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REPORT 2023

Pesticide residues in food

Joint FAO/WHO Meeting on Pesticide Residues

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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 Core Assessment Group on Pesticide Residues, Washington DC, United States of America, 19–28 September 2023

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Abbreviations

AChE	acetylcholinesterase
AD	administered dose
ADI	acceptable daily intake
ADME	absorption, distribution, metabolism, excretion
AGF	aspirated grain fractions
ALP	alkaline phosphatase
ALT	alanine transaminase
AR	administered radioactivity
ARfD	acute reference dose
as	as received
AST	aspartate transaminase
AUC, $AUC_{0-\infty}$	area under the concentration–time curve
BBCH	Biologische Bundesanstalt, Bundessortenamt und Chemische Industrie
BMD	benchmark dose
bw	body weight
CAC	Codex Alimentarius Commission
CAR/PXR	constitutive androstane receptor/pregnane X receptor
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
cGAP	critical GAP
ChE	cholinesterase
C_{max}	maximum concentration
DAA	days after application
DAFT	days after first treatment
DALA	days after last application
DAT	days after treatment
DM	dry matter
DNA	deoxyribonucleic acid
DT_{50}	time required for 50 percent dissipation of the initial concentration
dw	dry weight
EFSA	European Food Safety Authority
eq	equivalent(s)

ESI	electrospray ionization
FAO	Food and Agriculture Organization of the United Nations
$GABA_A$	γ-aminobutyric acid, type A
GAP	good agricultural practice
GC-ECD	gas chromatography–electron capture detector
GC-MS	gas chromatography–mass spectrometry
GC-NPD	nitrogen-phosphorus detectors
GD	gestation day
GECDE	global estimate of chronic dietary exposure
GEMS	Global Environment Monitoring System–Food Contamination Monitoring and Assessment Programme
GGTP	γ-glutamyl transpeptidase/transferase
GI	gastrointestinal
GLP	good laboratory practice
HBGV	health-based guidance values
Hb	haemoglobin
HCB	hexchlorobenzene
HPLC	high performance liquid chromatography
HPRT	hypoxanthine–guanine phosphoribosyl transferase
HR	highest residue level in the edible portion of a commodity
HR-P	highest residue level in a processed commodity
Ht	haematocrit
IEDI	International Estimated Daily Intake
IESTI	International Estimate of Short-Term Intake
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC_{50}	median lethal concentration
LC-MS/MS	liquid chromatography-tandem mass spectrometry
LD_{50}	median lethal dose
LLNA	local lymph node assay
LOAEL	lowest-observed-adverse-effect level
LOD	limit of detection
LOQ	limit of quantification

LP	large portion
mADI	microbiological ADI
mARfD	microbiological ARfD
MOA	mode of action
MRL	maximum residue limit
NIS	sodium/iodide symporter
NOAEC	no-observed-adverse-effect concentration
NOAEL	no-observed-adverse-effect level
NTE	neuropathy target esterase
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	pre-harvest interval
PND	postnatal day
Po	post-harvest
POD	point of departure
ppm	parts per million
PXR	pregnane X receptor
QuEChERS	quick, easy, cheap, effective, rugged and safe
QSAR	quantitative structure–activity relationship
RAC	raw agricultural commodity
RBC	red blood cell
RSD	relative standard deviation
RTI	re-treatment interval
SC	suspension concentrate
SCE	sister chromatid exchange
SD	standard deviation
SDHI	succinate dehydrogenase inhibitor
SPE	solid phase extraction
STMR	supervised trials median residue
STMR-P	supervised trials median residue in a processed commodity
$t_{½}$	half-life
T3	triiodothyronine
T4	thyroxine
THF	tetrahydrofuran
TLC	thin-layer chromatography

T_{max}	time to reach maximum concentration
TPO	thyroid peroxidase
TRR	total radioactive residues
TSH	thyroid stimulating hormone
TTC	threshold of toxicological concern
UDP-GT	uridine diphosphate glucuronosyltransferase
US	United States of America
USEPA	United States Environmental Protection Agency
v/v	volume for volume
WHO	World Health Organization
w/v	weight for volume
w/w	weight for weight

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 provided 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 provided 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.

1. Introduction

A Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR) was held at the Environmental Protection Agency of the United States, in Washington, DC, (USEPA) from 19 to 28 September 2023. FAO Panel Members met in preparatory sessions from 14 to 18 September.

The Meeting was opened by Mr Soren Madsen, WHO JMPR secretary. On behalf of FAO and WHO, Mr Madsen welcome and thanked the participants for providing their expertise and for devoting significant time and efforts to the work of JMPR, noting that this was the first physical JMPR meeting in the United States. Mr Madsen welcomed the new FAO secretariat, new panel members, as well as the new FAO editors. He further expressed his gratitude to the USEPA for hosting the 2023 JMPR meeting and invited Dr Edward Messina, director of the Office of Pesticide Programme of the US Environmental Protection Agency to address the Meeting. Dr Messina welcome the participants to USEPA and emphasized the invaluable contribution of JMPR to the scientific assessment of pesticide residues, He noted that the JMPR evaluations are well-known and recognized not only by governmental regulatory bodies but also by industry, and the public. The JMPR efforts to ensure that pesticides are used safely and effectively are a beacon for regulatory authorities around the world. The director highlighted the role of JMPR in protecting human health and fostering international trade by ensuring the safety of food and agricultural products.

Dr Guibiao Ye, the new FAO JMPR secretariat, took the opportunity to thank WHO for taking a leading role in organizing the meeting. He highlighted the importance of JMPR in food safety and food security. Dr Ye thanked experts for their hard work and great contribution to JMPR and looked forward to working together with them to achieve more for food safety in future.

Prior to the Meeting, the FAO and WHO JMPR Secretariats received declarations of conflicts of interest from their respective panels of experts. The WHO JMPR Secretary reported that all 36 WHO experts had completed the necessary identification and confidentiality forms, with 16 of them declaring interests. However, a review by the WHO Secretariat of these declarations did not identify any conflicts of interest that would impair the full participation of the 16 experts in any of the agenda items for JMPR 2023. The FAO JMPR Secretariat received declarations from all 17 of its experts, and upon review, identified no conflicts of interest that would affect their full participation in JMPR 2023 agenda items. The FAO secretariats reported the reviewing process and conclusions to the Meeting. Additionally, a list of participants and their professional profiles was published on the websites of FAO and WHO two weeks before the meeting. No objections to the selected experts were received from the public, thus both groups of experts from FAO and WHO were cleared for full participation without any identified conflicts of interest.

