue from each location. This resulted in the following dataset for almond nutmeat: < 0.01, < 0.01, 0.017, 0.023 and 0.024 mg/kg (n=5).

At a PHI of 7 days the almond hulls are already split, the possibility exists for the spray to reach the almond shells. The potential also exists for further contamination of the shells during harvest when the trees are shaken casusing the nuts to fall and come into contact with any spray residue on the soil. There is also potential for contamination of the almond nutmeat during de-shelling, i.e., transferred from the shell to the kernel, suggesting a possible cause for the residues detected in the trials, given spiridoclofen is not considered systemic.

Field trials involving coconuts were performed in Brazil.

GAP for coconut in Brazil is for one spray application at 0.0072 kg ai/hL (PHI 21 days). Field trials performed in Brazil did not match this GAP. In field trials from Brazil where three applications were made at rate equal to or higher than GAP rates (3 × 0.0072 kg ai/hL, PHI 21 days or 3 × 0.014 kg ai/hL, PHI 21 days), spirodiclofen residues in coconut (flesh and liquid) were not detected: < 0.05 mg/kg (n=6).

Field trials involving pecans were performed in the USA.

GAP for tree nuts in the USA is for one spray application at 0.60 kg ai/ha (PHI 7 days). In field trials from USA matching this GAP (1 × 0.587–0.603 kg ai/ha, PHI 7 days), spirodiclofen residues in pecan nutmeat were: < 0.01, < 0.01, < 0.01, < 0.01, 0.013 and 0.042, mg/kg (n=6) for low volume spraying and < 0.01, 0.011, 0.011, 0.015, 0.016 and 0.036 mg/kg (n=6) for normal highvolume or dilute spraying on/under the same locations/conditions. In addition, at one of the sites comparisons were made between SC formulations (< 0.01 and 0.011 mg/kg) and WG formulations (< 0.01 and < 0.01 mg/kg). In those cases where residues at a longer PHI were higher, these residues were used in the estimation.

The Meeting noted that the residue populations corresponding to low volume spraying and normal spraying were from similar populations (Mann-Whitney U test) and that the residue populations corresponding to SC and WG formulations were from similar populations. Because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprising of the highest residue from each location. This resulted in the following dataset for pecan nutmeat: 0.011, 0.011, 0.015, 0.016 and 0.042 mg/kg (n=5).

As with almonds, the Meeting considered that a consequence of the 7 day PHI could be pesticide contact with the shell and transferral of residues to the nutmeat during de-shelling, suggesting a possible cause for the residues detected in the trials.

The Meeting noted that the USA datasets from almonds and pecans were from similar populations (Mann-Whitney U test) and agreed that they could be combined. Spirodiclofen residues

in nutmeat were: < 0.01, < 0.01, 0.011, 0.011, 0.015, 0.016, 0.017, 0.023, 0.024 and 0.042 mg/kg (n=10).

The Meeting noted that the quantification limit in the Brazilian trials was higher than in the other trials. Therefore, it was not possible to verify the actual levels in coconut flesh and liquid. However, as the results of the Brazilian trials do not disagree with those of the US trials on tree nuts, the Meeting agreed that the USA data on almonds and pecans could be used to support a tree nut commodity group maximum residue level recommendation. The Meeting estimated a maximum residue level of 0.05 mg/kg for spirodiclofen on tree nuts and estimated a STMR of 0.0155 mg/kg for spirodiclofen in tree nuts (nutmeat).

The value derived from use of the NAFTA calculator (NAFTA 95/99 99th percentile) was 0.048 mg/kg, which was in agreement with the estimate made by the Meeting (after rounding up to one significant figure.

Seed for beverages and sweets (024)

Field trials involving coffee were performed in Brazil. GAP for coffee in Brazil is for one spray application at 0.012 kg ai/hL (PHI 21 days). Field trials performed in Brazil did not match this GAP. In field trials from Brazil where two applications were made (2 × 0.014 kg ai/hL, PHI 21 days), spirodiclofen residues in green coffee beans were not detected: < 0.03 mg/kg (n=3).

Since coffee beans (seeds) are not directly exposed to spirodiclofen and no residues are expected in green coffee beans, the Meeting considered three trials sufficient for a recommendation. The Meeting estimated a maximum residue level of 0.03(*) mg/kg for spirodiclofen in coffee beans and estimated a STMR of 0.03 mg/kg for spirodiclofen in coffee beans.

Statistical calculations were not possible, as all residues were below the LOQ.

Miscellaneous fodder and forage crops (052)

Field trials involving almond hulls were performed in the USA.

GAP for tree nuts in the USA is for one spray application at 0.60 kg ai/ha (PHI 7 days). In field trials from USA matching this GAP (1 × 0.593–0.617 kg ai/ha, PHI 6–7 days), spirodiclofen residues in almond hulls were: 1.2, 1.6, 2.1, 2.4, 3.8 and 5.5 mg/kg (n=6) for low volume sprays and 2.0, 3.5, 4.2, 5.9 and 6.8 mg/kg (n=5) for normal high volume sprays on/under the same locations/conditions. In addition, at two of the sites comparisons were made between SC formulations (1.2, 2.0, 3.8 and 5.9 mg/kg) and WG formulations (1.2, 1.5, 2.4 and 4.2 mg/kg). In those cases where residues at a longer PHI were higher, these residues were selected for use in the estimation.

The Meeting noted that the residue populations corresponding to low volume sprays and normal sprays were from similar populations (Mann-Whitney U test) and that the residue populations corresponding to SC and WG formulations were from similar populations (Mann-Whitney U test). Because only one residue should be selected per location, the Meeting agreed to use only one dataset, comprised of the highest residue from each location. This resulted in the following dataset for almond hulls: 2.0, 2.1, 3.5, 5.9 and 6.8 mg/kg (n=5).

The Meeting estimated a maximum residue level of 15 mg/kg for spirodiclofen in almond hulls and estimated an STMR value of 3.5 mg/kg for spirodiclofen in almond hulls.

The value derived from use of the NAFTA calculator (NAFTA 95/99 99th percentile) was 13.389 mg/kg, which was in agreement with the estimate made by the Meeting (after rounding up).

Dried herbs

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

GAP for hops in Germany is for one spray application at 0.43 kg ai/ha (PHI 14 days). In eight field trials from Germany matching this GAP (1 × 0.336–0.433 kg ai/ha, PHI 14 days), spirodiclofen residues in kiln-dried hop cones were 3.9, 6.6, 8.8, 11, 11, 14, 17, 24 mg/kg (n=8). In those cases where residues at alonger PHI were higher, these residues were selected for use in the estimation.

GAP for hops in the USA is for one spray application at 0.43 kg ai/ha (PHI 14 days). In a field trial from the USA matching this GAP (1 × 0.434–0.462 kg ai/ha, PHI 14 days), spirodiclofen residues in kiln-dried hop cones were 5.4 mg/kg (n=1).

The USA dataset was considered insufficient to support a recommendation and the Meeting agreed to use only the dataset from Germany. The Meeting estimated a maximum residue level of 40 mg/kg for spirodiclofen on hops, dry and estimated and STMR of 11 mg/kg for spirodiclofen in kiln dried hop cones.

The value derived from use of the NAFTA calculator (NAFTA 95/99 99th percentile) was 39 mg/kg, which was in agreement with the estimate made by the Meeting (after rounding up).

Fate of residues in storage

Not applicable.

Fate of residues during processing

The Meeting received information on the fate of spirodiclofen under simulated processing conditions and on the fate of incurred residues of spirodiclofen during the processing of oranges, apples, peaches, plums, grapes, strawberries and hops.

An aqueous solution of [dihydrofuranone-3-^{14}C]spirodiclofen was treated for 20 min at 90 °C at pH 4 (pasteurization), 60 min at 100 °C at pH 5 (brewing/baking/boiling), or for 20 min at 120 °C at pH 6 (sterilization). Spirodiclofen was stable at pH 4, but degraded at pH 5 and higher. After processing 99.1%, 35.4% and 37.3% of the applied radioactivity remained as unchanged spirodiclofen. Spirodiclofen is degraded by ester cleavage with the formation of spirodiclofen-enol.

For the preparation of orange marmalade, apple sauce, peach preserve, and wine juice processing procedures for the conditions were similar to pasteurisation and it is expected that the residues in processed commodities is primarily spirodiclofen (parent). However, in processing studies on grapes, where both parent and spirodiclofen-enol were quantified, the spirodiclofen-enol metabolite was found at quantifiable amounts in grape jelly, grape juice, and grape juice concentrate. The sum of spirodiclofen and spirodiclofen-enol residues in grape jelly, grape juice and grape juice concentrate was lower than in the RAC (9.5%, 17%, and 73% of the RAC residue, respectively). Since grape juice concentrate will be diluted before drinking, residues in these commodities would be unlikely to make a substantial contribution to the total residue intake. Also for the brewing process for hops the formation of spirodiclofen-enol is expected, but because of the large dilution, low residue levels are also anticipated. Since residue levels of spirodiclofen-enol in processed commodities were low, The Meeting concluded that the residue definition for plant commodities was also adequate for processed plant commodities.

Processing studies were undertaken for oranges, apples, peaches, plums, grapes, strawberries and hops. In the table below, relevant processing factors for these commodities are summarized. Using the STMR, the Meeting estimated STMR-Ps for these commodities as listed below. The Meeting considered the appropriate STMR-P to be used in the livestock dietary burden calculation or dietary intake calculation. The Meeting agreed to extrapolate the orange juice STMR-P to citrus juice.

Commodity	Processing factors	Processing factor (median or	STMR-P mg/kg

		best estimate)	
orange juice (single strength)	0.05	0.05	0.13 × 0.05 = 0.0065
orange pulp (dry, 93% DM)	1.4	1.4	0.13 × 1.4 = 0.18
apple juice (single strength)	< 0.02 (2), < 0.71 (3)	< 0.02	0.20 × 0.02 = 0.004
apple pomace (dry, 92–95% DM)	16, 17, 21	17	0.20 × 17 = 3.4
dried apples	< 0.02, 0.16	0.09	0.20 × 0.09 = 0.018
prunes (=dried plums, 70–71% DM)	2.5	2.5	0.315 × 2.5 = 0.79
raisins (76–83% DM)	0.95, 1.8, 2.1, 2.1, 2.7, 4.0	2.1	0.063 × 2.1 = 0.13
grape juice (single strength)	< 0.006, 0.0081, < 0.54 (3)	0.0081	0.063 × 0.0081 = 0.00051
white wine	< 0.28 (2)	< 0.28	0.063 × 0.28 = 0.018
beer (from hops)	< 0.001 (2), < 0.004, < 0.005	< 0.001	11 × 0.001 = 0.011

Based on an STMR of 0.20 mg/kg for apple, a processing factor of 1.4 and a correction for 92% dry matter, the Meeting estimated a maximum residue level of 4 mg/kg for apple pomace dry on a dry weight basis.

Based on an HR of 0.11 mg/kg for grape bunches and a processing factor of 2.1, The Meeting estimated a maximum residue level of 0.3 mg/kg for raisins.

Farm animal dietary burden

The Meeting estimated the dietary burden of spirodiclofen residues in farm animals from the livestock diets from US-Canada, EU and Australia in the table of OECD Feedstuffs (Annex 6 of the 2006 JMPR report). Almond hulls, apple pomace and citrus pulp were the only feedstuffs relevant for cattle. Poultry dietary burden was not considered as no exposure to spirodiclofen through pesticide treated feed was evaluated by the Meeting. A mean and maximum dietary burden of 0.74 ppm on a dry matter basis was estimated for beef cattle in Europe and Australia and a mean and maximum dietary burden of 0.39 ppm on a dry matter basis was estimated for dairy cattle in US and Australia as is shown in the table below.

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

	US	EU	AU
	mean/max	mean/max	mean/max
beef cattle	0.02	0.74 a	0.74 a
dairy cattle	0.39 b	0.37	0.39 b

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

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

Farm animal feeding studies

The Meeting received a lactating cow feeding study. Three groups of three lactating Holstein cows were dosed once daily, via capsules, at levels of 1.29, 3.93 and 13.1 ppm dry weight feed for 29 consecutive days. Milk was collected throughout the study on days 0, 4, 8, 12, 16, 20, 24, 26 and 28 and tissues were collected on day 29 within 8 hours after the last dose.

No residues of spirodiclofen or spirodiclofen-enol were found, except in one cream sample (0.011 mg/kg spirodiclofen), one fat sample (0.021 mg/kg spirodiclofen) and one kidney sample (0.094 mg/kg spirodiclofen-enol) on day 28 (cream) or day 29 (tissues) from the highest dose level (13.1 ppm).

Animal commodity maximum residue levels

In a feeding study where lactating cows were dosed at 1.29 ppm dry feed, no residues (sum of spirodiclofen and spirodiclofen-enol) were found in tissues and milk. As a consequence, no residues are anticipated in tissues and milk at the mean and maximum calculated dietary burden of 0.74 ppm.

The Meeting estimated a maximum residue level for spirodiclofen of 0.004(*) mg/kg for milks and 0.01(*) mg/kg for meat from mammals other than marine mammals and 0.05(*) mg/kg for mammalian edible offal. The Meeting estimated STMRs 0 mg/kg in milk, muscle/fat, and edible offal of mammals. The residue in animal commodities is considered fat-soluble.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) for spirodiclofen was calculated from recommendations for STMRs for raw commodities in combination with consumption data for corresponding food commodities. The results are shown in Annex 3.

The International Estimated Daily Intakes (IEDI) of spirodiclofen in the 13 GEMS/Food Consumption Cluster Diets, based on the estimated STMRs were in the range 0–9% of the maximum ADI of 0.01 mg/kg bw. The Meeting concluded that the long-term intake of residues of spirodiclofen from uses considered by the Meeting is unlikely to present a public health concern.

Short-term intake

No ARfD was considered necessary. The Meeting concluded that the short-term intake of residues of spirodiclofen from uses considered by the Meeting is unlikely to present a public health concern.

5.22 ZOXAMIDE (227)

RESIDUE AND ANALYTICAL ASPECTS

Zoxamide, a benzamide fungicide, was first evaluated by the 2007 JMPR which allocated ADI of 0-0.5 mg/kg bw and agreed that an ARfD was unnecessary. The definition of residues for plant commodities for compliance with the MRL and for estimation of dietary intake was zoxamide.

The 2007 JMPR estimated a maximum residue level for cucumber of 1 mg/kg on the basis of supervised trials conducted in Europe and the Polish GAP. The current Meeting received information on a new use pattern for cucurbits in the USA, with a shorter PHI, which was used for the estimation of a maximum residue level for cucurbits.

Results of supervised trials on crops

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points in a data set is less than 15 or when there are a large number of values < LOQ.

Fruiting vegetables, Cucurbits

The Meeting evaluated the results of supervised outdoor trials conducted on cucurbits in the USA submitted to the 2007 JMPR against the new US GAP.

Six trials were conducted on cucumber in the USA in compliance with the GAP of the USA for cucurbits (maximum rate of 0.22 kg ai/ha, 8 applications, PHI 0 days). The residues in rank order were: 0.01, 0.02, 0.03, 0.05, 0.12, 0.13 mg/kg.

Six trials on cantaloupe were conducted in the USA in compliance with US GAP for cucurbits. The residues in rank order were: 0.04, 0.06, 0.08, 0.37, 0.44, 0.73 mg/kg.

Five trials on summer squash were conducted in the USA in compliance with US GAP for cucurbits. The residues in rank order were: 0.08, 0.10, 0.15, 0.19, 0.39 mg/kg.

On the basis the trial results on cantaloupe which gave the highest residues in the group, the Meeting estimated a maximum residue level of 2 mg/kg for fruiting vegetables, cucurbits. The Meeting estimated an STMR of 0.225 mg/kg. The previously recommended maximum residue level of 1 mg/kg for cucumber should be withdrawn.

The maximum residue level estimate derived from use of the NAFTA calculator was 1.8 mg/kg (UCLMedian 95th). The normal JMPR procedure is to use one significant figure for maximum residue levels below 10 mg/kg. Rounding up the value obtained from the calculator results in an estimate of 2 mg/kg, which coincides with the recommendation of the present Meeting.

DIETARY RISK ASSESSMENT

Long-term intake

The IEDIs of zoxamide were calculated for the 13 GEMS/Food Consumption Cluster Diets using STMRs/STMR-Ps estimated by the current and 2007 JMPR (Annex 3). The ADI is 0-0.5 mg/kg bw

and the calculated IEDIs were 0–0.3% of the maximum ADI. The Meeting concluded that the long-term intakes of residues of zoxamide, resulting from the uses considered by the current and 2007 JMPR, are unlikely to present a public health concern.

Short-term intake

The 2007 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of residues of zoxamide is unlikely to present a public concern.

RECOMMENDATIONS

1. In order to assist collection and submission of the appropriate information for estimation of residue levels in/on spices, the Meeting re-emphasized that:

- The minimum number of datapoints required for each pesticide–spice commodity combination is 59;
- Where residue data are available for several spice commodities belonging to one group of spices, the JMPR will evaluate the residue data and if the residue distributions can be considered similar, then the JMPR may recommend a MRL for the commodity group;
- The JMPR cannot make any recommendations for pesticide classes such as organophosphates, carbamates, pyrethroids. If it is claimed, for instance, that no organophosphorous compounds were detected in 20 samples of a spice commodity, then it must be specified which compounds have been looked for and what were the respective LOQ and recovery values. The method performance parameters indicated must be supported with appropriate data on method validation.

In addition, the supporting information should be provided as specified in the JMPR reports on actual agricultural, storage and processing practice, the need for post-harvest protection, etc.

Comprehensive information on data requirements is also available in the second edition of the FAO Manual (section 3.6) published at the FAO website

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

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

3. The present Meeting reiterated the statement of the 2008 JMPR that, for small datasets, the NAFTA White Paper and reviews of the performance of the calculator suggest a large uncertainty in such estimates of high percentiles of dietary intake. Use of other tools and experience is needed to ensure that MRL estimates are realistic.

FUTURE WORK

The items listed below are tentatively scheduled to be considered by the Meeting in 2011 and 2012. The compounds listed include those recommended as priorities by the CCPR at its Forty-first and earlier sessions and compounds scheduled for re-evaluation within the CCPR periodic review programme.

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

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

http://www.who.int/ipcs/food/en/

2011 JMPR

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
NEW COMPOUNDS	**NEW COMPOUNDS**
MCPA [Nufarm] - USA	MCPA -
emamectin-benzoate	emamectin-benzoate
clopyralid	clopyralid
ethaboxam	ethaboxam
dinotefuran	dinotefuran
PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
diquat (031)	diquat (031)
etofenprox (184)	etofenprox (184)
dicofol (026)	dicofol (026)
dichlorvos (025)	dithianon (028)
fenpropathrin (185)	cycloxydim (179)
fenbutatin oxide (109)	tebuconazole (189)
EVALUATIONS	**EVALUATIONS**
	cyfluthrin (157)
	cypermethrin (118)
	acephate (95)
	profenofos (171)
	spinosad (203)

2012 JMPR

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
NEW COMPOUNDS	**NEW COMPOUNDS**
Sulfoxaflor	Sulfoxaflor
PERIODIC RE-EVALUATIONS	**PERIODIC RE-EVALUATIONS**
amitraz (122)	amitraz (122)
bentazone (172) (BASF)	bentazone (172)
disulfoton (74) – [Bayer CropScience] support from USA	disulfoton (74)
fenvalerate (119)	fenvalerate (119)
glufosinate-ammonium (175)	glufosinate-ammonium (175)
tecnazene (115)	tecnazene (115)
aldicarb (117)	fenpropathrin (185)
	dichlorvos (025)
	fenbutatin oxide (109)

TOXICOLOGICAL EVALUATIONS	RESIDUE EVALUATIONS
EVALUATIONS	**EVALUATIONS**
	oxamyl (126)
	methoxyfenozide
	Spinetoram

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 2009 MEETING

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		
Benalaxyl (155)**	VC 0424	Cucumber	W	0.05		
ADI: 0–0.07 mg/kg bw	FB 0269	Grapes	0.3	0.2	0.12	0.17
ARfD: 0.1 mg/kg bw	DH 1100	Hops, dry	W	0.2		
(women of childbearing age)	VL 0482	Lettuce, Head	1		0.07	0.43
	VC 0046	Melons, except watermelon	0.3	0.1	0.02	0.05
ARfD: Unnecessary	VA 0385	Onion, Bulb	0.02 *	0.2	0	0
(general population)	HS 0444	Peppers Chilli, dried	W	0.5		
	VO 0445	Peppers, Sweet (including pimento or pimiento)	W	0.05		
	VR 0589	Potato	0.02 *	0.02 *	0	0
	VO 0448	Tomato	0.2	0.5	0.035	0.05
	VC 0432	Watermelon	0.1		0.02	0.02
	JF 0269	Grape juice			0.018	
	JF 0448	Tomato juice			0.005	
		Tomato preserve			0.006	
		Tomato pureé			0.012	
		Wine			0.035	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: benalaxyl.						
Bifenthrin (178)** ADI: 0–0.01 mg/kg bw ARfD: 0.01 mg/kg bw						
Boscalid (221)	AM 0660	Almond hulls	15	15	4.1	13
ADI: 0–0.04 mg/kg bw	FP 0226	Apple	2	2	0.365	
ARfD: Unnecessary	FI 0327	Banana	0.6	0.2	0.05	
	GC 0640	Barley	0.5		0.075	
	FB 0018	Berries and other small fruits (except strawberries and grapes)	10	10	2.53	
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	5		1.52	2.7
	VA 0035	Bulb vegetables	5		1.02	
	GC 0080	Cereal grains (except barley, oats, rye and wheat)	0.1		0.05	
	SB 0716	Coffee beans	0.05 *	0.05 *	0.05	
	DF 0269	Dried grapes (= currants,	10	10	2.6	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		Raisins and Sultanas)				
	MO 0105	Edible offal (Mammalian)	0.2		0.16	
	PE 0112	Eggs	0.02		0.02	
	VC 0045	Fruiting vegetables, Cucurbits	3		0.565	
	VO 0050	Fruiting vegetables, other than Cucurbits (except fungi, mushroom and sweet corn)	3		0.565	
	FB 0269	Grapes	5	5	1.09	
	FI 0341	Kiwifruit	5	5	0.073	
	VL 0053	Leafy vegetables	30		2.95	
	VP 0060	Legume vegetables	3		0.5	
	MM 0095	Meat (from mammals other than marine mammals)	0.7 (fat)		0.18 (fat) 0.035 (muscle)	
	FM 0183	Milk fats	2		0.64	
	ML 0106	Milks	0.1		0.066	
	GC 0647	Oats	0.5		0.075	
	SO 0088	Oilseed	1		0.145	
	HS 0444	Peppers Chilli, dried	10		1.4	
	TN 0675	Pistachio nut	1	1	0.27	
	PO 0111	Poultry, Edible offal of	0.02		0.02	
	PF 0111	Poultry fats	0.02		0.02	
	PM 0110	Poultry meat	0.02		0.02	
	DF 0014	Prunes [c]	10		3.39	
	VD 0070	Pulses	3		0.12	
	VR 0075	Root and tuber vegetables	2		0.305	0.71
	GC 0650	Rye	0.5		0.075	
	FS 0012	Stone fruits	3	3.0	1.21	
	AS 0081	Straw and fodder (dry) of cereal grains (except straw and fodder of barley, oats, rye and wheat)	5 [b]		1.25 [b]	3.2 [a, b]
	AS 0640	Barley straw and fodder, dry	50 [b]		9 [b]	30.7 [a, b]
	AS 0647	Oats straw and fodder, dry	50 [b]		9 [b]	30.7 [a, b]
	AS 0650	Rye straw and fodder, dry	50 [b]		9 [b]	30.7 [a, b]
	AS 0654	Wheat straw and fodder, dry	50 [b]		9 [b]	30.7 [a, b]
	FB 0275	Strawberry	3		0.555	
	TN 0085	Tree nuts (except pistachio)	0.05 *	0.05 *	0.05	
	GC 0654	Wheat	0.5		0.075	
	JF 0269	Grape juice			0.46	
		Pot barley			0.026	
	OR 0541	Soya bean oil, refined			0.061	
	JF 0048	Tomato juice			0.085	
	VW 0448	Tomato paste			0.413	
		Tomato puree			0.136	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	CF 0654	Wheat bran, processed			0.32	
	CF 1210	Wheat germ			0.1	
	CF 1211	Wheat, flour			0.026	
	CF 1212	Wheat wholemeal			0.092	
		Wine			0.38	
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. [a] Highest residue. [b] Calculated on a dry weight basis. [c] The dried fruit.						
Buprofezin (173) ADI: 0–0.009 mg/kg bw ARfD: 0.5 mg/kg bw	AM 0660	Almond hulls	2		0.23	1.76
	TN 0660	Almonds	0.05 *		0.05	0.05
	FP 0226	Apple	3		0.28	0.99
	FS 0013	Cherries	2		0.73	1.32
	VC 0424	Cucumber	W [b]	0.2		
	MO 0105	Edible offal (Mammalian)	0.05 *	0.05 *	0	0
	VC 0045	Fruiting vegetables, Cucurbits	0.7		0.19	0.41
	FB 0269	Grapes	1		0.17	0.74
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	2		0.37	1.63
	MM 0095	Meat (from mammals other than marine mammals)	0.05 *	0.05 *	0	0
	ML 0106	Milks	0.01 *	0.01 *	0	0
	FS 0245	Nectarine	9		1.355	8.13
	FT 0305	Olives	5		1.125	1.66
	FS 0247	Peach	9		1.355	8.13
	FP 0230	Pear	6		1.09	3.64
	VO 0051	Peppers	2		0.33	1.1
	HS 0444	Peppers chilli, dried	10		2.31	7.7
	FS 0014	Plums (including Prunes)	2		0.155	0.55
	FB 0275	Strawberry	3		0.44	1.24
	JF 0226	Apple juice			0.16	
	JF 0269	Grape juice			0.098	
		Olive oil			3.49	
	DF 0014	Prunes [c]			0.465	1.65
		White wine			0.15	
		Red wine			0.1	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: buprofezin. [a] Dry weight basis [b] Replaced by a new maximum residue level for fruiting vegetables, Cucurbits. [c] The dried fruit.						
Cadusafos (174)** ADI: 0–0.0005 mg/kg bw ARfD: 0.001 mg/kg bw						

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Carbofuran (096) ADI: 0–0.001 mg/kg bw ARfD: 0.001 mg/kg bw		Banana Citrus			0.02	0.01
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.						
Chlorothalonil (081)** ADI: 0–0.02 mg/kg bw ARfD: 0.6 mg/kg bw 4-Hydroxy-2,5,6-trichloroisophthalonitrile [a] ADI: 0–0.008 mg/kg bw ARfD: 0.03 mg/kg bw [a] Company Code SDS-3701						
Chlorpyrifos-methyl (090)** ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	FP 0226	Apple	W [a]	0.5		
	AB 0226	Apple pomace, dry	2		0.22	
	VS 0620	Artichoke, Globe	W	0.1		
	GC 0640	Barley	3 Po		2.1	2.2
	VB 0041	Cabbages, Head	W	0.1		
	MF 0812	Cattle fat	W [a]	0.05		
	MM 0812	Cattle meat	W [a]	0.05		
	MO 0812	Cattle, Edible offal of	W [a]	0.05		
	PF 0840	Chicken fat	W [a]	0.05		
	PM 0840	Chicken meat	W [a]	0.05		
	PO 0840	Chicken, Edible offal of	W [a]	0.05		
	VL 0467	Chinese cabbage (type Pe-tsai)	W	0.1		
	FC 0001	Citrus fruits	2		0.01	0.01
	VP 0526	Common bean (pods and/or immature seeds)	W	0.1		
	FT 0295	Date	W	0.05		
	MO 0105	Edible offal (Mammalian)	0.01		0	0
	VO 0440	Egg plant	1	0.1	0.06	0.72
	PE 0112	Eggs	0.01 *	0.05	0	0
	FB 0269	Grapes	1	0.2	0.02	0.53
	AB 0269	Grape pomace, dry	5		0.075	
	VL 0482	Lettuce, Head	W	0.1		
	GC 0645	Maize	3 Po		2.1	2.2
	MM 0095	Meat (from mammals other than marine mammals)	0.1 (fat)		0.03 (fat) 0 (muscle)	0.055 (fat) 0 (muscle)
	ML 0106	Milks	0.01 *	0.01	0.0006	
	FM 0183	Milk fats	0.01*	0.01	0.0006	
	VO 0450	Mushrooms	W	0.01 *		
	FC 0004	Oranges, Sweet, Sour (including Orange-like hybrids): several cultivars	W [a]	0.5		
	JF 0004	Orange juice			0	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	FS 0247	Peach	W	0.5		
	VO 0051	Peppers	1	0.5	0.06	0.72
	HS 0444	Peppers Chilli, dried	10	5	0.6	
	FP 0009	Pome fruits	1		0.06	0.56
	VR 0589	Potato	0.01 *		0	0
	PO 0111	Poultry, Edible offal of	0.01 *		0	0
	PO 0110	Poultry meat	0.01 (fat)		0.004 (fat) 0 (muscle)	0.004 (fat) 0 (muscle)
	VR 0494	Radish	W	0.1		
	GC 0649	Rice	W	0.1		
	GC 0651	Sorghum	W	10 Po		
	FS 0012	Stone fruits	0.5		0.02	0.26
	FB 0275	Strawberry	0.06		0.01	0.04
	DT 1114	Tea, Green, Black (black, fermented and dried)	W	0.1		
	VO 0448	Tomato	1	0.5	0.06	0.92
	GC 0654	Wheat	3 Po	10 Po	2.1	2.2
	CM 0654	Wheat bran, unprocessed	6PoP	20 PoP	5.14	5.39
	CF 1211	Wheat flour	W	2 PoP	0.525	0.55
	CP 1211	White bread	W	0.5 PoP	0.105	0.11
	CF 1210	Wheat germ	5 PoP		3.99	4.18
	CF 1212	Wheat wholemeal			3	4.7
	CP 1212	Wholemeal bread	W	2 PoP	1.01	1.06
		Beer			0.002	
	DF 5263	Raisins			0.001	0.001
	JF 448	Tomato juice			0.002	
		Tomato puree			0.016	
		Wine			0.002	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: chlorpyrifos-methyl. The residue is fat-soluble. [a] Replaced by commodity group MRL						
Cycloxydim (179) ** ADI: 0–0.07 mg/kg bw ARfD: 2 mg/kg bw for women of childbearing age unnecessary for general population						
Cypermethrins (118) Group ADI: 0–0.02 mg/kg bw Group ARfD: 0.04 mg/kg bw	GC 0640	Barley	2 [e] Po C [f]		1.38	1.5
	GC 0080	Cereal grains (except rice)	W	0.3 [g]		
	GC 0080	Cereal grains (except rice, barley, oats, rye and wheat)	0.3 [e] Acz		0.035	
	PE 0112	Eggs	0.01 *	0.01 *	0.0042	0.0060
	GC 0647	Oats	2 [e] Po C		1.38	1.5
	PM 0110	Poultry meat	0.1 (fat)	0.05 *	0.002 (muscle) 0.034 (fat)	0.007 (muscle) 0.048 (fat)
	GC 0650	Rye	2 [e] Po C		1.38	1.5

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	GC 0654	Wheat	2 [e] Po C		1.38	1.5
	CM 0654	Wheat bran, unprocessed	5 PoP C		3.45	3.75
		Beer			0.04	
	CF 1211	Wheat flour			0.48 C	0.53
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. [e] Replacing previous MRL for Cereal grains, except rice. [f] 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 [g] Replaced by Cereal grains, except rice, barley, oats, rye and wheat.						
Fenbuconazole (197) ADI: 0–0.03 mg/kg bw	AM 0660	Almond hulls	3		0.45	
	AB 0226	Apple pomace, dry	1		0.3	
	FB 0020	Blueberries	0.5		0.06	0.2
	MF 0812	Cattle fat	W [a]	0.05 *		
	MO 1280	Cattle, Kidney	W [a]	0.05 *		
	MO 1281	Cattle, Liver	W [a]	0.05		
	MM 0812	Cattle meat	W [a]	0.05 *		
	ML 0812	Cattle milk	W [a]	0.05 *		
	FB 0265	Cranberry	1		0.13	0.45
	MO 0105	Edible offal (Mammalian)	0.1		0.02	0.09
	PE 0112	Eggs	0.01 *	0.05 *	0	0
	MM 0095	Meat (from mammals other than marine mammals)	0.01		0.003	0.01
	ML 0106	Milks	0.01 *		0	
	SO 0697	Peanut	0.1		0.03	0.05
	AL 0697	Peanut fodder	15		2.3	7.1
	TN 0672	Pecan	W	0.05 *		
	VO 0051	Peppers	0.6		0.15	0.21
	HS 0444	Peppers Chilli, dried	2		1.5	2.0
	FS 0014	Plums (including Prunes)	0.3		0.08	0.17
	FP 0009	Pome fruits	0.5	0.1	0.12	0.28
	PF 0111	Poultry fats	W	0.05 *		
	PM 0110	Poultry meat	0.01 *	0.05 *	0	0
	PO 0111	Poultry, Edible offal of	0.01 *	0.05 *	0	0
	TN 0085	Tree nuts	0.01 *		0	0
	JF 0226	Apple juice			0.01	
	OR 0697	Peanut oil, edible			0.04	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: fenbuconazole. The residue is fat-soluble. [a] Replaced by commodity group MRL.						
Fluopicolide (235)* ADI: 0–0.08 mg/kg bw ARfD: 0.6 mg/kg bw (women of childbearing age)	VB 0402	Brussels sprouts	0.2		0.04 (0.01) [a]	0.13 (0.01)
	VB 0041	Cabbages, Head	7		1.2 (0.01) [a]	4 (0.02)
	VS 0624	Celery	20		1.4 (0.01) [a]	14 (0.04)
	HS 0444	Peppers Chilli, dried	7		0.91 (0.01)	7 (0.01)
	PE 0112	Eggs	0.01 *		0 (0)	0 (0)

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
2,6-dichlorobenzamide	VB 0042	Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	2		0.385 (0.01) [a]	0.69 (0.01)
ADI: 0–0.02 mg/kg bw	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.07 (0.01) [a, b] 0.01 (0.01) [a, c]	0.3(0.01) [b] 0.01(0.01) [c]
ARfD: 0.6 mg/kg bw (general population)	VO 0050	Fruiting vegetables, other than Cucurbits (except mushrooms and sweet corn)	1		0.16 (0.01) [a]	0.58 (0.01)
	FB 0269	Grapes	2		0.38 (0.01) [a]	1.2 (0.04)
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	10		2.47 (0.045) [a]	7.8 (0.06)
	AB 0269	Grape pomace, dry	7			
	VL 0053	Leafy vegetables	30		8.6 (0.07) [a]	17 (0.19)
	MO 0105	Edible offal (Mammalian)	0.01 *		0 (0) [a]	0 (0)
	ML 0106	Milks	0.02		0 (0) [a]	
	MM 0095	Meat (from mammals other than marine mammals)	0.01 *(fat)		0 (0) [a]	0 (0)
	VA 0385	Onion, Bulb	1		0.07 (0.01) [a]	0.58 (0.01)
	VA 0387	Onion, Welsh	10		2.1 (0.01) [a]	4.5 (0.01)
	PM 0110	Poultry meat	0.01 *		0 (0) [a]	0 (0)
	PO 0111	Poultry, Edible offal of	0.01 *		0 (0) [a]	0 (0)
	AS 0081	Straw and fodder (dry) of cereal grains	0.2			
	JF 0448	Tomato juice			0.048 (0.01) [a]	
		Tomato puree			0.288 (0.01) [a]	
	VW 0448	Tomato paste			0.352 (0.01) [a]	
		White wine			0.16 (0.01) [a]	
		Red wine			0.12 (0.01) [a]	
Definition of the residue (for compliance with the MRL) for plant and animal commodities: fluopicolide. Definition of the residue (for estimation of dietary intake) for plant and animal commodities: fluopicolide and 2,6-dichlorobenzamide measured separately. The residue is fat-soluble. [a] Values in brackets are for residues of 2,6-dichlorobenzamide. [b] Values are for fruit with edible peel. [c] Values are for fruit with inedible peel.						
Haloxyfop (194)**	AL 1021	Alfalfa forage (green)	W [a]	5 [36]		
ADI: 0–0.0007 mg/kg bw	FI 0327	Banana	0.02 *	0.05 *	0	0
ARfD: 0.08 mg/kg bw	VD 0071	Beans (dry)	3		0.335	
	VP 0061	Beans, except broad bean and soya bean	0.5		0.085	0.26
	MO 1280	Cattle, kidney	W [b]	1		
	MO 1281	Cattle, liver	W [b]	0.5		
	MM 0812	Cattle meat	W [b]	0.05		
	ML 0812	Cattle milk	W [b]	0.3		
	PE 0840	Chicken eggs	W [c]	0.01 *		

[36] Fresh weight basis.

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	PM 0840	Chicken meat	W [c]	0.01 * [37]		
	PO 0840	Chicken, Edible offal of	W [c]	0.05		
	VD 0524	Chick-pea (dry)	0.05		0.02	
	FC 0001	Citrus fruits	0.02 *	0.05 *	0	0
	SB 0716	Coffee beans	0.02 *		0	0
	SO 0691	Cotton seed	0.7	0.2	0.1	
	OC 0691	Cotton seed oil, crude	W	0.5		
	MO 0105	Edible offal (Mammalian)	2		0.27	1.42
	PE 0112	Eggs	0.1		0.022	0.05
	AM 1051	Fodder beet	0.4	0.3	0.02	0.30
	AV 1051	Fodder beet leaves or tops	W [a]	0.3 [38]		
	FB 0269	Grapes	0.02 *	0.05 *	0	0
	MM 0095	Meat (from mammals other than marine mammals)	0.5 (fat)		0.035 (fat) 0.006 (muscle)	0.33 (fat) 0.041 (muscle)
	FM 0183	Milk fats	7		0.87	
	ML 0106	Milks	0.3		0.033	
	VA 0385	Onion, Bulb	0.2		0.035	0.12
	SO 0697	Peanut	W	0.05		
	AL 0697	Peanut fodder	5		2.1	3.0
	VD 0072	Peas (dry)	0.2		0.04	
	VP 0063	Peas (pods and succulent = immature seeds)	0.7	0.2	0.11	0.53
	VP 0064	Peas, shelled (succulent seeds)	1		0.08	0.75
	FP 0009	Pome fruits	0.02 *	0.05 *	0	0
	VR 0589	Potato	W	0.1		
	PM 0110	Poultry meat	0.7 (fat)		0.13 (fat) 0.032 (muscle)	0.52 (fat) 0.11 (muscle)
	PO 0111	Poultry, Edible offal of	0.7		0.21	0.61
	VD 0070	Pulses	W [d]	0.2		
	SO 0495	Rape seed	3	2	0.07	
	OC 0495	Rape seed oil, crude	W [e]	5	0.17	
	OR 0495	Rape seed oil, edible	W [e]	5	0.16	
	CM 1206	Rice bran, unprocessed	W	0.02 *		
	CM 0649	Rice, husked	W	0.02 *		
	CM 1205	Rice, polished	W	0.02 *		
	VD 0541	Soya bean (dry)	2		0.055	
	OC 0541	Soya bean oil, crude	W [f]	0.2	0.044	
	OR 0541	Soya bean oil, refined	W [f]	0.2	0.041	
	FS 0012	Stone fruits	0.02 *		0	0
	VR 0596	Sugar beet	0.4	0.3	0.02	0.30
	AV 0596	Sugar beet leaves or tops	W [a]	0.3		
	SO 0702	Sunflower seed	0.3	0.2	0.05	

Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: sum of haloxyfop (including haloxyfop-P), its esters and its conjugates expressed as haloxyfop.

[a] The current policy is not to recommend maximum residue levels for fresh animal forages, but to use the data in livestock

[37] With adhering skin.

[38] Fresh weight basis.