During the Meeting, the FAO Panel of Experts was responsible for reviewing residue and analytical aspects of the pesticides under consideration, including data on their metabolism, fate in the environment and use patterns, and for estimating the maximum levels of residues that might occur as a result of use of the pesticides according to good agricultural practice (GAP). Maximum residue levels and supervised trials median residue (STMR) values were estimated for

commodities of animal origin. The WHO Core Assessment Group was responsible for reviewing toxicological and related data in order to establish acceptable daily intakes (ADIs) and acute reference doses (ARfDs), where necessary.

The Meeting evaluated 35 pesticides, including seven new compounds and four compounds that were re-evaluated within the periodic review programme of the CCPR, for toxicity or residues, or both.

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

The Meeting also estimated the dietary exposures (both short-term and long-term) of the pesticides reviewed and, on this basis, performed a dietary risk assessment in relation to the relevant ADI and where necessary ARfD. Cases in which ADIs or ARfDs may be exceeded were clearly indicated in order to facilitate the decision-making process by CCPR.

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

R, residue and analytical aspects; T, toxicological evaluation

* New compound

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

2. General consideration items

2.1 Developments in dietary exposure methodology for pesticide residues in foods

Principles of dietary exposure assessment

As outlined in the Codex Alimentarius Commission Procedural manual (FAO/WHO, 2023):

> *"Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups."*

This is reiterated in updated Chapter 6 of Environmental Health Criteria 240 (EHC 240: Section 6.1.2; WHO/FAO, 2020).

> *"Dietary exposure assessments should cover the general population as well as specific population subgroups that have been identified as relevant from toxicological profiling (e.g. infants, children, pregnant women, older adults)".*

Individuals likely to have dietary exposures at the top end of the distribution of exposure due to factors such as their dietary habits (for example, high consumers) or age, are always a subpopulation of interest, and (in the bullet point that follows the above):

> *"Information on high-percentile dietary exposures may be expected to cover all groups that may not have typical food consumption patterns (e.g. people with diabetes or people with specific diets, such as vegans or vegetarians)."*

Additionally, the Codex Committee on Pesticide Residues (CCPR, 2015) endorsed a recommendation in 2015:

> *The JMPR Secretariat also referred to future developments to improve the characterization of chronic risks expected to occur for exposure during less than life-time. An upcoming meeting organized jointly by JECFA and JMPR Secretariats would be convened. The Committee supported this initiative and the development of an approach for appropriate scenarios.*

and again in 2023 (CCPR, 2023):

> *"Ask JECFA and JMPR to continue working towards harmonizing their risk assessment methodologies, including ways to establish single, harmonized acceptable daily intake values and MRLs for dual-use compounds."*

Background

The JMPR currently estimates chronic dietary exposure to pesticide residues in foods by the International Estimated Daily Intake (IEDI) using the GEMS/Food cluster diets (Sy *et al.*, 2013) to provide food consumption information, and supervised trials median residue values (STMR) for residues in food commodities. The GEMS/Food cluster diets are derived from national food balance sheet information, grouped into clusters of countries with similar food profiles (Sy *et al*., 2013). The GEMS/Food cluster diets express food available for consumption on a per capita basis (population mean) for a group of countries but do not provide any information on subpopulations, high consumers or variability between or within countries within a cluster.

Datasets containing individual food consumption information (individual dietary records) are the most appropriate for chronic dietary exposure assessment (EFSA/EMA, 2022; WHO/FAO, 2020). Such datasets allow consideration of population subgroups and provide information on the distribution of dietary exposures, including highly exposed subpopulations.

FAO and WHO have collated individual food consumption data from national dietary surveys to support chronic dietary exposure assessment and created the FAO/WHO chronic individual food consumption database – Summary statistics (CIFOCOss; see the following link for details: https://apps.who.int/foscollab/Download/DownloadConso). Currently, approximately 40 countries have shared their national data which are available for international risk assessment, including more than 200 population subgroups, disaggregated by age and/or sex. Surveys are required to include food consumption data from at least two non-consecutive survey days, with summary statistics reported for consumers-only and the total survey population.

The availability of the CIFOCOss resource coincided with a FAO/WHO Expert Meeting held in November 2011 on dietary exposure assessment methodologies for residues of veterinary drugs (WHO, 2012).

The above 2011 FAO/WHO Expert Meeting considered an existing validated approach as a possible candidate for using summary statistics of food consumption data to estimate high dietary exposure. This approach used the population mean food consumption for all except the two highest contributing foods, for which a high percentile (95th or 97.5th) of the consumer-only food consumption distribution was used (Pesticide Safety Directorate, 2004).

This FAO/WHO Expert Meeting considered that, in the longer term, an individual would be a high-level consumer (one from the high end of the distribution of normal food consumption amounts) of only one category of food, and that their consumption of other foods containing the residue would remain at the total population mean. The 2011 FAO/WHO Expert Meeting proposed a global estimate of chronic dietary exposure (GECDE) methodology. The GECDE approach is based on summary statistics of national food consumption data from CIFOCOss. The Expert Meeting proposed that for high-level consumption the 97.5th percentile food consumption values for consumers-only should be used, to be derived from surveys with individual records two or more days in duration averaged for each individual. The 97.5th percentile was proposed because it was most commonly reported in the data submitted. However, the experts recognized that the 90th or 95th percentile could also be considered to represent chronic (regular) high consumption.

In any case, they considered it essential to document information on the number of consumers upon which any percentile is based to demonstrate that the estimate is sufficiently robust.

A FAO/WHO Expert Working Group, established following the 2016 JECFA and the 2014 JMPR Meetings (Arcella *et al*., 2019), further developed the GECDE approach, including:

- consideration of residues of dual-use compounds (used as both veterinary drugs and pesticides);
- consideration of the appropriateness of the GECDE for compounds with toxicological concerns over less-than-lifetime exposure time frames. Less-than-lifetime toxicological concerns may refer to a life stage (infancy, childhood, women during pregnancy) or high exposure for a period less than lifetime (for example, due to seasonal use of a pesticide or veterinary drug, or seasonal consumption of a food);
- substitution of the 97.5th percentile consumer food consumption for a single food by the highest reliable percentile (HRP) consumer food consumption. If there are more than 180 consumers of a commodity, a 97.5th percentile food consumption for consumers-only is used; if there are more than 60 but fewer than 181 consumers, a 95th percentile food consumption is used; if there are more than 30 but fewer than 61 consumers, a 90th percentile food consumption is used, and if there are more than 10 but fewer than 31 consumers, a median food consumption is used and in the report of the working group there is indication that if there are fewer than 11 consumers, only the mean food consumption for the whole population is used.

During the current JMPR Meeting, an evaluation was undertaken of the CIFOCOss dataset to determine how often the consumers-only 97.5th percentile consumption figure would be the HRP. It was determined that the 97.5th percentile would be relevant for 7 percent of foods, with the 95th percentile being relevant for 9 percent of foods, the 90th percentile for 8 percent of foods, the median (50th percentile) for 16 percent of foods and the mean would actually be selected for 60 percent of the foods.

Trialing GECDE at JMPR

Based on a general consideration developed at JMPR 2018 as part of a trial exercise, the GECDE model developed by JECFA (veterinary drugs) in 2011 (WHO, 2012) was used for estimating less-than-lifetime dietary exposure to pesticide residues for population subgroups of toxicological concern, as identified using the decision tree for toxicological profiling. Mean estimates of dietary exposure were derived using food consumption data from CIFOCOss (GECDE-mean) in addition to the original GECDE (GECDE-high).

Since 2019, JMPR reports have included a summary of the estimates of dietary exposure derived using the GECDE method in section 4 and sometimes in the dietary exposure section of individual compounds for which less-than-lifetime toxicity issues have been identified. In section 4, GECDE (mean and high) estimates are derived for each country-cohort combination for all (general population), all adults, female adults, children and adolescents, infants and toddlers.

Foods in CIFOCOss are described using the FoodEx 2 food classification hierarchy (up to level 7) that includes both individual food commodities and composite foods (that is, food containing multiple ingredients). A recipe tool has been developed by the Netherlands National

Institute for Public Health and the Environment (RIVM, acting as a WHO collaborating centre) and this is currently being refined. This project applies standard recipes to composite foods to identify ingredients that may contain residues of the pesticide of interest and develops appropriately weighted STMRs for composite foods. It has been incorporated into the GECDE calculations conducted by JMPR.

Comparison of dietary exposure estimates from the GECDE and IEDI

At JMPR 2022 the exposure group carried out comparisons of dietary exposure estimates derived from GECDE and IEDI. It was considered that the most appropriate GECDE metric for comparison was the mean dietary exposure estimate for adults, as this is the closest estimate to a population mean dietary exposure. In most cases the differences between the GECDE-mean estimate and the IEDI value were within a factor of two. Following the 2022 JMPR, some marked differences were noted between the results from IEDI and GECDE-mean assessments. To provide further context for differences between IEDI and GECDE-mean estimates, several instances were examined in more detail to determine the basis for the differences.

Limited analysis suggests that at least part of the difference observed between dietary exposure estimates based on IEDI and GECDE mean is due to the clustering process behind IEDI.

For chronic dietary exposure assessment, a high percentile estimate of dietary exposure has been shown to be between two- and five-fold higher than the mean estimate of dietary exposure (US FDA, 2006). The upper limits of the GECDE-mean and GECDE-high mostly conform to this expectation.

Advantages of the GECDE

The GECDE includes the ability to derive life-stage specific estimates of dietary exposure, to provide information on the variability in dietary exposure across countries and within countries. The IEDI does not incorporate these features.

The flexibility of being able to use the GECDE for subpopulation groups should ideally be combined with further development of the decision-making process based on toxicological profiling of compounds, to ensure that dietary exposure estimates are matched to the risk assessment requirements and are reported for the appropriate population subgroups where relevant.

The ability to use food consumption data from a large number of countries and population subgroups from the CIFOCOss database in the GECDE calculations can assist in identifying vulnerable groups for consideration during risk management.

Further improvements to the GECDE method

Further development of the GECDE method will include:

- improved consideration of complex foods, where a commodity (or commodities) of interest may be components of the complex food; work on the recipe tool to disaggregate complex foods into their component ingredients and to assign residue values to the ingredients is well advanced and will continue as required;
- identification of key foods driving exceedances of the ADI in a format to support decision-making by CCPR;

- provision of additional information about the estimates of dietary exposure to assist decision-making by CCPR (for example, information on the number/proportion of population groups or subgroups where an exceedance of the ADI has been calculated);
- incorporation of quality checks on the appropriateness of input and output high percentiles of food consumption amounts used in the GECDE method (for example, the ratio of consumer mean to consumer HRP may be calculated to examine whether the distribution of consumer intakes follows an expected pattern).

Discussion in JMPR 2023 about the implementation of GECDE

The Meeting recognized that the introduction of food consumption data reported by individuals at the national level provides relevant information such as consumed quantities, sex, gender and individual variabilities. This information is not available through food balance sheets that are intended to estimate the availability of food per capita within clusters of countries.

The Meeting agreed that the GECDE-mean reasonably reflects the mean estimated dietary exposure of the general population and the mean dietary exposure of specific population groups that may have a higher exposure than the general population.

Regarding the GECD-high, the Meeting raised concerns that the use of consumers-only high percentiles from two-day dietary survey data may unrealistically overestimate food consumption, and therefore dietary exposure and risk estimates. Specifically that consumers-only mean and high percentiles decline as the number of consumption days increases. It was further highlighted that this overestimation may be greater where the proportion of consumers is low.

Decisions of the JMPR

The Meeting agreed that JMPR should:

- transition from the use of the IEDI to the use of GECDE-mean;
- continue to investigate implementation and modification options for the GECDE-high for the assessment of dietary exposure to pesticide residues for chronic and shorter-than-lifetime assessments with the aim of a transition to adoption;
- further investigate the degree of conservatism in the GECDE (mean and high) and the IEDI;
- encourage and support the continued collection of surveys of individual dietary records of at least two non-consecutive days duration, and the future transition to the use of these resources as the basis for dietary exposure assessment by JMPR.

References

Arcella D, Boobis A, Cressey P, Erdely H, Fattori V, Leblanc JC, *et al.*2019. Harmonized methodology to assess chronic dietary exposure to residues from compounds used as pesticide and veterinary drug. *Critical Reviews in Toxicology*, 49(1), 1–10. https://doi.org/10.1080/10408444.2019.1578729

CCPR. 2015. Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission 38th Session, Geneva, 6–11 July 2015. Report of the 47th session of the Codex Committee on Pesticide Residues. Beijing, 23–18 April 2015. (see para 30).

CCPR. 2023. Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission 46th Session, Rome, 27November–2 December 2023. Report of the 54th session of the Codex Committee on Pesticide Residues. Beijing, 26 June–1 July 2023. (See par 216, Recommendation 1.