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
dietary burden calculations. [b] Recommendations for Cattle kidney and Cattle liver are withdrawn, to be replaced by a recommendation for mammalian edible offal. Recommendations for Cattle meat and Cattle milk are withdrawn and replaced by recommendations for mammalian meat and milks. [c] Recommendations for Chicken eggs, meat and edible offal are withdrawn, to be replaced by recommendations for poultry commodities. [d] The recommendation for Pulses is withdrawn to be replaced by recommendations for individual commodities. [e] The recommendations for maximum residue levels for rape seed oils are withdrawn, because they are covered by the recommendation for Rape seed. [f] The recommendations for maximum residue levels for Soya bean oils are withdrawn, because they are covered by the recommendation for soya bean (dry).						
Hexythiazox (176)**	FP 0226	Apple	W [a]	0.5		
ADI: 0–0.03 mg/kg bw	FS 0013	Cherries	W [a]	1		
ARfD: Unnecessary	FC 0001	Citrus fruits	0.5	0.5	0.074 (pulp)	
	VP 0526	Common bean (pods and/or immature seeds)	W	0.5		
	VC 0424	Cucumber	W	0.1		
	FB 0279	Currant, Red, White	W	0.2		
	FT 0295	Date	2		0.26	
	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	1		0.32	
	MO 0105	Edible offal (Mammalian)	0.05		0.01	
	VO 0440	Egg plant	0.1		0.05	
	PE 0112	Eggs	0.05		0.002	
	VC 0045	Fruiting vegetables, Cucurbits (except watermelon)	0.05		0.05	
	AB 0269	Grape pomace, dry	15 (dry)			
	FB 0269	Grapes	1	1	0.2	
	DH 1100	Hops, dry	W	2		
	MF 0100	Mammalian fats (except milk fats)	0.05		0.01	
	MM 0095	Meat (from mammals other than marine mammals)	0.05		0.01 (fat) 0 (muscle)	
	FM 0183	Milk fats	0.05		0.01	
	ML 0106	Milks	0.05		0.01	
	FS 0247	Peach	W [a]	1		
	FP 0230	Pear	W [a]	0.5		
	FS 0014	Plums (including Prunes)	W [a]	0.2		
	FP 0009	Pome fruits	0.4		0.11	
	PM 0110	Poultry meat	0.05 * (fat)		0.002 (fat) 0 (muscle)	
	PO 0111	Poultry, Edible offal of	0.05		0.01	
	DF 0014	Prunes [b]	1		0.41	
	FS 0012	Stone fruits	0.3		0.09	
	FB 0275	Strawberry	W	0.5		
	VO 0448	Tomato	0.1	0.1	0.05	
	TN 0085	Tree nuts	0.05 *		0	
	JF 0269	Grape juice			0.084	
	JF 0004	Orange juice			0.024	
		Wine			0.01	
Definition of the residue (for compliance with the MRL) for plant commodities: hexythiazox. Definition of the residue (for estimation of dietary intake) for plant commodities: sum of hexythiazox and all metabolites						

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3-), expressed as hexythiazox. Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities: sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3-), expressed as hexythiazox. The residue is fat-soluble. [a] Replaced by commodity group MRL. [b] The dried fruit						
Indoxacarb (216) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	VD 0527	Cowpea, dry	0.1		0.02	
	FB 0265	Cranberry	1		0.15	0.69
	VC 0424	Cucumber	W [a]	0.2		
	MO 0105	Edible offal (Mammalian)	0.05	0.05	0.014	0.030
	PE 0112	Eggs	0.02	0.01 *	0.01	0.02
	VC 0045	Fruiting vegetables, Cucurbits	0.5		0.06 [b] (0.02[c])	0.39 [b] (0.02[c])
	MM 0095	Meat (from mammals other than marine mammals)	2 (fat)	1 (fat)	0.01 (muscle) 0.38 (fat)	0.039 (muscle) 1.07 (fat)
	VC 0046	Melons, except watermelons	W [a]	0.1		
	FM 0183	Milk fats	2	2	0.78	
	ML 0106	Milks	0.1	0.1	0.037	
	HH 0738	Mints	15		3.5	6.8
	FS 0247	Peach	W [a]	0.3		
	PM 0110	Poultry meat	0.01 * (fat)	0.01 * (fat)	0 (muscle) 0.025 (fat)	0 (muscle) 0.05 (fat)
	PO 0111	Poultry, Edible offal of	0.01 *	0.01 *	0	0
	DF 0014	Prunes [d]	3		0.68	2.6
	FS 0012	Stone fruits	1		0.17	0.64
		Mint oil			0.05	
		Plum jam			0.17	
		Plum juice			0.06	
		Plum pomace, wet			0.14	
		Plum puree			0.22	
		Plums, canned			0.11	
Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities: sum of indoxacarb and its R enantiomer. Definition of the residue for estimation of dietary intake for animal commodities: sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb. The residue is fat-soluble. [a] Replaced by commodity group MRL. [b] STMR and HR values in whole fruit [c] STMR and HR values in edible portion (pulp). [d] The dried fruit.						
Metaflumizone (236)* ADI: 0–0.1 mg/kg bw ARfD: Unnecessary	VB 0402	Brussels sprouts	0.8		0.125	
	VL 0467	Chinese cabbage, (type Pe-tsai)	3		0.49	
	MO 0105	Edible offal (Mammalian)	0.02 *		0.013	
	VO 0440	Egg plant	0.6		0.18	
	VL 0482	Lettuce, Head	7		2.0	
	MM 0095	Meat (from mammals other than marine mammals)	0.02 * (fat)		0.013 (muscle) 0.013 (fat)	
	ML 0106	Milks	0.01 *		0.007	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	FM 0183	Milk fats	0.02		0.013	
	VO 0051	Peppers	0.6		0.18	
	HS 0444	Peppers Chilli, dried	6		1.8	
	VR 0589	Potato	0.02 *		0	
	VO 0448	Tomato	0.6		0.12	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer. The residue is fat-soluble.						
Methoxyfenozide (209)	FI 0326	Avocado	0.7		0.13	0.41
	VP 0526	Common bean (pods and/or immature seeds)	2		0.065	0.99
ADI: 0–0.1 mg/kg bw	VP 0062	Beans, shelled	0.3		0.05	0.18
ARfD: 0.9 mg/kg bw	VD 0071	Beans, dry	0.5		0.05	
	FB 0020	Blueberries	4		1.25	2
	VR 0577	Carrot	0.5		0.13	0.31
	FC 0001	Citrus fruits	0.7		0.05	0.05
	VD 0527	Cowpea (dry)	5		0.56	
	FB 0265	Cranberry	0.7	0.7	0.1	0.39
	MO 0105	Edible offal (Mammalian)	0.1	0.02	0.051	0.057
	MF 0100	Mammalian fats (except milk fats)	0.2		0.094	0.162
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)	0.05	0.094 (fat) 0.019 (muscle)	0.162 (fat) 0.025 (muscle)
	ML 0106	Milks	0.05		0.030	
	FI 0350	Papaya	1		0.31	0.33
	SO 0697	Peanut	0.03		0.01	0.016
	AL 0697	Peanut fodder	80		13.5	51
	OR 0697	Peanut oil, edible	0.1		0.029	
	VP 0064	Peas, shelled (succulent seeds)	0.3		0.05	0.18
	VR 0494	Radish	0.4		0.08	0.1
	VL 0494	Radish leaves (including Radish tops)	7		0.75	4.0
	FB 0275	Strawberry	2		0.24	1.2
	VR 0596	Sugar beet	0.3		0.11	0.18
	VR 0508	Sweet potato	0.02		0.01	0.012
	JF 0001	Citrus juice			0.011	
	DM 0596	Sugar beet molasses			0.126	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: methoxyfenozide. The residue is fat-soluble, but is not classed as fat-soluble with respect to its distribution in milk.						
Paraquat (057)	GC 0649	Rice	0.05	W	0	0
ADI: 0–0.005 mg/kg bw	AS 0649	Rice straw and fodder, dry	0.05	—	0.01	0.04
ARfD: 0.006 mg/kg bw						
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: paraquat cation.						

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Prochloraz (142) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	VO 0450	Mushrooms	3	40	0.71	1.4
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: sum of prochloraz and its metabolites containing the 2,4,6-trichlorphenol moiety, expressed as prochloraz. The residue is fat-soluble.						
Prothioconazole (232) ADI: 0–0.05mg/kg bw ARfD: 0.8 mg/kg bw (women of childbearing age) ARfD: Unnecessary (general population)	GC 0640	Barley	0.2	0.05	0.035	
		Barley forage (fresh)			1.2	5.4
	AS 0640	Barley straw and fodder, dry	W [a]	2		
	MO 0105	Edible offal (Mammalian)	0.5	0.02	0.05 (liver) 0.025 (kidney)	0.23 (liver) 0.15 (kidney)
	AS 0164	Fodder (dry) of cereal grains	5		1.5	4.8
	MF 0100	Mammalian fats (except milk fats)	W	0.01	0.01	0.02
	MM 0095	Meat (from mammals other than marine mammals)	0.01	0.01	0.01	0.01
Prothioconazole-desthio ADI: 0–0.01 mg/kg bw ARfD: 0.01 mg/kg bw (women of childbearing age) ARfD: 1 mg/kg bw (general population)	ML 0106	Milks	0.004*	0.004*	0.004	
	AS 0647	Oat straw, and fodder, dry	W [a]	2		
	VD 0070	Pulses (except Soya bean, dry)	1		0.05	
	SO 0495	Rape seed	0.1	0.05	0.02	
	AS 0650	Rye straw and fodder, dry	W [a]	2		
	VR 0596	Sugar beet	0.3		0.05	
	AS 0081	Straw and fodder (dry) of cereal grains	4		0.65	1.9
	OS 0653	Triticale straw	W [a]	2		
	GC 0654	Wheat	0.1	0.05	0.02	
	CF 1211	Wheat flour	W	0.05	0.008	
	OS 0654	Wheat straw	W [a]	2	0.65	1.9
	OR 0495	Rape seed oil, edible			0.014	
	CM 0654	Wheat bran, unprocessed			0.048	
	CF 1210	Wheat germ			0.04	
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. [a] Replaced by commodity group MRL.						
Spirodiclofen (237)* ADI: 0–0.01 mg/kg bw ARfD: Unnecessary	AM 0660	Almond hulls	15		3.5	
	AB 0226	Apple pomace, dry	4 [a]		3.4	
	FC 0001	Citrus fruits	0.4		0.13 [b] 0.02 [c]	
	SB 0716	Coffee beans	0.03 *		0.03	

Pesticide (Codex reference number)	CCN	Commodity	Recommended MRL mg/kg		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VC 0424	Cucumber	0.07		0.03	
	FB 0021	Currants, Black, Red, White	1		0.040	
	DF 0269	Dried grapes (= Currants, Raisins and Sultanas)	0.3 [a]		0.13	
	MO 0105	Edible offal (Mammalian)	0.05 *		0	
	FB 0269	Grapes	0.2		0.059	
	VC 0425	Gherkin	0.07		0.03	
	DH 1100	Hops, dry	40		11	
	ML 0106	Milks	0.004 *		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01 * (fat)		0	
	FI 0350	Papaya	0.03 *		0.03	
	VO 0445	Peppers, Sweet (including pimento or pimiento)	0.2		0.08	
	FP 0009	Pome fruits	0.8		0.20	
	FS 0012	Stone fruits	2		0.315	
	FB 0275	Strawberry	2		0.0615	
	VO 0448	Tomato	0.5		0.08	
	TN 0085	Tree nuts	0.05		0.0155	
	JC 0001	Citrus juice			0.0065	
	JF 0226	Apple juice			0.004	
	DF 0226	Apples, dried			0.018	
	JF 0269	Grape juice			0.00051	
	-	Wine			0.018	
		Beer (from hops)			0.011	
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities: spirodiclofen. Definition of the residue for compliance with the MRL for animal commodities: spirodiclofen. Definition of the residue for estimation of dietary intake for animal commodities: the sum of spirodiclofen and spirodiclofen-enol, expressed as spirodiclofen. The residue is fat-soluble. [a] Dry weight basis. [b] Whole fruit. [c] Edible portion.						
Zoxamide (227) ADI: 0–0.5 mg/kg bw ARfD: Unnecessary	VC 0424	Cucumber	W [a]	1		
	VC 0045	Fruiting vegetables, Cucurbits	2	—	0.225	-
Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities: zoxamide. [a] Replaced by commodity group MRL.						

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), 2009 (R)
Bendiocarb (137)	1982 (T,R), 1984 (T,R), 1989 (R), 1990 (R)
Benomyl (069)	1973 (T,R), 1975 (T,R), 1978 (T,R), 1983 (T,R),

	1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (R)
Bentazone (172)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1995 (R), 1998 (T,R), 1999 (corr. to 1998 report), 2004(T)
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), 2009 (T)
Binapacryl (003)	1969 (T,R), 1974 (R), 1982 (T), 1984 (R), 1985 (T,R)
Bioresmethrin (093)	1975 (R), 1976 (T,R), 1991 (T,R)
Biphenyl	See Diphenyl
Bitertanol (144)	1983 (T), 1984 (R), 1986 (R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1998 (T), 1999 (R), 2002 (R)
Boscalid (221)	2006 (T, R), 2008 (R), 2009 (R)
Bromide ion (047)	1968 (R), 1969 (T,R), 1971 (R), 1979 (R), 1981 (R), 1983 (R), 1988 (T,R), 1989 (R), 1992 (R)
Bromomethane (052)	1965 (T,R), 1966 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R), 1992 (R)
Bromophos (004)	1972 (T,R), 1975 (R), 1977 (T,R), 1982 (R), 1984 (R), 1985 (R)
Bromophos-ethyl (005)	1972 (T,R), 1975 (T,R), 1977 (R)
Bromopropylate (070)	1973 (T,R), 1993 (T,R)
Butocarboxim (139)	1983 (R), 1984 (T), 1985 (T), 1986 (R)
Buprofezin (173)	1991 (T,R), 1995 (R), 1996 (corr. to 1995 report.), 1999 (R), 2008 (T, R), 2009 (R)
sec-Butylamine (089)	1975 (T,R), 1977 (R), 1978 (T,R), 1979 (R), 1980 (R), 1981 (T), 1984 (T,R: withdrawal of temporary ADI, but no evaluation)
Cadusafos (174)	1991 (T,R), 1992 (R), 1992 (R), 2009 (T)
Campheclor (071)	1968 (T,R), 1973 (T,R)
Captafol (006)	1969 (T,R), 1973 (T,R), 1974 (R), 1976 (R), 1977 (T,R), 1982 (T), 1985 (T,R), 1986 (corr. to 1985 report), 1990 (R), 1999 (acute Rf D)
Captan (007)	1965 (T), 1969 (T,R), 1973 (T), 1974 (R), 1977 (T,R), 1978 (T,R), 1980 (R), 1982 (T), 1984 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1995 (T), 1997 (R), 2000 (R), 2004 (T), 2007 (T)
Carbaryl (008)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (T,R), 1970 (R), 1973 (T,R), 1975 (R), 1976 (R), 1977 (R), 1979 (R), 1984 (R), 1996 (T), 2001 (T), 2002 (R), 2007 (R)
Carbendazim (072)	1973 (T,R), 1976 (R), 1977 (T), 1978 (R), 1983 (T,R), 1985 (T,R), 1987 (R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2003 (R), 2005 (T)
Carbofuran (096)	1976 (T,R), 1979 (T,R), 1980 (T), 1982 (T),

	1991 (R), 1993 (R), 1996 (T), 1997 (R), 1999 (corr. to 1997 report), 2002 (T, R), 2003 (R) (See also carbosulfan), 2004 (R), 2008 (T), 2009 (R)
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), 2009 (T)
Chlorpropham (201)	1965 (T), 2000 (T), 2001 (R), 2005 (T), 2008 (R)
Chlorpyrifos (017)	1972 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1981 (R), 1982 (T,R), 1983 (R), 1989 (R), 1995 (R), 1999 (T), 2000 (R), 2004 (R), 2006 (R)
Chlorpyrifos-methyl (090)	1975 (T,R), 1976 (R, Annex I only), 1979 (R), 1990, (R), 1991 (T,R), 1992 (T and corr. to 1991 report), 1993 (R), 1994 (R), 2001 (T), 2009 (T,R)
Chlorthion	1965 (T)
Clethodim (187)	1994 (T,R), 1997 (R), 1999 (R), 2002 (R)
Clofentezine (156)	1986 (T,R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 2005 (T), 2007 (R)
Coumaphos (018)	1968 (T,R), 1972 (R), 1975 (R), 1978 (R), 1980 (T,R), 1983 (R), 1987 (T), 1990 (T,R)

Crufomate (019)	1968 (T,R), 1972 (R)
Cyanophenfos (091)	1975 (T,R), 1978 (T: ADI extended, but no evaluation), 1980, (T), 1982 (R), 1983 (T)
Cycloxydim (179)	1992 (T,R), 1993 (R), 2009 (T)
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(s) (118)	1979 (T,R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R), 2009 (R)
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), 2009 (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)
Fluopicolide (235)	2009 (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), 2009 (R)
Heptachlor (043)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R), 1974 (R), 1975 (R), 1977 (R), 1987 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1993 (R), 1994 (R)
Hexachlorobenzene (044)	1969 (T,R), 1973 (T,R), 1974 (T,R), 1978(T), 1985 (R)
Hexaconazole (170)	1990 (T,R), 1991 (R and corr. to 1990 R evaluation), 1993 (R)
Hexythiazox (176)	1991 (T,R), 1994 (R), 1998 (R), 2008 (T), 2009 (R)
Hydrogen cyanide (045)	1965 (T,R)
Hydrogen phosphide (046)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1971 (R)
Imazalil (110)	1977 (T,R), 1980 (T,R), 1984 (T,R), 1985 (T,R), 1986 (T), 1988 (R), 1989 (R), 1991 (T), 1994 (R), 2000 (T), 2001 (T), 2005 (T)
Imidacloprid (206)	2001 (T), 2002 (R), 2006 (R), 2008 (R)
Indoxacarb (216)	2005 (T,R), 2007 (R), 2009 (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)
Metaflumizone (236)	2009 (T,R)
Methacrifos (125)	1980 (T,R), 1982 (T), 1986 (T), 1988 (T), 1990 (T,R), 1992 (R)
Methamidophos (100)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T,R), 1984 (R), 1985 (T), 1989 (R), 1990 (T,R), 1994 (R), 1996 (R), 1997 (R), 2002 (T), 2003 (R), 2004 (R, corr. to 2003 report)
Methidathion (051)	1972 (T,R), 1975 (T,R), 1979 (R), 1992 (T,R), 1994 (R), 1997 (T)
Methiocarb (132)	1981 (T,R), 1983 (T,R), 1984 (T), 1985 (T), 1986 (R), 1987 (T,R), 1988 (R), 1998 (T), 1999 (R), 2005 (R)
Methomyl (094)	1975 (R), 1976 (R), 1977 (R), 1978 (R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (T,R), 1990 (R), 1991 (R), 2001 (T,R), 2004 (R), 2008 (R)
Methoprene (147)	1984 (T,R), 1986 (R), 1987 (T and corr. to 1986 report), 1988 (R), 1989 (R), 2001 (T), 2005 (R)
Methoxychlor	1965 (T), 1977 (T)
Methoxyfenozide (209)	2003 (T, R), 2004 (corr. to 2003 report), 2006 (R), 2009 (R)
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), 2009 (R)
Parathion (058)	1965 (T), 1967 (T,R), 1969 (R), 1970 (R), 1984 (R), 1991 (R), 1995 (T,R), 1997 (R), 2000 (R)
Parathion-methyl (059)	1965 (T), 1968 (T,R), 1972 (R), 1975 (T,R), 1978 (T,R), 1979 (T), 1980 (T), 1982 (T), 1984 (T,R), 1991 (R), 1992 (R), 1994 (R), 1995 (T), 2000 (R), 2003 (R)
Penconazole (182)	1992 (T,R), 1995 (R)
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), 2009 (R)
Procymidone(136)	1981 (R), 1982 (T), 1989 (T,R), 1990 (R), 1991 (corr. to 1990 Annex I), 1993 (R), 1998 (R), 2007 (T)
Profenofos (171)	1990 (T,R), 1992 (R), 1994 (R), 1995 (R), 2007 (T), 2008 (R)
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), 2009 (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)
Spirodiclifen (237)	2009 (T,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), 2009 (corr. to 2008 report)
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), 2009 (R)

ANNEX 3: INTERNATIONAL ESTIMATED DAILY INTAKES OF PESTICIDE RESIDUES

BENALAXYL (155) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0700 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FB 0269	Grape (incl dried, excl juice, excl wine)	0.12	1.9	0.2	20.8	2.5	25.4	3.1	11.4	1.4	9.2	1.1	6.8	0.8
JF 0269	Grape juice	0.019	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0	1.0	0.0
VL 0482	Lettuce, head	0.07	0.1	0.0	12.3	0.9	1.3	0.1	0.1	0.0	0.1	0.0	0.0	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
-	Onion, dry	0	4.3	0.0	45.6	0.0	27.4	0.0	30.2	0.0	22.1	0.0	12.2	0.0
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
VO 0448	Tomato (excl juice, incl paste, incl peeled)	0.035	5.3	0.2	184.4	6.5	117.5	4.1	58.1	2.0	23.0	0.8	21.9	0.8
JF 0448	Tomato juice	0.0077	5.2	0.0	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.1	15.2	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
-	Wine	0.023	1.3	0.0	76.8	1.8	1.1	0.0	15.4	0.4	68.8	1.6	25.6	0.6
	Total intake (µg/person)=			0.7		13.0		8.7		4.5		3.8		2.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			4200		4200		4200		4200		4200		4200
	%ADI=			0.0%		0.3%		0.2%		0.1%		0.1%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

BENALAXL (155) 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 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
FB 0269	Grape (incl dried, excl juice, excl wine)	0.12	1.2	0.1	3.4	0.4	0.8	0.1	0.2	0.0	1.2	0.1	5.3	0.6	10.4	1.2
JF 0269	Grape juice	0.019	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
VL 0482	Lettuce, head	0.07	2.4	0.2	7.0	0.5	0.2	0.0	0.6	0.0	2.0	0.1	2.4	0.2	15.7	1.1
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
-	Onion, dry	0	16.8	0.0	8.6	0.0	6.9	0.0	12.1	0.0	18.6	0.0	23.8	0.0	28.4	0.0
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
VO 0448	Tomato (excl juice, incl paste, incl peeled)	0.035	23.5	0.8	30.7	1.1	14.9	0.5	7.2	0.3	35.6	1.2	6.9	0.2	46.5	1.6
JF 0448	Tomato juice	0.0077	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	0.3

BENALAXL (155) 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 diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
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
-	Wine	0.023	1.0	0.0	0.9	0.0	6.8	0.2	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.7
	Total intake (µg/person)=			2.1		2.4		0.9		0.7		1.8		1.6		5.6
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			3850		4200		4200		4200		4200		3850		4200
	%ADI=			0.1%		0.1%		0.0%		0.0%		0.0%		0.0%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
TN 0660	Almond	0.050	0.0	0.0	1.9	0.1	1.0	0.1	0.0	0.0	1.0	0.1	0.8	0.0
FP 0226	Apple (excl juice)	0.365	0.3	0.1	56.3	20.5	18.4	6.7	38.3	14.0	40.6	14.8	28.3	10.3
JF 0226	Apple juice	0.030	0.0	0.0	2.8	0.1	0.1	0.0	1.1	0.0	6.8	0.2	7.4	0.2
FI 0327	Banana	0.050	38.8	1.9	17.4	0.9	16.0	0.8	6.6	0.3	21.5	1.1	33.8	1.7
GC 0640	Barley (incl pot, incl pearled, excl flour & grits, excl beer)	0.075	40.6	3.0	0.0	0.0	93.9	7.0	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
-	Barley flour and grits	0.026	0.0	0.0	0.3	0.0	10.8	0.3	0.3	0.0	0.5	0.0	0.9	0.0
-	Berries and other small fruits NES (excl blackberry, boysenberry, dewberry)	2.530	0.0	0.0	0.2	0.5	0.0	0.0	0.2	0.5	0.1	0.3	0.2	0.5
FB 0264	Blackberries	2.530	0.0	0.0	0.1	0.3	0.0	0.0	0.3	0.8	0.1	0.3	0.3	0.8
FB 0020	Blueberries	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.5	0.3	0.8	0.8	2.0
FB 4079	Boysenberry	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.8	0.0	0.0	0.3	0.8
TN 0662	Brazil nut	0.050	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
GC 0641	Buckwheat (incl flour, incl bran)	0.050	0.0	0.0	0.1	0.0	0.0	0.0	1.7	0.1	1.6	0.1	0.1	0.0
VA 0035	Bulb vegetables	2.200	8.5	18.7	60.3	132.7	37.7	82.9	37.2	81.8	31.8	70.0	16.7	36.7
VB 0041	Cabbage, head	1.520	1.2	1.8	14.4	21.9	2.7	4.1	16.4	24.9	15.4	23.4	18.5	28.1
TN 0295	Cashew nut	0.050	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0
-	Cereal preparations NES	0.050	0.0	0.0	0.5	0.0	0.6	0.0	0.3	0.0	0.7	0.0	1.5	0.1

Annex 3

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
TN 0664	Chestnut	0.050	0.0	0.0	1.7	0.1	0.0	0.0	0.2	0.0	0.3	0.0	0.0	0.0
TN 0665	Coconut (incl oil)	0.050	2.9	0.1	13.5	0.7	2.1	0.1	1.5	0.1	1.8	0.1	8.9	0.4
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.050	3.1	0.2	12.6	0.6	2.9	0.1	1.4	0.1	10.1	0.5	18.0	0.9
FB 0265	Cranberries	2.530	0.1	0.3	0.0	0.0	0.0	0.0	0.3	0.8	0.0	0.0	0.6	1.5
FB 0021	Currants, red, black, white	2.530	0.0	0.0	0.0	0.0	0.0	0.0	2.2	5.6	3.1	7.8	2.0	5.1
FB 0266	Dewberries, incl boysen- & loganberry	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.8	0.0	0.0	0.3	0.8
MO 0105	Edible offal (mammalian)	0.160	3.9	0.6	14.4	2.3	5.2	0.8	11.8	1.9	11.7	1.9	7.6	1.2
VO 0440	Egg plant (= aubergine)	0.565	1.7	1.0	17.5	9.9	12.3	6.9	1.7	1.0	0.8	0.5	0.4	0.2
PE 0112	Eggs	0.020	2.5	0.1	29.7	0.6	25.1	0.5	24.5	0.5	37.8	0.8	27.4	0.5
FB 0267	Elderberries	2.530	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VC 0045	Fruiting vegetables, cucurbits	0.565	26.6	15.0	107.5	60.7	95.9	54.2	82.2	46.4	25.4	14.4	23.2	13.1
FB 0268	Gooseberries	2.530	0.0	0.0	12.0	30.4	0.0	0.0	0.6	1.5	1.1	2.8	0.2	0.5
FB 0269	Grape (excl dried, excl juice, excl wine)	1.090	1.9	2.0	9.2	10.1	23.8	26.0	9.8	10.7	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.460	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.6	1.0	0.5
DF 0269	Grape, dried (= currants, raisins and sultanas)	2.600	0.0	0.0	2.9	7.5	0.4	1.0	0.4	1.0	2.3	6.0	1.7	4.4
TN 0666	Hazelnut	0.050	0.0	0.0	2.1	0.1	0.0	0.0	0.1	0.0	1.3	0.1	0.3	0.0
FI 0341	Kiwi fruit	0.073	0.0	0.0	2.9	0.2	0.1	0.0	0.2	0.0	2.7	0.2	1.8	0.1
VL 0053	Leafy vegetables	2.950	5.8	17.1	45.6	134.5	10.9	32.2	26.8	79.1	18.7	55.2	38.9	114.8
VP 0060	Legume vegetables	0.500	6.1	3.1	23.0	11.5	18.0	9.0	12.8	6.4	26.9	13.5	5.3	2.7
TN 0669	Macadamia nut	0.050	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0645	Maize (incl flour, incl oil, incl beer)	0.050	82.7	4.1	148.4	7.4	135.9	6.8	31.8	1.6	33.3	1.7	7.5	0.4
MF 0100	Mammalian fats (except milk fats)	0.180	0.8	0.1	10.0	1.8	0.9	0.2	6.6	1.2	11.8	2.1	3.7	0.7
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.180	5.5	1.0	23.3	4.2	7.7	1.4	11.0	2.0	18.0	3.2	26.3	4.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.035	22.2	0.8	93.2	3.3	30.8	1.1	44.1	1.5	72.2	2.5	105.0	3.7
ML 0106	Milks (excl processed products)	0.066	68.8	4.5	190.6	12.6	79.4	5.2	302.6	20.0	179.6	11.9	237.9	15.7
GC 0646	Millet (incl flour, incl beer)	0.050	15.8	0.8	0.1	0.0	0.8	0.0	5.6	0.3	0.2	0.0	0.1	0.0
GC 0647	Oats (incl rolled)	0.050	1.4	0.1	0.6	0.0	0.2	0.0	4.2	0.2	5.7	0.3	8.9	0.4
SO 0088	Oilseed	0.145	22.3	3.2	65.2	9.5	35.4	5.1	52.0	7.5	62.1	9.0	39.4	5.7
VO 0442	Okra	0.565	3.9	2.2	1.0	0.6	5.3	3.0	0.1	0.1	0.0	0.0	0.0	0.0
TN 0672	Pecan	0.050	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VO 0051	Peppers	0.565	1.4	0.8	29.9	16.9	13.0	7.3	6.3	3.6	6.2	3.5	4.0	2.3

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
TN 0673	Pine nut	0.050	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0675	Pistachio nut	0.270	0.0	0.0	0.7	0.2	0.5	0.1	0.9	0.2	0.3	0.1	0.0	0.0
DF 0014	Plum, dried (prunes)	3.390	0.0	0.0	0.2	0.7	0.0	0.0	0.1	0.3	0.5	1.7	0.6	2.0
GC 0656	Popcorn	0.050	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	0.020	7.1	0.1	58.5	1.2	31.9	0.6	24.0	0.5	61.0	1.2	27.3	0.5
PO 0111	Poultry, edible offal of	0.020	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	0.020	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
VD 0070	Pulses	0.120	54.5	6.5	62.9	7.5	51.4	6.2	36.8	4.4	49.4	5.9	47.9	5.7
FB 0272	Raspberries, red, black	2.530	0.0	0.0	0.0	0.0	0.0	0.0	1.8	4.6	0.9	2.3	0.2	0.5
GC 0649	Rice (incl husked, incl polished)	0.050	91.0	4.6	31.6	1.6	94.6	4.7	33.2	1.7	12.7	0.6	12.7	0.6
VR0075	Root and tuber vegetables	0.305	528.2	161.1	352.8	107.6	78.5	23.9	270.3	82.4	324.1	98.9	261.3	79.7
FB 0273	Rose hips	2.530	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0650	Rye (excl flour)	0.075	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
CF 1250	Rye flour	0.026	0.0	0.0	2.8	0.1	0.2	0.0	18.7	0.5	19.8	0.5	35.2	0.9
CF 1251	Rye wholemeal	0.092	0.1	0.0	3.7	0.3	0.3	0.0	24.3	2.2	25.8	2.4	45.8	4.2
GC 0651	Sorghum (incl flour, incl beer)	0.050	36.9	1.8	0.0	0.0	10.2	0.5	0.0	0.0	0.0	0.0	0.0	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.210	0.7	0.8	44.1	53.4	14.1	17.1	26.6	32.2	26.3	31.8	8.3	10.0
FB 0275	Strawberry	0.555	0.0	0.0	5.0	2.8	2.0	1.1	1.7	0.9	5.2	2.9	4.1	2.3
VO 0448	Tomato (excl juice, excl paste, incl peeled)	0.565	3.3	1.9	179.2	101.2	103.5	58.5	54.1	30.6	7.8	4.4	3.9	2.2
JF 0448	Tomato juice	0.085	5.2	0.4	0.5	0.0	0.4	0.0	2.1	0.2	6.9	0.6	15.2	1.3
-d	Tomato paste	0.413	0.5	0.2	1.3	0.5	3.5	1.4	1.0	0.4	3.8	1.6	4.5	1.9
TN 0085	Tree nuts	0.050	4.2	0.2	21.5	1.1	3.9	0.2	3.0	0.2	5.5	0.3	10.2	0.5
-	Tree nuts NES (excl pecan nuts)	0.050	1.3	0.1	0.2	0.0	0.3	0.0	0.2	0.0	0.0	0.0	0.1	0.0
GC 0653	Triticale (excl flour)	0.075	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Triticale flour	0.026	0.0	0.0	89.1	2.3	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0
FB 0019	Vaccinium berries (incl. bearberry)	2.530	0.1	0.3	0.0	0.0	0.0	0.0	0.5	1.3	0.3	0.8	1.4	3.5
TN 0678	Walnut	0.050	0.0	0.0	1.3	0.1	0.0	0.0	0.1	0.0	0.3	0.0	0.1	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.075	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	0.320	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-d	Wheat bulgur wholemeal	0.092	5.5	0.5	10.2	0.9	0.7	0.1	0.2	0.0	0.1	0.0	0.0	0.0
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.026	63.4	1.6	296.3	7.7	327.5	8.5	300.0	7.8	181.6	4.7	166.2	4.3
CF 1210	Wheat germ	0.100	0.0	0.0	1.3	0.1	0.0	0.0	1.3	0.1	0.9	0.1	1.2	0.1

Annex 3

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
CF 1212	Wheat wholemeal	0.092	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.026	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	0.092	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.1
-	Wine	0.380	1.3	0.5	76.8	29.2	1.1	0.4	15.4	5.9	68.8	26.1	25.6	9.7
	Total intake (µg/person)=			263.5		821.2		386.6		494.0		436.7		392.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			2400		2400		2400		2400		2400		2400
	%ADI=			11.0%		34.2%		16.1%		20.6%		18.2%		16.4%
	Rounded %ADI=			10%		30%		20%		20%		20%		20%

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
TN 0660	Almond	0.050	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0
FP 0226	Apple (excl juice)	0.365	14.3	5.2	9.4	3.4	2.1	0.7	0.0	0.0	8.8	3.2	16.6	6.0	27.8	10.1
JF 0226	Apple juice	0.030	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.2
FI 0327	Banana	0.050	21.4	1.1	36.6	1.8	11.4	0.6	9.2	0.5	70.2	3.5	40.5	2.0	32.6	1.6
GC 0640	Barley (incl pot, incl pearled, excl flour & grits, excl beer)	0.075	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
-	Barley flour and grits	0.026	0.4	0.0	0.0	0.0	0.1	0.0	0.0	0.0	1.0	0.0	0.8	0.0	0.0	0.0
-	Berries and other small fruits NES (excl blackberry, boysenberry, dewberry)	2.530	0.2	0.5	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 0264	Blackberries	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.3	0.0	0.0	0.3	0.8
FB 0020	Blueberries	2.530	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	3.3
FB 4079	Boysenberry	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.3	0.0	0.0	0.0	0.0
TN 0662	Brazil nut	0.050	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
GC 0641	Buckwheat (incl flour, incl bran)	0.050	1.0	0.1	0.0	0.0	0.2	0.0	0.1	0.0	0.5	0.0	2.0	0.1	0.1	0.0
VA 0035	Bulb vegetables	2.200	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

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day 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 0041	Cabbage, head	1.520	10.0	15.2	1.0	1.5	7.2	10.9	1.0	1.5	1.4	2.1	23.9	36.3	17.0	25.8
TN 0295	Cashew nut	0.050	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.6	0.0
-	Cereal preparations NES	0.050	0.4	0.0	2.8	0.1	1.2	0.1	0.2	0.0	0.2	0.0	0.3	0.0	0.3	0.0
TN 0664	Chestnut	0.050	0.5	0.0	0.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.1	0.0	0.0
TN 0665	Coconut (incl oil)	0.050	15.3	0.8	13.4	0.7	9.3	0.5	1.6	0.1	18.9	0.9	26.7	1.3	3.4	0.2
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0.050	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
FB 0265	Cranberries	2.530	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	6.3
FB 0021	Currants, red, black, white	2.530	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	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.3	0.0	0.0	0.1	0.3
MO 0105	Edible offal (mammalian)	0.160	4.8	0.8	10.7	1.7	4.0	0.6	4.0	0.6	6.5	1.0	6.6	1.1	5.6	0.9
VO 0440	Egg plant (= aubergine)	0.565	20.1	11.4	0.1	0.1	0.6	0.3	6.3	3.6	0.5	0.3	6.3	3.6	0.7	0.4
PE 0112	Eggs	0.020	22.1	0.4	71.5	1.4	16.6	0.3	5.1	0.1	17.6	0.4	35.2	0.7	57.4	1.1
FB 0267	Elderberries	2.530	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VC 0045	Fruiting vegetables, cucurbits	0.565	69.7	39.4	25.9	14.6	14.9	8.4	18.0	10.2	18.7	10.6	39.1	22.1	44.2	25.0
FB 0268	Gooseberries	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	2.5	0.0	0.0	0.0	0.0
FB 0269	Grape (excl dried, excl juice, excl wine)	1.090	1.2	1.3	2.6	2.8	0.0	0.0	0.2	0.2	0.0	0.0	3.7	4.0	0.0	0.0
JF 0269	Grape juice	0.460	0.0	0.0	0.1	0.0	1.0	0.5	0.0	0.0	0.6	0.3	0.4	0.2	3.6	1.7
DF 0269	Grape, dried (= currants, raisins and sultanas)	2.600	0.0	0.0	0.2	0.5	0.2	0.5	0.0	0.0	0.3	0.8	0.4	1.0	2.6	6.8
TN 0666	Hazelnut	0.050	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 0341	Kiwi fruit	0.073	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	1.6	0.1	1.0	0.1
VL 0053	Leafy vegetables	2.950	40.8	120.4	12.0	35.4	12.5	36.9	9.5	28.0	5.4	15.9	50.0	147.5	39.9	117.7
VP 0060	Legume vegetables	0.500	19.6	9.8	6.2	3.1	6.9	3.5	6.0	3.0	1.7	0.9	29.5	14.8	26.3	13.2
TN 0669	Macadamia nut	0.050	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0645	Maize (incl flour, incl oil, incl beer)	0.050	35.2	1.8	298.6	14.9	248.1	12.4	57.4	2.9	63.1	3.2	58.6	2.9	85.5	4.3
MF 0100	Mammalian fats (except milk fats)	0.180	2.2	0.4	18.6	3.3	0.5	0.1	0.8	0.1	5.7	1.0	4.5	0.8	18.2	3.3
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.180	11.0	2.0	17.9	3.2	6.1	1.1	5.7	1.0	16.4	3.0	12.2	2.2	31.7	5.7
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.035	43.8	1.5	71.5	2.5	24.5	0.9	22.9	0.8	65.7	2.3	48.9	1.7	126.6	4.4
ML 0106	Milks (excl processed products)	0.066	66.0	4.4	121.1	8.0	81.6	5.4	102.4	6.8	207.7	13.7	57.0	3.8	287.9	19.0
GC 0646	Millet (incl flour, incl beer)	0.050	13.0	0.7	0.0	0.0	8.3	0.4	96.9	4.8	0.0	0.0	0.4	0.0	0.0	0.0
GC 0647	Oats (incl rolled)	0.050	0.2	0.0	2.0	0.1	0.8	0.0	0.0	0.0	3.5	0.2	0.7	0.0	7.6	0.4
SO 0088	Oilseed	0.145	26.2	3.8	19.8	2.9	24.9	3.6	39.9	5.8	7.4	1.1	62.7	9.1	29.9	4.3

Annex 3

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / 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 0442	Okra	0.565	4.1	2.3	1.0	0.6	7.0	4.0	15.9	9.0	1.1	0.6	3.9	2.2	0.2	0.1
TN 0672	Pecan	0.050	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
VO 0051	Peppers	0.565	8.7	4.9	22.4	12.7	8.4	4.7	9.4	5.3	3.3	1.9	5.3	3.0	8.9	5.0
TN 0673	Pine nut	0.050	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
TN 0675	Pistachio nut	0.270	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
DF 0014	Plum, dried (prunes)	3.390	0.1	0.3	0.2	0.7	0.0	0.0	0.0	0.0	0.2	0.7	0.2	0.7	0.6	2.0
GC 0656	Popcorn	0.050	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	0.020	17.6	0.4	131.3	2.6	25.1	0.5	4.7	0.1	145.9	2.9	27.7	0.6	115.1	2.3
PO 0111	Poultry, edible offal of	0.020	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	0.020	0.1	0.0	8.2	0.2	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	4.2	0.1
VD 0070	Pulses	0.120	41.9	5.0	91.8	11.0	35.9	4.3	45.2	5.4	160.0	19.2	59.5	7.1	140.1	16.8
FB 0272	Raspberries, red, black	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.5	0.0	0.0	0.5	1.3
GC 0649	Rice (incl husked, incl polished)	0.050	376.9	18.8	64.3	3.2	38.0	1.9	74.3	3.7	238.4	11.9	381.3	19.1	34.6	1.7
VR0075	Root and tuber vegetables	0.305	139.1	42.4	109.8	33.5	409.6	124.9	444.6	135.6	145.3	44.3	127.0	38.7	225.6	68.8
FB 0273	Rose hips	2.530	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
GC 0650	Rye (excl flour)	0.075	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.9	0.1	0.0	0.0
CF 1250	Rye flour	0.026	0.3	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.6	0.0
CF 1251	Rye wholemeal	0.092	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.1	0.8	0.1
GC 0651	Sorghum (incl flour, incl beer)	0.050	9.8	0.5	19.9	1.0	18.6	0.9	112.3	5.6	0.1	0.0	3.3	0.2	3.0	0.2
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	1.210	6.7	8.1	4.3	5.2	1.4	1.7	0.1	0.1	4.9	6.0	4.9	6.0	17.7	21.4
FB 0275	Strawberry	0.555	0.0	0.0	1.8	1.0	0.1	0.1	0.0	0.0	0.3	0.2	6.2	3.4	5.9	3.3
VO 0448	Tomato (excl juice, excl paste, incl peeled)	0.565	23.1	13.1	22.3	12.6	12.5	7.0	5.6	3.2	33.2	18.8	1.3	0.7	41.7	23.6
JF 0448	Tomato juice	0.085	0.0	0.0	0.8	0.1	0.1	0.0	7.2	0.6	0.0	0.0	2.4	0.2	45.2	3.8
-d	Tomato paste	0.413	0.1	0.0	2.1	0.9	0.6	0.2	0.4	0.2	0.6	0.2	1.4	0.6	1.2	0.5
TN 0085	Tree nuts	0.050	16.3	0.8	15.7	0.8	9.7	0.5	1.9	0.1	19.1	1.0	29.0	1.5	5.6	0.3
-	Tree nuts NES (excl pecan nuts)	0.050	0.1	0.0	1.4	0.1	0.2	0.0	0.3	0.0	0.0	0.0	0.3	0.0	0.4	0.0
GC 0653	Triticale (excl flour)	0.075	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Triticale flour	0.026	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
FB 0019	Vaccinium berries (incl. bearberry)	2.530	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.8	9.6
TN 0678	Walnut	0.050	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.4	0.0
GC 0654	Wheat (excl bulgur wholemeal, excl flour)	0.075	0.0	0.0	0.9	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.320	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0400 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / 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
-d	Wheat bulgur wholemeal	0.092	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)	0.026	133.0	3.5	60.1	1.6	52.4	1.4	32.2	0.8	87.7	2.3	79.6	2.1	180.1	4.7
CF 1210	Wheat germ	0.100	0.1	0.0	48.1	4.8	1.8	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.1
CF 1212	Wheat wholemeal	0.092	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.026	0.0	0.0	2.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CP 1212	Wholemeal bread	0.092	0.0	0.0	2.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.380	1.0	0.4	0.9	0.3	6.8	2.6	0.1	0.0	3.4	1.3	3.6	1.4	31.0	11.8
	Total intake (µg/person)=			391.1		261.1		264.2		283.0		236.4		453.4		508.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			2200		2400		2400		2400		2400		2200		2400
	%ADI=			17.8%		10.9%		11.0%		11.8%		9.8%		20.6%		21.2%
	Rounded %ADI=			20%		10%		10%		10%		10%		20%		20%

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
TN 0660	Almond	0.05	0.0	0.0	1.9	0.1	1.0	0.1	0.0	0.0	1.0	0.1	0.8	0.0
FP 0226	Apple (excl juice)	0.28	0.3	0.1	56.3	15.8	18.4	5.1	38.3	10.7	40.6	11.4	28.3	7.9
JF 0226	Apple juice	0.16	0.0	0.0	2.8	0.4	0.1	0.0	1.1	0.2	6.8	1.1	7.4	1.2
FS 0013	Cherries	0.73	0.0	0.0	6.8	5.0	0.9	0.7	6.2	4.5	3.6	2.6	0.4	0.3
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.04	15.7	0.6	86.5	3.5	52.6	2.1	24.2	1.0	16.2	0.6	12.0	0.5
-	Citrus juice NES	0.13	0.0	0.0	1.7	0.2	0.1	0.0	0.0	0.0	1.1	0.1	0.3	0.0
VC 0045	Fruiting vegetables, cucurbits	0.195	26.6	5.1	107.5	20.4	95.9	18.2	82.2	15.6	25.4	4.8	23.2	4.4
FB 0269	Grape (excl dried, excl juice, excl wine)	0.17	1.9	0.3	9.2	1.6	23.8	4.0	9.8	1.7	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.098	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.37	0.0	0.0	2.9	1.1	0.4	0.1	0.4	0.1	2.3	0.9	1.7	0.6

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 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 0203	Grapefruit juice	0.13	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.1	0.2	0.0
-d	Lemon juice	0.13	0.0	0.0	0.9	0.1	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.1
-	Mandarin + mandarin-like hybrid juice	0.13	0.0	0.0	1.4	0.2	0.9	0.1	0.4	0.1	0.7	0.1	0.9	0.1
FI 0345	Mango (incl juice, incl pulp)	0.01	6.3	0.1	1.0	0.0	4.6	0.0	0.2	0.0	0.7	0.0	0.3	0.0
FS 0245	Nectarine	1.355	0.0	0.0	0.5	0.7	3.3	4.5	1.8	2.4	2.8	3.8	1.6	2.2
FT 0305	Olive (table olives, only)	1.125	0.0	0.0	4.8	5.4	0.8	0.9	0.4	0.5	1.0	1.1	0.8	0.9
OR 0305	Olive oil, refined	3.49	0.0	0.0	14.3	49.9	3.9	13.6	0.0	0.0	1.5	5.2	0.8	2.8
JF 0004	Orange juice	0.13	0.0	0.0	2.1	0.3	4.4	0.6	1.4	0.2	16.2	2.1	22.6	2.9
FS 0247	Peach	1.355	0.2	0.3	24.8	33.6	3.3	4.5	1.8	2.4	5.4	7.3	1.6	2.2
FP 0230	Pear	1.09	0.1	0.1	22.3	24.3	2.8	3.1	4.8	5.2	10.7	11.7	6.8	7.4
VO 0051	Peppers	0.33	1.4	0.5	29.9	9.9	13.0	4.3	6.3	2.1	6.2	2.0	4.0	1.3
FS 0014	Plum (excl dried)	0.155	0.1	0.0	5.3	0.8	2.5	0.4	7.0	1.1	5.5	0.8	0.9	0.1
DF 0014	Plum, dried (prunes)	0.465	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.3
FB 0275	Strawberry	0.44	0.0	0.0	5.0	2.2	2.0	0.9	1.7	0.7	5.2	2.3	4.1	1.8
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.24	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	5.2	0.3	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.4	15.2	0.8
-d	Tomato paste	0.22	0.5	0.1	1.3	0.3	3.5	0.8	1.0	0.2	3.8	0.8	4.5	1.0
-d	Tomato, peeled	0.041	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.2	3.2	0.1
-	Wine	0.15	1.3	0.2	76.8	11.5	1.1	0.2	15.4	2.3	68.8	10.3	25.6	3.8
	Total intake (µg/person)=			7.8		256.9		97.1		63.3		70.6		43.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			540		540		540		540		540		540
	%ADI=			1.5%		47.6%		18.0%		11.7%		13.1%		8.0%
	Rounded %ADI=			1%		50%		20%		10%		10%		8%

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
TN 0660	Almond	0.05	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.3	0.0
FP 0226	Apple (excl juice)	0.28	14.3	4.0	9.4	2.6	2.1	0.6	0.0	0.0	8.8	2.5	16.6	4.6	27.8	7.8
JF 0226	Apple juice	0.16	0.1	0.0	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.9
FS 0013	Cherries	0.73	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.2	2.5	1.8
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.04	15.1	0.6	153.9	6.2	3.4	0.1	41.7	1.7	218.9	8.8	23.1	0.9	18.0	0.7
-	Citrus juice NES	0.13	0.0	0.0	0.0	0.0	0.5	0.1	0.0	0.0	0.0	0.0	0.3	0.0	0.1	0.0
VC 0045	Fruiting vegetables, cucurbits	0.195	69.7	13.2	25.9	4.9	14.9	2.8	18.0	3.4	18.7	3.6	39.1	7.4	44.2	8.4
FB 0269	Grape (excl dried, excl juice, excl wine)	0.17	1.2	0.2	2.6	0.4	0.0	0.0	0.2	0.0	0.0	0.0	3.7	0.6	0.0	0.0
JF 0269	Grape juice	0.098	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.0	3.6	0.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.37	0.0	0.0	0.2	0.1	0.2	0.1	0.0	0.0	0.3	0.1	0.4	0.1	2.6	1.0
JF 0203	Grapefruit juice	0.13	0.0	0.0	0.0	0.0	0.5	0.1	0.0	0.0	0.0	0.0	0.3	0.0	2.4	0.3
-d	Lemon juice	0.13	0.3	0.0	0.0	0.0	1.0	0.1	0.3	0.0	0.0	0.0	0.5	0.1	2.6	0.3
-	Mandarin + mandarin-like hybrid juice	0.13	0.5	0.1	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	1.4	0.2	0.0	0.0
FI 0345	Mango (incl juice, incl pulp)	0.01	12.7	0.1	26.2	0.3	6.1	0.1	12.7	0.1	9.2	0.1	8.0	0.1	1.9	0.0
FS 0245	Nectarine	1.355	1.7	2.3	1.7	2.3	0.0	0.0	0.0	0.0	1.0	1.4	1.7	2.3	1.4	1.9
FT 0305	Olive (table olives, only)	1.125	0.0	0.0	0.1	0.1	0.0	0.0	0.0	0.0	0.6	0.7	0.0	0.0	1.0	1.1
OR 0305	Olive oil, refined	3.49	0.0	0.0	0.1	0.3	0.0	0.0	0.0	0.0	0.3	1.0	0.3	1.0	1.6	5.6
JF 0004	Orange juice	0.13	0.2	0.0	1.0	0.1	3.5	0.5	0.0	0.0	1.3	0.2	6.4	0.8	56.8	7.4
FS 0247	Peach	1.355	1.7	2.3	1.7	2.3	1.1	1.5	0.1	0.1	1.0	1.4	1.7	2.3	10.2	13.8
FP 0230	Pear	1.09	6.4	7.0	1.9	2.1	1.2	1.3	0.0	0.0	1.8	2.0	6.9	7.5	7.8	8.5
VO 0051	Peppers	0.33	8.7	2.9	22.4	7.4	8.4	2.8	9.4	3.1	3.3	1.1	5.3	1.7	8.9	2.9
FS 0014	Plum (excl dried)	0.155	3.0	0.5	0.8	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.9	0.1	0.5	0.1
DF 0014	Plum, dried (prunes)	0.465	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.1	0.6	0.3
FB 0275	Strawberry	0.44	0.0	0.0	1.8	0.8	0.1	0.0	0.0	0.0	0.3	0.1	6.2	2.7	5.9	2.6
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.24	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	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.4	0.0	0.0	2.4	0.1	45.2	2.4
-d	Tomato paste	0.22	0.1	0.0	2.1	0.5	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.3
-d	Tomato, peeled	0.041	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
-	Wine	0.15	1.0	0.2	0.9	0.1	6.8	1.0	0.1	0.0	3.4	0.5	3.6	0.5	31.0	4.7
	Total intake (µg/person)=			38.9		32.7		13.9		9.4		32.1		34.8		81.3
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60

Annex 3

BUPROFEZIN (173) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0090 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
	ADI (µg/person)=			495		540		540		540		540		495		540
	%ADI=			7.9%		6.0%		2.6%		1.7%		5.9%		7.0%		15.1%
	Rounded %ADI=			8%		6%		3%		2%		6%		7%		20%

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
JF 0226	Apple juice	0.005	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	2.1	40.6	85.3	0.0	0.0	93.9	197.2	0.0	0.0	0.0	0.0	3.8	8.1
-	Barley beer	0.002	18.3	0.0	84.1	0.2	4.1	0.0	66.0	0.1	243.1	0.5	161.3	0.3
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.01	15.7	0.2	100.5	1.0	63.2	0.6	27.8	0.3	52.6	0.5	56.9	0.6
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
VO 0440	Egg plant (= aubergine)	0.06	1.7	0.1	17.5	1.1	12.3	0.7	1.7	0.1	0.8	0.0	0.4	0.0
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0269	Grape (excl dried, incl juice, excl wine)	0.02	1.9	0.0	9.4	0.2	24.0	0.5	9.9	0.2	2.0	0.0	1.4	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.001	0.0	0.0	2.9	0.0	0.4	0.0	0.4	0.0	2.3	0.0	1.7	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	2.1	82.7	173.7	148.4	311.6	135.9	285.4	31.8	66.8	33.3	69.9	7.5	15.8
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.03	5.5	0.2	23.3	0.7	7.7	0.2	11.0	0.3	18.0	0.5	26.3	0.8
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0
ML 0106	Milks (excl processed products)	0.0006	68.8	0.0	190.6	0.1	79.4	0.0	302.6	0.2	179.6	0.1	237.9	0.1
VO 0051	Peppers	0.06	1.4	0.1	29.9	1.8	13.0	0.8	6.3	0.4	6.2	0.4	4.0	0.2
FP 0009	Pome fruit (excl apple juice)	0.06	0.5	0.0	79.9	4.8	21.8	1.3	43.6	2.6	51.5	3.1	35.1	2.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	19.1	0.0	160.8	0.0	61.2	0.0	243.6	0.0	230.1	0.0	204.7	0.0
PM 0110	Poultry meat: 10% as fat	0.004	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A		B		C		D		E		F	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.02	0.7	0.0	44.7	0.9	14.1	0.3	26.9	0.5	27.7	0.6	10.0	0.2
FB 0275	Strawberry	0.01	0.0	0.0	5.0	0.1	2.0	0.0	1.7	0.0	5.2	0.1	4.1	0.0
VO 0448	Tomato (excl juice, incl paste, incl peeled)	0.06	5.3	0.3	184.4	11.1	117.5	7.1	58.1	3.5	23.0	1.4	21.9	1.3
JF 0448	Tomato juice	0.002	5.2	0.0	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.0	15.2	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	2.1	6.0	12.6	11.1	23.3	0.8	1.6	0.2	0.4	0.2	0.5	0.0	0.0
CM 0654	Wheat bran, unprocessed	5.14	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.525	63.4	33.3	296.3	155.6	327.5	171.9	300.0	157.5	181.6	95.3	166.2	87.3
CF 1210	Wheat germ	3.99	0.0	0.0	1.3	5.2	0.0	0.0	1.3	5.2	0.9	3.6	1.2	4.8
CF 1212	Wheat wholemeal	2.1	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.105	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.1
CP 1212	Wholemeal bread	1.06	0.0	0.0	0.1	0.1	0.0	0.0	0.1	0.1	0.1	0.1	1.0	1.1
-	Wine	0.002	1.3	0.0	76.8	0.2	1.1	0.0	15.4	0.0	68.8	0.1	25.6	0.1
Total intake (µg/person)=		305.8				517.8		667.7		238.3		176.8		122.9
Bodyweight per region (kg bw) =		60				60		60		60		60		60
ADI (µg/person)=		600				600		600		600		600		600
%ADI=		51.0%				86.3%		111.3%		39.7%		29.5%		20.5%
Rounded %ADI=		50%				90%		110%		40%		30%		20%

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G		H		I		J		K		L		M	
			diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.005	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.0
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	2.1	1.5	3.2	0.0	-0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.8	0.0	0.1
-	Barley beer	0.002	21.9	0.0	102.7	0.2	29.5	0.1	12.6	0.0	100.9	0.2	82.2	0.2	218.8	0.4
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0.01	17.3	0.2	156.8	1.6	14.9	0.1	42.5	0.4	222.8	2.2	40.4	0.4	132.3	1.3
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0440	Egg plant (= aubergine)	0.06	20.1	1.2	0.1	0.0	0.6	0.0	6.3	0.4	0.5	0.0	6.3	0.4	0.7	0.0

Annex 3

CHLOPRYRIFOS METHYL (090) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day 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
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0269	Grape (excl dried, incl juice, excl wine)	0.02	1.2	0.0	2.7	0.1	1.4	0.0	0.2	0.0	0.8	0.0	4.3	0.1	5.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.001	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.0	2.6	0.0
GC 0645	Maize (incl flour, incl oil, incl beer)	2.1	35.2	73.9	298.6	627.1	248.1	521.0	57.4	120.5	63.1	132.5	58.6	123.1	85.5	179.6
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.03	11.0	0.3	17.9	0.5	6.1	0.2	5.7	0.2	16.4	0.5	12.2	0.4	31.7	0.9
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0	43.8	0.0	71.5	0.0	24.5	0.0	22.9	0.0	65.7	0.0	48.9	0.0	126.6	0.0
ML 0106	Milks (excl processed products)	0.0006	66.0	0.0	121.1	0.1	81.6	0.0	102.4	0.1	207.7	0.1	57.0	0.0	287.9	0.2
VO 0051	Peppers	0.06	8.7	0.5	22.4	1.3	8.4	0.5	9.4	0.6	3.3	0.2	5.3	0.3	8.9	0.5
FP 0009	Pome fruit (excl apple juice)	0.06	20.8	1.2	11.6	0.7	3.3	0.2	0.1	0.0	10.7	0.6	23.6	1.4	36.9	2.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0	52.7	0.0	57.1	0.0	50.1	0.0	4.3	0.0	54.7	0.0	41.0	0.0	168.0	0.0
PM 0110	Poultry meat: 10% as fat	0.004	1.8	0.0	13.1	0.1	2.5	0.0	0.5	0.0	14.6	0.1	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.02	7.0	0.1	4.9	0.1	1.4	0.0	0.1	0.0	5.5	0.1	5.5	0.1	19.4	0.4
FB 0275	Strawberry	0.01	0.0	0.0	1.8	0.0	0.1	0.0	0.0	0.0	0.3	0.0	6.2	0.1	5.9	0.1
VO 0448	Tomato (excl juice, incl paste, incl peeled)	0.06	23.5	1.4	30.7	1.8	14.9	0.9	7.2	0.4	35.6	2.1	6.9	0.4	46.5	2.8
JF 0448	Tomato juice	0.002	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.0	0.0	0.0	2.4	0.0	45.2	0.1
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	2.1	0.0	0.0	0.9	1.8	0.0	0.0	0.0	0.1	0.1	0.2	0.0	0.0	0.1	0.1
CM 0654	Wheat bran, unprocessed	5.14	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.525	133.0	69.8	60.1	31.6	52.4	27.5	32.2	16.9	87.7	46.0	79.6	41.8	180.1	94.6
CF 1210	Wheat germ	3.99	0.1	0.4	48.1	191.9	1.8	7.2	0.0	0.0	0.0	0.0	0.0	0.0	0.6	2.4
CF 1212	Wheat wholemeal	2.1	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CP 1211	White bread	0.105	0.0	0.0	2.2	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CP 1212	Wholemeal bread	1.06	0.0	0.0	2.2	2.3	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.002	1.0	0.0	0.9	0.0	6.8	0.0	0.1	0.0	3.4	0.0	3.6	0.0	31.0	0.1
Total intake (µg/person)=				152.5		861.3		558.0		139.6		185.0		169.4		286.0
Bodyweight per region (kg bw) =				55		60		60		60		60		55		60
ADI (µg/person)=				550		600		600		600		600		550		600
%ADI=				27.7 %		143.6 %		93.0%		23.3%		30.8%		30.8%		47.7%
Rounded %ADI=				30%		140%		90%		20%		30%		30%		50%

CYPERMETHRIN (119) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0200 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A 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
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	1.38	40.6	56.0	0.0	0.0	93.9	129.6	0.0	0.0	0.0	0.0	3.8	5.3
-	Barley beer	0.04	18.3	0.7	84.1	3.4	4.1	0.2	66.0	2.6	243.1	9.7	161.3	6.5
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	Cabbage, 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
-	Cereal grains (excl rice)	0.035	117.1	4.1	197.6	6.9	143.4	5.0	0.0	0.0	0.0	0.0	0.0	0.0
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	0.0042	2.5	0.0	29.7	0.1	25.1	0.1	24.5	0.1	37.8	0.2	27.4	0.1
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
GC 0647	Oats (incl rolled)	1.38	1.4	1.9	0.6	0.8	0.2	0.3	4.2	5.8	5.7	7.9	8.9	12.3
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

Annex 3

CYPERMETHRIN (119)		International Estimated Daily Intake (IEDI)							ADI = 0 - 0.0200 mg/kg bw					
		STMR or	Diets: g/person/day		Intake = daily intake: µg/person									
Codex Code	Commodity	STMR-P mg/kg	A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
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
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	0.034	0.7	0.0	5.9	0.2	3.2	0.1	2.4	0.1	6.1	0.2	2.7	0.1
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	0.003	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
GC 0650	Rye (incl flour)	1.38	0.1	0.1	3.7	5.1	0.3	0.4	24.3	33.5	25.8	35.6	45.8	63.2
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
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	1.38	6.0	8.3	11.1	15.3	0.8	1.0	0.2	0.3	0.2	0.3	0.0	0.0
CM 0654	Wheat bran, unprocessed	3.45	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.48	63.4	30.4	296.3	142.2	327.5	157.2	300.0	144.0	181.6	87.2	166.2	79.8
-	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)=			171.9		288.1		388.3		254.7		204.6		213.4
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1200		1200		1200		1200		1200		1200
	%ADI=			14.3%		24.0%		32.4%		21.2%		17.0%		17.8 %
	Rounded %ADI=			10%		20%		30%		20%		20%		20%

CYPERMETHRIN (119) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0200 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VS 0620	Artichoke globe	0.023	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
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, excl beer)	1.38	1.5	2.1	0.0	-0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.5	0.0	0.1
-	Barley beer	0.04	21.9	0.9	102.7	4.1	29.5	1.2	12.6	0.5	100.9	4.0	82.2	3.3	218.8	8.8
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	Cabbage, 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
-	Cereal grains (excl rice)	0.035	43.2	1.5	239.1	8.4	252.8	8.8	256.8	9.0	0.0	0.0	0.0	0.0	0.0	0.0
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	0.0042	22.1	0.1	71.5	0.3	16.6	0.1	5.1	0.0	17.6	0.1	35.2	0.1	57.4	0.2
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
GC 0647	Oats (incl rolled)	1.38	0.2	0.3	2.0	2.8	0.8	1.1	0.0	0.0	3.5	4.8	0.7	1.0	7.6	10.5
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

Annex 3

CYPERMETHRIN (119) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0200 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G 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)	0.01	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
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	0.034	1.8	0.1	13.1	0.4	2.5	0.1	0.5	0.0	14.6	0.5	2.8	0.1	11.5	0.4
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	0.003	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
GC 0650	Rye (incl flour)	1.38	0.4	0.6	0.0	0.0	0.2	0.3	0.1	0.1	0.1	0.1	0.9	1.2	0.8	1.1
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
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	1.38	0.0	0.0	0.9	1.2	0.0	0.0	0.0	0.1	0.1	0.1	0.0	0.0	0.1	0.1
CM 0654	Wheat bran, unprocessed	3.45	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.48	133.0	63.8	60.1	28.8	52.4	25.2	32.2	15.5	87.7	42.1	79.6	38.2	180.1	86.4
-	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)=			318.9		117.8		78.8		89.9		218.3		296.6		186.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1100		1200		1200		1200		1200		1100		1200
	%ADI=			29.0%		9.8%		6.6%		7.5%		18.2%		27.0%		15.6%
	Rounded %ADI=			30%		10%		7%		7%		20%		30%		20%

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person							
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.01	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.1	7.4	0.1
DF 0226	Apple, dried	0.3	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0240	Apricot (incl dried)	0.25	0.3	0.1	6.2	1.6	3.9	1.0	3.2	0.8	2.0	0.5	0.8	0.2
FI 0327	Banana	0.01	38.8	0.4	17.4	0.2	16.0	0.2	6.6	0.1	21.5	0.2	33.8	0.3
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.03	40.6	1.2	16.8	0.5	93.9	2.8	13.2	0.4	48.6	1.5	36.1	1.1
FB 0020	Blueberries	0.06	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.3	0.0	0.8	0.0
FS 0013	Cherries	0.36	0.0	0.0	6.8	2.4	0.9	0.3	6.2	2.2	3.6	1.3	0.4	0.1
FB 0265	Cranberries	0.13	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.1
VC 0424	Cucumber	0.025	0.3	0.0	12.7	0.3	5.9	0.1	11.5	0.3	6.1	0.2	7.1	0.2
MO 0105	Edible offal (mammalian)	0.02	3.9	0.1	14.4	0.3	5.2	0.1	11.8	0.2	11.7	0.2	7.6	0.2
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0269	Grape (incl dried, excl juice, excl wine)	0.3	1.9	0.6	20.8	6.3	25.4	7.6	11.4	3.4	9.2	2.8	6.8	2.0
JF 0269	Grape juice	0.03	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0	1.0	0.0
MM 0095	Meat from mammals other than marine mammals	0.003	27.7	0.1	116.5	0.3	38.5	0.1	55.1	0.2	90.2	0.3	131.3	0.4
VC 0046	Melons, except watermelon	0.025	3.6	0.1	26.7	0.7	22.6	0.6	11.5	0.3	5.6	0.1	2.0	0.1
ML 0106	Milks (excl processed products)	0	68.8	0.0	190.6	0.0	79.4	0.0	302.6	0.0	179.6	0.0	237.9	0.0
FS 0247	Peach	0.25	0.2	0.1	24.8	6.2	3.3	0.8	1.8	0.5	5.4	1.4	1.6	0.4
OR 0697	Peanut oil, edible	0.04	1.7	0.1	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.1	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.03	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
VO 0051	Peppers	0.15	1.4	0.2	29.9	4.5	13.0	2.0	6.3	0.9	6.2	0.9	4.0	0.6
FS 0014	Plum (incl dried)	0.08	0.1	0.0	5.9	0.5	2.5	0.2	7.3	0.6	6.9	0.6	2.6	0.2
FP 0009	Pome fruit (excl apple juice)	0.12	0.5	0.1	79.9	9.6	21.8	2.6	43.6	5.2	51.5	6.2	35.1	4.2
PM 0110	Poultry meat	0	7.1	0.0	58.5	0.0	31.9	0.0	24.0	0.0	61.0	0.0	27.3	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
SO 0495	Rape seed (incl oil)	0.05	0.9	0.0	1.8	0.1	2.5	0.1	1.9	0.1	35.7	1.8	26.1	1.3
GC 0650	Rye (incl flour)	0.02	0.1	0.0	3.7	0.1	0.3	0.0	24.3	0.5	25.8	0.5	45.8	0.9
VC 0431	Squash, summer (= courgette, zuchini)	0.02	0.0	0.0	8.3	0.2	11.4	0.2	7.3	0.1	3.2	0.1	0.3	0.0
SO 0702	Sunflower seed (incl oil)	0.02	0.7	0.0	44.5	0.9	20.5	0.4	29.6	0.6	21.2	0.4	5.4	0.1
TN 0085	Tree nuts	0	4.2	0.0	21.5	0.0	3.9	0.0	3.0	0.0	5.5	0.0	10.2	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.02	6.0	0.1	11.1	0.2	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-

Annex 3

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person							
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.025	63.4	1.6	296.3	7.4	327.5	8.2	300.0	7.5	181.6	4.5	166.2	4.2
CP 1212	Wholemeal bread	0.046	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0	0.1	0.0	1.0	0.0
-	Wine	0.018	1.3	0.0	76.8	1.4	1.1	0.0	15.4	0.3	68.8	1.2	25.6	0.5
	Total intake (µg/person)=			4.7		43.6		27.5		24.3		24.8		17.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			0.3%		2.4%		1.5%		1.3%		1.4%		1.0%
	Rounded %ADI=			0%		2%		2%		1%		1%		1%

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person									
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.01	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.1
DF 0226	Apple, dried	0.3	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
FS 0240	Apricot (incl dried)	0.25	0.2	0.1	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.1	0.0	1.1	0.3
FI 0327	Banana	0.01	21.4	0.2	36.6	0.4	11.4	0.1	9.2	0.1	70.2	0.7	40.5	0.4	32.6	0.3
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.03	5.9	0.2	20.5	0.6	5.9	0.2	2.5	0.1	20.2	0.6	16.8	0.5	43.8	1.3
FB 0020	Blueberries	0.06	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	0.1
FS 0013	Cherries	0.36	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.1	2.5	0.9
FB 0265	Cranberries	0.13	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.3
VC 0424	Cucumber	0.025	7.9	0.2	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.1	5.3	0.1
MO 0105	Edible offal (mammalian)	0.02	4.8	0.1	10.7	0.2	4.0	0.1	4.0	0.1	6.5	0.1	6.6	0.1	5.6	0.1
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0269	Grape (incl dried, excl juice, excl wine)	0.3	1.2	0.4	3.4	1.0	0.8	0.2	0.2	0.0	1.2	0.4	5.3	1.6	10.4	3.1
JF 0269	Grape juice	0.03	0.0	0.0	0.1	0.0	1.0	0.0	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.1

FENBUCONAZOLE (197) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person									
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
MM 0095	Meat from mammals other than marine mammals	0.003	54.8	0.2	89.4	0.3	30.6	0.1	28.6	0.1	82.1	0.2	61.1	0.2	158.3	0.5
VC 0046	Melons, except watermelon	0.025	7.5	0.2	6.1	0.2	0.7	0.0	1.4	0.0	2.5	0.1	6.9	0.2	12.4	0.3
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
FS 0247	Peach	0.25	1.7	0.4	1.7	0.4	1.1	0.3	0.1	0.0	1.0	0.3	1.7	0.4	10.2	2.6
OR 0697	Peanut oil, edible	0.04	3.0	0.1	0.3	0.0	1.5	0.1	7.9	0.3	0.3	0.0	0.0	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.03	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.1	0.2	0.0	0.7	0.0	6.0	0.2
VO 0051	Peppers	0.15	8.7	1.3	22.4	3.4	8.4	1.3	9.4	1.4	3.3	0.5	5.3	0.8	8.9	1.3
FS 0014	Plum (incl dried)	0.08	3.3	0.3	1.4	0.1	0.1	0.0	0.0	0.0	0.6	0.0	1.5	0.1	2.2	0.2
FP 0009	Pome fruit (excl apple juice)	0.12	20.8	2.5	11.6	1.4	3.3	0.4	0.1	0.0	10.7	1.3	23.6	2.8	36.9	4.4
PM 0110	Poultry meat	0	17.6	0.0	131.3	0.0	25.1	0.0	4.7	0.0	145.9	0.0	27.7	0.0	115.1	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
SO 0495	Rape seed (incl oil)	0.05	9.9	0.5	5.9	0.3	0.3	0.0	1.0	0.1	0.0	0.0	15.5	0.8	9.9	0.5
GC 0650	Rye (incl flour)	0.02	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
VC 0431	Squash, summer (= courgette, zuchini)	0.02	2.4	0.0	1.5	0.0	0.0	0.0	0.0	0.0	3.8	0.1	2.2	0.0	2.5	0.1
SO 0702	Sunflower seed (incl oil)	0.02	2.7	0.1	8.8	0.2	13.5	0.3	0.2	0.0	3.6	0.1	0.6	0.0	10.4	0.2
TN 0085	Tree nuts	0	16.3	0.0	15.7	0.0	9.7	0.0	1.9	0.0	19.1	0.0	29.0	0.0	5.6	0.0
GC 0654	Wheat (incl bulgur wholemeal, excl flour)	0.02	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.26	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.025	133.0	3.3	60.1	1.5	52.4	1.3	32.2	0.8	87.7	2.2	79.6	2.0	180.1	4.5
CP 1212	Wholemeal bread	0.046	0.0	0.0	2.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
-	Wine	0.018	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.6
	Total intake (µg/person)=			10.0		10.2		4.6		3.2		6.6		10.4		22.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			1650		1800		1800		1800		1800		1650		1800
	%ADI=			0.6%		0.6%		0.3%		0.2%		0.4%		0.6%		1.2%
	Rounded %ADI=			1%		1%		0%		0%		0%		1%		1%

Annex 3

FLUOPICOLIDE (235) International Estimated Daily Intake (IEDI) ADI = 0–0.0800 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
VB 0402	Brussels sprouts	0.04	0.0	0.0	0.1	0.0	2.8	0.1	5.5	0.2	1.5	0.1	1.9	0.1
VB 0041	Cabbage, head	1.2	1.2	1.4	14.4	17.3	2.7	3.2	16.4	19.7	15.4	18.5	18.5	22.2
VS 0624	Celery	1.4	0.0	0.0	0.9	1.3	0.0	0.0	2.0	2.8	1.5	2.1	0.0	0.0
VC 0423	Chayote	0.07	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
VC 0424	Cucumber	0.07	0.3	0.0	12.7	0.9	5.9	0.4	11.5	0.8	6.1	0.4	7.1	0.5
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
VO 0440	Egg plant (= aubergine)	0.13	1.7	0.2	17.5	2.3	12.3	1.6	1.7	0.2	0.8	0.1	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
VB 0042	Flowerhead brassicas	0.385	0.2	0.1	11.1	4.3	3.6	1.4	0.4	0.2	7.7	3.0	4.1	1.6
VC 0425	Gherkin	0.01	0.3	0.0	12.7	0.1	5.9	0.1	11.5	0.1	6.1	0.1	7.1	0.1
FB 0269	Grape (incl dried, incl juice, incl wine)	0.38	3.7	1.4	128.5	48.8	27.1	10.3	33.1	12.6	107.5	40.9	44.0	16.7
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.4	0.0	0.0	2.9	4.1	0.4	0.6	0.4	0.6	2.3	3.2	1.7	2.4
VL 0053	Leafy vegetables	8.6	5.8	49.9	45.6	392.2	10.9	93.7	26.8	230.5	18.7	160.8	38.9	334.5
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	0.01	3.6	0.0	26.7	0.3	22.6	0.2	11.5	0.1	5.6	0.1	2.0	0.0
ML 0106	Milks (excl processed products)	0	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	0.13	3.9	0.5	1.0	0.1	5.3	0.7	0.1	0.0	0.0	0.0	0.0	0.0
–	Onion, dry	0.07	4.3	0.3	45.6	3.2	27.4	1.9	30.2	2.1	22.1	1.5	12.2	0.9
VA 0387	Onion, Welsh	2.1	0.3	0.6	1.0	2.1	1.4	2.9	0.3	0.6	0.3	0.6	0.6	1.3
VO 0051	Peppers	0.13	1.4	0.2	29.9	3.9	13.0	1.7	6.3	0.8	6.2	0.8	4.0	0.5
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
VC 0431	Squash, summer (= courgette, zucchini)	0.07	0.0	0.0	8.3	0.6	11.4	0.8	7.3	0.5	3.2	0.2	0.3	0.0
-d	Squashes & pumpkins & gourds	0.01	16.3	0.2	12.3	0.1	14.4	0.1	21.9	0.2	3.2	0.0	1.0	0.0
VO 0448	Tomato (incl juice, incl paste, incl peeled)	0.13	11.8	1.5	185.0	24.1	118.0	15.3	60.7	7.9	31.6	4.1	40.9	5.3
VC 0432	Watermelon	0.01	6.1	0.1	43.1	0.4	47.1	0.5	25.8	0.3	4.4	0.0	6.0	0.1
VC 0433	Winter squash (= pumpkin)	0.01	0.0	0.0	0.5	0.0	1.5	0.0	7.3	0.1	0.0	0.0	0.3	0.0
	Total intake (µg/person) =			56.5		505.9		135.6		280.3		236.5		386.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person) =			4800		4800		4800		4800		4800		4800

FLUOPICOLIDE (235) International Estimated Daily Intake (IEDI) ADI = 0–0.0800 mg/kg bw

		STMR or	Diets: g/person/day												Intake = daily intake: µg/person
		STMR-P	A		B		C		D		E		F		
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	
	%ADI =			1.2%		10.5%		2.8%		5.8%		4.9%		8.0%	
	Rounded %ADI =			1%		10%		3%		6%		5%		8%	

FLUOPICOLIDE (235) International Estimated Daily Intake (IEDI) ADI = 0–0.0800 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person									
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB 0402	Brussels sprouts	0.04	3.4	0.1	0.4	0.0	0.0	0.0	0.0	0.0	0.5	0.0	7.9	0.3	0.3	0.0
VB 0041	Cabbage, head	1.2	10.0	12.0	1.0	1.2	7.2	8.6	1.0	1.2	1.4	1.7	23.9	28.7	17.0	20.4
VS 0624	Celery	1.4	0.0	0.0	0.3	0.4	0.0	0.0	0.0	0.0	1.0	1.4	0.0	0.0	4.2	5.9
VC 0423	Chayote	0.07	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
VC 0424	Cucumber	0.07	7.9	0.6	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.4	5.3	0.4
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0440	Egg plant (= aubergine)	0.13	20.1	2.6	0.1	0.0	0.6	0.1	6.3	0.8	0.5	0.1	6.3	0.8	0.7	0.1
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VB 0042	Flowerhead brassicas	0.385	9.6	3.7	7.9	3.0	0.6	0.2	0.2	0.1	0.9	0.3	1.1	0.4	8.0	3.1
VC 0425	Gherkin	0.01	7.9	0.1	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)	0.38	2.6	1.0	4.8	1.8	11.7	4.4	0.3	0.1	6.8	2.6	10.9	4.1	58.8	22.3
DF 0269	Grape, dried (= currants, raisins and sultanas)	1.4	0.0	0.0	0.2	0.3	0.2	0.3	0.0	0.0	0.3	0.4	0.4	0.6	2.6	3.6
VL 0053	Leafy vegetables	8.6	40.8	350.9	12.0	103.2	12.5	107.5	9.5	81.7	5.4	46.4	50.0	430.0	39.9	343.1
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	0.01	7.5	0.1	6.1	0.1	0.7	0.0	1.4	0.0	2.5	0.0	6.9	0.1	12.4	0.1
ML 0106	Milks (excl processed products)	0	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	0.13	4.1	0.5	1.0	0.1	7.0	0.9	15.9	2.1	1.1	0.1	3.9	0.5	0.2	0.0
–	Onion, dry	0.07	16.8	1.2	8.6	0.6	6.9	0.5	12.1	0.8	18.6	1.3	23.8	1.7	28.4	2.0
VA 0387	Onion, Welsh	2.1	0.1	0.2	4.8	10.1	0.1	0.2	1.0	2.1	1.0	2.1	2.7	5.7	0.6	1.3

Annex 3

FLUOPICOLIDE (235) International Estimated Daily Intake (IEDI) ADI = 0–0.0800 mg/kg bw

		STMR or	Diets: g/person/day													
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VO 0051	Peppers	0.13	8.7	1.1	22.4	2.9	8.4	1.1	9.4	1.2	3.3	0.4	5.3	0.7	8.9	1.2
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
VC 0431	Squash, summer (= courgette, zucchini)	0.07	2.4	0.2	1.5	0.1	0.0	0.0	0.0	0.0	3.8	0.3	2.2	0.2	2.5	0.2
-d	Squashes & pumpkins & gourds	0.01	7.1	0.1	4.6	0.0	11.3	0.1	3.0	0.0	7.0	0.1	6.7	0.1	7.6	0.1
VO 0448	Tomato (incl juice, incl paste, incl peeled)	0.13	23.5	3.1	31.7	4.1	15.0	2.0	16.2	2.1	35.6	4.6	9.9	1.3	103.0	13.4
VC 0432	Watermelon	0.01	39.3	0.4	14.0	0.1	2.5	0.0	13.6	0.1	8.4	0.1	14.5	0.1	13.6	0.1
VC 0433	Winter squash (= pumpkin)	0.01	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
	Total intake (µg/person) =			377.8		128.3		126.0		92.4		62.1		475.7		417.4
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person) =			4400		4800		4800		4800		4800		4400		4800
	%ADI =			8.6%		2.7%		2.6%		1.9%		1.3%		10.8%		8.7%
	Rounded %ADI =			9%		3%		3%		2%		1%		10%		9%

2,6-DICHLOROBENZAMIDE International Estimated Daily Intake (IEDI) ADI = 0–0.0200 mg/kg bw

		STMR or	Diets: g/person/day		Intake = daily intake: µg/person									
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB 0402	Brussels sprouts	0.01	0.0	0.0	0.1	0.0	2.8	0.0	5.5	0.1	1.5	0.0	1.9	0.0
VB 0041	Cabbage, head	0.01	1.2	0.0	14.4	0.1	2.7	0.0	16.4	0.2	15.4	0.2	18.5	0.2
VS 0624	Celery	0.01	0.0	0.0	0.9	0.0	0.0	0.0	2.0	0.0	1.5	0.0	0.0	0.0
VC 0423	Chayote	0.01	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
VC 0424	Cucumber	0.01	0.3	0.0	12.7	0.1	5.9	0.1	11.5	0.1	6.1	0.1	7.1	0.1
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
VO 0440	Egg plant (= aubergine)	0.01	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	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
VB 0042	Flowerhead brassicas	0.01	0.2	0.0	11.1	0.1	3.6	0.0	0.4	0.0	7.7	0.1	4.1	0.0
VC 0425	Gherkin	0.01	0.3	0.0	12.7	0.1	5.9	0.1	11.5	0.1	6.1	0.1	7.1	0.1

2,6-DICHLOROBENZAMIDE International Estimated Daily Intake (IEDI) ADI = 0–0.0200 mg/kg bw

		STMR or	Diets: g/person/day		Intake = daily intake: µg/person									
		STMR-P	A		B		C		D		E		F	
FB 0269	Grape (incl dried, incl juice, incl wine)	0.01	3.7	0.0	128.5	1.3	27.1	0.3	33.1	0.3	107.5	1.1	44.0	0.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.048	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 0482	Lettuce, head	0.01	0.1	0.0	12.3	0.1	1.3	0.0	0.1	0.0	0.1	0.0	0.0	0.0
VL 0483	Lettuce, leaf	0.01	0.0	0.0	9.2	0.1	1.0	0.0	0.1	0.0	5.4	0.1	18.0	0.2
MM 0095	Meat from mammals other than marine mammals	0	27.7	0.0	116.5	0.0	38.5	0.0	55.1	0.0	90.2	0.0	131.3	0.0
VC 0046	Melons, except watermelon	0.01	3.6	0.0	26.7	0.3	22.6	0.2	11.5	0.1	5.6	0.1	2.0	0.0
ML 0106	Milks (excl processed products)	0	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	0.01	3.9	0.0	1.0	0.0	5.3	0.1	0.1	0.0	0.0	0.0	0.0	0.0
-	Onion, dry	0.01	4.3	0.0	45.6	0.5	27.4	0.3	30.2	0.3	22.1	0.2	12.2	0.1
VA 0387	Onion, Welsh	0.01	0.3	0.0	1.0	0.0	1.4	0.0	0.3	0.0	0.3	0.0	0.6	0.0
VO 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
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
VC 0431	Squash, summer (= courgette, zucchini)	0.01	0.0	0.0	8.3	0.1	11.4	0.1	7.3	0.1	3.2	0.0	0.3	0.0
-d	Squashes & pumpkins & gourds	0.01	16.3	0.2	12.3	0.1	14.4	0.1	21.9	0.2	3.2	0.0	1.0	0.0
VO 0448	Tomato (incl juice, incl paste, incl peeled)	0.01	11.8	0.1	185.0	1.9	118.0	1.2	60.7	0.6	31.6	0.3	40.9	0.4
VC 0432	Watermelon	0.01	6.1	0.1	43.1	0.4	47.1	0.5	25.8	0.3	4.4	0.0	6.0	0.1
VC 0433	Winter squash (= pumpkin)	0.01	0.0	0.0	0.5	0.0	1.5	0.0	7.3	0.1	0.0	0.0	0.3	0.0
	Total intake (µg/person) =			0.6		5.9		3.3		2.6		2.4		1.8
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person) =			1200		1200		1200		1200		1200		1200
	%ADI =			0.0%		0.5%		0.3%		0.2%		0.2%		0.1%
	Rounded %ADI =			0%		0%		0%		0%		0%		0%

2,6-DICHLOROBENZAMIDE International Estimated Daily Intake (IEDI) ADI = 0–0.0200 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person									
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB 0402	Brussels sprouts	0.01	3.4	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.5	0.0	7.9	0.1	0.3	0.0
VB 0041	Cabbage, head	0.01	10.0	0.1	1.0	0.0	7.2	0.1	1.0	0.0	1.4	0.0	23.9	0.2	17.0	0.2