European Food Safety Authority (EFSA) and European Medicines Agency (EMA). 2022. Report on development of a harmonised approach to human dietary exposure assessment for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin. Parma, Amsterdam: EFSA, EMA; 2022 (EMA/CVMP/499555/2021).
FAO and WHO. 2023. Codex Alimentarius Commission Procedural Manual. Twenty-eighth edition, revised. Rome. https://doi.org/10.4060/cc5042en
JECFA. 2014. Evaluation of certain veterinary drug residues in food. Seventy-eighth report of the Joint FAO/WHO Committee on Food Additives (WHO Technical Report Series 988).
JECFA. 2016. Evaluation of certain veterinary drug residues in food. Eighty-first report of the Joint FAO/WHO Committee on Food Additives (WHO Technical Report Series 997).
Pesticide Safety Directorate. 2004. Instructions for carrying out long term consumer risk assessment using CRD's ten consumer model.
Sy MM, Feinberg M, Verger P, Barre T, Clemencon S, Crepet A. 2013. New approach for the assessment of cluster diets. *Food and Chemical Toxicology,* 52, 180–187. https://doi.org/10.1016/j.fct.2012.11.005
US FDA.2006. U.S. Food & Drug administration guidance document. Guidance for industry: estimating dietary intake of substances in food. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food
FAO and WHO. 2012. Joint FAO/WHO Expert Meeting on dietary exposure assessment methodologies for residues of veterinary drugs, including report of stakeholder meeting, 7–11 November 2011, Rome, Italy. WHO Geneva.
FAO and WHO. 2009. Environmental Health Criteria 240, Principles and methods for the risk assessment of chemicals in food. WHO, Geneva.

2.2 Development of guidance on the assessment and interpretation of nonlinear toxicokinetics

Following the recommendation of JMPR 2022 an electronic working group (eWG) on the assessment and interpretation of nonlinear toxicokinetics commenced development of draft guidance on the assessment and interpretation of nonlinear toxicokinetics. The eWG held virtual meetings on several occasions throughout 2022. The scope of the guidance was discussed, and a first draft prepared. Feedback was sought from the current Meeting.
This guidance is structured around three overarching aims:

- to aid and facilitate the recognition of toxicologically relevant non-linearity in toxicology studies;
- to provide guidance on the appropriateness of dose selection in toxicology studies when nonlinear toxicokinetics is considered to occur;
- to provide guidance on when nonlinearity is, or is not, likely to be relevant to the determination of health-based guidance values, risk assessment and risk management.

While the guidance will incorporate a data interpretation procedure, the document explicitly refrains from providing specific recommendations on decision making when toxicologically relevant nonlinearity is present. Decision making should always follow a case-by-case assessment, based on sound scientific principles and weight of evidence, regardless of the presence of toxicokinetic linearity or otherwise.
The first draft of JMPR guidance for interpreting nonlinear toxicokinetics has been prepared.

The draft guidance covers:

- the biological basis for nonlinearity in toxicokinetics;
- in vivo data and approaches used to determine nonlinearity in the major toxicokinetic processes of absorption distribution, metabolism and excretion;

- in vitro data and approaches used to characterize nonlinearity in toxicokinetic processes;
- the implications of nonlinearity in relationship to dose–response relationships, determination of points of departure, interspecies extrapolation, intraspecies variability and health-based guidance values;
- the implications of nonlinearity when providing advice on potential risks to consumers;
- criteria for establishing nonlinearity in toxicokinetics and toxicokinetic processes;
- statistically-, graphically- and physiologically-based toxicokinetic and other modelling approaches;
- interpretation of data provided in support of the nonlinearity of toxicokinetics and toxicokinetic processes;
- suitability of dose selection and study designs submitted by sponsors, based on the supporting information provided on toxicokinetics.
- suggestions for the use of toxicokinetic data to better design studies;
- suggestions on study designs to facilitate the generation of usable toxicokinetic data;
- brief guidance on the broader uses of toxicokinetics in risk assessment;
- case studies and examples to illustrate key points.

Recommendations

The Meeting expressed general agreement with the outline of the draft guidance and recommended that the eWG proceeds with the development of the guidance, aiming for completion by the next JMPR Meeting in 2024.

To facilitate development of the guidance, examples and case studies (both in vivo and in vitro) in the following areas would be of value. Stakeholders are encouraged to submit relevant studies in the following areas:

- nonlinear toxicokinetics due to reduced absorption;
- nonlinear toxicokinetics due to capacity limitation in first-pass metabolism;
- nonlinear toxicokinetics resulting from dose-dependent changes in distribution (including plasma protein binding and transport-dependent cellular uptake/efflux);
- nonlinear kinetics resulting from capacity limitation in elimination processes (including enzymatic transformation, auto-induction, auto-inhibition, transport-dependent excretion and re-uptake);
- nonlinear metabolic activation (that is, conversion to a more toxic metabolite) and its implications for study design and interpretation.

2.3 The need for sponsors to provide accurate chemical structures and related information on metabolites

At recent JMPR Meetings an approach to assess the toxicological relevance of metabolites and degradates has been proposed. In silico and read-across methods are frequently employed in relation to the threshold of toxicological concern (TTC). In particular, in silico analysis for genotoxicity prediction increasingly plays an important role in the weight-of-evidence approach

for genotoxicity (*Pesticide residues in food: guidance document for WHO monographers and reviewers, 2015, www.who.int/publications/i/item/WHO-HSE-FOS-2015.1*). Accurate information on the chemical structure of metabolites is essential for in silico analysis. If the raw data for a chemical structure obtained from analytical methods is incorrectly transferred to a Markush structure and chemical name, the in silico analysis for genotoxicity prediction will lead to scientifically inappropriate conclusions. Additionally, when a Markush structure is assessed in silico, sponsors should provide the output for all possible structural variants. Therefore, sponsors should ensure that Markush representations of compounds are accurate, and all plausible structures are covered in the analysis. While it is the sponsors responsibility to carry out in silico analyses, corresponding SMILES codes should accompany the results.

2.4 Resolving inconsistent assessment of common metabolites

Close to the finalization of the assessments at the 2022 Meeting of JMPR, it was identified in the case of several pyrazole-based pesticides, that the conclusions on some common metabolites differed (for instance assessed against a TTC versus covered by the parent health-based guidance value) depending on the parent compound. The reasons for the inconsistencies were investigated and found to include:

- different toxicological information had been presented on a metabolite from different parent compounds, for example, one dossier presented only in silico data while another contained data from toxicity studies;
- the naming of compounds differed across different parent compounds, with respect for example to company codes and chemical names;
- chemical structures were presented in a different manner (mirror images, presentation of terminal groups such as CH3), which meant any similarities were only evident on an in-depth check but not on an initial viewing of the individual pesticides.

In addition to the pyrazole group there are a number of types of pesticide chemistry which give rise to metabolites that are common to two or more compounds within a group. Companies developing the pesticides will be aware that other companies are producing compounds based on the same common moiety. In order to facilitate JMPR in making a consistent assessment of the same metabolite, sponsors are requested to form an industry Task Force and make a single toxicological submission for common metabolites of a group of pesticides (as has been done for some triazole metabolites).

2.5 On the rolling submission of data

In the JMPR call for data, sponsors are requested to submit all data and studies, both published and unpublished, for the toxicological and/or residue evaluations of the compounds. Several chemical dossiers submitted for evaluation were subject to multiple progressive updates and submissions over the course of evaluation (rolling submission of data). This practice causes confusion, disruption and delay in evaluation. This is particularly so when the new material is submitted close to the JMPR Meeting date. It is recommended that a single, fully complete, chemical dossier should be submitted in response to the call for data, rather than a long series

of updated dossiers or dossier variations over time. This issue has been the subject of previous comments by the JMPR Meetings in 2015, 2018 and 2019.