Annex 3

2,6-DICHLOROBENZAMIDE International Estimated Daily Intake (IEDI) ADI = 0–0.0200 mg/kg bw

		STMR or	Diets: g/person/day													
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VS 0624	Celery	0.01	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	4.2	0.0
VC 0423	Chayote	0.01	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
VC 0424	Cucumber	0.01	7.9	0.1	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.1	5.3	0.1
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VO 0440	Egg plant (= aubergine)	0.01	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	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
VB 0042	Flowerhead brassicas	0.01	9.6	0.1	7.9	0.1	0.6	0.0	0.2	0.0	0.9	0.0	1.1	0.0	8.0	0.1
VC 0425	Gherkin	0.01	7.9	0.1	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)	0.01	2.6	0.0	4.8	0.0	11.7	0.1	0.3	0.0	6.8	0.1	10.9	0.1	58.8	0.6
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.048	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 0482	Lettuce, head	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	15.7	0.2
VL 0483	Lettuce, leaf	0.01	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	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	0.01	7.5	0.1	6.1	0.1	0.7	0.0	1.4	0.0	2.5	0.0	6.9	0.1	12.4	0.1
ML 0106	Milks (excl processed products)	0	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	0.01	4.1	0.0	1.0	0.0	7.0	0.1	15.9	0.2	1.1	0.0	3.9	0.0	0.2	0.0
-	Onion, dry	0.01	16.8	0.2	8.6	0.1	6.9	0.1	12.1	0.1	18.6	0.2	23.8	0.2	28.4	0.3
VA 0387	Onion, Welsh	0.01	0.1	0.0	4.8	0.0	0.1	0.0	1.0	0.0	1.0	0.0	2.7	0.0	0.6	0.0
VO 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
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
VC 0431	Squash, summer (= courgette, zucchini)	0.01	2.4	0.0	1.5	0.0	0.0	0.0	0.0	0.0	3.8	0.0	2.2	0.0	2.5	0.0
-d	Squashes & pumpkins & gourds	0.01	7.1	0.1	4.6	0.0	11.3	0.1	3.0	0.0	7.0	0.1	6.7	0.1	7.6	0.1
VO 0448	Tomato (incl juice, incl paste, incl peeled)	0.01	23.5	0.2	31.7	0.3	15.0	0.2	16.2	0.2	35.6	0.4	9.9	0.1	103.0	1.0
VC 0432	Watermelon	0.01	39.3	0.4	14.0	0.1	2.5	0.0	13.6	0.1	8.4	0.1	14.5	0.1	13.6	0.1
VC 0433	Winter squash (= pumpkin)	0.01	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
	Total intake (µg/person) =			1.8		1.2		0.7		0.8		1.0		1.4		3.1
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person) =			1100		1200		1200		1200		1200		1100		1200
	%ADI =			0.2%		0.1%		0.1%		0.1%		0.1%		0.1%		0.3%
	Rounded %ADI =			0%		0%		0%		0%		0%		0%		0%

HALOXYFOP (194) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0007 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person							
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0	38.8	0.0	17.4	0.0	16.0	0.0	6.6	0.0	21.5	0.0	33.8	0.0
VD 0071	Beans (dry)	0.335	15.8	5.3	6.1	2.0	1.7	0.6	6.3	2.1	1.8	0.6	5.0	1.7
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.085	1.0	0.1	17.4	1.5	7.5	0.6	0.9	0.1	16.4	1.4	0.1	0.0
VD 0524	Chick-pea (dry)	0.02	3.3	0.1	5.8	0.1	3.2	0.1	3.1	0.1	0.2	0.0	0.1	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0	15.7	0.0	100.5	0.0	63.2	0.0	27.8	0.0	52.6	0.0	56.9	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0	3.1	0.0	12.6	0.0	2.9	0.0	1.4	0.0	10.1	0.0	18.0	0.0
SO 0691	Cotton seed (for oil processing only)	0.1	5.6	0.6	30.6	3.1	10.6	1.1	41.3	4.1	0.0	0.0	1.9	0.2
MO 0105	Edible offal (mammalian)	0.27	3.9	1.1	14.4	3.9	5.2	1.4	11.8	3.2	11.7	3.2	7.6	2.1
PE 0112	Eggs	0.022	2.5	0.1	29.7	0.7	25.1	0.6	24.5	0.5	37.8	0.8	27.4	0.6
FB 0269	Grape (excl dried, excl juice, excl wine)	0	1.9	0.0	9.2	0.0	23.8	0.0	9.8	0.0	0.0	0.0	0.0	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.04	5.5	0.2	23.3	0.8	7.7	0.3	11.0	0.4	18.0	0.6	26.3	0.9
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.006	22.2	0.1	93.2	0.6	30.8	0.2	44.1	0.3	72.2	0.4	105.0	0.6
ML 0106	Milks (excl processed products)	0.033	68.8	2.3	190.6	6.3	79.4	2.6	302.6	10.0	179.6	5.9	237.9	7.9
VA 0385	Onion, bulb (= dry + green onion)	0.035	5.5	0.2	49.5	1.7	33.0	1.2	31.3	1.1	23.2	0.8	14.6	0.5
VD 0072	Peas (dry) (= field pea + cowpea)	0.04	6.8	0.3	1.3	0.1	1.0	0.0	2.3	0.1	4.6	0.2	3.4	0.1
VP 0063	Peas (green pods and/or immature seeds)	0.11	0.1	0.0	2.9	0.3	6.0	0.7	0.6	0.1	9.7	1.1	5.2	0.6
VP 0064	Peas, shelled (immature seeds only)	0.08	0.0	0.0	0.9	0.1	6.0	0.5	0.6	0.0	9.7	0.8	3.2	0.3
FP 0009	Pome fruit (incl apple juice)	0	0.5	0.0	84.1	0.0	21.9	0.0	45.2	0.0	61.7	0.0	46.2	0.0
PM 0110	Poultry meat: 10% as fat	0.13	0.7	0.1	5.9	0.8	3.2	0.4	2.4	0.3	6.1	0.8	2.7	0.4
PM 0110	Poultry meat: 90% as muscle	0.032	6.4	0.2	52.7	1.7	28.7	0.9	21.6	0.7	54.9	1.8	24.6	0.8
PO 0111	Poultry, edible offal of	0.21	0.4	0.1	0.4	0.1	1.7	0.4	0.1	0.0	0.6	0.1	0.2	0.0
SO 0495	Rape seed (excl oil)	0.11	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	0.16	0.3	0.0	0.7	0.1	1.0	0.2	0.7	0.1	13.7	2.2	10.0	1.6
VD 0541	Soya bean (dry, excl oil)	0.055	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	0.041	1.6	0.1	6.5	0.3	6.0	0.2	4.0	0.2	6.3	0.3	7.0	0.3
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0	0.7	0.0	44.7	0.0	14.1	0.0	26.9	0.0	27.7	0.0	10.0	0.0
VR 0596	Sugar beet	0.02	0.0	0.0	40.7	0.8	0.0	0.0	0.1	0.0	6.0	0.1	0.1	0.0
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
	Total intake (µg/person)=			10.8		27.0		12.9		24.8		22.1		18.8
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			42		42		42		42		42		42
	%ADI=			25.7%		64.4%		30.6%		59.1%		52.7%		44.7%
	Rounded %ADI=			30%		60%		30%		60%		50%		40%

Annex 3

HALOXYFOP (194) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0007 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person									
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FI 0327	Banana	0	21.4	0.0	36.6	0.0	11.4	0.0	9.2	0.0	70.2	0.0	40.5	0.0	32.6	0.0
VD 0071	Beans (dry)	0.335	3.4	1.1	25.5	8.5	7.8	2.6	2.1	0.7	44.7	15.0	5.5	1.8	7.3	2.4
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.085	2.6	0.2	2.6	0.2	1.0	0.1	0.5	0.0	0.6	0.1	2.8	0.2	9.8	0.8
VD 0524	Chick-pea (dry)	0.02	5.0	0.1	0.5	0.0	0.6	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.6	0.0
FC 0001	Citrus fruit (incl lemon juice, incl mandarin juice, incl orange juice, incl grapefruit juice, incl NES juice)	0	17.3	0.0	156.8	0.0	14.9	0.0	42.5	0.0	222.8	0.0	40.4	0.0	132.3	0.0
SB 0716	Coffee beans (incl green, incl extracts, incl roasted)	0	0.2	0.0	7.0	0.0	0.5	0.0	0.2	0.0	5.3	0.0	5.7	0.0	12.4	0.0
SO 0691	Cotton seed (for oil processing only)	0.1	6.3	0.6	4.4	0.4	6.3	0.6	8.8	0.9	9.4	0.9	34.4	3.4	7.5	0.8
MO 0105	Edible offal (mammalian)	0.27	4.8	1.3	10.7	2.9	4.0	1.1	4.0	1.1	6.5	1.8	6.6	1.8	5.6	1.5
PE 0112	Eggs	0.022	22.1	0.5	71.5	1.6	16.6	0.4	5.1	0.1	17.6	0.4	35.2	0.8	57.4	1.3
FB 0269	Grape (excl dried, excl juice, excl wine)	0	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
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.04	11.0	0.4	17.9	0.6	6.1	0.2	5.7	0.2	16.4	0.6	12.2	0.4	31.7	1.1
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.006	43.8	0.3	71.5	0.4	24.5	0.1	22.9	0.1	65.7	0.4	48.9	0.3	126.6	0.8
ML 0106	Milks (excl processed products)	0.033	66.0	2.2	121.1	4.0	81.6	2.7	102.4	3.4	207.7	6.9	57.0	1.9	287.9	9.5
VA 0385	Onion, bulb (= dry + green onion)	0.035	17.4	0.6	27.9	1.0	7.3	0.3	16.0	0.6	22.8	0.8	34.5	1.2	30.1	1.1
VD 0072	Peas (dry) (= field pea + cowpea)	0.04	1.8	0.1	2.2	0.1	3.2	0.1	26.7	1.1	1.5	0.1	1.8	0.1	1.8	0.1
VP 0063	Peas (green pods and/or immature seeds)	0.11	3.9	0.4	1.6	0.2	0.4	0.0	0.0	0.0	0.9	0.1	1.0	0.1	8.6	0.9
VP 0064	Peas, shelled (immature seeds only)	0.08	3.9	0.3	1.6	0.1	0.0	0.0	0.0	0.0	0.4	0.0	1.0	0.1	0.8	0.1
FP 0009	Pome fruit (incl apple juice)	0	20.9	0.0	12.3	0.0	3.4	0.0	0.1	0.0	11.7	0.0	24.9	0.0	45.4	0.0
PM 0110	Poultry meat: 10% as fat	0.13	1.8	0.2	13.1	1.7	2.5	0.3	0.5	0.1	14.6	1.9	2.8	0.4	11.5	1.5
PM 0110	Poultry meat: 90% as muscle	0.032	15.8	0.5	118.2	3.8	22.6	0.7	4.2	0.1	131.3	4.2	24.9	0.8	103.6	3.3
PO 0111	Poultry, edible offal of	0.21	0.4	0.1	1.0	0.2	1.9	0.4	0.0	0.0	0.7	0.1	1.0	0.2	0.3	0.1
SO 0495	Rape seed (excl oil)	0.11	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	0.16	3.8	0.6	2.3	0.4	0.1	0.0	0.4	0.1	0.0	0.0	6.0	1.0	3.8	0.6
VD 0541	Soya bean (dry, excl oil)	0.055	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	0.041	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
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0	7.0	0.0	4.9	0.0	1.4	0.0	0.1	0.0	5.5	0.0	5.5	0.0	19.4	0.0
VR 0596	Sugar beet	0.02	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.3
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

HALOXYFOP (194) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0007 mg/kg bw

		STMR or	Diets: g/person/day		Intake = daily intake: µg/person											
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
	Total intake (µg/person)=			10.0		27.0		10.5		8.7		34.2		14.9		27.5
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			38.5		42		42		42		42		38.5		42
	%ADI=			25.9%		64.4%		25.0%		20.6%		81.3%		38.6%		65.5%
	Rounded %ADI=			30%		60%		20%		20%		80%		40%		70%

HEXYTHIAZOX (176) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 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
VC 0423	Chayote	0.0500	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
-JF 0001?	Citrus juice NES	0.0240	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
VC 0424	Cucumber	0.0500	0.3	0.0	12.7	0.6	5.9	0.3	11.5	0.6	6.1	0.3	7.1	0.4
FT 0295	Date	0.2600	0.8	0.2	1.4	0.4	31.5	8.2	5.1	1.3	0.3	0.1	0.2	0.1
MO 0105	Edible offal (mammalian)	0.0100	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)	0.0500	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	0.0020	2.5	0.0	29.7	0.1	25.1	0.1	24.5	0.0	37.8	0.1	27.4	0.1
VC 0425	Gherkin	0.0500	0.3	0.0	12.7	0.6	5.9	0.3	11.5	0.6	6.1	0.3	7.1	0.4
FB 0269	Grape (excl dried, excl juice, excl wine)	0.2000	1.9	0.4	9.2	1.8	23.8	4.8	9.8	2.0	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.0840	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.1	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.3200	0.0	0.0	2.9	0.9	0.4	0.1	0.4	0.1	2.3	0.7	1.7	0.5
JF 0203	Grapefruit juice	0.0240	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	1.1	0.0	0.2	0.0
FC 0002	Lemon + lime + citrus fruit NES (excl lemon juice, excl NES juice)	0.0770	10.4	0.8	11.4	0.9	11.5	0.9	7.4	0.6	0.8	0.1	0.8	0.1
-d	Lemon juice	0.0240	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
MF 0100	Mammalian fats (except milk fats)	0.0100	0.8	0.0	10.0	0.1	0.9	0.0	6.6	0.1	11.8	0.1	3.7	0.0
FC 0003	Mandarin + mandarin-like hybrid (excl juice)	0.0770	0.6	0.0	16.0	1.2	10.3	0.8	4.6	0.4	8.4	0.6	9.7	0.7
-	Mandarin + mandarin-like hybrid juice	0.0240	0.0	0.0	1.4	0.0	0.9	0.0	0.4	0.0	0.7	0.0	0.9	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.0100	5.5	0.1	23.3	0.2	7.7	0.1	11.0	0.1	18.0	0.2	26.3	0.3
MM 0095	Meat from mammals other than marine mammals:	0.0000	22.2	0.0	93.2	0.0	30.8	0.0	44.1	0.0	72.2	0.0	105.0	0.0

Annex 3

HEXYTHIAZOX (176) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0300 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	80% as muscle													
VC 0046	Melons, except watermelon	0.0500	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)	0.0100	68.8	0.7	190.6	1.9	79.4	0.8	302.6	3.0	179.6	1.8	237.9	2.4
JF 0004	Orange juice	0.0240	0.0	0.0	2.1	0.1	4.4	0.1	1.4	0.0	16.2	0.4	22.6	0.5
FC 0004	Orange, sweet, sour + orange-like hybrid (excl juice)	0.0770	4.2	0.3	54.1	4.2	30.1	2.3	11.9	0.9	0.2	0.0	0.5	0.0
VO 0051	Peppers	0.0500	1.4	0.1	29.9	1.5	13.0	0.7	6.3	0.3	6.2	0.3	4.0	0.2
DF 0014	Plum, dried (prunes)	0.4100	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.2
FP 0009	Pome fruit (incl apple juice)	0.1100	0.5	0.1	84.1	9.3	21.9	2.4	45.2	5.0	61.7	6.8	46.2	5.1
PM 0110	Poultry meat: 10% as fat	0.0020	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	0.0000	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0.0100	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	0.0020	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.4	0.0	0.1	0.0
FC 0005	Shaddock or pomelo + shaddock-like hybrid (excl juice)	0.0770	0.5	0.0	4.9	0.4	0.7	0.1	0.3	0.0	6.8	0.5	1.0	0.1
-d	Squashes & pumpkins & gourds	0.0500	16.3	0.8	12.3	0.6	14.4	0.7	21.9	1.1	3.2	0.2	1.0	0.1
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.0900	0.7	0.1	44.1	4.0	14.1	1.3	26.6	2.4	26.3	2.4	8.3	0.7
FC 4031	Tangelo	0.0770	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VO 0448	Tomato (incl juice, incl paste, incl peeled)	0.0500	11.8	0.6	185.0	9.3	118.0	5.9	60.7	3.0	31.6	1.6	40.9	2.0
TN 0085	Tree nuts	0.0000	4.2	0.0	21.5	0.0	3.9	0.0	3.0	0.0	5.5	0.0	10.2	0.0
-	Wine	0.0100	1.3	0.0	76.8	0.8	1.1	0.0	15.4	0.2	68.8	0.7	25.6	0.3
	Total intake (µg/person)=			4.5		41.3		31.6		22.5		18.0		14.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			1800		1800		1800		1800		1800		1800
	%ADI=			0.2%		2.3%		1.8%		1.3%		1.0%		0.8%
	Rounded %ADI=			0%		2%		2%		1%		1%		1%

INDOXACARB (216) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
FP 0226	Apple (excl juice)	0.21	0.3	0.1	56.3	11.8	18.4	3.9	38.3	8.0	40.6	8.5	28.3	5.9
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
VB 0400	Broccoli	0.055	0.0	0.0	0.7	0.0	1.2	0.1	0.1	0.0	4.2	0.2	4.0	0.2
VB 0041	Cabbage, head	0.435	1.2	0.5	14.4	6.3	2.7	1.2	16.4	7.1	15.4	6.7	18.5	8.0
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
VC 0423	Chayote	0.06	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VD 0524	Chick-pea (dry)	0.02	3.3	0.1	5.8	0.1	3.2	0.1	3.1	0.1	0.2	0.0	0.1	0.0
OR 0691	Cotton seed oil, edible	0.013	0.9	0.0	4.9	0.1	1.7	0.0	6.6	0.1	0.0	0.0	0.3	0.0
VD 0527	Cowpea (dry)	0.02	3.9	0.1	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FB 0265	Cranberries	0.15	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.1
VC 0424	Cucumber	0.06	0.3	0.0	12.7	0.8	5.9	0.4	11.5	0.7	6.1	0.4	7.1	0.4
MO 0105	Edible offal (mammalian)	0.014	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)	0.11	1.7	0.2	17.5	1.9	12.3	1.4	1.7	0.2	0.8	0.1	0.4	0.0
PE 0112	Eggs	0.01	2.5	0.0	29.7	0.3	25.1	0.3	24.5	0.2	37.8	0.4	27.4	0.3
VC 0425	Gherkin	0.06	0.3	0.0	12.7	0.8	5.9	0.4	11.5	0.7	6.1	0.4	7.1	0.4
FB 0269	Grape (excl dried, excl juice, excl wine)	0.3	1.9	0.6	9.2	2.8	23.8	7.1	9.8	2.9	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.002	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.0	1.0	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.81	0.0	0.0	2.9	2.3	0.4	0.3	0.4	0.3	2.3	1.9	1.7	1.4
VL 0482	Lettuce, head	2.8	0.1	0.3	12.3	34.4	1.3	3.6	0.1	0.3	0.1	0.3	0.0	0.0
VL 0483	Lettuce, leaf	6.6	0.0	0.0	9.2	60.7	1.0	6.6	0.1	0.7	5.4	35.6	18.0	118.8
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.38	5.5	2.1	23.3	8.9	7.7	2.9	11.0	4.2	18.0	6.9	26.3	10.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.01	22.2	0.2	93.2	0.9	30.8	0.3	44.1	0.4	72.2	0.7	105.0	1.1
VC 0046	Melons, except watermelon	0.02	3.6	0.1	26.7	0.5	22.6	0.5	11.5	0.2	5.6	0.1	2.0	0.0
ML 0106	Milks (excl processed products)	0.037	68.8	2.5	190.6	7.1	79.4	2.9	302.6	11.2	179.6	6.6	237.9	8.8
HH 0738	Mints	3.5	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VD 0536	Mung bean (dry)	0.02	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
OR 0697	Peanut oil, edible	0.003	1.7	0.0	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
FP 0230	Pear	0.051	0.1	0.0	22.3	1.1	2.8	0.1	4.8	0.2	10.7	0.5	6.8	0.3
VO 0051	Peppers	0.038	1.4	0.1	29.9	1.1	13.0	0.5	6.3	0.2	6.2	0.2	4.0	0.2
DF 0014	Plum, dried (prunes)	0.68	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.1	0.5	0.3	0.6	0.4

Annex 3

INDOXACARB (216) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	19.1	0.2	160.8	1.6	61.2	0.6	243.6	2.4	230.1	2.3	204.7	2.0
PM 0110	Poultry meat: 10% as fat	0.025	0.7	0.0	5.9	0.1	3.2	0.1	2.4	0.1	6.1	0.2	2.7	0.1
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
VD 0541	Soya bean (dry, excl oil)	0.027	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	0.018	1.6	0.0	6.5	0.1	6.0	0.1	4.0	0.1	6.3	0.1	7.0	0.1
VC 0431	Squash, summer (= courgette, zuchini)	0.06	0.0	0.0	8.3	0.5	11.4	0.7	7.3	0.4	3.2	0.2	0.3	0.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.17	0.7	0.1	44.1	7.5	14.1	2.4	26.6	4.5	26.3	4.5	8.3	1.4
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)	0.11	3.3	0.4	179.2	19.7	103.5	11.4	54.1	5.9	7.8	0.9	3.9	0.4
JF 0448	Tomato juice	0.022	5.2	0.1	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.2	15.2	0.3
-d	Tomato paste	0.21	0.5	0.1	1.3	0.3	3.5	0.7	1.0	0.2	3.8	0.8	4.5	0.9
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
-	Wine	0.018	1.3	0.0	76.8	1.4	1.1	0.0	15.4	0.3	68.8	1.2	25.6	0.5
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
	Total intake (µg/person)=			8.1		174.6		49.6		52.9		80.6		162.6
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			1.4%		29.1%		8.3%		8.8%		13.4%		27.1%
	Rounded %ADI=			1%		30%		8%		9%		10%		30%

INDOXACARB (216) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FP 0226	Apple (excl juice)	0.21	14.3	3.0	9.4	2.0	2.1	0.4	0.0	0.0	8.8	1.8	16.6	3.5	27.8	5.8
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
VB 0400	Broccoli	0.055	3.2	0.2	7.8	0.4	0.0	0.0	0.0	0.0	0.3	0.0	0.4	0.0	6.6	0.4
VB 0041	Cabbage, head	0.435	10.0	4.4	1.0	0.4	7.2	3.1	1.0	0.4	1.4	0.6	23.9	10.4	17.0	7.4

INDOXACARB (216) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
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
VC 0423	Chayote	0.06	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VD 0524	Chick-pea (dry)	0.02	5.0	0.1	0.5	0.0	0.6	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.6	0.0
OR 0691	Cotton seed oil, edible	0.013	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
VD 0527	Cowpea (dry)	0.02	0.2	0.0	0.8	0.0	2.5	0.1	25.9	0.5	0.2	0.0	1.2	0.0	0.1	0.0
FB 0265	Cranberries	0.15	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
VC 0424	Cucumber	0.06	7.9	0.5	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.3	5.3	0.3
MO 0105	Edible offal (mammalian)	0.014	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)	0.11	20.1	2.2	0.1	0.0	0.6	0.1	6.3	0.7	0.5	0.1	6.3	0.7	0.7	0.1
PE 0112	Eggs	0.01	22.1	0.2	71.5	0.7	16.6	0.2	5.1	0.1	17.6	0.2	35.2	0.4	57.4	0.6
VC 0425	Gherkin	0.06	7.9	0.5	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.3	5.3	0.3
FB 0269	Grape (excl dried, excl juice, excl wine)	0.3	1.2	0.4	2.6	0.8	0.0	0.0	0.2	0.0	0.0	0.0	3.7	1.1	0.0	0.0
JF 0269	Grape juice	0.002	0.0	0.0	0.1	0.0	1.0	0.0	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.81	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.2	0.4	0.3	2.6	2.1
VL 0482	Lettuce, head	2.8	2.4	6.7	7.0	19.6	0.2	0.6	0.6	1.7	2.0	5.6	2.4	6.7	15.7	44.0
VL 0483	Lettuce, leaf	6.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	16.5
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.38	11.0	4.2	17.9	6.8	6.1	2.3	5.7	2.2	16.4	6.2	12.2	4.6	31.7	12.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.01	43.8	0.4	71.5	0.7	24.5	0.2	22.9	0.2	65.7	0.7	48.9	0.5	126.6	1.3
VC 0046	Melons, except watermelon	0.02	7.5	0.2	6.1	0.1	0.7	0.0	1.4	0.0	2.5	0.1	6.9	0.1	12.4	0.2
ML 0106	Milks (excl processed products)	0.037	66.0	2.4	121.1	4.5	81.6	3.0	102.4	3.8	207.7	7.7	57.0	2.1	287.9	10.7
HH 0738	Mints	3.5	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
VD 0536	Mung bean (dry)	0.02	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
OR 0697	Peanut oil, edible	0.003	3.0	0.0	0.3	0.0	1.5	0.0	7.9	0.0	0.3	0.0	0.0	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	0.7	0.0	1.4	0.0	1.3	0.0	3.6	0.0	0.2	0.0	0.7	0.0	6.0	0.1
FP 0230	Pear	0.051	6.4	0.3	1.9	0.1	1.2	0.1	0.0	0.0	1.8	0.1	6.9	0.4	7.8	0.4
VO 0051	Peppers	0.038	8.7	0.3	22.4	0.9	8.4	0.3	9.4	0.4	3.3	0.1	5.3	0.2	8.9	0.3
DF 0014	Plum, dried (prunes)	0.68	0.1	0.1	0.2	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.1	0.6	0.4
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.01	52.7	0.5	57.1	0.6	50.1	0.5	4.3	0.0	54.7	0.5	41.0	0.4	168.0	1.7
PM 0110	Poultry meat: 10% as fat	0.025	1.8	0.0	13.1	0.3	2.5	0.1	0.5	0.0	14.6	0.4	2.8	0.1	11.5	0.3
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0

Annex 3

INDOXACARB (216) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	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)	0.027	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	0.018	4.3	0.1	10.6	0.2	2.0	0.0	1.4	0.0	19.5	0.4	9.2	0.2	22.0	0.4
VC 0431	Squash, summer (= courgette, zuchini)	0.06	2.4	0.1	1.5	0.1	0.0	0.0	0.0	0.0	3.8	0.2	2.2	0.1	2.5	0.2
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.17	6.7	1.1	4.3	0.7	1.4	0.2	0.1	0.0	4.9	0.8	4.9	0.8	17.7	3.0
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)	0.11	23.1	2.5	22.3	2.5	12.5	1.4	5.6	0.6	33.2	3.7	1.3	0.1	41.7	4.6
JF 0448	Tomato juice	0.022	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.2	0.0	0.0	2.4	0.1	45.2	1.0
-d	Tomato paste	0.21	0.1	0.0	2.1	0.4	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.3
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
-	Wine	0.018	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.6
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
	Total intake (µg/person)=			31.6		42.7		13.2		11.5		30.1		34.6		115.7
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			5.7%		7.1%		2.2%		1.9%		5.0%		6.3%		19.3%
	Rounded %ADI=			6%		7%		2%		2%		5%		6%		20%

METAFLUMIZONE (236) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
VB 0402	Brussels sprouts	0.125	0.0	0.0	0.1	0.0	2.8	0.4	5.5	0.7	1.5	0.2	1.9	0.2
VL 0466	Chinese cabbage, type pak-choi	0.49	0.3	0.1	2.6	1.3	2.8	1.4	5.5	2.7	0.1	0.0	1.9	0.9
MO 0105	Edible offal (mammalian)	0.013	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)	0.18	1.7	0.3	17.5	3.2	12.3	2.2	1.7	0.3	0.8	0.1	0.4	0.1
VL 0482	Lettuce, head	2	0.1	0.2	12.3	24.6	1.3	2.6	0.1	0.2	0.1	0.2	0.0	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.013	5.5	0.1	23.3	0.3	7.7	0.1	11.0	0.1	18.0	0.2	26.3	0.3
MM 0095	Meat from mammals other than marine mammals:	0.013	22.2	0.3	93.2	1.2	30.8	0.4	44.1	0.6	72.2	0.9	105.0	1.4

METAFLUMIZONE (236) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	80% as muscle													
ML 0106	Milks	0.007	68.8	0.5	190.6	1.3	79.4	0.6	302.6	2.1	179.6	1.3	237.9	1.7
VO 0444	Peppers, chilli	0.18	0.7	0.1	14.9	2.7	4.1	0.7	3.2	0.6	3.1	0.6	2.0	0.4
VO 0445	Peppers, sweet (incl. pim(i)ento)	0.18	0.7	0.1	14.9	2.7	8.8	1.6	3.2	0.6	3.1	0.6	2.0	0.4
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
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.12	1.3	0.2	178.4	21.4	102.8	12.3	53.4	6.4	1.6	0.2	0.0	0.0
JF 0448	Tomato juice	0.02	5.2	0.1	0.5	0.0	0.4	0.0	2.1	0.0	6.9	0.1	15.2	0.3
-d	Tomato paste	0.1	0.5	0.1	1.3	0.1	3.5	0.4	1.0	0.1	3.8	0.4	4.5	0.5
-d	Tomato, peeled	0.02	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.1	3.2	0.1
	Total intake (µg/person)=			2.1		59.0		22.7		14.6		5.1		6.2
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			6000		6000		6000		6000		6000		6000
	%ADI=			0.0%		1.0%		0.4%		0.2%		0.1%		0.1%
	Rounded %ADI=			0%		1%		0%		0%		0%		0%

METAFLUMIZONE (236) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VB 0402	Brussels sprouts	0.125	3.4	0.4	0.4	0.1	0.0	0.0	0.0	0.0	0.5	0.1	7.9	1.0	0.3	0.0
VL 0466	Chinese cabbage, type pak-choi	0.49	3.4	1.7	2.8	1.4	2.4	1.2	0.3	0.1	0.5	0.2	7.9	3.9	0.3	0.1
MO 0105	Edible offal (mammalian)	0.013	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)	0.18	20.1	3.6	0.1	0.0	0.6	0.1	6.3	1.1	0.5	0.1	6.3	1.1	0.7	0.1
VL 0482	Lettuce, head	2	2.4	4.8	7.0	14.0	0.2	0.4	0.6	1.2	2.0	4.0	2.4	4.8	15.7	31.4
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.013	11.0	0.1	17.9	0.2	6.1	0.1	5.7	0.1	16.4	0.2	12.2	0.2	31.7	0.4
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.013	43.8	0.6	71.5	0.9	24.5	0.3	22.9	0.3	65.7	0.9	48.9	0.6	126.6	1.6
ML 0106	Milks	0.007	66.0	0.5	121.1	0.8	81.6	0.6	102.4	0.7	207.7	1.5	57.0	0.4	287.9	2.0
VO 0444	Peppers, chilli	0.18	8.7	1.6	13.0	2.3	4.2	0.8	4.7	0.8	1.7	0.3	2.6	0.5	4.4	0.8

Annex 3

METAFLUMIZONE (236) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G 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)	0.18	0.0	0.0	9.4	1.7	4.2	0.8	4.7	0.8	1.7	0.3	2.6	0.5	4.4	0.8
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
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.12	22.8	2.7	4.1	0.5	12.3	1.5	1.8	0.2	32.8	3.9	0.4	0.0	27.3	3.3
JF 0448	Tomato juice	0.02	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.1	0.0	0.0	2.4	0.0	45.2	0.9
-d	Tomato paste	0.1	0.1	0.0	2.1	0.2	0.6	0.1	0.4	0.0	0.6	0.1	1.4	0.1	1.2	0.1
-d	Tomato, peeled	0.02	0.2	0.0	14.5	0.3	0.2	0.0	0.0	0.0	0.3	0.0	0.8	0.0	1.2	0.0
	Total intake (µg/person)=			16.1		22.6		5.8		5.7		11.6		13.3		41.8
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			5500		6000		6000		6000		6000		5500		6000
	%ADI=			0.3%		0.4%		0.1%		0.1%		0.2%		0.2%		0.7%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		1%

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
JF 0226	Apple juice	0.13	0.0	0.0	2.8	0.4	0.1	0.0	1.1	0.1	6.8	0.9	7.4	1.0
FI 0326	Avocado	0.13	3.7	0.5	1.0	0.1	0.2	0.0	0.0	0.0	0.9	0.1	0.8	0.1
VD 0071	Beans (dry)	0.05	15.8	0.8	6.1	0.3	1.7	0.1	6.3	0.3	1.8	0.1	5.0	0.3
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.065	1.0	0.1	17.4	1.1	7.5	0.5	0.9	0.1	16.4	1.1	0.1	0.0
VP 0062	Beans, shelled (immature seeds)	0.051	0.5	0.0	12.7	0.6	4.1	0.2	0.9	0.0	13.1	0.7	0.1	0.0
FB 0264	Blackberries	1.25	0.0	0.0	0.1	0.1	0.0	0.0	0.3	0.4	0.1	0.1	0.3	0.4
FB 0020	Blueberries	1.25	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.3	0.3	0.4	0.8	1.0
VB 0400	Broccoli	0.94	0.0	0.0	0.7	0.7	1.2	1.1	0.1	0.1	4.2	3.9	4.0	3.8
VB 0041	Cabbage, head	0.93	1.2	1.1	14.4	13.4	2.7	2.5	16.4	15.3	15.4	14.3	18.5	17.2
VR 0577	Carrot	0.13	0.6	0.1	15.1	2.0	8.1	1.1	13.9	1.8	27.1	3.5	28.4	3.7
VS 0624	Celery	3.4	0.0	0.0	0.9	3.1	0.0	0.0	2.0	6.8	1.5	5.1	0.0	0.0
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES	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

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
	juice)													
JF 0001	Citrus juice NES	0.011	0.0	0.0	1.7	0.0	0.1	0.0	0.0	0.0	1.1	0.0	0.3	0.0
OR 0691	Cotton seed oil, edible	0.46	0.9	0.4	4.9	2.3	1.7	0.8	6.6	3.0	0.0	0.0	0.3	0.1
VD 0527	Cowpea (dry)	0.56	3.9	2.2	0.0	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0
FB 0265	Cranberries	0.07	0.1	0.0	0.0	0.0	0.0	0.0	0.3	0.0	0.0	0.0	0.6	0.0
MO 0105	Edible offal (mammalian)	0.051	3.9	0.2	14.4	0.7	5.2	0.3	11.8	0.6	11.7	0.6	7.6	0.4
PE 0112	Eggs	0	2.5	0.0	29.7	0.0	25.1	0.0	24.5	0.0	37.8	0.0	27.4	0.0
FB 0269	Grape (excl dried, incl juice, incl wine)	0.1	3.7	0.4	116.9	11.7	25.5	2.6	31.5	3.2	98.3	9.8	37.2	3.7
FB 0269	Grape (incl dried, incl juice, incl wine)	0.1	3.7	0.4	128.5	12.9	27.1	2.7	33.1	3.3	107.5	10.8	44.0	4.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.86	0.0	0.0	2.9	2.5	0.4	0.3	0.4	0.3	2.3	2.0	1.7	1.5
JF 0203	Grapefruit juice	0.011	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	0.011	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
VL 0482	Lettuce, head	6.1	0.1	0.6	12.3	75.0	1.3	7.9	0.1	0.6	0.1	0.6	0.0	0.0
VL 0483	Lettuce, leaf	12	0.0	0.0	9.2	110.4	1.0	12.0	0.1	1.2	5.4	64.8	18.0	216.0
MF 0100	Mammalian fats (except milk fats)	0.094	0.8	0.1	10.0	0.9	0.9	0.1	6.6	0.6	11.8	1.1	3.7	0.3
FC 0003	Mandarin + mandarin-like hybrid (incl juice)	0.05	0.6	0.0	19.1	1.0	12.3	0.6	5.5	0.3	9.9	0.5	11.7	0.6
-	Mandarin + mandarin-like hybrid juice	0.011	0.0	0.0	1.4	0.0	0.9	0.0	0.4	0.0	0.7	0.0	0.9	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.094	5.5	0.5	23.3	2.2	7.7	0.7	11.0	1.0	18.0	1.7	26.3	2.5
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.019	22.2	0.4	93.2	1.8	30.8	0.6	44.1	0.8	72.2	1.4	105.0	2.0
ML 0106	Milks (excl processed products)	0.03	68.8	2.1	190.6	5.7	79.4	2.4	302.6	9.1	179.6	5.4	237.9	7.1
VL 0485	Mustard greens	16	0.3	4.8	0.3	4.8	0.0	0.0	5.5	88.0	0.0	0.0	1.9	30.4
JF 0004	Orange juice	0.011	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.2	22.6	0.2
FI 0350	Papaya	0.31	5.1	1.6	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
OR 0697	Peanut oil, edible	0.029	1.7	0.0	0.8	0.0	0.5	0.0	0.1	0.0	1.4	0.0	0.4	0.0
SO 0697	Peanut, shelled (excl oil)	0.01	1.5	0.0	1.3	0.0	1.0	0.0	0.5	0.0	0.8	0.0	0.5	0.0
VP 0064	Peas, shelled (immature seeds only)	0.051	0.0	0.0	0.9	0.0	6.0	0.3	0.6	0.0	9.7	0.5	3.2	0.2
VO 0051	Peppers	0.16	1.4	0.2	29.9	4.8	13.0	2.1	6.3	1.0	6.2	1.0	4.0	0.6
DF 0014	Plum, dried (prunes)	0.34	0.0	0.0	0.2	0.1	0.0	0.0	0.1	0.0	0.5	0.2	0.6	0.2
FP 0009	Pome fruit (excl apple juice)	1	0.5	0.5	79.9	79.9	21.8	21.8	43.6	43.6	51.5	51.5	35.1	35.1
PM 0110	Poultry meat: 10% as fat	0	0.7	0.0	5.9	0.0	3.2	0.0	2.4	0.0	6.1	0.0	2.7	0.0
PM 0110	Poultry meat: 90% as muscle	0	6.4	0.0	52.7	0.0	28.7	0.0	21.6	0.0	54.9	0.0	24.6	0.0

Annex 3

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person											
			A diet	intake	B diet	intake	C diet	intake	D diet	intake	E diet	intake	F diet	intake
PO 0111	Poultry, edible offal of	0	0.4	0.0	0.4	0.0	1.7	0.0	0.1	0.0	0.6	0.0	0.2	0.0
VR 0494	Radish	0.08	0.0	0.0	1.3	0.1	0.6	0.0	2.0	0.2	1.2	0.1	0.0	0.0
VL 0502	Spinach	15	0.0	0.0	5.0	75.0	1.1	16.5	0.1	1.5	2.6	39.0	0.1	1.5
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.34	0.7	0.2	44.7	15.2	14.1	4.8	26.9	9.1	27.7	9.4	10.0	3.4
FB 0275	Strawberry	0.24	0.0	0.0	5.0	1.2	2.0	0.5	1.7	0.4	5.2	1.2	4.1	1.0
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
VR 0508	Sweet potato	0.01	60.5	0.6	0.6	0.0	5.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.2	1.3	0.3	178.4	35.7	102.8	20.6	53.4	10.7	1.6	0.3	0.0	0.0
JF 0448	Tomato juice	0.06	5.2	0.3	0.5	0.0	0.4	0.0	2.1	0.1	6.9	0.4	15.2	0.9
VW 0448	Tomato paste	0.4	0.5	0.2	1.3	0.5	3.5	1.4	1.0	0.4	3.8	1.5	4.5	1.8
-d (?)	Tomato, peeled	0.042	0.1	0.0	0.4	0.0	0.5	0.0	0.4	0.0	4.9	0.2	3.2	0.1
TN 0085	Tree nuts	0.012	4.2	0.1	21.5	0.3	3.9	0.0	3.0	0.0	5.5	0.1	10.2	0.1
	Total intake (µg/person)=			19.4		470.9		107.4		205.6		235.4		342.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			6000		6000		6000		6000		6000		6000
	%ADI=			0.3%		7.8%		1.8%		3.4%		3.9%		5.7%
	Rounded %ADI=			0%		8%		2%		3%		4%		6%

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
JF 0226	Apple juice	0.13	0.1	0.0	0.5	0.1	0.1	0.0	0.0	0.0	0.7	0.1	0.9	0.1	5.7	0.7
FI 0326	Avocado	0.13	0.2	0.0	13.9	1.8	1.0	0.1	1.7	0.2	3.4	0.4	0.5	0.1	2.1	0.3
VD 0071	Beans (dry)	0.05	3.4	0.2	25.5	1.3	7.8	0.4	2.1	0.1	44.7	2.2	5.5	0.3	7.3	0.4
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	0.065	2.6	0.2	2.6	0.2	1.0	0.1	0.5	0.0	0.6	0.0	2.8	0.2	9.8	0.6
VP 0062	Beans, shelled (immature seeds)	0.051	2.6	0.1	1.9	0.1	1.0	0.1	0.5	0.0	0.3	0.0	1.8	0.1	9.0	0.5
FB 0264	Blackberries	1.25	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	0.4

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day Intake = daily intake: µg/person G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
FB 0020	Blueberries	1.25	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.6
VB 0400	Broccoli	0.94	3.2	3.0	7.8	7.3	0.0	0.0	0.0	0.0	0.3	0.3	0.4	0.4	6.6	6.2
VB 0041	Cabbage, head	0.93	10.0	9.3	1.0	0.9	7.2	6.7	1.0	0.9	1.4	1.3	23.9	22.2	17.0	15.8
VR 0577	Carrot	0.13	5.4	0.7	7.9	1.0	2.5	0.3	3.5	0.5	4.1	0.5	8.6	1.1	19.4	2.5
VS 0624	Celery	3.4	0.0	0.0	0.3	1.0	0.0	0.0	0.0	0.0	1.0	3.4	0.0	0.0	4.2	14.3
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
JF 0001	Citrus juice NES	0.011	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
OR 0691	Cotton seed oil, edible	0.46	1.0	0.5	0.7	0.3	1.0	0.5	1.4	0.6	1.5	0.7	5.5	2.5	1.2	0.6
VD 0527	Cowpea (dry)	0.56	0.2	0.1	0.8	0.4	2.5	1.4	25.9	14.5	0.2	0.1	1.2	0.7	0.1	0.1
FB 0265	Cranberries	0.07	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	0.2
MO 0105	Edible offal (mammalian)	0.051	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
PE 0112	Eggs	0	22.1	0.0	71.5	0.0	16.6	0.0	5.1	0.0	17.6	0.0	35.2	0.0	57.4	0.0
FB 0269	Grape (excl dried, incl juice, incl wine)	0.1	2.6	0.3	4.0	0.4	10.9	1.1	0.3	0.0	5.6	0.6	9.3	0.9	48.4	4.8
FB 0269	Grape (incl dried, incl juice, incl wine)	0.1	2.6	0.3	4.8	0.5	11.7	1.2	0.3	0.0	6.8	0.7	10.9	1.1	58.8	5.9
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.86	0.0	0.0	0.2	0.2	0.2	0.2	0.0	0.0	0.3	0.3	0.4	0.3	2.6	2.2
JF 0203	Grapefruit juice	0.011	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	0.011	0.3	0.0	0.0	0.0	1.0	0.0	0.3	0.0	0.0	0.0	0.5	0.0	2.6	0.0
VL 0482	Lettuce, head	6.1	2.4	14.6	7.0	42.7	0.2	1.2	0.6	3.7	2.0	12.2	2.4	14.6	15.7	95.8
VL 0483	Lettuce, leaf	12	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	30.0
MF 0100	Mammalian fats (except milk fats)	0.094	2.2	0.2	18.6	1.7	0.5	0.0	0.8	0.1	5.7	0.5	4.5	0.4	18.2	1.7
FC 0003	Mandarin + mandarin-like hybrid (incl juice)	0.05	7.0	0.4	6.5	0.3	0.8	0.0	0.2	0.0	9.3	0.5	19.1	1.0	6.5	0.3
-	Mandarin + mandarin-like hybrid juice	0.011	0.5	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	1.4	0.0	0.0	0.0
MM 0095	Meat from mammals other than marine mammals: 20% as fat	0.094	11.0	1.0	17.9	1.7	6.1	0.6	5.7	0.5	16.4	1.5	12.2	1.1	31.7	3.0
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	0.019	43.8	0.8	71.5	1.4	24.5	0.5	22.9	0.4	65.7	1.2	48.9	0.9	126.6	2.4
ML 0106	Milks (excl processed products)	0.03	66.0	2.0	121.1	3.6	81.6	2.4	102.4	3.1	207.7	6.2	57.0	1.7	287.9	8.6
VL 0485	Mustard greens	16	3.4	54.4	0.4	6.4	2.4	38.4	0.3	4.8	0.5	8.0	7.9	126.4	0.3	4.8
JF 0004	Orange juice	0.011	0.2	0.0	1.0	0.0	3.5	0.0	0.0	0.0	1.3	0.0	6.4	0.1	56.8	0.6
FI 0350	Papaya	0.31	1.3	0.4	11.5	3.6	1.6	0.5	13.7	4.2	14.5	4.5	1.0	0.3	0.6	0.2
OR 0697	Peanut oil, edible	0.029	3.0	0.1	0.3	0.0	1.5	0.0	7.9	0.2	0.3	0.0	0.0	0.0	0.4	0.0
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

Annex 3

METHOXYFENOZIDE (209) International Estimated Daily Intake (IEDI) ADI = 0 - 0.1000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day 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
VP 0064	Peas, shelled (immature seeds only)	0.051	3.9	0.2	1.6	0.1	0.0	0.0	0.0	0.0	0.4	0.0	1.0	0.1	0.8	0.0
VO 0051	Peppers	0.16	8.7	1.4	22.4	3.6	8.4	1.3	9.4	1.5	3.3	0.5	5.3	0.8	8.9	1.4
DF 0014	Plum, dried (prunes)	0.34	0.1	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.1	0.6	0.2
FP 0009	Pome fruit (excl apple juice)	1	20.8	20.8	11.6	11.6	3.3	3.3	0.1	0.1	10.7	10.7	23.6	23.6	36.9	36.9
PM 0110	Poultry meat: 10% as fat	0	1.8	0.0	13.1	0.0	2.5	0.0	0.5	0.0	14.6	0.0	2.8	0.0	11.5	0.0
PM 0110	Poultry meat: 90% as muscle	0	15.8	0.0	118.2	0.0	22.6	0.0	4.2	0.0	131.3	0.0	24.9	0.0	103.6	0.0
PO 0111	Poultry, edible offal of	0	0.4	0.0	1.0	0.0	1.9	0.0	0.0	0.0	0.7	0.0	1.0	0.0	0.3	0.0
VR 0494	Radish	0.08	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	1.0	0.1	0.0	0.0	0.3	0.0
VL 0502	Spinach	15	9.4	141.0	0.4	6.0	0.0	0.0	0.0	0.0	0.2	3.0	4.3	64.5	2.0	30.0
FS 0012	Stone fruit (incl dried plums, incl dried apricots)	0.34	7.0	2.4	4.9	1.7	1.4	0.5	0.1	0.0	5.5	1.9	5.5	1.9	19.4	6.6
FB 0275	Strawberry	0.24	0.0	0.0	1.8	0.4	0.1	0.0	0.0	0.0	0.3	0.1	6.2	1.5	5.9	1.4
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
VR 0508	Sweet potato	0.01	47.4	0.5	7.8	0.1	22.0	0.2	20.9	0.2	5.5	0.1	20.8	0.2	6.1	0.1
VO 0448	Tomato (excl juice, excl paste, excl peeled)	0.2	22.8	4.6	4.1	0.8	12.3	2.5	1.8	0.4	32.8	6.6	0.4	0.1	27.3	5.5
JF 0448	Tomato juice	0.06	0.0	0.0	0.8	0.0	0.1	0.0	7.2	0.4	0.0	0.0	2.4	0.1	45.2	2.7
VW 0448	Tomato paste	0.4	0.1	0.0	2.1	0.8	0.6	0.2	0.4	0.2	0.6	0.2	1.4	0.6	1.2	0.5
-d (?)	Tomato, peeled	0.042	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	0.1
TN 0085	Tree nuts	0.012	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
	Total intake (µg/person)=			260.6		111.2		64.3		39.2		80.2		271.9		291.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			5500		6000		6000		6000		6000		5500		6000
	%ADI=			4.7%		1.9%		1.1%		0.7%		1.3%		4.9%		4.9%
	Rounded %ADI=			5%		2%		1%		1%		1%		5%		5%

PROTHIOCONAZOLE (232) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person 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)	0.035	40.6	1.4	16.8	0.6	93.9	3.3	13.2	0.5	48.6	1.7	36.1	1.3
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
-	Pulses (excl soya beans)	0.05	44.6	2.2	26.5	1.3	17.1	0.9	14.4	0.7	14.1	0.7	8.7	0.4
SO 0495	Rape seed (excl oil)	0.02	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0
OR 0495	Rape seed oil, edible	0.014	0.3	0.0	0.7	0.0	1.0	0.0	0.7	0.0	13.7	0.2	10.0	0.1
GC 0650	Rye (incl flour)	0.01	0.1	0.0	3.7	0.0	0.3	0.0	24.3	0.2	25.8	0.3	45.8	0.5
VR 0596	Sugar beet	0.05	0.0	0.0	40.7	2.0	0.0	0.0	0.1	0.0	6.0	0.3	0.1	0.0
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)	0.02	6.0	0.1	11.1	0.2	0.8	0.0	0.2	0.0	0.2	0.0	0.0	0.0
CM 0654	Wheat bran, unprocessed	0.048	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.008	63.4	0.5	296.3	2.4	327.5	2.6	300.0	2.4	181.6	1.5	166.2	1.3
CF 1210	Wheat germ	0.04	0.0	0.0	1.3	0.1	0.0	0.0	1.3	0.1	0.9	0.0	1.2	0.0
	Total intake (µg/person)=			5.1		10.6		7.8		6.4		7.1		6.5
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			600		600		600		600		600		600
	%ADI=			0.9%		1.8%		1.3%		1.1%		1.2%		1.1%
	Rounded %ADI=			1%		2%		1%		1%		1%		1%

Annex 3

PROTHIOCONAZOLE (232) International Estimated Daily Intake (IEDI) ADI = 0 - 0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
GC 0640	Barley (incl pot, incl pearled, incl flour & grits, incl beer)	0.035	5.9	0.2	20.5	0.7	5.9	0.2	2.5	0.1	20.2	0.7	16.8	0.6	43.8	1.5
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
-	Pulses (excl soya beans)	0.05	16.0	0.8	32.4	1.6	24.7	1.2	34.2	1.7	50.7	2.5	8.0	0.4	16.9	0.8
SO 0495	Rape seed (excl oil)	0.02	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OR 0495	Rape seed oil, edible	0.014	3.8	0.1	2.3	0.0	0.1	0.0	0.4	0.0	0.0	0.0	6.0	0.1	3.8	0.1
GC 0650	Rye (incl flour)	0.01	0.4	0.0	0.0	0.0	0.2	0.0	0.1	0.0	0.1	0.0	0.9	0.0	0.8	0.0
VR 0596	Sugar beet	0.05	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	14.3	0.7
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)	0.02	0.0	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	0.0
CM 0654	Wheat bran, unprocessed	0.048	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-	ND	-
CF 1211	Wheat flour (incl macaroni, bread, pastry, starch, gluten)	0.008	133.0	1.1	60.1	0.5	52.4	0.4	32.2	0.3	87.7	0.7	79.6	0.6	180.1	1.4
CF 1210	Wheat germ	0.04	0.1	0.0	48.1	1.9	1.8	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
	Total intake (µg/person)=			3.3		6.9		2.8		3.2		6.0		2.9		8.0
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			550		600		600		600		600		550		600
	%ADI=			0.6%		1.2%		0.5%		0.5%		1.0%		0.5%		1.3%
	Rounded %ADI=			1%		1%		0%		1%		1%		1%		1%

SPIRODICLOFEN (237) International Estimated Daily Intake (IEDI) ADI = 0–0.0100 mg/kg bw

		STMR or	Diets: g/person/day				Intake = daily intake: µg/person							
		STMR-P	A		B		C		D		E		F	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.004	0.0	0.0	2.8	0.0	0.1	0.0	1.1	0.0	6.8	0.0	7.4	0.0
DF 0226	Apple, dried	0.018	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
–	Barley beer	0.011	18.3	0.2	84.1	0.9	4.1	0.0	66.0	0.7	243.1	2.7	161.3	1.8
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.02	15.7	0.3	86.5	1.7	52.6	1.1	24.2	0.5	16.2	0.3	12.0	0.2
–	Citrus juice NES	0.0065	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)	0.03	3.1	0.1	12.6	0.4	2.9	0.1	1.4	0.0	10.1	0.3	18.0	0.5
VC 0424	Cucumber	0.03	0.3	0.0	12.7	0.4	5.9	0.2	11.5	0.3	6.1	0.2	7.1	0.2
FB 0021	Currants, red, black, white	0.04	0.0	0.0	0.0	0.0	0.0	0.0	2.2	0.1	3.1	0.1	2.0	0.1
MO 0105	Edible offal (mammalian)	0	3.9	0.0	14.4	0.0	5.2	0.0	11.8	0.0	11.7	0.0	7.6	0.0
VC 0425	Gherkin	0.03	0.3	0.0	12.7	0.4	5.9	0.2	11.5	0.3	6.1	0.2	7.1	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.059	1.9	0.1	9.2	0.5	23.8	1.4	9.8	0.6	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.00051	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)	0.13	0.0	0.0	2.9	0.4	0.4	0.1	0.4	0.1	2.3	0.3	1.7	0.2
JF 0203	Grapefruit juice	0.0065	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	0.0065	0.0	0.0	0.9	0.0	0.1	0.0	0.0	0.0	0.2	0.0	0.4	0.0
–	Mandarin + mandarin-like hybrid juice	0.0065	0.0	0.0	1.4	0.0	0.9	0.0	0.4	0.0	0.7	0.0	0.9	0.0
MM 0095	Meat from mammals other than marine mammals	0	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
JF 0004	Orange juice	0.0065	0.0	0.0	2.1	0.0	4.4	0.0	1.4	0.0	16.2	0.1	22.6	0.1
FI 0350	Papaya	0.03	5.1	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
VO 0445	Peppers, sweet (incl. pimiento)	0.08	0.7	0.1	14.9	1.2	8.8	0.7	3.2	0.3	3.1	0.2	2.0	0.2
DF 0014	Plum, dried (prunes)	0.79	0.0	0.0	0.2	0.2	0.0	0.0	0.1	0.1	0.5	0.4	0.6	0.5
FP 0009	Pome fruit (excl apple juice)	0.2	0.5	0.1	79.9	16.0	21.8	4.4	43.6	8.7	51.5	10.3	35.1	7.0
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.315	0.7	0.2	44.1	13.9	14.1	4.4	26.6	8.4	26.3	8.3	8.3	2.6
FB 0275	Strawberry	0.0615	0.0	0.0	5.0	0.3	2.0	0.1	1.7	0.1	5.2	0.3	4.1	0.3
VO 0448	Tomato (incl juice, incl paste, incl peeled)	0.08	11.8	0.9	185.0	14.8	118.0	9.4	60.7	4.9	31.6	2.5	40.9	3.3
TN 0085	Tree nuts	0.0155	4.2	0.1	21.5	0.3	3.9	0.1	3.0	0.0	5.5	0.1	10.2	0.2
–	Wine	0.018	1.3	0.0	76.8	1.4	1.1	0.0	15.4	0.3	68.8	1.2	25.6	0.5
	Total intake (µg/person) =			2.3		52.8		22.2		25.4		27.6		17.9
	Bodyweight per region (kg bw) =			60		60		60		60		60		60

Annex 3

SPIRODICLOFEN (237) International Estimated Daily Intake (IEDI) ADI = 0–0.0100 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
	ADI (µg/person) =			600		600		600		600		600		600
	%ADI =			0.4%		8.8%		3.7%		4.2%		4.6%		3.0%
	Rounded %ADI =			0%		9%		4%		4%		5%		3%

SPIRODICLOFEN (237) International Estimated Daily Intake (IEDI) ADI = 0–0.0100 mg/kg bw

		STMR or	Diets: g/person/day			Intake = daily intake: µg/person										
		STMR-P	G		H		I		J		K		L		M	
Codex Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
JF 0226	Apple juice	0.004	0.1	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	0.9	0.0	5.7	0.0
DF 0226	Apple, dried	0.018	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–	ND	–
–	Barley beer	0.011	21.9	0.2	102.7	1.1	29.5	0.3	12.6	0.1	100.9	1.1	82.2	0.9	218.8	2.4
FC 0001	Citrus fruit (excl lemon juice, excl mandarin juice, excl orange juice, excl grapefruit juice, excl NES juice)	0.02	15.1	0.3	153.9	3.1	3.4	0.1	41.7	0.8	218.9	4.4	23.1	0.5	18.0	0.4
–	Citrus juice NES	0.0065	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)	0.03	0.2	0.0	7.0	0.2	0.5	0.0	0.2	0.0	5.3	0.2	5.7	0.2	12.4	0.4
VC 0424	Cucumber	0.03	7.9	0.2	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.2	5.3	0.2
FB 0021	Currants, red, black, white	0.04	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MO 0105	Edible offal (mammalian)	0	4.8	0.0	10.7	0.0	4.0	0.0	4.0	0.0	6.5	0.0	6.6	0.0	5.6	0.0
VC 0425	Gherkin	0.03	7.9	0.2	0.6	0.0	0.2	0.0	0.0	0.0	0.4	0.0	5.5	0.2	5.3	0.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.059	1.2	0.1	2.6	0.2	0.0	0.0	0.2	0.0	0.0	0.0	3.7	0.2	0.0	0.0
JF 0269	Grape juice	0.00051	0.0	0.0	0.1	0.0	1.0	0.0	0.0	0.0	0.6	0.0	0.4	0.0	3.6	0.0
DF 0269	Grape, dried (= currants, raisins and sultanas)	0.13	0.0	0.0	0.2	0.0	0.2	0.0	0.0	0.0	0.3	0.0	0.4	0.1	2.6	0.3
JF 0203	Grapefruit juice	0.0065	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	0.0065	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
–	Mandarin + mandarin-like hybrid juice	0.0065	0.5	0.0	0.5	0.0	0.1	0.0	0.0	0.0	0.7	0.0	1.4	0.0	0.0	0.0
MM 0095	Meat from mammals other than marine mammals	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

SPIRODICLOFEN (237) International Estimated Daily Intake (IEDI) ADI = 0–0.0100 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day 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
ML 0106	Milks (excl processed products)	0	66.0	0.0	121.1	0.0	81.6	0.0	102.4	0.0	207.7	0.0	57.0	0.0	287.9	0.0
JF 0004	Orange juice	0.0065	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	0.4
FI 0350	Papaya	0.03	1.3	0.0	11.5	0.3	1.6	0.0	13.7	0.4	14.5	0.4	1.0	0.0	0.6	0.0
VO 0445	Peppers, sweet (incl. pimiento)	0.08	0.0	0.0	9.4	0.8	4.2	0.3	4.7	0.4	1.7	0.1	2.6	0.2	4.4	0.4
DF 0014	Plum, dried (prunes)	0.79	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	0.5
FP 0009	Pome fruit (excl apple juice)	0.2	20.8	4.2	11.6	2.3	3.3	0.7	0.1	0.0	10.7	2.1	23.6	4.7	36.9	7.4
FS 0012	Stone fruit (excl dried plums, incl dried apricots)	0.315	6.7	2.1	4.3	1.4	1.4	0.4	0.1	0.0	4.9	1.5	4.9	1.5	17.7	5.6
FB 0275	Strawberry	0.0615	0.0	0.0	1.8	0.1	0.1	0.0	0.0	0.0	0.3	0.0	6.2	0.4	5.9	0.4
VO 0448	Tomato (incl juice, incl paste, incl peeled)	0.08	23.5	1.9	31.7	2.5	15.0	1.2	16.2	1.3	35.6	2.8	9.9	0.8	103.0	8.2
TN 0085	Tree nuts	0.0155	16.3	0.3	15.7	0.2	9.7	0.2	1.9	0.0	19.1	0.3	29.0	0.4	5.6	0.1
–	Wine	0.018	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.6
	Total intake (µg/person) =			9.6		12.5		3.4		3.2		13.4		10.5		27.2
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person) =			550		600		600		600		600		550		600
	%ADI =			1.8%		2.1%		0.6%		0.5%		2.2%		1.9%		4.5%
	Rounded %ADI =			2%		2%		1%		1%		2%		2%		5%

ZOXAMIDE (227) International Estimated Daily Intake (IEDI) ADI = 0 - 0.5000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day A diet	Intake = daily intake: µg/person A intake	B diet	B intake	C diet	C intake	D diet	D intake	E diet	E intake	F diet	F intake
VC 0045	Fruiting vegetables, cucurbits	0.225	26.6	6.0	107.5	24.2	95.9	21.6	82.2	18.5	25.4	5.7	23.2	5.2
FB 0269	Grape (excl dried, excl juice, excl wine)	0.83	1.9	1.6	9.2	7.7	23.8	19.8	9.8	8.1	0.0	0.0	0.0	0.0
JF 0269	Grape juice	0.11	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	1.4	0.2	1.0	0.1
DF 0269	Grape, dried (= currants, raisins and sultanas)	2.4	0.0	0.0	2.9	7.0	0.4	1.0	0.4	1.0	2.3	5.5	1.7	4.1
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.02	19.1	0.4	160.8	3.2	61.2	1.2	243.6	4.9	230.1	4.6	204.7	4.1
VO 0448	Tomato (incl juice, excl paste, incl peeled)	0.195	9.8	1.9	179.8	35.1	104.0	20.3	56.7	11.1	16.4	3.2	22.9	4.5

Annex 3

ZOXAMIDE (227) International Estimated Daily Intake (IEDI) ADI = 0 - 0.5000 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
-d	Tomato paste	0.19	0.5	0.1	1.3	0.2	3.5	0.7	1.0	0.2	3.8	0.7	4.5	0.9
-	Wine	0.02	1.3	0.0	76.8	1.5	1.1	0.0	15.4	0.3	68.8	1.4	25.6	0.5
	Total intake (µg/person)=			10.0		78.9		64.5		44.0		21.3		19.3
	Bodyweight per region (kg bw) =			60		60		60		60		60		60
	ADI (µg/person)=			30000		30000		30000		30000		30000		30000
	%ADI=			0.0%		0.3%		0.2%		0.1%		0.1%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%

ZOXAMIDE (227) International Estimated Daily Intake (IEDI) ADI = 0 - 0.5000 mg/kg bw

Codex Code	Commodity	STMR or STMR-P mg/kg	Diets: g/person/day / Intake = daily intake: µg/person													
			G diet	intake	H diet	intake	I diet	intake	J diet	intake	K diet	intake	L diet	intake	M diet	intake
VC 0045	Fruiting vegetables, cucurbits	0.225	69.7	15.7	25.9	5.8	14.9	3.4	18.0	4.1	18.7	4.2	39.1	8.8	44.2	9.9
FB 0269	Grape (excl dried, excl juice, excl wine)	0.83	1.2	1.0	2.6	2.2	0.0	0.0	0.2	0.1	0.0	0.0	3.7	3.1	0.0	0.0
JF 0269	Grape juice	0.11	0.0	0.0	0.1	0.0	1.0	0.1	0.0	0.0	0.6	0.1	0.4	0.0	3.6	0.4
DF 0269	Grape, dried (= currants, raisins and sultanas)	2.4	0.0	0.0	0.2	0.5	0.2	0.5	0.0	0.0	0.3	0.7	0.4	1.0	2.6	6.2
VR 0589	Potato (incl flour, frozen, starch, tapioca)	0.02	52.7	1.1	57.1	1.1	50.1	1.0	4.3	0.1	54.7	1.1	41.0	0.8	168.0	3.4
VO 0448	Tomato (incl juice, excl paste, incl peeled)	0.195	23.1	4.5	23.3	4.5	12.6	2.5	14.6	2.8	33.2	6.5	4.3	0.8	98.2	19.1
-d	Tomato paste	0.19	0.1	0.0	2.1	0.4	0.6	0.1	0.4	0.1	0.6	0.1	1.4	0.3	1.2	0.2
-	Wine	0.02	1.0	0.0	0.9	0.0	6.8	0.1	0.1	0.0	3.4	0.1	3.6	0.1	31.0	0.6
	Total intake (µg/person)=			22.3		14.6		7.6		7.2		12.7		14.9		39.9
	Bodyweight per region (kg bw) =			55		60		60		60		60		55		60
	ADI (µg/person)=			27500		30000		30000		30000		30000		27500		30000
	%ADI=			0.1%		0.0%		0.0%		0.0%		0.0%		0.1%		0.1%
	Rounded %ADI=			0%		0%		0%		0%		0%		0%		0%

ANNEX 4: INTERNATIONAL ESTIMATES OF SHORT-TERM DIETARY INTAKES OF PESTICIDE RESIDUES

Benalaxyl (155) International estimate of short term intake (IESTI) for **GENERAL POPULATION** Acute RfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 4%

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 0269	Grape (excl wine)	-	0.17	AUS	67.0	513	125	FRA	118	3	2a	1.90	2%
JF 0269	Grape juice	-	0.018	FRA	52.2	696	-	-	ND	ND	3	ND	-
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.17	USA	65.0	70	-	-	ND	ND	1	0.18	0%
VL 0482	Lettuce, head	-	0.43	USA	65.0	213	450	JPN	450	3	2b	4.22	4%
VL 0482	Lettuce, head	-	0.43	USA	65.0	213	558	UNK	413	3	2b	4.22	4%
VL 0482	Lettuce, head	-	0.43	USA	65.0	213	539	USA	512	3	2b	4.22	4%
VL 0482	Lettuce, head	-	0.43	USA	65.0	213	450	BEL	360	3	2b	4.22	4%
VC 0046	Melons, except watermelon	-	0.05	FRA	52.2	1044	700	FRA	420	3	2a	1.80	2%
VC 0046	Melons, except watermelon	-	0.05	FRA	52.2	1044	700	JPN	700	3	2a	2.34	2%
VC 0046	Melons, except watermelon	-	0.05	FRA	52.2	1044	1000	USA	630	3	2a	2.21	2%
VC 0046	Melons, except watermelon	-	0.05	FRA	52.2	1044	720	BEL	540	3	2a	2.03	2%
VO 0448	Tomato	-	0.05	FRA	52.2	387	105	FRA	102	3	2a	0.57	1%
VO 0448	Tomato	-	0.05	FRA	52.2	387	150	JPN	150	3	2a	0.66	1%
VO 0448	Tomato	-	0.05	FRA	52.2	387	85	UNK	85	3	2a	0.53	1%
VO 0448	Tomato	-	0.05	FRA	52.2	387	123	USA	123	3	2a	0.61	1%
VO 0448	Tomato	-	0.05	FRA	52.2	387	150	BEL	143	3	2a	0.64	1%
JF 0448	Tomato juice	-	0.005	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	-	0.05	-	-	ND	-	-	ND	ND	ND	ND	-
-	Tomatoes peeled	-	0.05	-	-	ND	-	-	ND	ND	ND	ND	-
VC 0432	Watermelon	-	0.02	USA	65.0	1939	3000	JPN	3000	3	2b	1.79	2%
VC 0432	Watermelon	-	0.02	USA	65.0	1939	4518	USA	2078	3	2b	1.79	2%
-	Wine	-	0.035	FRA	52.2	1006	-	-	ND	ND	3	ND	-

Annex 4

Benalaxyl (155) International estimate of short term intake (IESTI) for **CHILDREN UP TO 6 YEARS**

Acute RfD= 0.100 mg/kg bw (100 µg/kg bw)
Maximum %ARfD: 9%

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 0269	Grape (excl wine)	-	0.17	AUS	19.0	342	125	FRA	118	3	2a	5.16	5%
JF 0269	Grape juice	-	0.018	FRA	18.9	500	-	-	ND	ND	3	ND	-
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.17	USA	15.0	59	-	-	ND	ND	1	0.67	1%
VL 0482	Lettuce, head	-	0.43	Thai	17.1	117	450	JPN	450	3	2b	8.81	9%
VL 0482	Lettuce, head	-	0.43	Thai	17.1	117	558	UNK	413	3	2b	8.81	9%
VL 0482	Lettuce, head	-	0.43	Thai	17.1	117	539	USA	512	3	2b	8.81	9%
VL 0482	Lettuce, head	-	0.43	Thai	17.1	117	450	BEL	360	3	2b	8.81	9%
VC 0046	Melons, except watermelon	-	0.05	FRA	18.9	597	700	FRA	420	3	2a	3.80	4%
VC 0046	Melons, except watermelon	-	0.05	FRA	18.9	597	700	JPN	700	3	2b	4.74	5%
VC 0046	Melons, except watermelon	-	0.05	FRA	18.9	597	1000	USA	630	3	2b	4.74	5%
VC 0046	Melons, except watermelon	-	0.05	FRA	18.9	597	720	BEL	540	3	2a	4.44	4%
VO 0448	Tomato	-	0.05	FRA	18.9	215	105	FRA	102	3	2a	1.11	1%
VO 0448	Tomato	-	0.05	FRA	18.9	215	150	JPN	150	3	2a	1.36	1%
VO 0448	Tomato	-	0.05	FRA	18.9	215	85	UNK	85	3	2a	1.02	1%
VO 0448	Tomato	-	0.05	FRA	18.9	215	123	USA	123	3	2a	1.22	1%
VO 0448	Tomato	-	0.05	FRA	18.9	215	150	BEL	143	3	2a	1.32	1%
JF 0448	Tomato juice	-	0.005	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	-	0.05	-	-	ND	-	-	ND	ND	ND	ND	-
-	Tomatoes peeled	-	0.05	-	-	ND	-	-	ND	ND	ND	ND	-
VC 0432	Watermelon	-	0.02	AUS	19.0	1473	3000	JPN	3000	3	2b	4.65	5%
VC 0432	Watermelon	-	0.02	AUS	19.0	1473	4518	USA	2078	3	2b	4.65	5%
-	Wine	-	0.035	FRA	18.9	89	-	-	ND	ND	3	ND	-

Annex 4

BUPROFEZIN (173) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.500 mg/kg bw (500 µg/kg bw) Maximum %ARfD: 30%

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
TN 0660	Almonds	-	0.05	JPN	52.6	74	-	-	ND	ND	1	0.07	0%
FP 0226	Apple	-	0.99	USA	65.0	1348	200	JPN	200	3	2a	26.62	5%
JF 0226	Apple juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-
FS 0013	Cherries	-	1.32	FRA	52.2	360	5	JPN	5	1	1	9.11	2%
VC 0424	Cucumber	-	0.41	FRA	52.2	348	400	FRA	360	3	2b	8.20	2%
VC 0425	Gherkin	-	0.41	NLD	63.0	96	116	USA	81	3	2a	1.68	0%
FB 0269	Grape (excl wine)	-	0.74	AUS	67.0	513	456	SWE	438	3	2a	15.34	3%
JF 0269	Grape juice	0.056	-	FRA	52.2	696	-	-	ND	ND	3	0.75	0%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.999	USA	65.0	70	-	-	ND	ND	1	1.08	0%
VC 0046	Melons, except watermelon	-	0.41	FRA	52.2	1044	700	JPN	700	3	2a	19.20	4%
VC 0046	Melons, except watermelon, stated as canteloupe, VC 4199	-	0.41	USA	65.0	606	500	JPN	500	3	2a	10.13	2%
FS 0245	Nectarine	-	8.13	FRA	52.2	604	136	USA	125	3	2a	133.12	30%
FT 0305	Olive	-	1.66	FRA	52.2	116	-	-	ND	ND	ND	ND	-
OR 0305	Olive oil, refined	3.49	-	FRA	52.2	48	-	-	ND	ND	3	3.18	1%
FS 0247	Peach	-	8.13	SAF	55.7	685	150	JPN	150	3	2a	143.79	30%
FP 0230	Pear	-	3.65	FRA	52.2	568	180	JPN	180	3	2a	64.88	10%
VO 0444	Peppers, chilli	-	1.1	USA	65.0	90	45	USA	43	3	2a	2.99	1%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	1.1	FRA	52.2	90	185	BEL	148	3	2b	5.71	1%
FS 0014	Plum (incl dried)	-	0.55	Thai	53.5	480	66	USA	62	3	2a	6.21	1%
DF 0014	Plum, dried (prunes)	-	1.63	USA	65.0	303	6	FRA	5	1	1	7.60	2%
VC 0431	Squash, summer (= courgette)	-	0.41	FRA	52.2	351	300	FRA	270	3	2a	7.00	1%
VC 0432	Watermelon	-	0.41	USA	65.0	1939	4518	USA	2078	3	2b	36.69	7%
-	Wine	0.102	-	FRA	52.2	1006	-	-	ND	ND	3	1.97	0%
VC 0433	Winter squash (= pumpkin), stated as pumpkin, VC 0429	-	0.41	SAF	55.7	1003	1000	JPN	1000	3	2a	22.10	4%

Annex 4

BUPROFEZIN (173) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.500 mg/kg bw (500 µg/kg bw) Maximum %ARfD: 50%

Codex Code	Commodity			Large portion diet			Unit weight						
		STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% ARfD rounded
TN 0660	Almonds	-	0.05	USA	15.0	13	-	-	ND	ND	1	0.04	0%
FP 0226	Apple	-	0.99	USA	15.0	679	200	JPN	200	3	2a	71.20	10%
JF 0226	Apple juice	0.18	-	-	-	ND	-	-	ND	ND	3	ND	-
FS 0013	Cherries	-	1.32	AUS	19.0	250	5	FRA	4	1	1	17.37	3%
VC 0424	Cucumber	-	0.41	NLD	17.0	162	400	FRA	360	3	2b	11.72	2%
VC 0425	Gherkin	-	0.41	NLD	17.0	56	116	USA	81	3	2b	4.02	1%
FB 0269	Grape (excl wine)	-	0.74	AUS	19.0	342	456	SWE	438	3	2b	39.96	8%
JF 0269	Grape juice	0.056	-	FRA	18.9	500	-	-	ND	ND	3	1.48	0%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.999	USA	15.0	59	-	-	ND	ND	1	3.95	1%
VC 0046	Melons, except watermelon	-	0.41	FRA	18.9	597	1000	USA	630	3	2b	38.84	8%
VC 0046	Melons, except watermelon, stated as canteloupe, VC 4199	-	0.41	USA	15.0	270	552	USA	276	3	2b	22.12	4%
FS 0245	Nectarine	-	8.13	AUS	19.0	302	136	USA	125	3	2a	236.34	50%
FS 0245	Nectarine	-	8.13	AUS	19.0	302	110	BEL	94	3	2a	209.28	40%
FT 0305	Olive	-	1.66	FRA	18.9	202	-	-	ND	ND	ND	ND	-
OR 0305	Olive oil, refined	3.49	-	FRA	18.9	25	-	-	ND	ND	3	4.61	1%
FS 0247	Peach	-	8.13	AUS	19.0	315	150	JPN	150	3	2a	263.37	50%
FP 0230	Pear	-	3.65	UNK	14.5	279	180	JPN	180	3	2a	160.85	30%
VO 0444	Peppers, chilli	-	1.1	AUS	19.0	31	45	USA	43	3	2b	5.30	1%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	1.1	Thai	17.1	71	119	USA	98	3	2b	13.73	3%
FS 0014	Plum (incl dried)	-	0.55	Thai	17.1	377	66	USA	62	3	2a	16.11	3%
DF 0014	Plum, dried (prunes)	-	1.63	AUS	19.0	170	6	FRA	5	1	1	14.59	3%
VC 0431	Squash, summer (= courgette)	-	0.41	AUS	19.0	219	300	FRA	270	3	2b	14.17	3%
VC 0432	Watermelon	-	0.41	AUS	19.0	1473	4518	USA	2078	3	2b	95.33	20%
-	Wine	0.102	-	FRA	18.9	89	-	-	ND	ND	3	0.48	0%
VC 0433	Winter squash (= pumpkin), stated as pumpkin, VC 0429	-	0.41	SAF	14.2	224	1000	JPN	1000	3	2b	19.43	4%

Annex 4

CARBOFURAN (096) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.001 mg/kg bw (1 µg/kg bw) Maximum %ARfD: 80%

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	-	0.02	FRA	52.2	714	720	JPN	720	3	2b	0.82	80%
FC 0206	Mandarin	-	0.01	FRA	52.2	639	168	USA	124	3	2a	0.17	20%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.01	FRA	52.2	1044	200	JPN	200	3	2a	0.28	30%

CARBOFURAN (096) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.001 mg/kg bw (1 µg/kg bw) Maximum %ARfD: 150%

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	-	0.02	FRA	18.9	477	900	FRA	612	3	2b	1.51	150%
FC 0206	Mandarin	-	0.01	JPN	15.9	353	168	USA	124	3	2a	0.38	40%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.01	UNK	14.5	495	200	JPN	200	3	2a	0.62	60%

CHORPYRIFOS METHYL (090) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.100 mg/kg bw (100 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
FP 0226	Apple	-	0.56	USA	65.0	1348	110	FRA	100	3	2a	13.34	10%
JF 0226	Apple juice	0.005	-	-	-	ND	-	-	ND	ND	3	ND	-
FS 0240	Apricot	-	0.26	FRA	52.2	369	40	FRA	37	3	2a	2.21	2%
GC 0640	Barley	-	2.2	NLD	63.0	378	-	-	ND	ND	3	ND	-
-	Barley beer	0.002	-	-	-	ND	-	-	ND	ND	3	ND	-

Annex 4

CHORPYRIFOS METHYL (090) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.100 mg/kg bw (100 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
FM 0812	Cattle milk fat	0.01	-	NLD	63.0	79	-	-	ND	ND	3	0.01	0%
FS 0013	Cherries	-	0.26	FRA	52.2	360	5	FRA	4	1	1	1.79	2%
MO 0105	Edible offal (mammalian)	-	0	FRA	52.2	327	-	-	ND	ND	1	0.00	0%
VO 0440	Egg plant	-	0.72	AUS	67.0	487	80	JPN	80	3	2a	6.95	7%
PE 0112	Eggs	-	0	Thai	53.5	195	-	-	ND	ND	1	0.00	0%
FB 0269	Grape (excl wine)	-	0.53	AUS	67.0	513	150	JPN	150	3	2a	6.43	6%
FC 0203	Grapefruit	-	0.01	JPN	52.6	947	400	JPN	400	3	2a	0.33	0%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.001	USA	65.0	70	-	-	ND	ND	1	0.00	0%
FC 0204	Lemon	-	0.01	FRA	52.2	111	100	FRA	64	3	2a	0.05	0%
FP 0228	Loquat	-	0.56	AUS	67.0	64	-	-	ND	ND	ND	ND	-
GC 0645	Maize	-	2.2	FRA	52.2	212	-	-	ND	ND	3	ND	-
MF 0100	Mammalian fats (except milk fats)	-	0.03	-	-	ND	-	-	ND	ND	1	ND	-
FC 0206	Mandarin	-	0.01	FRA	52.2	639	100	FRA	72	3	2a	0.15	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.055	AUS	67.0	104	-	-	ND	ND	1	0.02	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0	AUS	67.0	417	-	-	ND	ND	1	0.00	0%
ML 0106	Milks	0	-	USA	65.0	2466	-	-	ND	ND	3	0.00	0%
FS 0245	Nectarine	-	0.26	FRA	52.2	604	110	FRA	99	3	2a	4.00	4%
JF 0004	Orange juice	0	-	-	-	ND	-	-	ND	ND	3	ND	-
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.01	FRA	52.2	1044	190	FRA	137	3	2a	0.25	0%
FS 0247	Peach	-	0.26	SAF	55.7	685	110	FRA	99	3	2a	4.12	4%
FP 0230	Pear	-	0.56	FRA	52.2	568	100	FRA	89	3	2a	8.00	8%
VO 0444	Peppers, chilli	-	0.72	USA	65.0	90	45	USA	43	3	2a	1.96	2%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.72	FRA	52.2	90	172	UNK	160	3	2b	3.74	4%
FS 0014	Plum (incl dried)	-	0.26	Thai	53.5	480	40	JPN	40	3	2a	2.72	3%
VR 0589	Potato	-	0	FRA	52.2	639	200	FRA	160	3	2a	0.00	0%
PM 0110	Poultry meat: 10% as fat	-	0.004	AUS	67.0	43	-	-	ND	ND	1	0.00	0%
PM 0110	Poultry meat: 90% as muscle	-	0	AUS	67.0	388	-	-	ND	ND	1	0.00	0%
PO 0111	Poultry, edible offal of	-	0	USA	65.0	248	-	-	ND	ND	1	0.00	0%
PF 0111	Poultry, fats	-	0.01	USA	65.0	43	-	-	ND	ND	1	0.01	0%
FP 0231	Quince	-	0.56	AUS	67.0	175	92	USA	56	3	2a	2.40	2%

Annex 4

CHORPYRIFOS METHYL (090) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.100 mg/kg bw (100 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 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.01	Thai	53.5	554	210	FRA	126	3	2a	0.15	0%
FM 0822	Sheep milk fat	0.01	-	NLD	63.0	28	-	-	ND	ND	3	0.00	0%
FB 0275	Strawberry	-	0.04	FRA	52.2	531	14	FRA	13	1	1	0.41	0%
VO 0448	Tomato	-	0.92	FRA	52.2	387	105	FRA	102	3	2a	10.41	10%
JF 0448	Tomato juice	0.002	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0654	Wheat	-	2.2	FRA	52.2	703	-	-	ND	ND	ND	ND	-
CM 0654	Wheat bran, unprocessed	-	5.39	USA	65.0	80	-	-	ND	ND	1	6.63	7%
CF 1211	Wheat flour	-	0.55	FRA	52.2	479	-	-	ND	ND	1	5.04	5%
CF 1210	Wheat germ	-	4.18	FRA	52.2	174	-	-	ND	ND	1	13.92	10%
CF 1212	Wheat wholemeal	-	2.2	USA	65.0	155	-	-	ND	ND	1	5.26	5%
CP 1211	White bread	-	0.11	FRA	52.2	474	-	-	ND	ND	1	1.00	1%
CP 1212	Wholemeal bread	-	1.06	SAF	55.7	395	-	-	ND	ND	1	7.53	8%
-	Wine	0.002	-	FRA	52.2	1006	-	-	ND	ND	3	0.04	0%

CHORPYRIFOS METHYL (090) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 30%

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	0%
FP 0226	Apple	-	0.56	USA	15.0	679	110	FRA	100	3	2a	32.81	30%
JF 0226	Apple juice	0.005	-	-	-	ND	-	-	ND	ND	3	ND	-
FS 0240	Apricot	-	0.26	AUS	19.0	414	40	FRA	37	3	2a	6.69	7%
GC 0640	Barley	-	2.2	AUS	19.0	14	-	-	ND	ND	3	ND	-
-	Barley beer	0.002	-	-	-	ND	-	-	ND	ND	3	ND	-
FM 0812	Cattle milk fat	0.016	-	NLD	17.0	35	-	-	ND	ND	3	0.03	0%
FS 0013	Cherries	-	0.26	AUS	19.0	250	5	FRA	4	1	1	3.42	3%
MO 0105	Edible offal (mammalian)	-	0	FRA	18.9	86	-	-	ND	ND	1	0.00	0%