It may not be possible for JMPR to evaluate late submissions. Sponsors should note that the submission of an incomplete chemical dossier may result in an additional uncertainty factor in the toxicological evaluation.

Late submissions are leading to additional burdens for experts and ultimately delays in the discussions. For optimal use of the time and resources of the experts and the Joint Secretariat, the Meeting re-emphasized the importance of a complete submission of data on all compounds and their metabolites to enable JMPR to perform a state-of-knowledge risk assessment.

2.6 Why is a residue definition sometimes not agreed when there is an ADI/ARfD?

In response to a question raised at CCPR 2023, JMPR wishes to clarify why, even though an ADI/ARfD had been established, the residue cannot sometimes be defined.

While an ADI/ARfD is established for a pesticide active substance based on toxicity studies on that active substance, the residue present in commodities following the use of a pesticide may also contain one or more metabolites the safety of which needs to be assessed. These metabolites may be plant and/or livestock-specific and not present in the animals used in toxicity studies. Therefore, there is no direct link between having an ADI/ARfD for a pesticide active substance and the residue definition. In fact, it is not always possible to assess the safety of metabolites present in commodities in order to decide on their inclusion within the residue definition. The numbers of metabolites, their levels and toxicity are very variable. A scheme for assessing metabolites has been produced by the JMPR[1].

The levels of the active substance and its metabolites are often assessed using a radiolabelled version of the active substance. When it occurs that significant amounts of the radiolabel cannot be attributed to individual chemicals, the residue definition also cannot be concluded.

In summary, there might be toxicological or analytical issues that prevent the proper assessment of the safety of metabolites, and hence, prevent finalization of the residue definition despite the establishment of an ADI/ARfD for the active parent compound.

2.7 Enhancement of process

At JMPR's invitation, Mr Aaron Niman, chair of the electronic working group (EWG) on the Enhancement of CCPR and JMPR Operational Procedures, under the Codex Committee on Pesticide Residues (CCPR), presented the current state of the activities of the EWG in enhancing processes.

[1] https://iris.who.int/bitstream/handle/10665/144511/WHO_HSE_FOS_2015.1_eng.pdf?sequence=1

The Meeting considered some of the possibilities to enhance operational procedures and commented on some of the issues raised by the EWG. These included, among others, long-standing issues such as the enhancement of electronic quality of data, improved file naming and timely submission of full dossiers by the sponsors.

Other issues discussed included:

the challenges of the limited evaluation capacity available, as well as the option to engage full-time paid evaluators, with JMPR serving as peer reviewers;
early submission of data, allowing a quality control screen and the early elimination of unsatisfactory dossiers from the assessment process;
the focus on submission of only toxicological studies relevant to dietary exposure as a potential mechanism to reduce workload.

Noting that the JMPR Meetings are already intensive and long, any benefits that might result from either lengthening the Meeting or trying to timetable additional meetings were considered unlikely to increase output. The issue of adequate, timely submissions of data was also discussed above, under general considerations item 2.5.

2.8 Strategy and timing for JMPR re-evaluation of dithiocarbamates

A request has been received by JMPR from the CCPR, to prioritize dithiocarbamate fungicides for periodic review within the CCPR system.
The Meeting noted that this could be a very extensive task possibly occupying an entire JMPR Meeting, as there were 10 compounds in the group, with eight of them and two significant metabolites (ETU and PTU) previously evaluated by JMPR in the 1990s.

In an attempt to better identify the scale of the task and plan the best way forward, taking account of the extensive workload already planned for forthcoming JMPR Meetings, the Meeting agreed to request sponsors to respond to the following questions:

- Which of the dithiocarbamate compounds and metabolites do they intend to support for periodic review?
- What new toxicology data have been generated since the last JMPR evaluations on the compounds being supported?
- Do the new data address issues already identified as concerns for dithiocarbamates, for example endocrine activity or tumour mode of action?
- What is the extent of the additional published literature database?
- If information is to be made available on individual metabolites/degradants, how many common metabolites/degradants will this involve?
- Do current analytical methods provide data on individual metabolites present as the residue in commodities, or is the common moiety method (carbon disulfide) still the standard analytical methodology?
- For the compounds to be reviewed, what use patterns are being supported and how many field trials are likely to need evaluation?
- Will an industry task force be formed to coordinate a submission to JMPR (the Meeting's preferred option) or will there be numerous individual submissions?

3. Responses to specific concerns raised by the Codex Committee on Pesticide Residues (CCPR)

3.1 Indoxacarb (216)

At the Fifty-fourth CCPR meeting a concern form relating to indoxacarb was submitted. The European Union reported that in 2018 it had lowered its ADI and ARfD values, to 0.005 mg/kg bw per day based on maternal toxicity in the rat developmental study. Previously the ADI and ARfD were 0.006 mg/kg bw per day and 0.125 mg/kg bw respectively. Also, the European Union expressed concerns relating to the clarity of the JMPR conclusion on metabolite IN-JT333.

At the 2005 meeting JMPR established an ADI of 0–0.01 mg/kg bw on the basis of the NOAEL of 1.1 mg/kg bw per day in the one-year dog study; and an ARfD of 0.1 mg/kg bw on the basis of the NOAEL of 12.5 mg/kg bw in an acute neurotoxicity study.

The 2005 JMPR Meeting considered three rat developmental studies with indoxacarb (two pilot studies and the main 1997 study by Munley). The NOAELs in all three studies were concluded to be between 1.5 and 2 mg/kg bw per day. It is unclear from the EU documentation if the EU conclusion was based on findings in a different main study, which was available to the European Union but not to JMPR. There is no indication from the JMPR 2005 text that there were any biologically relevant effects at either 2 or 1 mg/kg bw per day in the main rat developmental study. The European Union is invited to explain in more detail the basis for their conclusion that the NOAEL for findings in a rat developmental study is 0.5 mg/kg bw per day, and how these findings might be produced by a single dose.

The European Union is correct in stating that the 2005 JMPR report on IN-JT333 does not specify how intakes should be addressed. The report describes acute, repeat (14-day) and genotoxicity studies which indicate it is more toxic than indoxacarb, but that it is not genotoxic.

Although the JMPR description of the approach to IN-JT333 is not conclusive, it is unclear why the European Union has a concern with dietary intakes of IN-JT333, as the EFSA conclusion indicates residues are unlikely to be above the limit of quantitation and agrees that IN-JT333 is not genotoxic. The Meeting performed an initial assessment using the LoQ and the threshold of toxicological concern (TTC) approach for non-genotoxic compounds (Cramer class III at 1.5 µg/kg bw per day) concerns with dietary exposures would be unlikely to be identified as this would equate to a 10kg person consuming approximately approx. 1.5kg of a commodity with a residue at 0.01 mg/kg.