Annex 4

CHORPYRIFOS METHYL (090) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 30%

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
VO 0440	Egg plant	-	0.72	JPN	15.9	219	80	JPN	80	3	2a	17.17	20%
PE 0112	Eggs	-	0	Thai	17.1	109	-	-	ND	ND	1	0.00	0%
FB 0269	Grape (excl wine)	-	0.53	AUS	19.0	342	150	JPN	150	3	2a	17.91	20%
FC 0203	Grapefruit	-	0.01	FRA	18.9	405	400	JPN	400	3	2a	0.64	1%
DF 0269	Grapes, dried (= currants, raisins and sultanas)	-	0.001	USA	15.0	59	-	-	ND	ND	1	0.00	0%
FP 0228	Loquat	-	0.56	-	-	ND	-	-	ND	ND	ND	ND	-
GC 0645	Maize	-	2.2	FRA	18.9	117	-	-	ND	ND	3	ND	-
FC 0206	Mandarin	-	0.01	JPN	15.9	353	100	FRA	72	3	2a	0.31	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.055	AUS	19.0	52	-	-	ND	ND	1	0.15	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0	AUS	19.0	208	-	-	ND	ND	1	0.00	0%
ML 0106	Milks	0.0006	-	USA	15.0	1286	-	-	ND	ND	3	0.05	0%
FS 0245	Nectarine	-	0.26	AUS	19.0	302	110	FRA	99	3	2a	6.84	7%
JF 0004	Orange juice	0	-	-	-	ND	-	-	ND	ND	3	ND	-
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.01	UNK	14.5	495	190	FRA	137	3	2a	0.53	1%
FS 0247	Peach	-	0.26	AUS	19.0	315	110	FRA	99	3	2a	7.03	7%
FP 0230	Pear	-	0.56	UNK	14.5	279	100	FRA	89	3	2a	17.65	20%
VO 0444	Peppers, chilli	-	0.72	AUS	19.0	31	45	USA	43	3	2b	3.47	3%
VO 0445	Peppers, sweet (incl. pim(i)ento)	-	0.72	Thai	17.1	71	172	UNK	160	3	2b	8.99	9%
FS 0014	Plum (incl dried)	-	0.26	Thai	17.1	377	40	JPN	40	3	2a	6.95	7%
VR 0589	Potato	-	0	SAF	14.2	300	200	FRA	160	3	2a	0.00	0%
PM 0110	Poultry meat: 10% as fat	-	0.004	AUS	19.0	22	-	-	ND	ND	1	0.00	0%
PM 0110	Poultry meat: 90% as muscle	-	0	AUS	19.0	201	-	-	ND	ND	1	0.00	0%
PO 0111	Poultry, edible offal of	-	0	FRA	18.9	99	-	-	ND	ND	1	0.00	0%
FP 0231	Quince	-	0.56	NLD	17.0	1	92	USA	56	3	2b	0.10	0%
FC 0005	Shaddock or pomelo + shaddock-like hybrid	-	0.01	Thai	17.1	327	210	FRA	126	3	2a	0.34	0%
FM 0822	Sheep milk fat	0.016	-	-	-	ND	-	-	ND	ND	3	ND	-

Annex 4

CHORPYRIFOS METHYL (090) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 30%

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	-	0.04	FRA	18.9	354	14	FRA	13	1	1	0.75	1%
VO 0448	Tomato	-	0.92	FRA	18.9	215	105	FRA	102	3	2a	20.40	20%
JF 0448	Tomato juice	0.002	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0654	Wheat	-	2.2	FRA	18.9	384	-	-	ND	ND	ND	ND	-
CM 0654	Wheat bran, unprocessed	-	5.39	USA	15.0	30	-	-	ND	ND	1	10.67	10%
CF 1211	Wheat flour	-	0.55	FRA	18.9	245	-	-	ND	ND	1	7.12	7%
CF 1210	Wheat germ	-	4.18	USA	15.0	8	-	-	ND	ND	1	2.22	2%
CF 1212	Wheat wholemeal	-	2.2	USA	15.0	74	-	-	ND	ND	1	10.80	10%
CP 1211	White bread	-	0.11	SAF	14.2	270	-	-	ND	ND	1	2.09	2%
CP 1212	Wholemeal bread	-	1.06	SAF	14.2	240	-	-	ND	ND	1	17.91	20%
-	Wine	0.002	-	FRA	18.9	89	-	-	ND	ND	3	0.01	0%

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.040 mg/kg bw (40 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	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
GC 0640	Barley	-	1.5	NLD	63.0	378	-	-	ND	ND	1	9.00	20%
GC 0640	Barley (beer only)	0.04	-	AUS	67.0	528	-	-	ND	ND	3	0.32	1%
PE 0112	Eggs	-	0.006	Thai	53.5	195	-	-	ND	ND	1	0.02	0%
GC 0647	Oats	-	1.5	FRA	62.3	305	-	-	ND	ND	1	7.35	20%
PM 0110	Poultry meat: 10% as fat	-	0.048	AUS	67.0	43	-	-	ND	ND	1	0.03	0%
PM 0110	Poultry meat: 90% as muscle	-	0.007	AUS	67.0	388	-	-	ND	ND	1	0.04	0%
GC 0650	Rye	-	1.5	NLD	63.0	77	-	-	ND	ND	1	1.83	5%
GC 0654	Wheat	-	1.5	USA	65.0	383	-	-	ND	ND	1	8.84	20%
CM 0654	Wheat bran, unprocessed	3.45	-	USA	65.0	80	-	-	ND	ND	3	4.24	10%
CF 1211	Wheat flour	0.48	-	USA	65.0	365	-	-	ND	ND	3	2.70	7%

CYPERMETHRIN (118) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.040 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
GC 0640	Barley	-	1.5	AUS	19.0	14	-	-	ND	ND	1	1.10	3%
GC 0640	Barley (beer only)	0.04	-	AUS	19.0	12	-	-	ND	ND	3	0.02	0%
PE 0112	Eggs	-	0.006	Thai	17.1	109	-	-	ND	ND	1	0.04	0%
GC 0647	Oats	-	1.5	USA	15.0	62	-	-	ND	ND	1	6.23	20%
PM 0110	Poultry meat: 10% as fat	-	0.048	AUS	19.0	22	-	-	ND	ND	1	0.06	0%
PM 0110	Poultry meat: 90% as muscle	-	0.007	AUS	19.0	201	-	-	ND	ND	1	0.07	0%
GC 0650	Rye	-	1.5	NLD	17.0	37	-	-	ND	ND	1	3.26	8%
GC 0654	Wheat	-	1.5	USA	15.0	151	-	-	ND	ND	1	15.11	40%
CM 0654	Wheat bran, unprocessed	3.45	-	USA	15.0	30	-	-	ND	ND	3	6.83	20%
CF 1211	Wheat flour	0.48	-	AUS	19.0	194	-	-	ND	ND	3	4.91	10%

FLUOPICOLIDE (235) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD = 0.600 mg/kg bw (600 µg/kg bw) Maximum %ARfD: 70%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FB 0269	Grape (incl wine)	–	1.2	FRA	52.2	1087	125	FRA	118	3	2a	30.40	5%
VB 0400	Broccoli	–	0.69	FRA	52.2	537	608	USA	474	3	2a	19.64	3%
VB 0402	Brussels sprouts	–	0.13	FRA	52.2	351	7	FRA	5	1	1	0.87	0%
VB 0041	Cabbage, head	–	4	SAF	55.7	362	771	UNK	540	3	2b	78.00	10%
VB 0404	Cauliflower (head)	–	0.69	UNK	70.1	579	1500	JPN	1500	3	2b	17.10	3%
VS 0624	Celery (whole)	–	14	FRA	52.2	238	700	BEL	462	3	2b	191.10	30%
VL 0464	Chard	–	17	NLD	63.0	569	–	–	ND	ND	ND	ND	–
VL 0469	Chicory leaves (head)	–	17	USA	65.0	40	53	USA	47	3	2b	31.62	5%
VL 0469	Chicory leaves (head)	–	17	USA	65.0	40	100	BEL	85	3	2b	31.62	5%
VL 0467	Chinese cabbage, type pe-tsai	–	17	AUS	67.0	571	1500	JPN	1500	3	2b	434.52	70%
VL 0470	Corn salad	–	17	FRA	52.2	84	–	–	ND	ND	ND	ND	–

Annex 4

FLUOPICOLIDE (235) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD = 0.600 mg/kg bw (600 µg/kg bw) Maximum %ARfD: 70%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VL 0510	Cos lettuce	–	17	JPN	52.6	144	–	–	ND	ND	ND	ND	–
VL 0472	Cress, garden	–	17	AUS	67.0	27	–	–	ND	ND	ND	ND	–
VC 0424	Cucumber	–	0.3	FRA	52.2	348	400	FRA	360	3	2b	6.00	1%
MO 0105	Edible offal (mammalian)	–	0	FRA	52.2	327	–	–	ND	ND	1	0.00	0%
VO 0440	Egg plant	–	0.58	AUS	67.0	487	548	USA	444	3	2a	11.90	2%
PE 0112	Eggs	–	0	Thai	53.5	195	–	–	ND	ND	1	0.00	0%
VL 0476	Endive	–	17	FRA	52.2	339	–	–	ND	ND	ND	ND	–
DF 0269	Grapes, dried (= currants, raisins and sultanas)	–	1.4	USA	65.0	70	–	–	ND	ND	1	1.51	0%
VL 0480	Kale	–	17	NLD	63.0	337	–	–	ND	ND	ND	ND	–
VL 0482	Lettuce, head	–	17	USA	65.0	213	450	JPN	450	3	2b	166.77	30%
VL 0483	Lettuce, leaf	–	17	NLD	63.0	152	160	BEL	144	3	2a	118.68	20%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	–	0	AUS	67.0	104	–	–	ND	ND	1	0.00	0%
VC 0046	Melons, except watermelon	–	0.01	FRA	52.2	1044	700	FRA	420	3	2a	0.36	0%
ML 0106	Milks	0.01	–	USA	65.0	2466	–	–	ND	ND	3	0.38	0%
VL 0485	Mustard greens	–	17	USA	65.0	228	–	–	ND	ND	ND	ND	–
VO 0442	Okra	–	0.58	USA	65.0	235	10	JPN	10	1	1	2.10	0%
VA 0385	Onion, bulb	–	0.58	NLD	63.0	172	140	FRA	126	3	2a	3.90	1%
VA 0387	Onion, Welsh	–	4.5	JPN	52.6	99	100	JPN	100	3	2b	25.52	4%
VO 0444	Peppers, chilli	–	0.58	USA	65.0	90	45	USA	43	3	2a	1.58	0%
VO 0445	Peppers, sweet (incl. pimiento)	–	0.58	FRA	52.2	90	172	UNK	160	3	2b	3.01	1%
PM 0110	Poultry meat	–	0	AUS	67.0	431	–	–	ND	ND	1	0.00	0%
PO 0111	Poultry, edible offal of	–	0	USA	65.0	248	–	–	ND	ND	1	0.00	0%
PF 0111	Poultry, fats	–	0	USA	65.0	43	–	–	ND	ND	1	0.00	0%
VL 0492	Purslane	–	17	NLD	63.0	476	–	–	ND	ND	ND	ND	–
VL 0502	Spinach (bunch)	–	17	NLD	63.0	820	300	JPN	300	3	2a	383.07	60%
VC 0431	Squash, summer (= courgette)	–	0.3	FRA	52.2	351	300	FRA	270	3	2a	5.12	1%
–	Squashes & pumpkins & gourds	–	0.01	–	–	ND	–	–	ND	ND	ND	ND	–
VO 0448	Tomato	–	0.58	FRA	52.2	387	105	FRA	102	3	2a	6.56	1%
JF 0448	Tomato juice	0.048	–	–	–	ND	–	–	ND	ND	3	ND	–

Annex 4

FLUOPICOLIDE (235) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD = 0.600 mg/kg bw (600 µg/kg bw) Maximum %ARfD: 70%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
-	Tomato paste	0.352	–	–	–	ND	–	–	ND	ND	ND	ND	–
VL 0506	Turnip greens	–	17	USA	65.0	353	–	–	ND	ND	ND	ND	–
VL 0473	Watercress	–	17	AUS	67.0	86	–	–	ND	ND	ND	ND	–
VC 0432	Watermelon	–	0.01	USA	65.0	1939	4518	USA	2078	3	2b	0.89	0%
VC 0433	Winter squash (= pumpkin)	–	0.01	USA	65.0	729	1000	JPN	1000	3	2b	0.34	0%

2,6-DICHLOROBENZAMIDE International estimate of short term intake (IESTI) GENERAL POPULATION ARfD = 0.600 mg/kg bw (600 µg/kg bw) Maximum %ARfD: 1%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FB 0269	Grape (incl wine)	–	0.04	FRA	52.2	1087	125	FRA	118	3	2a	1.01	0%
VB 0400	Broccoli	–	0.01	FRA	52.2	537	608	USA	474	3	2a	0.28	0%
VB 0402	Brussels sprouts	–	0.01	FRA	52.2	351	7	FRA	5	1	1	0.07	0%
VB 0041	Cabbage, head	–	0.02	SAF	55.7	362	771	UNK	540	3	2b	0.39	0%
VB 0404	Cauliflower (head)	–	0.01	UNK	70.1	579	1500	JPN	1500	3	2b	0.25	0%
VS 0624	Celery (whole)	–	0.04	FRA	52.2	238	700	BEL	462	3	2b	0.55	0%
VL 0464	Chard	–	0.19	NLD	63.0	569	–	–	ND	ND	ND	ND	–
VL 0469	Chicory leaves (head)	–	0.19	USA	65.0	40	53	USA	47	3	2b	0.35	0%
VL 0469	Chicory leaves (head)	–	0.19	USA	65.0	40	100	BEL	85	3	2b	0.35	0%
VL 0467	Chinese cabbage, type pe-tsai	–	0.19	AUS	67.0	571	1500	JPN	1500	3	2b	4.86	1%
VL 0470	Corn salad	–	0.19	FRA	52.2	84	–	–	ND	ND	ND	ND	–
VL 0510	Cos lettuce	–	0.19	JPN	52.6	144	–	–	ND	ND	ND	ND	–
VL 0472	Cress, garden	–	0.19	AUS	67.0	27	–	–	ND	ND	ND	ND	–
VC 0424	Cucumber	–	0.01	FRA	52.2	348	400	FRA	360	3	2b	0.20	0%
MO 0105	Edible offal (mammalian)	–	0	FRA	52.2	327	–	–	ND	ND	1	0.00	0%

Annex 4

2,6-DICHLOROBENZAMIDE International estimate of short term intake (IESTI) ARfD = 0.600 mg/kg bw (600 µg/kg bw)

GENERAL POPULATION Maximum %ARfD: 1%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VO 0440	Egg plant	–	0.01	AUS	67.0	487	548	USA	444	3	2a	0.21	0%
PE 0112	Eggs	–	0	Thai	53.5	195	–	–	ND	ND	1	0.00	0%
VL 0476	Endive	–	0.19	FRA	52.2	339	–	–	ND	ND	ND	ND	–
DF 0269	Grapes, dried (= currants, raisins and sultanas)	–	0.06	USA	65.0	70	–	–	ND	ND	1	0.06	0%
VL 0480	Kale	–	0.19	NLD	63.0	337	–	–	ND	ND	ND	ND	–
VL 0482	Lettuce, head	–	0.19	USA	65.0	213	450	JPN	450	3	2b	1.86	0%
VL 0483	Lettuce, leaf	–	0.19	NLD	63.0	152	160	BEL	144	3	2a	1.33	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	–	0	AUS	67.0	104	–	–	ND	ND	1	0.00	0%
VC 0046	Melons, except watermelon	–	0.01	FRA	52.2	1044	700	FRA	420	3	2a	0.36	0%
ML 0106	Milks	0	–	USA	65.0	2466	–	–	ND	ND	3	0.00	0%
VL 0485	Mustard greens	–	0.19	USA	65.0	228	–	–	ND	ND	ND	ND	–
VO 0442	Okra	–	0.01	USA	65.0	235	10	JPN	10	1	1	0.04	0%
VA 0385	Onion, bulb	–	0.01	NLD	63.0	172	140	FRA	126	3	2a	0.07	0%
VA 0387	Onion, Welsh	–	0.01	JPN	52.6	99	100	JPN	100	3	2b	0.06	0%
VO 0444	Peppers, chilli	–	0.01	USA	65.0	90	45	USA	43	3	2a	0.03	0%
VO 0445	Peppers, sweet (incl. pimiento)	–	0.01	FRA	52.2	90	172	UNK	160	3	2b	0.05	0%
PM 0110	Poultry meat	–	0	AUS	67.0	431	–	–	ND	ND	1	0.00	0%
PO 0111	Poultry, edible offal of	–	0	USA	65.0	248	–	–	ND	ND	1	0.00	0%
PF 0111	Poultry, fats	–	0	USA	65.0	43	–	–	ND	ND	1	0.00	0%
VL 0492	Purslane	–	0.19	NLD	63.0	476	–	–	ND	ND	ND	ND	–
VL 0502	Spinach (bunch)	–	0.19	NLD	63.0	820	300	JPN	300	3	2a	4.28	1%
VC 0431	Squash, summer (= courgette)	–	0.01	FRA	52.2	351	300	FRA	270	3	2a	0.17	0%
-	Squashes & pumpkins & gourds	–	0.01	–	–	ND	–	–	ND	ND	ND	ND	–
VO 0448	Tomato	–	0.01	FRA	52.2	387	105	FRA	102	3	2a	0.11	0%
JF 0448	Tomato juice	0.01	–	–	–	ND	–	–	ND	ND	3	ND	–
–	Tomato paste	0.01	–	–	–	ND	–	–	ND	ND	ND	ND	–
VL 0506	Turnip greens	–	0.19	USA	65.0	353	–	–	ND	ND	ND	ND	–
VL 0473	Watercress	–	0.19	AUS	67.0	86	–	–	ND	ND	ND	ND	–
VC 0432	Watermelon	–	0.01	USA	65.0	1939	4518	USA	2078	3	2b	0.89	0%

Annex 4

2,6-DICHLOROBENZAMIDE International estimate of short term intake (IESTI) ARfD = 0.600 mg/kg bw (600 µg/kg bw)

GENERAL POPULATION Maximum %ARfD: 1%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VC 0433	Winter squash (= pumpkin)	–	0.01	USA	65.0	729	1000	JPN	1000	3	2b	0.34	0%

2,6-DICHLOROBENZAMIDE International estimate of short term intake (IESTI) ARfD = 0.600 mg/kg bw (600 µg/kg bw)

CHILDREN UP TO 6 YEARS Maximum %ARfD: 2%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
FB 0269	Grape (incl wine)	–	0.04	JPN	15.9	388	125	FRA	118	3	2a	1.57	0%
VB 0400	Broccoli	–	0.01	FRA	18.9	254	608	USA	474	3	2b	0.40	0%
VB 0402	Brussels sprouts	–	0.01	NLD	17.0	213	7	FRA	5	1	1	0.13	0%
VB 0041	Cabbage, head	–	0.02	SAF	14.2	220	771	UNK	540	3	2b	0.93	0%
VB 0404	Cauliflower (head)	–	0.01	NLD	17.0	209	1500	JPN	1500	3	2b	0.37	0%
VS 0624	Celery (whole)	–	0.04	FRA	18.9	157	700	BEL	462	3	2b	1.00	0%
VL 0464	Chard	–	0.19	FRA	18.9	47	–	–	ND	ND	ND	ND	–
VL 0469	Chicory leaves (head)	–	0.19	USA	15.0	19	53	USA	47	3	2b	0.71	0%
VL 0469	Chicory leaves (head)	–	0.19	USA	15.0	19	100	BEL	85	3	2b	0.71	0%
VL 0467	Chinese cabbage, type pe-tsai	–	0.19	JPN	15.9	147	1500	JPN	1500	3	2b	5.26	1%
VL 0470	Corn salad	–	0.19	FRA	18.9	40	–	–	ND	ND	ND	ND	–
VL 0510	Cos lettuce	–	0.19	–	–	ND	–	–	ND	ND	ND	ND	–
VL 0472	Cress, garden	–	0.19	–	–	ND	–	–	ND	ND	ND	ND	–
VC 0424	Cucumber	–	0.01	NLD	17.0	162	400	FRA	360	3	2b	0.29	0%
MO 0105	Edible offal (mammalian)	–	0	FRA	18.9	86	–	–	ND	ND	1	0.00	0%
VO 0440	Egg plant	–	0.01	JPN	15.9	219	548	USA	444	3	2b	0.41	0%
PE 0112	Eggs	–	0	Thai	17.1	109	–	–	ND	ND	1	0.00	0%
VL 0476	Endive	–	0.19	NLD	17.0	212	–	–	ND	ND	ND	ND	–
DF 0269	Grapes, dried (= currants, raisins and	–	0.06	USA	15.0	59	–	–	ND	ND	1	0.24	0%

Annex 4

2,6-DICHLOROBENZAMIDE International estimate of short term intake (IESTI) ARfD = 0.600 mg/kg bw (600 µg/kg bw)

CHILDREN UP TO 6 YEARS Maximum %ARfD: 2%

				Large portion diet			Unit weight						
Codex Code	Commodity	STMR or STMR-P mg/kg	HR or HR-P mg/kg	Country	Body weight (kg)	Large portion, g/person	Unit weight, g	Country	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
	sultanas)												
VL 0480	Kale	–	0.19	NLD	17.0	149	–	–	ND	ND	ND	ND	–
VL 0482	Lettuce, head	–	0.19	Thai	17.1	117	450	JPN	450	3	2b	3.89	1%
VL 0483	Lettuce, leaf	–	0.19	NLD	17.0	102	160	BEL	144	3	2b	3.42	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	–	0	AUS	19.0	52	–	–	ND	ND	1	0.00	0%
VC 0046	Melons, except watermelon	–	0.01	FRA	18.9	597	700	FRA	420	3	2a	0.76	0%
ML 0106	Milks	0	–	USA	15.0	1286	–	–	ND	ND	3	0.00	0%
VL 0485	Mustard greens	–	0.19	USA	15.0	53	–	–	ND	ND	ND	ND	–
VO 0442	Okra	–	0.01	USA	15.0	203	10	JPN	10	1	1	0.14	0%
VA 0385	Onion, bulb	–	0.01	NLD	17.0	86	140	FRA	126	3	2b	0.15	0%
VA 0387	Onion, Welsh	–	0.01	JPN	15.9	49	100	JPN	100	3	2b	0.09	0%
VO 0444	Peppers, chilli	–	0.01	AUS	19.0	31	45	USA	43	3	2b	0.05	0%
VO 0445	Peppers, sweet (incl. pimiento)	–	0.01	Thai	17.1	71	172	UNK	160	3	2b	0.12	0%
PM 0110	Poultry meat	–	0	AUS	19.0	224	–	–	ND	ND	1	0.00	0%
PO 0111	Poultry, edible offal of	–	0	FRA	18.9	99	–	–	ND	ND	1	0.00	0%
PF 0111	Poultry, fats	–	0	USA	15.0	16	–	–	ND	ND	1	0.00	0%
VL 0492	Purslane	–	0.19	–	–	ND	–	–	ND	ND	ND	ND	–
VL 0502	Spinach (bunch)	–	0.19	SAF	14.2	420	300	JPN	300	3	2a	13.65	2%
VC 0431	Squash, summer (= courgette)	–	0.01	AUS	19.0	219	300	FRA	270	3	2b	0.35	0%
-	Squashes & pumpkins & gourds	–	0.01	–	–	ND	–	–	ND	ND	ND	ND	–
VO 0448	Tomato	–	0.01	FRA	18.9	215	105	FRA	102	3	2a	0.22	0%
JF 0448	Tomato juice	0.01	–	–	–	ND	–	–	ND	ND	3	ND	–
–	Tomato paste	0.01	–	–	–	ND	–	–	ND	ND	ND	ND	–
VL 0506	Turnip greens	–	0.19	USA	15.0	90	–	–	ND	ND	ND	ND	–
VL 0473	Watercress	–	0.19	AUS	19.0	6	–	–	ND	ND	ND	ND	–
VC 0432	Watermelon	–	0.01	AUS	19.0	1473	4518	USA	2078	3	2b	2.33	0%
VC 0433	Winter squash (= pumpkin)	–	0.01	USA	15.0	169	1000	JPN	1000	3	2b	0.34	0%

HALOXYFOP (194) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.080 mg/kg bw (80 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
FP 0226	Apple	-	0	USA	65.0	1348	110	FRA	100	3	2a	0.00	0%
FI 0327	Banana	-	0	FRA	52.2	714	900	FRA	612	3	2a	0.00	0%
VD 0071	Beans (dry)	0.335	-	FRA	52.2	360	-	-	ND	ND	3	2.31	3%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.26	FRA	52.2	261	-	-	ND	ND	1	1.30	2%
ML 0812	Cattle milk	0.033	-	FRA	52.2	2516	-	-	ND	ND	3	1.59	2%
FM 0812	Cattle milk fat	0.87	-	NLD	63.0	79	-	-	ND	ND	3	1.10	1%
PE 0840	Chicken eggs	-	0.05	FRA	52.2	383	-	-	ND	ND	1	0.37	0%
VD 0524	Chick-pea (dry)	0.02	-	USA	65.0	205	-	-	ND	ND	3	0.06	0%
SB 0716	Coffee beans	0	-	FRA	52.2	117	-	-	ND	ND	3	0.00	0%
SO 0691	Cotton seed	0.1	-	USA	65.0	3	-	-	ND	ND	3	0.01	0%
MO 0105	Edible offal (mammalian)	-	1.42	FRA	52.2	327	-	-	ND	ND	1	8.90	10%
PE 0112	Eggs	-	0.05	Thai	53.5	195	-	-	ND	ND	1	0.18	0%
VP 0528	Garden pea (green pods & immature seeds) DNA	-	0.53	USA	65.0	244	-	-	ND	ND	1	1.99	2%
FB 0269	Grape (incl wine)	-	0	FRA	52.2	1087	125	FRA	118	3	2a	0.00	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.33	AUS	67.0	104	-	-	ND	ND	1	0.51	1%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.041	AUS	67.0	417	-	-	ND	ND	1	0.26	0%
ML 0106	Milks	0.033	-	USA	65.0	2466	-	-	ND	ND	3	1.25	2%
VA 0385	Onion, bulb	-	0.12	NLD	63.0	172	140	FRA	126	3	2a	0.81	1%
VA 0385	Onion, bulb	-	0.12	NLD	63.0	172	115	BEL	106	3	2a	0.73	1%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0	FRA	52.2	1044	190	FRA	137	3	2a	0.00	0%
FS 0247	Peach	-	0	SAF	55.7	685	110	FRA	99	3	2a	0.00	0%
VD 0072	Peas (dry)	0.04	-	FRA	52.2	356	-	-	ND	ND	3	0.27	0%
VP 0063	Peas (green pods & immature seeds)	-	0.53	JPN	52.6	63	-	-	ND	ND	1	0.63	1%
VP 0064	Peas, shelled (immature seeds)	-	0.75	FRA	52.2	435	-	-	ND	ND	1	6.25	8%
PM 0110	Poultry meat: 10% as fat	-	0.52	AUS	67.0	43	-	-	ND	ND	1	0.33	0%
PM 0110	Poultry meat: 90% as muscle	-	0.11	AUS	67.0	388	-	-	ND	ND	1	0.64	1%
PO 0111	Poultry, edible offal of	-	0.61	USA	65.0	248	-	-	ND	ND	1	2.32	3%
OR 0495	Rape seed oil, edible	0.16	-	AUS	67.0	65	-	-	ND	ND	3	0.16	0%

Annex 4

HALOXYFOP (194) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.080 mg/kg bw (80 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
VD 0541	Soya bean (dry)	0.055	-	JPN	52.6	159	-	-	ND	ND	3	0.17	0%
OR 0541	Soya bean oil, refined	0.041	-	USA	65.0	98	-	-	ND	ND	3	0.06	0%
SO 0702	Sunflower seed	0.05	-	USA	65.0	193	-	-	ND	ND	3	0.15	0%

HALOXYFOP (194) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.080 mg/kg bw (80 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
FP 0226	Apple	-	0	USA	15.0	679	110	FRA	100	3	2a	0.00	0%
FI 0327	Banana	-	0	FRA	18.9	477	900	FRA	612	3	2b	0.00	0%
VD 0071	Beans (dry)	0.335	-	AUS	19.0	222	-	-	ND	ND	3	3.91	5%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.26	FRA	18.9	215	-	-	ND	ND	1	2.96	4%
ML 0812	Cattle milk	0.033	-	AUS	19.0	1450	-	-	ND	ND	3	2.52	3%
FM 0812	Cattle milk fat	0.87	-	NLD	17.0	35	-	-	ND	ND	3	1.77	2%
PE 0840	Chicken eggs	-	0.05	FRA	18.9	201	-	-	ND	ND	1	0.53	1%
VD 0524	Chick-pea (dry)	0.02	-	USA	15.0	34	-	-	ND	ND	3	0.05	0%
SB 0716	Coffee beans	0	-	FRA	18.9	70	-	-	ND	ND	3	0.00	0%
SO 0691	Cotton seed	0.1	-	USA	15.0	1	-	-	ND	ND	3	0.01	0%
MO 0105	Edible offal (mammalian)	-	1.42	FRA	18.9	86	-	-	ND	ND	1	6.49	8%
PE 0112	Eggs	-	0.05	Thai	17.1	109	-	-	ND	ND	1	0.32	0%
VP 0528	Garden pea (green pods & immature seeds)	-	0.53	USA	15.0	109	-	-	ND	ND	1	3.86	5%
FB 0269	Grape (incl wine)	-	0	JPN	15.9	388	125	FRA	118	3	2a	0.00	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.33	AUS	19.0	52	-	-	ND	ND	1	0.91	1%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.041	AUS	19.0	208	-	-	ND	ND	1	0.45	1%

HALOXYFOP (194) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.080 mg/kg bw (80 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	0.033	-	USA	15.0	1286	-	-	ND	ND	3	2.83	4%
VA 0385	Onion, bulb	-	0.12	NLD	17.0	86	140	FRA	126	3	2b	1.81	2%
VA 0385	Onion, bulb	-	0.12	NLD	17.0	86	115	BEL	106	3	2b	1.81	2%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0	UNK	14.5	495	190	FRA	137	3	2a	0.00	0%
FS 0247	Peach	-	0	AUS	19.0	315	110	FRA	99	3	2a	0.00	0%
VD 0072	Peas (dry)	0.04	-	USA	15.0	86	-	-	ND	ND	3	0.23	0%
VP 0063	Peas (green pods & immature seeds)	-	0.53	JPN	15.9	48	-	-	ND	ND	1	1.59	2%
VP 0064	Peas, shelled (immature seeds)	-	0.75	UNK	14.5	174	-	-	ND	ND	1	9.00	10%
PM 0110	Poultry meat: 10% as fat	-	0.52	AUS	19.0	22	-	-	ND	ND	1	0.61	1%
PM 0110	Poultry meat: 90% as muscle	-	0.11	AUS	19.0	201	-	-	ND	ND	1	1.17	1%
PO 0111	Poultry, edible offal of	-	0.61	FRA	18.9	99	-	-	ND	ND	1	3.21	4%
OR 0495	Rape seed oil, edible	0.16	-	AUS	19.0	18	-	-	ND	ND	3	0.15	0%
VD 0541	Soya bean (dry)	0.055	-	JPN	15.9	88	-	-	ND	ND	3	0.31	0%
OR 0541	Soya bean oil, refined	0.041	-	USA	15.0	35	-	-	ND	ND	3	0.10	0%
SO 0702	Sunflower seed	0.05	-	USA	15.0	24	-	-	ND	ND	3	0.08	0%

INDOXACARB (216) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 60%

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
FS 0240	Apricot	-	0.64	FRA	52.2	369	35	USA	34	3	2a	5.34	5%
FS 0013	Cherries	-	0.64	FRA	52.2	360	5	JPN	5	1	1	4.42	4%
VD 0527	Cowpea (dry)	0.02	-	USA	65.0	205	-	-	ND	ND	3	0.06	0%
FB 0265	Cranberries	-	0.69	USA	65.0	229	-	-	ND	ND	ND	ND	-
VC 0424	Cucumber	-	0.39	FRA	52.2	348	400	FRA	360	3	2b	7.80	8%
MO 0105	Edible offal (mammalian)	-	0.03	FRA	52.2	327	-	-	ND	ND	1	0.19	0%

Annex 4

INDOXACARB (216) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 60%

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
PE 0112	Eggs	-	0.02	Thai	53.5	195	-	-	ND	ND	1	0.07	0%
VC 0425	Gherkin	-	0.39	NLD	63.0	96	116	USA	81	3	2a	1.60	2%
VL 0483	Lettuce, leaf	-	8.4	NLD	63.0	152	160	BEL	144	3	2a	58.64	60%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	1.07	AUS	67.0	104	-	-	ND	ND	1	1.66	2%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.039	AUS	67.0	417	-	-	ND	ND	1	0.24	0%
VC 0046	Melons, except watermelon	-	0.2	FRA	52.2	1044	700	JPN	700	3	2a	9.36	9%
ML 0106	Milks	0.037	-	USA	65.0	2466	-	-	ND	ND	3	1.40	1%
FS 0245	Nectarine	-	0.64	FRA	52.2	604	136	USA	125	3	2a	10.48	10%
FS 0247	Peach	-	0.64	SAF	55.7	685	150	JPN	150	3	2a	11.32	10%
FS 0014	Plum (incl dried)	-	0.64	Thai	53.5	480	66	USA	62	3	2a	7.23	7%
DF 0014	Plum, dried (prunes)	-	2.6	USA	65.0	303	6	FRA	5	1	1	12.12	10%
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	AUS	67.0	388	-	-	ND	ND	1	0.00	0%
PO 0111	Poultry, edible offal of	-	0	USA	65.0	248	-	-	ND	ND	1	0.00	0%
VC 0431	Squash, summer (= courgette)	-	0.39	FRA	52.2	351	300	FRA	270	3	2a	6.66	7%
VC 0432	Watermelon	-	0.02	USA	65.0	1939	4518	USA	2078	3	2b	1.79	2%
VC 0433	Winter squash (= pumpkin)	-	0.02	USA	65.0	729	1000	JPN	1000	3	2b	0.67	1%

INDOXACARB (216) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 150%

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 0240	Apricot	-	0.64	AUS	19.0	414	35	USA	34	3	2a	16.22	20%
VC 0423	Chayote	-	0.39	AUS	19.0	105	-	-	ND	ND	ND	ND	-

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INDOXACARB (216) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.100 mg/kg bw (100 µg/kg bw) Maximum %ARfD: 150%

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 0013	Cherries	-	0.64	AUS	19.0	250	5	JPN	5	1	1	8.42	8%
VD 0527	Cowpea (dry)	0.02	-	USA	15.0	43	-	-	ND	ND	3	0.06	0%
FB 0265	Cranberries	-	0.69	USA	15.0	102	-	-	ND	ND	ND	ND	-
VC 0424	Cucumber	-	0.39	NLD	17.0	162	301	USA	286	3	2b	11.15	10%
MO 0105	Edible offal (mammalian)	-	0.03	FRA	18.9	86	-	-	ND	ND	1	0.14	0%
PE 0112	Eggs	-	0.02	Thai	17.1	109	-	-	ND	ND	1	0.13	0%
VC 0425	Gherkin	-	0.39	NLD	17.0	56	116	USA	81	3	2b	3.83	4%
VL 0483	Lettuce, leaf	-	8.4	NLD	17.0	102	160	BEL	144	3	2b	151.20	150%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	1.07	AUS	19.0	52	-	-	ND	ND	1	2.93	3%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.039	AUS	19.0	208	-	-	ND	ND	1	0.43	0%
VC 0046	Melons, except watermelon	-	0.2	FRA	18.9	597	1000	USA	630	3	2b	18.95	20%
ML 0106	Milks	0.037	-	USA	15.0	1286	-	-	ND	ND	3	3.17	3%
FS 0245	Nectarine	-	0.64	AUS	19.0	302	136	USA	125	3	2a	18.61	20%
FS 0247	Peach	-	0.64	AUS	19.0	315	150	JPN	150	3	2a	20.73	20%
FS 0014	Plum (incl dried)	-	0.64	Thai	17.1	377	66	USA	62	3	2a	18.75	20%
DF 0014	Plum, dried (prunes)	-	2.6	AUS	19.0	170	6	FRA	5	1	1	23.27	20%
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	AUS	19.0	201	-	-	ND	ND	1	0.00	0%
PO 0111	Poultry, edible offal of	-	0	FRA	18.9	99	-	-	ND	ND	1	0.00	0%
VC 0431	Squash, summer (= courgette)	-	0.39	AUS	19.0	219	300	FRA	270	3	2b	13.48	10%
VC 0432	Watermelon	-	0.02	AUS	19.0	1473	4518	USA	2078	3	2b	4.65	5%
VC 0433	Winter squash (= pumpkin)	-	0.02	USA	15.0	169	1000	JPN	1000	3	2b	0.67	1%

Annex 4

METHOXYFENOZIDE (209) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.900 mg/kg bw (900 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 0003	Mandarin + mandarin-like hybrid	-	0.05	FRA	52.2	639	-	-	ND	ND	ND	ND	-
FI 0326	Avocado	-	0.41	FRA	52.2	435	201	USA	151	3	2a	5.78	1%
VD 0071	Beans (dry)	0.05	-	FRA	52.2	360	-	-	ND	ND	3	0.35	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.99	FRA	52.2	261	-	-	ND	ND	ND	ND	-
VP 0062	Beans, shelled (immature seeds)	-	0.18	FRA	52.2	400	-	-	ND	ND	ND	ND	-
FB 0020	Blueberries	-	2	AUS	67.0	158	-	-	ND	ND	ND	ND	-
VR 0577	Carrot	-	0.31	FRA	52.2	348	100	FRA	89	3	2a	3.12	0%
MF 0812	Cattle fat	-	0.162	USA	65.0	60	-	-	ND	ND	1	0.15	0%
VD 0527	Cowpea (dry), stated as black-eyed pea VD 4467	0.56	-	NLD	63.0	28	-	-	ND	ND	3	0.25	0%
MO 0105	Edible offal (mammalian)	-	0.057	FRA	52.2	327	-	-	ND	ND	1	0.36	0%
MF 0814	Goat fat	-	0.162	USA	65.0	18	-	-	ND	ND	1	0.05	0%
MM 0095	Meat from mammals other than marine mammals	-	0.052	AUS	67.0	521	-	-	ND	ND	1	0.40	0%
ML 0106	Milks	0.03	-	USA	65.0	2466	-	-	ND	ND	3	1.14	0%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.05	FRA	52.2	1044	190	FRA	137	3	2a	1.26	0%
FI 0350	Papaya	-	0.33	USA	65.0	567	304	USA	204	3	2a	4.95	1%
OR 0697	Peanut oil, edible	0.029	-	AUS	67.0	54	-	-	ND	ND	3	0.02	0%
SO 0697	Peanut, shelled	-	0.016	FRA	52.2	135	-	-	ND	ND	3	ND	-
VP 0064	Peas, shelled (immature seeds)	-	0.18	FRA	52.2	435	-	-	ND	ND	ND	ND	-
MF 0818	Pig fat	-	0.162	AUS	67.0	144	-	-	ND	ND	1	0.35	0%
VR 0494	Radish	-	0.12	FRA	52.2	192	7	FRA	6	1	1	0.44	0%
FB 0275	Strawberry	-	1.2	FRA	52.2	531	14	FRA	13	1	1	12.22	1%
VR 0596	Sugar beet	-	0.18	-	-	ND	-	-	ND	ND	ND	ND	-
VR 0508	Sweet potato	-	0.012	USA	65.0	536	130	USA	105	3	2a	0.14	0%

Annex 4

METHOXYFENOZIDE (209) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.900 mg/kg bw (900 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
FC 0003	Mandarin + mandarin-like hybrid	-	0.05	FRA	18.9	277	-	-	ND	ND	ND	ND	-
FI 0326	Avocado	-	0.41	FRA	18.9	202	201	USA	151	3	2a	10.93	1%
VD 0071	Beans (dry)	0.05	-	AUS	19.0	222	-	-	ND	ND	3	0.58	0%
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	-	0.99	FRA	18.9	215	-	-	ND	ND	ND	ND	-
VP 0062	Beans, shelled (immature seeds)	-	0.18	FRA	18.9	220	-	-	ND	ND	ND	ND	-
FB 0020	Blueberries	-	2	USA	15.0	21	-	-	ND	ND	ND	ND	-
VR 0577	Carrot	-	0.31	FRA	18.9	196	100	FRA	89	3	2a	6.13	1%
MF 0812	Cattle fat	-	0.162	USA	15.0	27	-	-	ND	ND	1	0.29	0%
VD 0527	Cowpea (dry), stated as black-eyed pea VD 4467	0.56	-	NLD	17.0	28	-	-	ND	ND	3	0.92	0%
MO 0105	Edible offal (mammalian)	-	0.057	FRA	18.9	86	-	-	ND	ND	1	0.26	0%
MF 0814	Goat fat	-	0.162	USA	15.0	3	-	-	ND	ND	1	0.03	0%
MM 0095	Meat from mammals other than marine mammals	-	0.052	AUS	19.0	261	-	-	ND	ND	1	0.71	0%
ML 0106	Milks	0.03	-	USA	15.0	1286	-	-	ND	ND	3	2.57	0%
FC 0004	Orange, sweet, sour + orange-like hybrid	-	0.05	UNK	14.5	495	190	FRA	137	3	2a	2.65	0%
FI 0350	Papaya	-	0.33	USA	15.0	240	304	USA	204	3	2a	14.25	2%
OR 0697	Peanut oil, edible	0.029	-	AUS	19.0	9	-	-	ND	ND	3	0.01	0%
SO 0697	Peanut, shelled	-	0.016	USA	15.0	78	-	-	ND	ND	3	ND	-
VP 0064	Peas, shelled (immature seeds)	-	0.18	UNK	14.5	174	-	-	ND	ND	ND	ND	-
MF 0818	Pig fat	-	0.162	FRA	18.9	65	-	-	ND	ND	1	0.56	0%
VR 0494	Radish	-	0.12	FRA	18.9	112	7	FRA	6	1	1	0.71	0%
FB 0275	Strawberry	-	1.2	FRA	18.9	354	14	FRA	13	1	1	22.45	2%
VR 0596	Sugar beet	-	0.18	-	-	ND	-	-	ND	ND	ND	ND	-
VR 0508	Sweet potato	-	0.012	USA	15.0	166	130	USA	105	3	2a	0.30	0%