On the evidence presented by the European Union in the concern form, the Meeting sees no reason to propose reprioritization of the periodic review of indoxacarb.

3.2 Mefentrifluconazole (320)

Background

Mefentrifluconazole was evaluated as a new compound by the 2022 JMPR and maximum residue levels were estimated for a range of commodities. In evaluating mefentrifluconazole residues in leafy vegetables, the 2022 JMPR estimated maximum residue levels of 30 mg/kg for each of the subgroups of leafy greens and leaves of brassicacea.

However, the Meeting noted that the acute dietary exposure assessment showed that residues in leafy greens and leaves of Brassicacea exceeded the ARfD of 0.3 mg/kg bw for several subpopulations and that no alternative GAP was available. On the basis of this information, it was concluded that the estimated acute dietary exposure to residues of mefentrifluconazole for the consumption of commodities from the subgroup of leafy greens and leaves of Brassicaceae may present a health concern.

The current Meeting received a concern raised by the Delegation of the United States noting that the request was for a maximum residue level for head lettuce only and that no request was made for the group of leafy vegetables (including *Brassica* leafy vegetables).

Comments by the JMPR

The current meeting re-assessed the data for leafy greens in the context of the request in the concern form, and noted that the 2022 JMPR recommended a maximum residue level for the leafy greens subgroup, despite median residues for the representative crops being greater than 5-fold. Therefore, the Meeting withdraws its previous recommendation of 30 mg/kg for the subgroup of leafy greens. In turn, individual maximum residue levels for each of the representative crops should have been determined, as follows:

Leafy vegetables (including brassica leafy vegetables)

Leafy greens

The critical GAP is from the United States of America for leafy vegetables (including Brassica leafy vegetables); 3 × 146 g ai/ha, 7 day-RTI, 0-day PHI. The 2022 Meeting received trials from Canada and the United States on head lettuce, leaf lettuce, cos lettuce, spinach and radish leaves. All trials matched the critical GAP.

Mefentrifluconazole residues in head lettuce with wrapper leaves, in ranked order were (n = 8): 0.12, 0.27, 0.32, 0.89, 1.30, 1.50, 2.1 and 2.2 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg, an STMR of 1.095 mg/kg and an HR of 2.2 mg/kg for head lettuce.

Mefentrifluconazole residues in leaf lettuce in ranked order were (n = 7): 2.4, 2.7, 3.0, 4.2, 4.4, 6.4 and 7.2 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg, an STMR of 4.2 mg/kg and an HR of 8.3 mg/kg (based on the highest residue of replicate samples) for leaf lettuce.

Mefentrifluconazole in one sample of cos lettuce was 2.3 mg/kg. As there are an insufficient number of trials on cos lettuce, the current Meeting could not estimate a maximum residue level for cos lettuce.

Mefentrifluconazole residues in spinach in ranked order were (n = 8): 3.8, 4.6, 4.9, 5.2, 11, 12 (2) and 17 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg, an STMR of 8.1 mg/kg and an HR of 18 mg/kg (based on the highest residue of replicate samples) for spinach.

The Meeting noted that the acute dietary exposure assessment showed that residues in leaf lettuce exceeded the ARfD of 0.3 mg/kg bw, at 170 percent for Chinese children 1–6 years while residues in spinach exceeded the ARfD at 140 percent for Belgian toddlers. No alternative GAP was available.

RECOMMENDATIONS

On the basis of the data from supervised trials the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and International Estimate of Short-Term Intake (IESTI) assessment.

CCN	Commodity name	Recommended Maximum residue level (mg/kg)		STMR (-P) (mg/kg)	HR (-P) (mg/kg)
		New	Previous		
VL 2050	Leafy greens, subgroup of	W	30		
VL 0482	Head lettuce	5		1.095	2.2
VL 0483	Leaf lettuce[a]	15		4.2	8.3
VL 0502	Spinach[a]	30		8.1	18

[a]On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of mefentrifluconazole for the consumption of leaf lettuce and spinach may present a public health concern.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for mefentrifluconazole is 0–0.04 mg/kg bw. The IEDIs for mefentrifluconazole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the 2022 and current JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 4 to 20 percent of the maximum ADI.

Acute dietary exposure

The ARfD for mefentrifluconazole is 0.3 mg/kg bw. The IESTIs for mefentrifluconazole were re-calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the 2022 and current Meetings for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs were at or less than 100 percent of the ARfD, except for:
leaf lettuce (170 percent for Chinese children)
spinach (140 percent for Belgian toddlers).

The meeting concluded that acute dietary exposure to residues of mefentrifluconazole in commodities where the ARfD is exceeded may present a public health concern.

3.3 Metalaxyl (138)

The Meeting noted the concern submitted by the Republic of Korea regarding no recommendation given for 'ginseng, extracts' by the 2022 JMPR was withdrawn following clarification provided by the JMPR Secretariat during the CCPR 54.

3.4 Phosmet

At the Fifty-fourth CCPR Meeting, the European Union raised concerns regarding intake estimates for phosmet, which using EU modelling methods are up to 67 000 times the new EU ARfD value, and also concerns about the residue definition.

As a result of recent EU reviews (2020 and 2022) the European Union established ADI and ARfD values of 0.001 mg/kg bw per day for phosmet. These were on the basis of the NOAEL for the rat two-generation study and applying a 1000-fold safety factor due to concerns about the absence of a developmental neurotoxicity study and from epidemiological evidence.

In 1994 the JMPR established an ADI of 0–0.01 mg/kg bw on the basis of a NOAEL of 20 ppm (equal to 1.3 mg/kg bw per day) in a two-generation reproductive study in rats, based on parental/reproductive effects, and applying a 100-fold safety factor. This value was confirmed in by JMPR in 1998. In 1998 JMPR established an ARfD of 0.02 mg/kg bw on the basis of a NOAEL in a rabbit developmental study for minor skeletal variations, and applying a 100-fold safety factor. In 2003, JMPR reviewed the ARfD. A new ARfD was established at 0.2 mg/kg bw on the basis of a NOAEL of 2 mg/kg bw in an ethically valid human volunteer study using both males and females. The JMPR Meeting in 2003 concluded that the measurements performed in the human study were adequate to cover the most sensitive markers for phosmet toxicity.

Initially the JMPR secretariat was unable to confirm the intake estimate and requested the European Union provide additional details. Additional information was provided and this confirmed that the EU methodology was similar to that of JMPR. The EU intake estimates indicated that JMPR's existing ARfD could be exceeded by up to 300 percent.

The Meeting concluded that, as phosmet was last reviewed over 20 years ago and since then analytical methods have evolved and new intake estimates indicate that JMPR's ARfD could be exceeded, phosmet should be reprioritized within the CCPR periodic review scheme. The Meeting noted that periodic review of phosmet has been scheduled for 2024.

4. Dietary exposure assessment for pesticide residues in food

Emamectin and triflumuron were considered by the current Meeting for toxicology only and no dietary risk assessment was conducted.

For fluazinam and permethrin the toxicity of parent and/or metabolites could not be determined and no dietary exposure assessment was conducted.

Evaluation of prochloraz was deferred to the 2024 Meeting.

4.1 Chronic dietary exposure

International Estimate Of Daily Intake

At the current Meeting, an International Estimated Daily Intake (IEDI) was calculated for each compound for which an acceptable daily intake (ADI) was established. The IEDI was calculated by multiplying the median concentrations of residues by the average daily per capita consumption of treated commodities. The concentrations were supervised trials median residues [STMRs] and/or supervised trials median residues in a processed commodity [STMR-Ps]. The per capita food consumption amounts used were from the 17 Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) cluster diets. A detailed description of the method used to derive the cluster diets is included in the Environmental Health Criteria 240 (EHC 240) monograph.[2]

These IEDIs were expressed as a percentage of the maximum ADI for a 55 kg or 60 kg person, depending on the region covered by each cluster diet (see table below). The spreadsheet application is available at https://cdn.who.int/media/docs/default-source/food-safety/gems-food/iedi-calculation-vs04-17clusters.xlsx?sfvrsn=2dc46f36_2.

The detailed calculations of the chronic (long-term) dietary exposure assessments are given in Annex 3.

Chronic dietary exposure estimates using national dietary survey data

Food consumption data from national dietary surveys were used as the basis for estimating mean and high percentile chronic dietary exposure to pesticide residues for different age/sex groups.

In a continuation of the trial exercise, the global estimate of chronic dietary exposure (GECDE) model, developed by JECFA (veterinary drugs) in 2011,[3] was used for estimating high percentile dietary exposure to pesticide residues for population subgroups of toxicological concern, such as adult women (as a proxy for women of childbearing age), infants and toddlers, and young children and adolescents, in addition to all adults (as a proxy for the general population). The GECDE model is based on summary statistics derived from individual food

[2] FAO/WHO. 2009. Principles and methods for the risk assessment of chemicals in food. A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization. Geneva: World Health Organization (Environmental Health Criteria 240); https://www.who.int/publications/i/item/9789241572408

[3] FAO/WHO. 2012. Joint FAO/WHO Expert Meeting on Dietary Exposure Assessment Methodologies for Residues of Veterinary Drugs. Final Report including Report of Stakeholder Meeting. Geneva: World Health Organization (https://www.fao.org/fileadmin/user_upload/agns/pdf/jecfa/Dietary_Exposure_Assessment_Methodologies_for_Residues_of_Veterinary_Drugs.pdf)

consumption data from representative national surveys and takes account of consumption of one commodity at a high level (for consumers of that commodity only) plus consumption of the remaining commodities at a population mean level (the GECDE-high). Where all consumption data for all foods in the calculation are at a mean population level this is referred to as the GECDE-mean. The GECDE model is intended to be used when only summary statistics of food consumption are available.

Food consumption data suitable for use in the GECDE model are available in the WHO Chronic Individual Food Consumption – summary statistics (CIFOCOss) database, which contains summary statistics of food consumption data derived from national surveys that have two or more daily records per survey participant. For use in chronic dietary exposure assessments, results for each individual are averaged over the number of days of the survey prior to deriving population statistics. For many countries, different population subgroups are surveyed separately over different time periods and may use different approaches. In these cases it is not possible to combine these datasets to estimate dietary exposure for the population as a whole.

In the GECDE-mean and GECDE-high chronic dietary exposure estimates, the STMR residue levels are assigned to each relevant food with a maximum residue level recommendation for the pesticide. For multi-ingredient foods, a recipe tool developed by RIVM was used to disaggregate the food into its component ingredients to allow derivation of an ingredient weighted STMR. The estimates of GECDE-mean and GECDE-high are summarized in Table 1. In addition, the percentages of CIFOCOss cohorts for which the GECDE-mean and GEDCE-high exceed the ADI are also summarized in the table below.

Summary of chronic (long-term) dietary exposure assessments (IEDI) and chronic dietary exposure estimates using national dietary survey data (GECDE)

CCPR code	Pesticide	ADI (mg/kg bw)	Range of IEDI as % of maximum ADI	Range of dietary exposures across national dietary surveys (GECDE), as percent of maximum ADI			Percentage of cohorts in subpopulation groups exceeding the ADI[b]	
				Subpopulation group	Mean	High[a]	Mean	High
246	Acetamiprid	0–0.07	0–2	Adults, all	0–4	0–20	0	0
				Adults, female	0–4	0–20	0	0
				Children & adolescents	0–9	0–30	0	0
				Infants and toddler	1–10	3–30	0	0
221	Boscalid	0–0.04	10–60	Adults, all	1–50	6–120	0	5
				Adults, female	1–50	5–120	0	5
				Children & adolescents	1–160	6–320	2	30
				Infants and toddler	10–140	40–560	20	50
145	Carbosulfan[c]	0–0.01	0–2	Adults, all	0–10	0–80	0	0
				Adults, female	0–10	0–80	0	0
				Children & adolescents	0–70	0–390	0	2
				Infants and toddler	0–50	0–310	0	3
238	Clothianidin	0–0.1	0–2	Adults, all	0–3	0–5	0	0
				Adults, female	0–3	0–5	0	0
				Children & adolescents	0–7	1–10	0	0
				Infants and toddler	1–5	2–20	0	0
263	Cyantraniliprole	0–0.03	4–40	Adults, all	0–70	3–150	0	7
				Adults, female	0–70	3–140	0	7
				Children & adolescents	0–130	2–340	2	20
				Infants and toddler	10–110	30–420	7	50
273	Cyflumetofen	0–0.1	0–1	Adults, all	0–1	0–4	0	0
				Adults, female	0–1	0–4	0	0
				Children & adolescents	0–3	0–20	0	0