Annex 4

PHORATE (112) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.003 mg/kg bw (3 µg/kg bw) Maximum %ARfD: 80%

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 (using HR for French fries)	-	0.1026	FRA	52.2	639	216	UNK	216	3	2a	2.10	70%
VR 0589	Potato (using HR for potatoes, microwaved with peel)	-	0.0972	FRA	52.2	639	216	UNK	216	3	2a	1.99	70%

PHORATE (112) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.003 mg/kg bw (3 µg/kg bw) Maximum %ARfD: 190%

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 (using HR for French fries)	-	0.1026	SAF	14.2	300	216	UNK	216	3	2a	5.29	180%
VR 0589	Potato (using HR for potatoes, microwaved with peel)	-	0.0972	SAF	14.2	300	216	UNK	216	3	2a	5.01	170%

PROCHLORAZ (142) International estimate of short term intake (IESTI) for GENERAL POPULATION ARfD= 0.100 mg/kg bw (100 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
VO 0450	Mushrooms	-	1.4	FRA	52.2	243	21	UNK	20	1	1	6.52	7%

PROCHLORAZ (142) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 0.100 mg/kg bw (100 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
VO 0450	Mushrooms	-	1.4	FRA	18.9	157	21	UNK	20	1	1	11.66	10%

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for GENERAL POPULATION (EXCEPT WOMEN OF CHILD-BEARING AGE) ARfD= 1.000 mg/kg bw (1000 µg/kg bw) Maximum %ARfD: 0.18%

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 0596	Sugar beet	0.05	-	-	-	ND	-	-	ND	ND	ND	ND	-
VD 0520	Bambara groundnut (dry seed)	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0640	Barley	0.035	-	NLD	63.0	378	-	-	ND	ND	3	0.21	0.02%
VD 0071	Beans (dry)	0.05	-	FRA	52.2	360	-	-	ND	ND	3	0.35	0.03%
VD 0523	Broad bean (dry)	0.05	-	AUS	67.0	139	-	-	ND	ND	3	0.10	0.01%
VD 0524	Chick-pea (dry)	0.05	-	USA	65.0	205	-	-	ND	ND	3	0.16	0.02%
VD 0526	Common bean (dry)	0.05	-	FRA	52.2	360	-	-	ND	ND	3	0.35	0.03%
VD 0526	Common bean (dry), stated as kidney bean VD 4503	0.05	-	Thai	53.5	82	-	-	ND	ND	3	0.08	0.01%
VD 0527	Cowpea (dry)	0.05	-	USA	65.0	205	-	-	ND	ND	3	0.16	0.02%
VD 0527	Cowpea (dry), stated as black-eyed pea VD 4467	0.05	-	NLD	63.0	28	-	-	ND	ND	3	0.02	0.00%
VD 0561	Field pea (dry)	0.05	-	FRA	52.2	356	-	-	ND	ND	3	0.34	0.03%
VD 0561	Field pea (dry), stated as pea (dry), VD 4511	0.05	-	NLD	63.0	252	-	-	ND	ND	3	0.20	0.02%
MO 0098	Kidney of cattle, goats, pigs and sheep	-	0.15	USA	65.0	788	-	-	ND	ND	1	1.82	0.18%
VD 0533	Lentil (dry)	0.05	-	FRA	52.2	614	-	-	ND	ND	3	0.59	0.06%

Annex 4

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for ARfD= 1.000 mg/kg bw (1000 µg/kg bw)

GENERAL POPULATION (EXCEPT WOMEN OF CHILD-BEARING AGE) Maximum %ARfD: 0.18%

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 0534	Lima bean (dry)	0.05	-	USA	65.0	202	-	-	ND	ND	3	0.16	0.02%
MO 0099	Liver of cattle, goats, pigs and sheep	-	0.23	USA	65.0	380	-	-	ND	ND	1	1.34	0.13%
VD 0545	Lupin (dry)	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.02	AUS	67.0	104	-	-	ND	ND	1	0.03	0.00%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.01	AUS	67.0	417	-	-	ND	ND	1	0.06	0.01%
ML 0106	Milks	0.004	-	USA	65.0	2466	-	-	ND	ND	3	0.15	0.02%
VD 0536	Mung bean (dry)	0.05	-	Thai	53.5	80	-	-	ND	ND	3	0.08	0.01%
GC 0647	Oats	0.01	-	USA	65.0	175	-	-	ND	ND	ND	ND	-
SO 0697	Peanut, shelled	0.01	-	FRA	52.2	135	-	-	ND	ND	3	0.03	0.00%
VD 0072	Peas (dry)	0.05	-	FRA	52.2	356	-	-	ND	ND	3	0.34	0.03%
VD 0537	Pigeon pea	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
SO 0495	Rape seed	0.02	-	-	-	ND	-	-	ND	ND	3	ND	-
OR 0495	Rape seed oil, edible	0.014	-	AUS	67.0	65	-	-	ND	ND	3	0.01	0.00%
GC 0650	Rye	0.01	-	FRA	52.2	161	-	-	ND	ND	3	0.03	0.00%
GC 0653	Triticale	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0654	Wheat	0.02	-	FRA	52.2	703	-	-	ND	ND	ND	ND	-
CM 0654	Wheat bran, unprocessed	0.048	-	USA	65.0	80	-	-	ND	ND	ND	ND	-
CF 1211	Wheat flour	0.008	-	FRA	52.2	479	-	-	ND	ND	ND	ND	-
CF 1210	Wheat germ	0.04	-	FRA	52.2	174	-	-	ND	ND	3	0.13	0.01%

Annex 4

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for WOMEN OF CHILD-BEARING AGE ARfD= 0.010 mg/kg bw (10 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	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
VR 0596	Sugar beet	0.05	-	-	-	ND	-	-	ND	ND	ND	ND	-
VD 0520	Bambara groundnut (dry seed)	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0640	Barley	0.035	-	NLD	63.0	378	-	-	ND	ND	3	0.21	2%
VD 0071	Beans (dry)	0.05	-	FRA	52.2	360	-	-	ND	ND	3	0.35	3%
VD 0523	Broad bean (dry)	0.05	-	AUS	67.0	139	-	-	ND	ND	3	0.10	1%
VD 0524	Chick-pea (dry)	0.05	-	USA	65.0	205	-	-	ND	ND	3	0.16	2%
VD 0526	Common bean (dry)	0.05	-	FRA	52.2	360	-	-	ND	ND	3	0.35	3%
VD 0526	Common bean (dry), stated as kidney bean VD 4503	0.05	-	Thai	53.5	82	-	-	ND	ND	3	0.08	1%
VD 0527	Cowpea (dry)	0.05	-	USA	65.0	205	-	-	ND	ND	3	0.16	2%
VD 0527	Cowpea (dry), stated as black-eyed pea VD 4467	0.05	-	NLD	63.0	28	-	-	ND	ND	3	0.02	0%
VD 0561	Field pea (dry)	0.05	-	FRA	52.2	356	-	-	ND	ND	3	0.34	3%
VD 0561	Field pea (dry), stated as pea (dry), VD 4511	0.05	-	NLD	63.0	252	-	-	ND	ND	3	0.20	2%
MO 0098	Kidney of cattle, goats, pigs and sheep	-	0.15	USA	65.0	788	-	-	ND	ND	1	1.82	20%
VD 0533	Lentil (dry)	0.05	-	FRA	52.2	614	-	-	ND	ND	3	0.59	6%
VD 0534	Lima bean (dry)	0.05	-	USA	65.0	202	-	-	ND	ND	3	0.16	2%
MO 0099	Liver of cattle, goats, pigs and sheep	-	0.23	USA	65.0	380	-	-	ND	ND	1	1.34	10%
VD 0545	Lupin (dry)	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
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	-	0.01	AUS	67.0	417	-	-	ND	ND	1	0.06	1%
ML 0106	Milks	0.004	-	USA	65.0	2466	-	-	ND	ND	3	0.15	2%
VD 0536	Mung bean (dry)	0.05	-	Thai	53.5	80	-	-	ND	ND	3	0.08	1%
GC 0647	Oats	0.01	-	USA	65.0	175	-	-	ND	ND	ND	ND	-
SO 0697	Peanut, shelled	0.01	-	FRA	52.2	135	-	-	ND	ND	3	0.03	0%
VD 0072	Peas (dry)	0.05	-	FRA	52.2	356	-	-	ND	ND	3	0.34	3%
VD 0537	Pigeon pea	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
SO 0495	Rape seed	0.02	-	-	-	ND	-	-	ND	ND	3	ND	-
OR 0495	Rape seed oil, edible	0.014	-	AUS	67.0	65	-	-	ND	ND	3	0.01	0%

Annex 4

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for WOMEN OF CHILD-BEARING AGE ARfD= 0.010 mg/kg bw (10 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
GC 0650	Rye	0.01	-	FRA	52.2	161	-	-	ND	ND	3	0.03	0%
GC 0653	Triticale	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0654	Wheat	0.02	-	FRA	52.2	703	-	-	ND	ND	ND	ND	-
CM 0654	Wheat bran, unprocessed	0.048	-	USA	65.0	80	-	-	ND	ND	ND	ND	-
CF 1211	Wheat flour	0.008	-	FRA	52.2	479	-	-	ND	ND	ND	ND	-
CF 1210	Wheat germ	0.04	-	FRA	52.2	174	-	-	ND	ND	3	0.13	1%

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 1.000 mg/kg bw (1000 µg/kg bw) Maximum %ARfD: 0.2100%

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 0596	Sugar beet	0.05	-	-	-	ND	-	-	ND	ND	ND	ND	-
VD 0520	Bambara groundnut (dry seed)	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0640	Barley	0.035	-	AUS	19.0	14	-	-	ND	ND	3	0.03	0.00%
VD 0071	Beans (dry)	0.05	-	AUS	19.0	222	-	-	ND	ND	3	0.58	0.06%
VD 0523	Broad bean (dry)	0.05	-	AUS	19.0	32	-	-	ND	ND	3	0.08	0.01%
VD 0524	Chick-pea (dry)	0.05	-	USA	15.0	34	-	-	ND	ND	3	0.11	0.01%
VD 0526	Common bean (dry)	0.05	-	FRA	18.9	145	-	-	ND	ND	3	0.38	0.04%
VD 0526	Common bean (dry), stated as kidney bean VD 4503	0.05	-	Thai	17.1	45	-	-	ND	ND	3	0.13	0.01%
VD 0527	Cowpea (dry)	0.05	-	USA	15.0	43	-	-	ND	ND	3	0.14	0.01%
VD 0527	Cowpea (dry), stated as black-eyed pea VD 4467	0.05	-	NLD	17.0	28	-	-	ND	ND	3	0.08	0.01%
VD 0561	Field pea (dry)	0.05	-	USA	15.0	11	-	-	ND	ND	3	0.04	0.00%
VD 0561	Field pea (dry), stated as pea (dry), VD 4511	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-

Annex 4

PROTHIOCONAZOLE (232) International estimate of short term intake (IESTI) for CHILDREN UP TO 6 YEARS ARfD= 1.000 mg/kg bw (1000 µg/kg bw) Maximum %ARfD: 0.2100%

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 0098	Kidney of cattle, goats, pigs and sheep	-	0.15	USA	15.0	187	-	-	ND	ND	1	1.87	0.19%
VD 0533	Lentil (dry)	0.05	-	FRA	18.9	291	-	-	ND	ND	3	0.77	0.08%
VD 0534	Lima bean (dry)	0.05	-	USA	15.0	74	-	-	ND	ND	3	0.25	0.02%
MO 0099	Liver of cattle, goats, pigs and sheep	-	0.23	USA	15.0	136	-	-	ND	ND	1	2.09	0.21%
VD 0545	Lupin (dry)	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
MM 0095	Meat from mammals other than marine mammals: 20% as fat	-	0.02	AUS	19.0	52	-	-	ND	ND	1	0.05	0.01%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	-	0.01	AUS	19.0	208	-	-	ND	ND	1	0.11	0.01%
ML 0106	Milks	0.004	-	USA	15.0	1286	-	-	ND	ND	3	0.34	0.03%
VD 0536	Mung bean (dry)	0.05	-	Thai	17.1	56	-	-	ND	ND	3	0.17	0.02%
GC 0647	Oats	0.01	-	USA	15.0	62	-	-	ND	ND	ND	ND	-
SO 0697	Peanut, shelled	0.01	-	USA	15.0	78	-	-	ND	ND	3	0.05	0.01%
VD 0072	Peas (dry)	0.05	-	USA	15.0	86	-	-	ND	ND	3	0.29	0.03%
VD 0537	Pigeon pea	0.05	-	-	-	ND	-	-	ND	ND	3	ND	-
SO 0495	Rape seed	0.02	-	-	-	ND	-	-	ND	ND	3	ND	-
OR 0495	Rape seed oil, edible	0.014	-	AUS	19.0	18	-	-	ND	ND	3	0.01	0.00%
GC 0650	Rye	0.01	-	NLD	17.0	37	-	-	ND	ND	3	0.02	0.00%
GC 0653	Triticale	0.01	-	-	-	ND	-	-	ND	ND	3	ND	-
GC 0654	Wheat	0.02	-	FRA	18.9	384	-	-	ND	ND	ND	ND	-
CM 0654	Wheat bran, unprocessed	0.048	-	USA	15.0	30	-	-	ND	ND	ND	ND	-
CF 1211	Wheat flour	0.008	-	FRA	18.9	245	-	-	ND	ND	ND	ND	-
CF 1210	Wheat germ	0.04	-	USA	15.0	8	-	-	ND	ND	3	0.02	0.00%

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

1. Principles governing consumer safety in relation to pesticide residues. Report of a meeting of a WHO Expert Committee on Pesticide Residues held jointly with the FAO Panel of Experts on the Use of Pesticides in Agriculture. FAO Plant Production and Protection Division Report, No. PL/1961/11; WHO Technical Report Series, No. 240, 1962.

2. Evaluation of the toxicity of pesticide residues in food. Report of a Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1963/13; WHO/Food Add./23, 1964.

3. Evaluation of the toxicity of pesticide residues in food. Report of the Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues. FAO Meeting Report, No. PL/1965/10; WHO/Food Add./26.65, 1965.

4. Evaluation of the toxicity of pesticide residues in food. FAO Meeting Report, No. PL/1965/10/1; WHO/Food Add./27.65, 1965.

5. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. FAO Meeting Report, No. PL/1965/10/2; WHO/Food Add./28.65, 1965.

6. Pesticide residues in food. Joint report of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 73; WHO Technical Report Series, No. 370, 1967.

7. Evaluation of some pesticide residues in food. FAO/PL:CP/15; WHO/Food Add./67.32, 1967.

8. Pesticide residues. Report of the 1967 Joint Meeting of the FAO Working Party and the WHO Expert Committee. FAO Meeting Report, No. PL:1967/M/11; WHO Technical Report Series, No. 391, 1968.

9. 1967 Evaluations of some pesticide residues in food. FAO/PL:1967/M/11/1; WHO/Food Add./68.30, 1968.

10. Pesticide residues in food. Report of the 1968 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 78; WHO Technical Report Series, No. 417, 1968.

11. 1968 Evaluations of some pesticide residues in food. FAO/PL:1968/M/9/1; WHO/Food Add./69.35, 1969.

12. Pesticide residues in food. Report of the 1969 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Group on Pesticide Residues. FAO Agricultural Studies, No. 84; WHO Technical Report Series, No. 458, 1970.

13. 1969 Evaluations of some pesticide residues in food. FAO/PL:1969/M/17/1; WHO/Food Add./70.38, 1970.

14. Pesticide residues in food. Report of the 1970 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 87; WHO Technical Report Series, No. 4574, 1971.

15. 1970 Evaluations of some pesticide residues in food. AGP:1970/M/12/1; WHO/Food Add./71.42, 1971.

16. Pesticide residues in food. Report of the 1971 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 88; WHO Technical Report Series, No. 502, 1972.

17. 1971 Evaluations of some pesticide residues in food. AGP:1971/M/9/1; WHO Pesticide Residue Series, No. 1, 1972.

18. Pesticide residues in food. Report of the 1972 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 90; WHO Technical Report Series, No. 525, 1973.

19. 1972 Evaluations of some pesticide residues in food. AGP:1972/M/9/1; WHO Pesticide Residue Series, No. 2, 1973.

20. Pesticide residues in food. Report of the 1973 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 92; WHO Technical Report Series, No. 545, 1974.

21. 1973 Evaluations of some pesticide residues in food. FAO/AGP/1973/M/9/1; WHO Pesticide Residue Series, No. 3, 1974.

22. Pesticide residues in food. Report of the 1974 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Agricultural Studies, No. 97; WHO Technical Report Series, No. 574, 1975.

23. 1974 Evaluations of some pesticide residues in food. FAO/AGP/1974/M/11; WHO Pesticide Residue Series, No. 4, 1975.

24. Pesticide residues in food. Report of the 1975 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues. FAO Plant Production and Protection Series, No. 1; WHO Technical Report Series, No. 592, 1976.

25. 1975 Evaluations of some pesticide residues in food. AGP:1975/M/13; WHO Pesticide Residue Series, No. 5, 1976.

26. Pesticide residues in food. Report of the 1976 Joint Meeting of the FAO Panel of Experts on Pesticide Residues and the Environment and the WHO Expert Group on Pesticide Residues. FAO Food and Nutrition Series, No. 9; FAO Plant Production and Protection Series, No. 8; WHO Technical Report Series, No. 612, 1977.

27. 1976 Evaluations of some pesticide residues in food. AGP:1976/M/14, 1977.

28. Pesticide residues in food—1977. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues and Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 10 Rev, 1978.

29. Pesticide residues in food: 1977 evaluations. FAO Plant Production and Protection Paper 10 Suppl., 1978.

30. Pesticide residues in food—1978. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues and Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 15, 1979.

31. Pesticide residues in food: 1978 evaluations. FAO Plant Production and Protection Paper 15 Suppl., 1979.

32. Pesticide residues in food—1979. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 20, 1980.

33. Pesticide residues in food: 1979 evaluations. FAO Plant Production and Protection Paper 20 Suppl., 1980

34. Pesticide residues in food—1980. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 26, 1981.

35. Pesticide residues in food: 1980 evaluations. FAO Plant Production and Protection Paper 26 Suppl., 1981.

36. Pesticide residues in food—1981. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 37, 1982.

37. Pesticide residues in food: 1981 evaluations. FAO Plant Production and Protection Paper 42, 1982.

38. Pesticide residues in food—1982. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 46, 1982.

39. Pesticide residues in food: 1982 evaluations. FAO Plant Production and Protection Paper 49, 1983.

40. Pesticide residues in food—1983. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 56, 1985.

41. Pesticide residues in food: 1983 evaluations. FAO Plant Production and Protection Paper 61, 1985.

42. Pesticide residues in food—1984. Report of the Joint Meeting on Pesticide Residues. FAO Plant Production and Protection Paper 62, 1985.

43. Pesticide residues in food—1984 evaluations. FAO Plant Production and Protection Paper 67, 1985.

44. Pesticide residues in food—1985. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 68, 1986.

45. Pesticide residues in food—1985 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 72/1, 1986.

46. Pesticide residues in food—1985 evaluations. Part II. Toxicology. FAO Plant Production and Protection Paper 72/2, 1986.

47. Pesticide residues in food—1986. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 77, 1986.

48. Pesticide residues in food—1986 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 78, 1986.

49. Pesticide residues in food—1986 evaluations. Part II. Toxicology. FAO Plant Production and Protection Paper 78/2, 1987.

50. Pesticide residues in food—1987. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 84, 1987.

51. Pesticide residues in food—1987 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 86/1, 1988.

52. Pesticide residues in food—1987 evaluations. Part II. Toxicology. FAO Plant Production and Protection Paper 86/2, 1988.

53. Pesticide residues in food—1988. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 92, 1988.

54. Pesticide residues in food—1988 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 93/1, 1988.

55. Pesticide residues in food—1988 evaluations. Part II. Toxicology. FAO Plant Production and Protection Paper 93/2, 1989.

56. Pesticide residues in food—1989. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 99, 1989.

57. Pesticide residues in food—1989 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 100, 1990.

58. Pesticide residues in food—1989 evaluations. Part II. Toxicology. FAO Plant Production and Protection Paper 100/2, 1990.

59. Pesticide residues in food—1990. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 102, Rome, 1990.

60. Pesticide residues in food—1990 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 103/1, Rome, 1990.

61. Pesticide residues in food—1990 evaluations. Part II. Toxicology. World Health Organization, WHO/PCS/91.47, Geneva, 1991.

62. Pesticide residues in food—1991. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 111, Rome, 1991.

63. Pesticide residues in food—1991 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 113/1, Rome, 1991.

64. Pesticide residues in food—1991 evaluations. Part II. Toxicology. World Health Organization, WHO/PCS/92.52, Geneva, 1992.

65. Pesticide residues in food—1992. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 116, Rome, 1993.

66. Pesticide residues in food—1992 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 118, Rome, 1993.

67. Pesticide residues in food—1992 evaluations. Part II. Toxicology. World Health Organization, WHO/PCS/93.34, Geneva, 1993.

68. Pesticide residues in food—1993. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 122, Rome, 1994.

69. Pesticide residues in food—1993 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 124, Rome, 1994.

70. Pesticide residues in food—1993 evaluations. Part II. Toxicology. World Health Organization, WHO/PCS/94.4, Geneva, 1994.

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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.

Benalaxyl
Estimated maximum dietary burden of farm animals
BEEF CATTLE MAX/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
Grape pomace, dry	AB	2.8	STMR-P	100	2.8	0	0	20	0	0	0.56
Total						30	40	25	0	0	0.56

DAIRY CATTLE MAX/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
Grape pomace, dry	AB	2.8	STMR-P	100	2.8	0	0	20	0	0	0.56
Total						10	30	20	0	0	0.56

Boscalid
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
Peanut, hay	AL	29	HR	85	34.12	25		60	8.53		20.47
Vetch, hay	AL	29	HR	85	34.12		25			8.53	
Cowpea, hay	AL	29	HR	86	33.72		10	40		3.37	13.49
Alfalfa, hay	AL	29	HR	89	32.58	35			11.4		
Barley, hay	AS	30.7	HR	100	30.7	25			7.68		
Barley, straw	AS	30.7	HR	100	30.7		30			9.21	
Cabbage, heads and leaves	–	2.7	HR	15	18		20			3.6	
Swede, roots	VR	0.71	HR	10	7.1		15			1.07	
Apple, pomace, wet	AB	2.2	STMR-P	40	5.5	15			0.83		
Total						100	100	100	28.4	25.8	34.0

Boscalid
Estimated maximum dietary burden of farm animals
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
Peanut, hay	AL	29	HR	85	34.12	20		60	6.82		20.47
Vetch, hay	AL	29	HR	85	34.12	20	25		6.82	8.53	
Cowpea, hay	AL	29	HR	86	33.72		10			3.37	
Pea, hay	AL	29	HR	86	33.72			10			3.3
Alfalfa, hay	AL	29	HR	89	32.58		5			1.63	
Barley, hay	AS	30.7	HR	100	30.7	40		30	12.28		9.67
Barley, straw	AS	30.7	HR	100	30.7		30			9.21	
Cabbage, heads and leaves	–	2.7	HR	15	18		20			3.6	

Boscalid
Estimated maximum dietary burden of farm animals
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
Swede, roots	VR	0.71	HR	10	7.1		10			0.71	
Apple, pomace, wet	AB	2.2	STMR-P	40	5.5	10			0.55		
Turnip, root	VR	0.71	HR	15	4.73	10			0.47		
Total						100	100	100	27.0	27.1	33.4

Boscalid
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
Swede, roots	VR	0.71	HR	10	7.1		10			0.71	
Soybean, hulls	AL	0.25	STMR-P	90	0.28	20	10	5	0.06	0.03	0.01
Bean, seeds	VD	0.12	STMR	88	0.14	20	20	70	0.03	0.03	0.1
Barley, grain	GC	0.075	STMR	88	0.09	55	60	15	0.05	0.05	0.01
Rye, grain	GC	0.075	STMR	89	0.09			10			0.01
Soybean, meal		0.023	STMR-P	92	0.03	5			0.001		
Total						100	100	100	0.13	0.82	0.13

Boscalid
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
Soybean, hay	AL	29	HR	85	34.12		10			3.42	
Barley, straw	AS	30.7	HR	100	30.7		5			1.54	
Wheat, straw	AS	30.7	HR	100	30.7		5			1.54	
Cabbage, heads and leaves	–	2.7	HR	15	18		5			0.9	
Swede, roots	VR	0.71	HR	10	7.1		10			0.71	
Millet, hay	AS	3.2	HR	100	3.2		5			0.19	
Soybean, hulls	AL	0.25	STMR-P	90	0.28	10	5	5	0.03	0.01	0.01
Bean, seed	VD	0.12	STMR	86	0.14	20	20	70	0.03	0.03	0.1
Barley, grain	GC	0.075	STMR	86	0.09	70	35	15	0.06	0.03	0.01
Rye, grain	GC	0.075	STMR	86	0.09			10			0.01
Total						100	100	100	0.11	8.4	0.13

Buprofezin
Estimated maximum dietary burden of farm animals
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
Grape, wet pomace	–	2.7	STMR-P	15	18			20			3.6
Soybean, hay	AL	9.0	STMR	85	10.59	30		80	3.18		8.47
Vetch, hay	AL	9.0	STMR	85	10.59		25			2.65	
Cowpea, hay	AL	9.0	STMR	86	10.47		10			1.05	
Cabbage, (heads and leaves)	–	1.52	STMR	15	10.13		20			2.03	

Buprofezin

Estimated maximum dietary burden of farm animals

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
Alfalfa, hay	AL	9.0	STMR	89	10.11	30			3.03		
Barley, hay	AS	9.0	STMR	100	9.0	25			2.25		
Barley, straw	AS	9.0	STMR	100	9.0		30			2.7	
Apple, pomace	AB	2.2	STMR-P	40	5.5	15	15		0.83	0.83	
Total						100	100	100	9.3	9.3	12.1

Buprofezin

Estimated maximum 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
Grape, wet pomace	–	2.7	STMR-P	15	18			20			3.6
Peanut, hay	AL	9.0	STMR	85	10.59			60			6.35
Vetch, hay	AL	9.0	STMR	85	10.59	40	25		4.24	2.65	
Cowpea, hay	AL	9.0	STMR	86	10.47		10			1.05	
Pea, hay	AL	9.0	STMR	86	10.23			10			1.02
Cabbage, (heads and leaves)	–	1.52	STMR	15	10.13		20			2.03	
Kale, leaves	–	1.52	STMR	15	10.13			10			10.1
Alfalfa, hay	AL	9.0	STMR	89	10.11		5			0.51	
Barley, hay	AS	9.0	STMR	100	9.0	40			3.6		
Barley, straw	AS	9.0	STMR	100	9.0		30			2.7	
Apple, pomace wet	AB	2.2	STMR-P	40	5.5	10	10		0.55	0.55	
Almond, hulls	AM	4.1	STMR	90	4.56	10			0.46		
Total						100	100	100	8.8	9.5	12.0

Buprofezin

Estimated maximum dietary burden of farm animals

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
Swede, roots	VR	0.305	STMR	10	3.05		10			0.3	
Soybean, hulls	AL	0.25	STMR-P	90	0.28	20	10	5	0.06	0.03	0.01
Bean, seeds	VD	0.12	STMR	88	0.14	20	20	70	0.03	0.03	0.1
Barley, grain	GC	0.075	STMR	88	0.09	60	60		0.05	0.05	
Rye, grain	GC	0.075	STMR	89	0.09			25			0.2
Total						100	100	100	0.14	0.41	0.13

Buprofezin

Estimated maximum dietary burden of farm animals

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
Soybean, hay	AL	9	STMR	86	10.47		10			1.05	
Cabbage, head	–	1.52	STMR	15	10.13		5			0.51	

Buprofezin
Estimated maximum dietary burden of farm animals
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
Wheat, straw	AS	9	STMR	100	9		10			0.9	
Swede, roots	VR	0.305	STMR	10	3.05		10			0.3	
Soybean, hulls	AL	0.25	STMR-P	90	0.28	10		5	0.03		0.01
Bean, seeds	VD	0.12	STMR	88	0.14	20	20	70	0.03	0.03	0.1
Barley, grain	GC	0.075	STMR	88	0.09	70	45		0.06	0.04	
Wheat, grain	GC	0.075	STMR	89	0.09			25			0.02
Total						100	100	100	0.12	2.82	0.13

Chlorpyrifos methyl (090)
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
corn	GC	2.2	HR	88	2.500	60	70	70	1.50	1.75	1.75
wheat byproducts	CC	5.39	HR P	88	6.125	40	30	40	2.45	1.84	2.45
Total						100	100	110	3.95	3.59	4.20

Chlorpyrifos methyl (090)
Estimated maximum dietary burden of farm animals
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
barley	GC	2.2	HR	88	2.500	45	40	40	1.13	1.00	1.00
wheat byproducts	CC	5.39	HR P	88	6.125	40	30	40	2.45	1.84	2.45
Apple pomace, wet	AB	0.445	STMR-P	40	1.113	10	10	10	0.11	0.11	0.11
Total						95	80	90	3.69	2.95	3.56

Chlorpyrifos methyl (090)
Estimated mean dietary burden of farm animals
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	GC	2.1	STMR	88	2.386	60	70	60	1.43	1.67	1.43
wheat byproducts	CC	5.14	STMR-P	88	5.841	40	30	40	2.34	1.75	2.34
Total						100	100	100	3.77	3.42	3.77

Chlorpyrifos methyl (090)
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		2.1	STMR	88	2.386	45	40	40	1.07	0.95	0.95
wheat byproducts	CC	5.14	STMR-P	88	5.841	40	30	40	2.34	1.75	2.34

Chlorpyrifos methyl (090)

Apple pomace, wet	AB	0.455	STMR-P	40	1.138	10	10	10	0.11	0.11	0.11
Total						95	80	90	3.52	2.82	3.40

Chlorpyrifos methyl (090)
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		2.2	HR	88	2.500	50	70	15	1.25	1.75	0.38
wheat byproducts	CC	5.39	HR P	88	6.125	50	20	20	3.06	1.23	1.23
Total						100	90	35	4.31	2.98	1.60

Chlorpyrifos methyl (090)
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
wheat	GC	2.2	HR	89	2.472	25	30	70	0.62	0.74	1.73
wheat byproducts	CC	5.39	HR P	88	6.125	50	20	20	3.06	1.23	1.23
Total						75	50	90	3.68	1.97	2.96

Chlorpyrifos methyl (090)
Estimated mean dietary burden of farm animals
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
barley grain		2.1	STMR	88	2.386	50	70	15	1.19	1.67	0.36
wheat byproducts	CC	5.14	STMR-P	88	5.841	50	20	20	2.92	1.17	1.17
Total						100	90	35	4.11	2.84	1.53

Chlorpyrifos methyl (090)
Estimated mean dietary burden of farm animals
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
wheat		2.1	STMR	88	2.386	25	30	70	0.60	0.72	1.67
wheat byproducts	CC	5.14	STMR-P	88	5.841	50	20	20	2.92	1.17	1.17
Total						75	50	90	3.52	1.88	2.84

Chlorpyrifos methyl (090)
Estimated maximum dietary burden of farm animals
SWINE breed 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	GC	2.2	HR	88	2.500	30	50	60	0.75	1.25	1.50
wheat byproducts	CC	5.39	HR P	88	6.125	70	50	40	4.29	3.06	2.45
Total						100	100	100	5.04	4.31	3.95

Chlorpyrifos methyl (090)
Estimated mean dietary burden of farm animals
SWINE breed 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	GC	2.1	STMR	88	2.386	30	50	60	0.72	1.19	1.43
wheat byproducts	CC	5.14	STMR-P	88	5.841	70	50	40	4.09	2.92	2.34
Total						100	100	100	4.80	4.11	3.77

Chlorpyrifos methyl (090)
Estimated maximum dietary burden of farm animals
SWINE finish 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	GC	2.2	HR	88	2.500	50	50	60	1.25	1.25	1.50
wheat byproducts	CC	5.39	HR P	88	6.125	50	50	40	3.06	3.06	2.45
Total						100	100	100	4.31	4.31	3.95

Chlorpyrifos methyl (090)
Estimated mean dietary burden of farm animals
SWINE finish 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	GC	2.1	STMR	88	2.386	50	50	60	1.19	1.19	1.43
wheat byproducts	CC	5.14	STMR-P	88	5.841	50	50	40	2.92	2.92	2.34
Total						100	100	100	4.11	4.11	3.77

Cypermethrin
Estimated maximum dietary burden of livestock
BEEF CATTLE MAX

Commodity	Commod	Residue	Basis	% Dry	Residue dw	Diet content (%)			Residue contribution (ppm)		
	group	mg/kg		matter	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Alfalfa forage	AL	11	high residue	35	31.4	60	70	100	18.9	22.0	31.4
Sugar beet leaves or tops	AV	8.3	high residue	100	8.30		20			1.66	
Barley straw	AS AF	6.9	high residue	100	6.90	10	10		0.69	0.69	
Maize fodder	AS AF	6.9	high residue	100	6.90	15			1.04		
Barley forage	AS AF	1.4	high residue	30	4.67	5			0.23		
Wheat milled (bran)	CM	3.75	HR-P	88	4.26	10			0.43		
Total						100	100	100	21.2	24.4	31.4

As well as the commodities shown in the table for beef and dairy cattle, the following were also considered: alfalfa fodder, barley grain, bean forage (green), beans (dry), cabbage heads, leaves, carrot culls, grape pomace, maize, maize forage, oat straw, oats, pea hay or pea fodder (dry), pea vines (green), peas (dry), rice, rice straw and fodder, rye, soya bean (dry), wheat and wheat straw and fodder.

Cypermethrin
Estimated maximum dietary burden of livestock
DAIRY CATTLE MAX

Commodity	Commod	Residue	Basis	% Dry	Residue dw	Diet content (%)			Residue contribution (ppm)		
	group	mg/kg		matter	mg/kg	US-CAN	EU	AU	US-CAN	EU	AU
Alfalfa forage	AL	11	high residue	35	31.4	40	40	60	12.6	12.6	18.9
Sugar beet leaves or tops	AV	8.3	high residue	100	8.30		30			2.49	
Barley straw	AS AF	6.9	high residue	100	6.90	10	30	20	0.69	2.07	1.38

Cypermethrin
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
Maize fodder	AS AF	6.9	high residue	100	6.90	5		20	0.35		1.38
Wheat forage	AS AF	1.4	high residue	25	5.60	25			1.40		
Wheat milled (bran)	CM	3.75	HR-P	88	4.26	20			0.85		
Total						100	100	100	15.9	17.1	21.6

Cypermethrin
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
Wheat milled, bran	CM	3.75	HR-P	88	4.26	50	20	20	2.131	0.852	0.852
Barley grain	GC	1.5	high residue	88	1.70	50	70	15	0.852	1.193	0.256
Rye grain	GC	1.5	high residue	88	1.70			35			0.597
Wheat grain	GC	1.5	high residue	89	1.69			20			0.337
Carrot culls	VR	0.01	HR	12	0.083		10			0.008	
Bean seed	VD	0.05	STMR	88	0.057			10			0.006
Total						100	100	100	2.98	2.05	2.05

As well as the commodities shown in the table for poultry broilers and layers, the following were also considered: maize forage, maize grain, oat grain, oat straw, pea seed, pea straw, rice grain, wheat forage and wheat straw.

Cypermethrin
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	
Barley straw	AS AF	6.9	high residue	100	6.90		5			0.345	
Maize fodder	AS AF	6.9	high residue	100	6.90		5			0.345	
Cabbage heads leaves	VB	0.65	high residue	15	4.33		5			0.217	
Wheat milled, bran	CM	3.75	HR-P	88	4.26	50	20	20	2.131	0.852	0.852
Barley grain	GC	1.5	high residue	88	1.70	50	50	15	0.852	0.852	0.256
Rye grain	GC	1.5	high residue	88	1.70			20			0.341
Wheat grain	GC	1.5	high residue	89	1.69			20			0.337
Bean seed	VD	0.05	STMR	88	0.057			25			0.014
Total						100	100	100	2.98	3.89	1.80

Fenbuconazole
Estimated maximum dietary burden
BEEF 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
Apple pomace, wet	AB	0.30	STMR-P	40	0.750	20	20		0.15	0.15	0.00
Barley straw	AS	2.4	HR	89	2.697		10		0.00	0.27	0.00
Barley grain	GC	0.03	STMR	88	0.034	35	50		0.01	0.02	0.00
Rye grain	GC	0.02	STMR	88	0.023				0.00	0.00	0.00
Wheat straw	AS	2.5	HR	88	2.841	10	20	40	0.28	0.57	1.14
Wheat grain	GC	0.02	STMR	89	0.022				0.00	0.00	0.00
Almond hulls	AM	0.45	STMR	90	0.500	10			0.05		0.00

Fenbuconazole
Estimated maximum dietary burden
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
Peanut hay	AL	7.14	HR	85	8.400	25		60	2.10		5.04
Peanut meal	SO	0.015	STMR	85	0.018				0.00	0.00	0.00
Total						100	100	100	2.60	1.00	6.18

Fenbuconazole
Estimated maximum dietary burden
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
Apple pomace, wet	AB	0.3	STMR-P	40	0.750	10	10	10	0.08	0.08	0.08
Barley straw	AS	2.4	HR	89	2.697		10		0.00	0.27	0.00
Barley grain	GC	0.03	STMR	88	0.034	45	40		0.02	0.01	0.00
Rye grain	GC	0.02	STMR	88	0.023				0.00	0.00	
Wheat straw	AS	2.5	HR	88	2.841	10	20	20	0.28	0.57	0.57
Wheat grain	GC	0.02	STMR	89	0.022				0.00	0.00	0.00
Almond hulls	AM	0.45	STMR	90	0.500	10		10	0.05		0.05
Peanut hay	AL	7.14	HR	85	8.400	20		60	1.68		5.04
Peanut meal	SO	0.015	STMR	85	0.018	5	10		0.00	0.00	0.00
Total						100	90	100	2.11	0.93	5.73

Fenbuconazole
Estimated maximum dietary burden
POULTRY - LAYER MAX

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
Barley straw	AS	2.4	HR	89	2.697					0.00	
Barley grain	GC	0.03	STMR	88	0.034	70	80	15	0.02	0.03	0.01
Rye grain	GC	0.02	STMR	88	0.023			35	0.00	0.00	0.01
Wheat straw	AS	2.5	HR	88	2.841		10			0.28	
Wheat grain	GC	0.02	STMR	89	0.022			5	0.00	0.00	0.00
Peanut meal	SO	0.015	STMR	85	0.018	25	10	10	0.00	0.00	0.00
Total						95	100	65	0.03	0.31	0.02

Fenbuconazole
Estimated mean dietary burden
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
Apple pomace, wet	AB	0.30	STMR-P	40	0.750	20	20		0.15	0.15	0.00
Barley straw	AS	0.94	STMR	89	1.056	10	30	40	0.11	0.32	0.42
Barley grain	GC	0.03	STMR	88	0.034	35	50		0.01	0.02	0.00
Rye grain	GC	0.02	STMR	88	0.023				0.00	0.00	0.00
Wheat straw	AS	0.79	STMR	88	0.898				0.00	0.00	0.00
Wheat grain	GC	0.02	STMR	89	0.022				0.00	0.00	0.00
Almond hulls	AM	0.45	STMR	90	0.500	10			0.05		0.00
Peanut hay	AL	2.33	STMR	85	2.741	25		60	0.69		1.64

Fenbuconazole
Estimated mean dietary burden
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
Peanut meal	SO	0.015	STMR	85	0.018				0.00	0.00	0.00
Total						100	100	100	1.00	0.48	2.07

Fenbuconazole
Estimated mean dietary burden
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
Apple pomace, wet	AB	0.3	STMR-P	40	0.750	10	10	10	0.08	0.08	0.08
Barley straw	AS	0.94	STMR	89	1.056	10	30	20	0.11	0.32	0.21
Barley grain	GC	0.03	STMR	88	0.034	45	40		0.02	0.01	0.00
Rye grain	GC	0.02	STMR	88	0.023				0.00	0.00	
Wheat straw	AS	0.79	STMR	88	0.898				0.00	0.00	0.00
Wheat grain	GC	0.02	STMR	89	0.022				0.00	0.00	0.00
Almond hulls	AM	0.45	STMR	90	0.500	10		10	0.05		0.05
Peanut hay	AL	2.33	STMR	85	2.741	20		60	0.55		1.64
Peanut meal	SO	0.015	STMR	85	0.018	5	10		0.00	0.00	0.00
Total						100	90	100	0.80	0.41	1.98

Fenbuconazole
Estimated 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
Barley grain	GC	0.03	STMR	88	0.034	75	70	15	0.03	0.02	0.01
Rye grain	GC	0.02	STMR	88	0.023	5		50	0.00	0.00	0.01
Wheat grain	GC	0.02	STMR	89	0.022			5	0.00	0.00	0.00
Peanut meal	SO	0.015	STMR	85	0.018	20	10	10	0.00	0.00	0.00
Total						100	80	80	0.03	0.03	0.02

Fenbuconazole
Estimated mean dietary burden
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
Barley straw	AS	0.94	STMR	89	1.056		5			0.05	
Barley grain	GC	0.03	STMR	88	0.034	70	80	15	0.02	0.03	0.01
Rye grain	GC	0.02	STMR	88	0.023			35	0.00	0.00	0.01
Wheat straw	AS	0.79	STMR	88	0.898		5			0.04	
Wheat grain	GC	0.02	STMR	89	0.022			5	0.00	0.00	0.00
Peanut meal	SO	0.015	STMR	85	0.018	25	10	10	0.00	0.00	0.00
Total						95	100	65	0.03	0.13	0.02

Fluopicolide

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	1.387	STMR-P	15	9.247			20			1.85
Cabbage leaves		3.800	HR	15	25.333		20			5.07	
Barley forage		0.040	HR	30	0.133						
Barley hay		0.120	HR	88	0.136						
Barley straw		0.120	HR	89	0.135						
Barley grain		0.010	STMR	88	0.011	50	60		0.01	0.01	
Oat forage		0.040	HR	30	0.133						
Oat hay		0.120	HR	90	0.133						
Oat straw		0.120	HR	90	0.133						
Oat grain		0.010	STMR	89	0.011						
Soya bean seed		0.010	STMR	89	0.011						
Soya bean hay		0.030	HR	85	0.035						
Wheat forage		0.040	HR	25	0.160	25	20	80	0.04	0.03	0.13
Wheat hay		0.120	HR	88	0.136	25			0.03		
Wheat straw		0.120	HR	88	0.136						
Wheat grain		0.010	STMR	89	0.011						
Total						100	100	100	0.08	5.11	1.98

Fluopicolide

Estimated maximum dietary burden of farm animals

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
Grape pomace, wet	AB	1.387	STMR-P	15	9.247			20			1.85
Cabbage leaves		3.800	HR	15	25.333		20			5.07	
Barley forage		0.040	HR	30	0.133						
Barley hay		0.120	HR	88	0.136						
Barley straw		0.120	HR	89	0.135						
Barley grain		0.010	STMR	88	0.011	45			0.01		
Oat forage		0.040	HR	30	0.133						
Oat hay		0.120	HR	90	0.133						
Oat straw		0.120	HR	90	0.133						
Oat grain		0.010	STMR	89	0.011						
Soya bean seed		0.010	STMR	89	0.011						
Soya bean hay		0.030	HR	85	0.035						
Wheat forage		0.040	HR	25	0.160	40	20	60	0.06	0.03	0.10
Wheat hay		0.120	HR	88	0.136	15			0.02		
Wheat straw		0.120	HR	88	0.136		20			0.03	
Wheat grain		0.010	STMR	89	0.011		40	20		0.00	0.00
Total						100	100	100	0.09	5.13	1.95

Fluopicolide

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
Cabbage leaves		3.8	HR	15	25.333		5			1.27	
Soya bean seed		0.01	STMR	89	0.011	20	20	15	0.00	0.00	0.00
Barley grain		0.01	STMR	88	0.011		70			0.01	
Oat grain		0.01	STMR	89	0.011			15			0.00

Fluopicolide
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
Wheat grain		0.01	HR	89	0.011	80		70	0.01		0.01
Total						100	95	100	0.011	1.277	0.011

Fluopicolide
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
Soya bean seed		0.01	STMR	89	0.011	20		15	0.00		0.00
Barley straw		0.12	HR	89	0.135						
Barley grain		0.01	STMR	88	0.011	10	90	15	0.00	0.01	0.00
Oat forage		0.04	HR	30	0.133						
Oat hay		0.12	HR	90	0.133						
Oat grain		0.01	STMR	89	0.011			15			0.00
Wheat forage		0.04	HR	25	0.160		10			0.02	
Wheat hay		0.12	HR	88	0.136						
Wheat straw		0.12	HR	88	0.136						
Wheat grain		0.01	STMR	89	0.011	70		55	0.01		0.01
Total						100	100	100	0.011	0.026	0.011

Fluopicolide
Estimated mean dietary burden of farm animals
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
Grape pomace, wet	AB	1.387	STMR-P	15	9.247			20			1.85
Cabbage leaves		0.800	STMR	15	5.333		20			1.07	
Barley forage		0.015	STMR	30	0.050						
Barley hay		0.060	STMR	88	0.068						
Barley straw		0.060	STMR	89	0.067						
Barley grain		0.010	STMR	88	0.011	50	50		0.01	0.01	
Oat forage		0.015	STMR	30	0.050						
Oat hay		0.060	STMR	90	0.067						
Oat straw		0.060	STMR	90	0.067						
Oat grain		0.010	STMR	89	0.011						
Soya bean seed		0.010	STMR	89	0.011	15	10	20	0.00	0.00	0.00
Soya bean hay		0.010	STMR	85	0.012						
Wheat forage		0.015	STMR	25	0.060	10			0.01		
Wheat hay		0.060	STMR	88	0.068	25			0.02		
Wheat straw		0.060	STMR	88	0.068		20			0.01	
Wheat grain		0.010	STMR	89	0.011			60			0.01
Total						100	100	100	0.03	1.09	1.86

Fluopicolide
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
Grape pomace, wet	AB	1.387	STMR-P	15	9.247			20			1.85
Cabbage leaves		0.800	STMR	15	5.333		20			1.07	
Barley forage		0.015	STMR	30	0.050						
Barley hay		0.060	STMR	88	0.068						
Barley straw		0.060	STMR	89	0.067						
Barley grain		0.010	STMR	88	0.011						
Oat forage		0.015	STMR	30	0.050						
Oat hay		0.060	STMR	90	0.067						
Oat straw		0.060	STMR	90	0.067						
Oat grain		0.010	STMR	89	0.011						
Soya bean seed		0.010	STMR	89	0.011						
Soya bean hay		0.010	STMR	85	0.012						
Wheat forage		0.015	STMR	25	0.060	40	20	60	0.02	0.01	0.04
Wheat hay		0.060	STMR	88	0.068	40	20	20	0.03	0.01	0.01
Wheat straw		0.060	STMR	88	0.068						
Wheat grain		0.010	STMR	89	0.011	20	40		0.00	0.00	
Total						100	100	100	0.05	1.10	1.90

Fluopicolide
Estimated mean dietary burden of farm animals
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
Cabbage leaves		0.800	STMR	15	5.333		5			0.27	
Soya bean seed		0.010	STMR	89	0.011	20	20	15	0.00	0.00	0.00
Barley grain		0.010	STMR	88	0.011		5	15		0.00	0.00
Oat grain		0.010	STMR	89	0.011						
Wheat grain		0.010	STMR	89	0.011	80	70	70	0.01	0.01	0.01
Total						100	100	100	0.011	0.277	0.011

Fluopicolide
Estimated mean dietary burden of farm animals
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
Soya bean seed		0.010	STMR	89	0.011	20	15	15	0.00	0.00	0.00
Barley straw		0.060	STMR	89	0.067						
Barley grain		0.010	STMR	88	0.011	10		15	0.00		0.00
Oat forage		0.015	STMR	30	0.050						
Oat hay		0.060	STMR	90	0.067						
Oat grain		0.010	STMR	89	0.011			15			0.00
Wheat forage		0.015	STMR	25	0.060		10			0.01	
Wheat hay		0.060	STMR	88	0.068						
Wheat straw		0.060	STMR	88	0.068		10			0.01	
Wheat grain		0.010	STMR	89	0.011	70	65	55	0.01	0.01	0.01
Total						100	100	100	0.011	0.022	0.011

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated maximum dietary burden of farm animals

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
Rape forage	AV	6.8	high residue	30	22.667	20	10	100	4.53	2.27	22.67
Alfalfa forage	AL	3.1	high residue	35	8.857	60	70		5.31	6.20	
Beet, mangel fodder	AM	0.30	high residue	15	2.000		20			0.40	
Bean seed	VD	0.335	STMR	88	0.381	15			0.06		
Canola meal	SO	0.10	STMR-P	88	0.114	5			0.01		
Total						100	100	100	9.91	8.87	22.67

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated maximum dietary burden of farm animals
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
Rape forage	AV	6.8	high residue	30	22.667	20	10	40	4.53	2.27	9.07
Alfalfa forage	AL	3.1	high residue	35	8.857	40	40	60	3.54	3.54	5.31
Beet, mangel fodder	AM	0.30	high residue	15	2.000		25			0.50	
Beet, sugar tops	AV	0.38	high residue	23	1.652		10			0.17	
Bean seed	VD	0.335	STMR	88	0.381	15	15		0.06	0.06	
Canola meal	SO	0.10	STMR-P	88	0.114	15			0.02		
Cotton, undelinted seed	SO	0.10	STMR	88	0.114	10			0.01		
Total						100	100	100	8.16	6.53	14.38

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated maximum dietary burden of farm animals
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
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Canola meal	SO	0.10	STMR-P	88	0.114	15	18	5	0.017	0.020	0.006
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075	25	22	20	0.019	0.017	0.015
Total						60	60	95	0.11	0.11	0.29

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated maximum dietary burden of farm animals
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
Rape forage	AV	6.8	HR	30	22.667		10			2.267	
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Soya bean forage	AL	0.18	HR	56	0.321		10			0.032	
Canola meal	SO	0.10	STMR-P	88	0.114	15	10	5	0.017	0.011	0.006
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075	20	15	20	0.015	0.011	0.015
Total						55	65	95	0.11	2.40	0.29

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated mean dietary burden of farm animals
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
Rape forage	AV	3.9	STMR	30	13.000	20	10	100	2.60	1.30	13.00
Alfalfa forage	AL	1.1	STMR	35	3.143	60	70		1.89	2.20	

Beet, sugar tops	AV	0.11	STMR	23	0.478		10			0.05	
Bean seed	VD	0.335	STMR	88	0.381	15	10		0.06	0.04	
Canola meal	SO	0.10	STMR-P	88	0.114	5			0.01		
Total						100	100	100	4.55	3.59	13.00

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated mean dietary burden of farm animals
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
Rape forage	AV	3.9	STMR	30	13.000	20	10	40	2.60	1.30	5.20
Alfalfa forage (Australia)	AL	1.1	STMR	35	3.143	40	40	60	1.26	1.26	1.89
Beet, sugar tops	AV	0.11	STMR	23	0.391		10			0.04	
Bean seed	VD	0.335	STMR	88	0.381	15	20		0.06	0.08	
Beet, mangel fodder	AM	0.02	STMR	15	0.133		20			0.03	
Canola meal	SO	0.10	STMR-P	88	0.114	15			0.02		
Cotton, undelinted seed	SO	0.10	STMR	88	0.114	10			0.01		
Total						100	100	100	3.94	2.70	7.09

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated mean dietary burden of farm animals
POULTRY - BROILER 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
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Canola meal	SO	0.10	STMR-P	88	0.114	15	18	5	0.017	0.020	0.006
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075	25	22	20	0.019	0.017	0.015
Total						60	60	95	0.11	0.11	0.29

Haloxyfop – Livestock dietary burdens
Tier 1. Estimated mean dietary burden of farm animals
POULTRY - LAYER 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
Rape forage	AV	3.9	STMR	30	13.000		10			1.300	
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Soya bean forage	AL	0.075	STMR	56	0.125		10			0.013	
Canola meal	SO	0.10	STMR-P	88	0.114	15	10	5	0.017	0.011	0.006
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075	20	15	20	0.015	0.011	0.015
Total						55	65	95	0.11	1.41	0.29

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated maximum dietary burden of farm animals
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
Rape forage (Europe)	AV	6.8	high residue	30	22.667		10			2.27	
Alfalfa forage (Australia)	AL	3.1	high residue	35	8.857			100			8.86
Peanut hay	AL	3.00	high residue	85	3.529	25			0.88		
Beet, mangel fodder	AM	0.30	high residue	15	2.000		30			0.60	
Beet, sugar tops	AV	0.38	high residue	23	1.652		10			0.17	
Bean seed	VD	0.335	STMR	88	0.381	15	20		0.06	0.08	
Canola meal	SO	0.10	STMR-P	88	0.114	15			0.02		
Cotton, undelinted seed	SO	0.10	STMR	88	0.114	10			0.01		

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated maximum dietary burden of farm animals
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
Beet sugar, molasses	AV DM?	0.063	STMR-P	75	0.084	10			0.01		
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075		20			0.02	
Beet, sugar, dried pulp	AV AB?	0.008	STMR-P	88	0.009	10			0.00		
Total						85	90	100	0.98	3.12	8.86

As well as the commodities shown in the table for beef and dairy cattle, the following were also considered: pea seed, soybean forage, and soya bean seed.

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated maximum dietary burden of farm animals
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
Rape forage (Europe)	AV	6.8	high residue	30	22.667		10			2.27	
Alfalfa forage (Australia)	AL	3.1	high residue	35	8.857			60			5.31
Rape forage (Australia)	AV	5.0	high residue	100	5.000			40			2.00
Peanut hay	AL	3.00	high residue	85	3.529	20			0.71		
Beet, mangel fodder	AM	0.30	high residue	15	2.000		25			0.50	
Beet, sugar tops	AV	0.38	high residue	23	1.652		10			0.17	
Bean seed	VD	0.335	STMR	88	0.381	15	20		0.06	0.08	
Canola meal	SO	0.10	STMR-P	88	0.114	15	10		0.02	0.01	
Cotton, undelinted seed	SO	0.10	STMR	88	0.114	10			0.01		
Beet sugar, molasses	AV DM?	0.063	STMR-P	75	0.084	10			0.01		
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075		15			0.01	
Beet, sugar, dried pulp	AV AB?	0.008	STMR-P	88	0.009	10			0.00		
Total						80	90	100	0.80	3.03	7.31

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated maximum dietary burden of farm animals
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
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Canola meal	SO	0.10	STMR-P	88	0.114	15	18	5	0.017	0.020	0.006
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075	25	22	20	0.019	0.017	0.015
Total						60	60	95	0.11	0.11	0.29

As well as the commodities shown in the table for poultry broilers and layers, the following were also considered: sugar beet tops, pea seed and soya bean seed.

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated maximum dietary burden of farm animals
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
Rape forage (Europe)	AV	6.8	HR	30	22.667		10			2.267	
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Soya bean forage (Europe)	AL	0.18	HR	56	0.321		10			0.032	
Canola meal	SO	0.10	STMR-P	88	0.114	15	10	5	0.017	0.011	0.006
Soya bean meal	SO	0.069	STMR-P	92	0.075	20	15	20	0.015	0.011	0.015

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated maximum dietary burden of farm animals

Total					55		65	95	0.11		2.40	0.29

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated mean dietary burden of farm animals
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
Rape forage (Europe)	AV	3.9	STMR	30	13.000		10			1.30	
Alfalfa forage (Australia)	AL	1.1	STMR	35	3.143			100			3.14
Peanut hay	AL	2.10	STMR	85	2.471	25			0.62		
Beet, sugar tops	AV	0.11	STMR	23	0.391		20			0.08	
Bean seed	VD	0.335	STMR	88	0.381	15	20		0.06	0.08	
Beet, mangel fodder	AM	0.02	STMR	15	0.133		30			0.04	
Canola meal	SO	0.10	STMR-P	88	0.114	15			0.02		
Cotton, undelinted seed	SO	0.10	STMR	88	0.114	10			0.01		
Beet sugar, molasses	AV	0.063	STMR-P	75	0.084	10			0.01		
Soya bean meal	SO	0.069	STMR-P	92	0.075		20			0.02	
Beet, sugar, dried pulp	AV	0.008	STMR-P	88	0.009	10			0.00		
Total						85	100	100	0.71	1.51	3.14

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated mean dietary burden of farm animals
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
Rape forage (Europe)	AV	3.9	STMR	30	13.000		10			1.30	
Alfalfa forage (Australia)	AL	1.1	STMR	35	3.143			60			1.89
Peanut hay	AL	2.10	STMR	85	2.471	20			0.49		
Rape forage (Australia)	AV	1.3	STMR	100	1.300			40			0.52
Beet, sugar tops	AV	0.11	STMR	23	0.391		10			0.04	
Bean seed	VD	0.335	STMR	88	0.381	15	20		0.06	0.08	
Beet, mangel fodder	AM	0.02	STMR	15	0.133		25			0.03	
Canola meal	SO	0.10	STMR-P	88	0.114	15	10		0.02	0.01	
Cotton, undelinted seed	SO	0.10	STMR	88	0.114	10			0.01		
Beet sugar, molasses	AV DM?	0.063	STMR-P	75	0.084	10			0.01		
Soya bean meal	SO	0.069	STMR-P	92	0.075		15			0.01	
Beet, sugar, dried pulp	AV AB?	0.008	STMR-P	88	0.009	10			0.00		
Total						80	90	100	0.59	1.47	2.41

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated mean dietary burden of farm animals
POULTRY - BROILER 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
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Canola meal	SO	0.10	STMR-P	88	0.114	15	18	5	0.017	0.020	0.006
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075	25	22	20	0.019	0.017	0.015
Total						60	60	95	0.11	0.11	0.29

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated mean dietary burden of farm animals
POULTRY - LAYER MEAN

Haloxyfop – Livestock dietary burdens
Tier 2. Estimated mean dietary burden of farm animals

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
Rape forage	AV	3.9	STMR	30	13.000		10			1.300	
Bean seed	VD	0.335	STMR	88	0.381	20	20	70	0.076	0.076	0.266
Soybean forage (Europe)	AL	0.075	STMR	56	0.116		10			0.012	
Canola meal	SO	0.10	STMR-P	88	0.114	15	10	5	0.017	0.011	0.006
Soya bean meal	SO AB?	0.069	STMR-P	92	0.075	20	15	20	0.015	0.011	0.015
Total						55	65	95	0.11	1.41	0.29

Hexythiazox
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
Citrus, dried pulp	AB	0.25	STMR-P	91	0.27	10	20		0.027	0.054	
Corn (field), forage/silage	AF	1.7	HR	40	4.25	40	80	80	1.7	3.4	3.4
Grape, pomace wet	-	2.0	STMR-P	15	13.3		0	20	0	0	2.66
Total						50	100	100	1.7	3.5	6.1

Hexythiazox
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
Citrus, dried pulp	AB	0.25	STMR-P	91	0.27	10	20		0.027	0.054	
Corn (field), forage/silage	AF	1.7	HR	40	4.25	50	60	80	2.125	2.55	3.4
Grape, pomace wet	-	2.0	STMR-P	15	13.3			20			2.66
Total						60	80	100	2.2	3.0	6.1

Hexythiazox
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
Corn (field), forage/silage	AF	1.7	HR	40	4.25		10			0.425	
Total						0	10	0	0	0.4	0

Hexythiazox
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
Citrus, dried pulp	AB	0.25	STMR-P	91	0.27	10	20		0.027	0.054	
Corn (field), forage/silage	AF	0.91	STMR	40	2.275	40	80	80	0.91	1.82	1.82
Grape, pomace wet	-	2.0	STMR-P	15	13.3			20			2.46
Total						50	100	100	0.9	1.9	4.5

Hexythiazox
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
Citrus, dried pulp	AB	0.25	STMR-P	91	0.27	10	20		0.027	0.054	0
Corn (field), forage/silage	AF	0.91	STMR	40	2.275	50	60	80	1.138	1.365	1.82
Grape, pomace wet	-	2.0	STMR-P	15	13.3			20	0	0	2.66
Total						60	80	100	1.2	1.4	4.5

Hexythiazox
Estimated mean dietary burden of farm animals
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
Total						0	0	0	0	0	0

Hexythiazox
Estimated mean dietary burden of farm animals
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/silage	AF	0.91	STMR	40	2.275		10			0.228	
Total						0	10	0	0	0.228	0

Indoxacarb
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
Alfalfa fodder	AL	43	hr	100	43	35		20	15		9
Alfalfa forage	AL	28	hr	100	28		70	20		20	6
Cabbage heads and leaves	VB	2	hr	15	0.3		5			0.02	
Corn stover	AS	15	hr	100	15	25	25		3.8	3.8	
Cotton seed	SO	0.36	STMR	88	0.32	15			0.05		
Peanut fodder	AL	45	hr	100	45	25		60	11		27
Total						100	100	100	30	23	41

Indoxacarb
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
Alfalfa fodder	AL	43	hr	100	43	20	40		8.6	17	
Apple pomace, wet	AB	0.55	STMR-P	40	0.22	10	10		0.02	0.02	
Cabbage heads and leaves	VB	2.0	hr	15	0.3		20			0.06	
Corn stover	AS	15	hr	100	15	15	20	40	2.3	3.0	6.0
Cotton seed	SO	0.36	STMR	88	0.32	25	10		0.08	0.03	
Peanut fodder	AL	45	hr	100	45	20		60	9.0		27
Soya bean hulls	AM	0.23	STMR	90	0.21	10			0.02		
Total						100	100	100	20	20	33

Indoxacarb

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
Chickpea (dry)	VD	0.02	STMR	90	0.02			5			0.0009
Mungbean (dry)	VD	0.02	STMR	88	0.02			50			0.009
Peanut meal	SO	0.0012	STMR	85	0.001	25	10	5	0.0003	0.0001	0.0001
Potato culls	VR	0.0085	hr	20	0.002		10			0.0002	
Soya bean (dry)	VD	0.027	STMR	89	0.02	20	20	15	0.005	0.005	0.004
Soya bean hulls	AM	0.23	STMR	90	0.21	20	10	5	0.041	0.021	0.010
Soya bean meal	AM	0.0038	STMR	92	0.003	20	30	20	0.001	0.001	0.001
Total						85	80	100	0.047	0.027	0.024

Indoxacarb
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
Cabbage heads and leaves	VB	2.0	hr	15	0.3		5			0.02	
Chickpea (dry)	VD	0.02	STMR	90	0.02		5	5		0.001	0.001
Corn stover	AS	15	hr	100	15		10			1.5	
Mungbean (dry)	VD	0.02	STMR	88	0.02			50			0.009
Peanut meal	SO	0.0012	STMR	85	0.001	25	10	5	0.0003	0.0001	0.0001
Potato culls	VR	0.0085	hr	20	0.002		10			0.0002	
Soya bean (dry)	VD	0.027	STMR	89	0.02	20	15	15	0.005	0.004	0.004
Soya bean hulls	AM	0.23	STMR	90	0.21	10	5	5	0.021	0.010	0.010
Soya bean meal	AM	0.0038	STMR	92	0.003	25	20	20	0.001	0.001	0.001
Total						80	80	100	0.027	1.5	0.024

Indoxacarb
Estimated median 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
Alfalfa fodder	AL	16	STMR	100	16	35		20	5.6		3.2
Alfalfa forage	AL	16	STMR	100	16		70	20		11	3.2
Apple pomace, wet	AB	0.55	STMR-P	40	0.22		5			0.01	
Corn stover	AS	7.8	STMR	100	7.8	25	25		2.0	2.0	
Cotton seed	SO	0.36	STMR	88	0.32	15			0.05		
Peanut fodder	AL	18	STMR	100	18	25		60	4.5		11
Total						100	100	100	12	13	17

Indoxacarb
Estimated median 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
Alfalfa fodder	AL	16	STMR	100	16	20	40		3.2	6.4	
Apple pomace, wet	AB	0.55	STMR-P	40	0.22	10	10		0.02	0.02	
Cabbage heads and leaves	VB	0.44	STMR	15	0.065		10			0.01	
Corn stover	AS	7.8	STMR	100	7.8	15	20	40	1.2	1.6	3.1

Cotton seed	SO	0.36	STMR	88	0.32	25	10		0.08	0.03	
Peanut fodder	AL	18	STMR	100	18	20		60	3.6		11
Soya bean hulls	AM	0.23	STMR	90	0.21	10	10		0.02	0.02	
Total						100	100	100	8.1	8.0	14

Indoxacarb

Estimated median 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
Chickpea (dry)	VD	0.02	STMR	90	0.02			5			0.0009
Mungbean (dry)	VD	0.02	STMR	88	0.02			50			0.009
Peanut meal	SO	0.0012	STMR	85	0.001	25	10	5	0.0003	0.0001	0.0001
Potato culls	VR	0.003	STMR-P	20	0.001		10			0.0001	
Soya bean (dry)	VD	0.027	STMR	89	0.02	20	20	15	0.005	0.005	0.004
Soya bean hulls	AM	0.23	STMR	90	0.21	20	10	5	0.041	0.021	0.010
Soya bean meal	AM	0.0038	STMR	92	0.003	20	30	20	0.001	0.001	0.0007
Total						85	80	100	0.047	0.027	0.024

Indoxacarb

Estimated median 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
Cabbage heads and leaves	VB	0.44	STMR	15	0.065		5			0.00	
Chickpea (dry)	VD	0.02	STMR	90	0.02		5	5		0.001	0.001
Corn stover	AS	7.8	STMR	100	7.8		10			0.78	
Mungbean (dry)	VD	0.02	STMR	88	0.02			50			0.009
Peanut meal	SO	0.0012	STMR	85	0.001	25	10	5	0.0003	0.0001	0.0001
Potato culls	VR	0.003	STMR-P	20	0.001		10			0.0001	
Soya bean (dry)	VD	0.027	STMR	89	0.02	20	15	15	0.005	0.004	0.004
Soya bean hulls	AM	0.23	STMR	90	0.21	10	5	5	0.021	0.010	0.010
Soya bean meal	AM	0.0038	STMR	92	0.003	25	20	20	0.001	0.001	0.001
Total						80	80	100	0.027	0.80	0.024

hr = highest residue

Metaflumizone (236)

Estimated mean dietary burden of farm animals

BEEF CATTLE MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Tomato pomace, wet	AB	0.25	STMR-P	20	1.800	0	0	10			0.13
Total						30	50	20	0.00	0.00	0.13

DAIRY CATTLE MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%)			Residue contribution (ppm)		
						US-CAN	EU	AU	US-CAN	EU	AU
Tomato pomace, wet	AB	0.25	STMR-P	20	1.800	0	0	10			0.13
Total						10	50	20	0.00	0.00	0.13

Metaflumizone (236)
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
Tomato pomace, wet	AB	0.25	STMR-P	20	1.800	0	0	10			0.13
Total						30	50	20	0.00	0.00	0.13

Metaflumizone (236)
Estimated maximum dietary burden of farm animals
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
Tomato pomace, wet	AB	0.25	STMR-P	20	1.800	0	0	10			0.13
Total						10	50	10	0.00	0.00	0.13

Methoxyfenozide (209)
Estimated maximum dietary burden of farm animals
BEEF CATTLE Maximum

Commodity	Basis	Res mg/kg	DM %	Res dw mg/kg	Diet portion %			Residue contribution mg/kg		
					US-Can	EU	Au	US-Can	EU	Au
Bean forage	HR	32	35	91	30	*	60	27.4		54.9
Sugar beet, tops	HR	10	23	43	*	0	*		0.0	
Maize forage	HR	22	40	55		80	0	0.0	44.0	0.0
Maize fodder	HR	46	83	55	5	0	0	2.8	0.0	0.0
Peanut fodder	HR	51	85	60	25	*	40	15.0		24.0
Maize	HR	0.02	88	0.023		0	0	0.0	0.0	0.0
Almond hulls	STMR	13	90	14	10	*	0	1.4		0.0
Apple pomace	STMR	1.3	40	3.2	20	20	0	0.7	0.7	0.0
Cotton meal	STMR	0.21	89	0.24	5	0	0	0.0	0.0	0.0
Cotton undelinted seed	STMR	0.46	88	0.52	0	*	0	0.0		0.0
Cotton hulls	STMR	0.06	90	0.071	0	*	0	0.0		0.0
Cotton byproducts	STMR	11	90	12	5	*	*	0.6		
				Sum	100	100	100	47.92	44.65	78.86

Methoxyfenozide (209)
Estimated median dietary burden of farm animals
DAIRY CATTLE Maximum

Commodity	Basis	Res mg/kg	DM %	Res dw mg/kg	Diet portion %			Residue contribution mg/kg		
					US-Can	EU	Au	US-Can	EU	Au
Bean forage	HR	32	35	91	0	20	70	0.0	18.3	64.0
Sugar beet, tops	HR	10	23	43	*	0	*		0.0	
Maize forage	HR	22	40	55	30	20	0	16.5	11.0	0.0
Maize fodder	HR	46	83	55	0	20	0	0.0	11.1	0.0
Peanut fodder	HR	51	85	60	20	*	30	12.0		18.0
Maize	HR	0.02	88	0.023	0	15	0	0.0	0.0	0.0
Almond hulls	STMR	13	90	14	10	*	0	1.4		0.0
Apple pomace	STMR	1.3	40	3.2	10	10	0	0.3	0.3	0.0
Cotton meal	STMR	0.21	89	0.24	5	5	0	0.0	0.0	0.0
Cotton undelinted seed	STMR	0.46	88	0.52	25	10	0	0.1	0.1	0.0
Cotton hulls	STMR	0.06	90	0.071	0	*	0	0.0		0.0
Cotton byproducts	STMR	11	90	12	*	*	*			
				Sum	100	100	100	30.41	40.76	82.00

Methoxyfenozide (209)
Estimated median dietary burden of farm animals
BEEF CATTLE Median

Commodity	Basis	Res mg/kg	DM %	Res dw mg/kg	Diet portion %			Residue contribution mg/kg		
					US-Can	EU	Au	US-Can	EU	Au
Forages					60	80	100			
Bean forage	STMR	5.95	35	17	30	*	60	5.1		10.2
Sugar beet, tops	STMR	3.7	23	16	*	20	*		3.2	
Maize forage	STMR	4.5	40	11		60		0.0	6.8	0.0
Maize fodder	STMR	8.2	83	9.9	5	0		0.5	0.0	0.0
Peanut fodder	STMR	13.5	85	16	25	*	40	4.0		6.4
Maize	STMR	0.02	88	0.023		0		0.0	0.0	0.0
Almond hulls	STMR	13	90	14	10	*		1.4		0.0
Apple pomace	STMR	1.3	40	3.2	20	20		0.7	0.7	0.0
Cotton meal	STMR	0.21	89	0.24		0		0.0	0.0	0.0
Cotton undelinted seed	STMR	0.46	88	0.52	5	*		0.0		0.0
Cotton hulls	STMR	0.06	90	0.071		*		0.0		0.0
Cotton byproducts	STMR	11	90	12	5	*	*	0.6		
				Sum	100	100	100	12.30	10.62	16.55

Methoxyfenozide (209)
Estimated median dietary burden of farm animals
DAIRY CATTLE Median

Commodity	Basis	Res mg/kg	DM %	Res dw mg/kg	Diet portion %			Residue contribution mg/kg		
					US-Can	EU	Au	US-Can	EU	Au
Forages					50	60	100			
Bean forage	STMR	5.95	35	17	20	20	70	3.4	3.4	11.9
Sugar beet, tops	STMR	3.7	23	16	*	30	*		4.8	
Maize forage	STMR	4.5	40	11	10	10	0	1.1	1.1	0.0
Maize fodder	STMR	8.2	83	9.9	0	0	0	0.0	0.0	0.0
Peanut fodder	STMR	13.5	85	16	20	*	30	3.2		4.8
Maize	STMR	0.02	88	0.023	0	15	0	0.0	0.0	0.0
Almond hulls	STMR	13	90	14	10	*	0	1.4		0.0
Apple pomace	STMR	1.3	40	3.2	10	10	0	0.3	0.3	0.0
Cotton meal	STMR	0.21	89	0.24	5	5	0	0.0	0.0	0.0
Cotton undelinted seed	STMR	0.46	88	0.52	25	10	0	0.1	0.1	0.0
Cotton hulls	STMR	0.06	90	0.071	0	*	0	0.0		0.0
Cotton byproducts	STMR	11	90	12	*	*	*			
				Sum	100	100	100	9.61	9.74	16.66

Prothioconazole (232)
Estimated maximum dietary burden of farm animals
BEEF CATTLE MAX

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
Barley forage	AF, AS	5.4	high residue	30	18.0	5	5		0.9	0.9	
Barley grain	GC	0.035	STMR	88	0.04	40	55		0.02	0.02	
Beet, sugar –dried pulp		0.05	STMR	88	0.06					0.01	
Wheat asp grain fn		5.0	STMR	85	5.88	5			0.29		
Wheat forage	AF, AS	5.4	high residue	25	21.6	25	20	100	5.4	4.32	21.6
Wheat hay	AF, AS	4.8	high residue	100	4.8	25	20		1.2	0.96	
Total						100	100	100	7.81	6.21	21.6

Prothioconazole (232)
Estimated maximum dietary burden of farm animals

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
Barley forage	AF, AS	5.4	high residue	30	18.0		10			1.8	
Barley grain	GC	0.035	STMR	88	0.04	20	40	40	0.01	0.02	0.02
Beet, sugar – dried pulp		0.05	STMR	88	0.06		10			0.01	
Wheat – asp grain fract		5.0	STMR	85	5.88						
Wheat forage	AF, AS	5.4	high residue	25	21.6	40	20	60	8.64	4.32	12.96
Wheat hay	AF, AS	4.8	high residue	100	4.8	40	20		1.92	0.96	
Total						100	100	100	10.57	7.1	12.97

As well as the commodities shown in the table for beef and dairy cattle, the following were also considered: hay and straw of other cereal grains, pulses (except soy bean, dry), oat grain and forage, peanut meal, rape seed meal, rye grain and forage, sugar beet tops, triticale grain and forage and wheat grain

Prothioconazole (232)
Estimated mean dietary burden of farm animals
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
Barley forage	AF, AS	1.2	STMR	30	4.0	5	10		0.2	0.4	
Barley grain	GC	0.035	STMR	88	0.04	50	50		0.02	0.02	
Beet, sugar - tops	AV	1.5	STMR	23	6.52		20			1.3	
Oat forage	AV	0.96	STMR	30	3.2						
Wheat forage	AF, AS	1.2	STMR	25	4.8	25	20	100	1.2	0.96	4.8
Wheat hay	AF, AS	1.5	STMR	100	1.5	20			0.3	0.32	
Total						100	100	100	**1.72**	**2.68**	**4.8**

Prothioconazole (232)
Estimated mean dietary burden of farm animals
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
Barley forage	AF, AS	1.2	STMR	30	4.0		10			0.4	
Barley grain	GC	0.035	STMR	88	0.04	45	40	10	0.02	0.02	
Beet, sugar - tops	AV	1.5	STMR	23	6.52		30			1.96	
Oat forage	AV	0.96	STMR	30	3.2			30			0.96
Wheat forage	AF, AS	1.2	STMR	25	4.8	40	20	60	1.92	0.96	2.88
Wheat hay	AF, AS	1.5	STMR	100	1.5	15			0.23		
Total						100	100	100	**2.16**	**3.33**	**3.84**

Spirodiclofen(237)
Estimated mean dietary burden of farm animals
BEEF CATTLE MEAN

Commodity	CC	Residue mg/kg	Basis	DM %	Residue dw mg/kg	Diet content (%) US	EU	AU	JP	Residue contribution (ppm) US	EU	AU	JP
Almond hulls	AB	3.5	STMR	90	3.889			10				0.39	
Apple pomace, dry	AB	3.4	STMR-P	92	3.696		20	20			0.74	0.74	
Citrus pulp, dry	AB	0.18	STMR-P	93	0.194	10	5	30		0.02	0.01	0.06	
Grape pomace, dry	AB		STMR-P	15	0.000			20				0.00	
Total						10	25	80	0	0.02	0.75	1.19	0.00

Spirodiclofen(237)
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	EU	AU	JP	US	EU	AU	JP
Almond hulls	AB	3.5	STMR	90	3.889	10		10		0.39		0.39	
Apple pomace, dry	AB	3.4	STMR-P	92	3.696	10	10	10		0.37	0.37	0.37	
Citrus pulp, dry	AB	0.18	STMR-P	93	0.194	10	20	30		0.02	0.04	0.06	
Grape pomace, dry	AB		STMR-P	15	0.000			20				0.00	
Total						30	30	70	0	0.78	0.41	0.82	0.00

Spirodiclofen(237)
Estimated maximum dietary burden of farm animals
BEEF CATTLE MAX MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)				Residue contribution (ppm)			
		mg/kg		%	mg/kg	US	EU	AU	JP	US	EU	AU	JP
Almond hulls	AB	3.5	STMR	90	3.889			10				0.39	
Apple pomace, dry	AB	3.4	STMR-P	92	3.696		20	20			0.74	0.74	
Citrus pulp, dry	AB	0.18	STMR-P	93	0.194	10	5	30		0.02	0.01	0.06	
Grape pomace, dry	AB		STMR-P	15	0.000			20				0.00	
Total						10	25	80	0	0.02	0.75	1.19	0.00

Spirodiclofen(237)
Estimated maximum dietary burden of farm animals
DAIRY CATTLE MAX MAX

Commodity	CC	Residue	Basis	DM	Residue dw	Diet content (%)				Residue contribution (ppm)			
		mg/kg		%	mg/kg	US	EU	AU	JP	US	EU	AU	JP
Almond hulls	AB	3.5	STMR	90	3.889	10		10		0.39		0.39	
Apple pomace, dry	AB	3.4	STMR-P	92	3.696	10	10	10		0.37	0.37	0.37	
Citrus pulp, dry	AB	0.18	STMR-P	93	0.194	10	20	30		0.02	0.04	0.06	
Grape pomace, dry	AB		STMR-P	15	0.000			20				0.00	
Total						30	30	70	0	0.78	0.41	0.82	0.00

CORRIGENDA – CORRECTIONS TO THE REPORT OF THE 2008 MEETING

Pesticide residues in food—2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 193, 2009.

Page 270, paragraph 3, line 11 should read:

The NOAEL in a 2-year 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.

The table on page 272 should read:

Levels relevant to risk assessment for prothioconazole-desthio

Species	Study	Effect	NOAEL	LOAEL
Mouse	Single dose LD_{50}	Toxicity	100 mg/kg bw	500 mg/kg bw
	Two-year 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]	—

Changes are shown in bold. Only significant factual errors and omissions are listed.

Under General Considerations p. 27replace the following entries

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	0.055	0.06	5	LN, 99th	0.2	0.2	
Elderberries	4	0.26	0.7		0.345	0	NA		2	There are too few datapoints to usethe NAFTA calculation
Leek	12	0.03	0.44	0.21	0.195	0	μ ± 3SD	0.5	1	There are too few datapoints to usethe NAFTA calculation
Sweet corn	4	< 0.1			0.1	4	NA		0.1	There are too few datapoints to usethe

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)	
										NAFTA calculation
Carrot	13	0.07	0.22	0.14	0.11	3	LN, 99th	0.28	0.5	23% of the values < LOQ
Maize	4	0.01			0.1		NA		0.1	There are too few datapoints to usethe NAFTA calculation
Barley straw	36	0.16	19	3.6	2.4	0	LN, 95th	22.6	30	

5.23 Tebuconazole

p.341 para 1, **insert:** peanuts in the listed crops.

p.342 Elderberries, para 2 **change**HR of 0.73 mg/kg to **0.70 mg/kg**.

p. 344 Brassica vegetables, para 4 **change** STMRof 0.05 mg/kg to **0.07 mg/kg**.

p. 346 Tomato, para 1 **change** STMR of 0.15 mg/kg to **0.19 mg/kg**.

p. 348 Peanut, para 4 **change** STMR of 0.03 mg/kg to **0.04 mg/kg**.

p. 348Rape seed, para 5 **change** STMR of 0.09 mg/kg to **0.085 mg/kg**.

Annex 1. Replace with the following entries

Pesticide (Codex reference no.)	CCN	Commodity	Recommended MRL, mg/kg		STMR or STMR-P, mg/kg	HR or HR-P mg/kg
			New	Previous		
Tebuconazole (189)	OR 0495	Rape seed	0.5	0.05	0.085	
		Tomato peeles			0.054	

Annex 4. Replace with the following entries

TEBUCONAZOLE (189) International estimate of short term intake (IESTI) for ARfD= not yet considered

GENERAL POPULATION

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
FB 0267	Elderberries	-	**0.7**	NLD	63.0	21	-	-	ND	ND	1	**0.24**	-
DF 0014	Plum, dried (prunes)	-	**0.36**	USA	65.0	303	6	FRA	5	1	3.00	0.84	-
JF 0448	Tomato juice	**0.1**	-	-	-	ND	-	-	ND	ND	3	ND	-
-	Tomato paste	**0.16**	-	-	-	ND	-	-	ND	ND	3	ND	-

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FAO TECHNICAL PAPERS

FAO PLANT PRODUCTION AND PROTECTION PAPERS

1	Horticulture: a select bibliography, 1976 (E)
2	Cotton specialists and research institutions in selected countries, 1976 (E)
3	Food legumes: distribution, adaptability and biology of yield, 1977 (E F S)
4	Soybean production in the tropics, 1977 (C E F S)
4 Rev.1	Soybean production in the tropics (first revision), 1982 (E)
5	Les systèmes pastoraux sahéliens, 1977 (F)
6	Pest resistance to pesticides and crop loss assessment – Vol. 1, 1977 (E F S)
6/2	Pest resistance to pesticides and crop loss assessment – Vol. 2, 1979 (E F S)
6/3	Pest resistance to pesticides and crop loss assessment – Vol. 3, 1981 (E F S)
7	Rodent pest biology and control – Bibliography 1970-74, 1977 (E)
8	Tropical pasture seed production, 1979 (E F** S**)
9	Food legume crops: improvement and production, 1977 (E)
10	Pesticide residues in food, 1977 – Report, 1978 (E F S)
10 Rev.	Pesticide residues in food 1977 – Report, 1978 (E)
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The annual Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues was held in Geneva, Switzerland, from 16 to 25 September 2009. The FAO Panel of Experts had met in preparatory sessions from 11 to 15 September. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural 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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