CCPR code	Pesticide	ADI (mg/kg bw)	Range of IEDI as % of maximum ADI	Range of dietary exposures across national dietary surveys (GECDE), as percent of maximum ADI			Percentage of cohorts in subpopulation groups exceeding the ADI[b]	
				Subpopulation group	Mean	High[a]	Mean	High
				Infants and toddler	0–5	0–20	0	0
118	Cypermethrin, zeta	0–0.02	7–30	Adults, all Adults, female Children & adolescents Infants and toddler	1–30 1–30 3–70 5–70	1–80 1–80 3–310 30–250	0 0 0 3	0 0 10 40
135	Deltamethrin	0–0.01	30–100	Adults, all Adults, female Children & adolescents Infants and toddler	2–250 2–250 7–520 10–170	2–490 2–490 7–1100 20–430	2 2 10 3	7 7 20 30
224	Difenoconazole	0–0.01	20–100	Adults, all Adults, female Children & adolescents Infants and toddler	1–120 1–120 1–430 40–230	1–490 1–490 20–1400 110–760	5 5 20 70	20 20 60 100
130	Diflubenzuron	0–0.02	3–20	Adults, all Adults, female Children & adolescents Infants and toddler	0–20 0–20 0–40 4–60	0–50 0–60 2–80 10–120	0 0 0 0	0 0 0 7
331	Dimethylnaphthalene (1,4)	0–0.3	0–20	Adults, all Adults, female Children & adolescents Infants and toddler	0–6 0–7 0–20 0–20	0–20 0–20 0–50 0–60	0 0 0 0	0 0 0 0
255	Dinotefuran	0–0.2	0–2	Adults, all Adults, female Children & adolescents Infants and toddler	0–10 0–10 1–30 1–20	0–30 0–30 1–60 2–60	0 0 0 0	0 0 0 0

CCPR code	Pesticide	ADI (mg/kg bw)	Range of IEDI as % of maximum ADI	Range of dietary exposures across national dietary surveys (GECDE), as percent of maximum ADI			Percentage of cohorts in subpopulation groups exceeding the ADI[b]	
				Subpopulation group	Mean	High[a]	Mean	High
	Florylpicoxamid	0–0.1	0–1	Adults, all Adults, female Children & adolescents Infants and toddler	0–1 0–1 0–3 0–3	0–5 0–4 0–10 0–10	0 0 0 0	0 0 0 0
243	Fluopyram	0–0.01	10–80	Adults, all Adults, female Children & adolescents Infants and toddler	0–100 0–100 3–240 30–270	0–320 0–650 20–770 110–920	0 1 30 80	30 20 70 100
267	Imazapyr	0–3	0–0	Adults, all Adults, female Children & adolescents Infants and toddler	0–0 0–0 0–0 0–0	0–0 0–0 0–0 0–0	0 0 0 0	0 0 0 0
111	Iprodione	0–0.06	0–3	Adults, all Adults, female Children & adolescents Infants and toddler	0–30 0–30 0–60 0–190	0–370 0–230 0–770 1–1000	0 0 0 30	5 2 30 60
334	Isocycloseram	0–0.02	1–4	Adults, all Adults, female Children & adolescents Infants and toddler	0–7 0–8 0–20 1–20	0–30 0–20 1–70 4–80	0 0 0 0	0 0 0 0
330	Isoflucypram	0–0.06	0–1	Adults, all Adults, female Children & adolescents Infants and toddler	0–0 0–0 0–1 0–1	0–1 0–1 0–1 0–2	0 0 0 0	0 0 0 0
335	Isotianil	0–0.05	0–0	Adults, all Adults, female	0–0 0–0	0–1 0–1	0 0	0 0

CCPR code	Pesticide	ADI (mg/kg bw)	Range of IEDI as % of maximum ADI	Range of dietary exposures across national dietary surveys (GECDE), as percent of maximum ADI			Percentage of cohorts in subpopulation groups exceeding the ADI[b]	
				Subpopulation group	Mean	High[a]	Mean	High
				Children & adolescents	0–0	0–3	0	0
				Infants and toddler	0–1	0–3	0	0
336	Mepiquat chloride	0–0.3	0–1	Adults, all	0–1	0–4	0	0
				Adults, female	0–1	0–3	0	0
				Children & adolescents	0–1	0–9	0	0
				Infants and toddler	0–1	0–10	0	0
291	Oxathiapiprolin	0–4	0–0	Adults, all	0–0	0–1	0	0
				Adults, female	0–0	0–1	0	0
				Children & adolescents	0–0	0–2	0	0
				Infants and toddler	0–0	0–2	0	0
062	Piperonyl butoxide	0–0.2	20–40	Adults, all	0–180	0–370	2	10
				Adults, female	0–180	0–370	2	9
				Children & adolescents	0–370	0–830	8	30
				Infants and toddler	8–130	30–470	3	40
160	Propiconazole	0–0.07	2–20	Adults, all	0–60	0–120	0	2
				Adults, female	0–50	0–110	0	1
				Children & adolescents	0–100	0–210	2	6
				Infants and toddler	2–70	20–230	0	10
063	Pyrethrins	0–0.04	0–1	Adults, all	0–5	0–9	0	0
				Adults, female	0–5	0–9	0	0
				Children & adolescents	0–10	0–20	0	0
				Infants and toddler	0–5	0–20	0	0
245	Thiamethoxam	0–0.08	1–7	Adults, all	0–20	1–40	0	0
				Adults, female	0–20	1–40	0	0
				Children & adolescents	1–40	2–80	0	0
				Infants and toddler	3–20	5–80	0	0

CCPR code	Pesticide	ADI (mg/kg bw)	Range of IEDI as % of maximum ADI	Range of dietary exposures across national dietary surveys (GECDE), as percent of maximum ADI			Percentage of cohorts in subpopulation groups exceeding the ADI[b]	
				Subpopulation group	Mean	High[a]	Mean	High
77	Thiophanate-methyl	0–0.09	0–0	Adults, all	0–0	0–0	0	0
				Adults, female	0–0	0–0	0	0
				Children & adolescents	0–0	0–0	0	0
				Infants and toddler	0–0	0–0	0	0
337	Tricyclazole	0–0.05	0–0	Adults, all	0–0	0–0	0	0
				Adults, female	0–0	0–0	0	0
				Children & adolescents	0–0	0–1	0	0
				Infants and toddler	0–0	0–1	0	0

ADI: acceptable daily intake; bw: body weight; CCPR: Codex Committee on Pesticide Residues; IEDI: International Estimated Daily Intake; CIFOCOss: Chronic Individual Food Consumption summary statistics; GECDE: global estimate of chronic dietary exposure; IEDI: International Estimated Daily Intake; NA: Not Assessed

a. For each national survey in the CIFOCOss database, for the GECDE-high model for a specified age or age/sex group, a high percentile dietary exposure was first calculated for each commodity with an assigned STMR: if there were more than 180 consumers of a commodity, a 97.5th percentile dietary exposure for consumers only was derived; if there were more than 60 but fewer than 181 consumers, a 95th percentile dietary exposure was derived; if there were more than 30 but fewer than 61 consumers, a 90th percentile dietary exposure was derived; and if there were more than 10 but fewer than 31 consumers, a median dietary exposure was derived. If there were fewer than 11 consumers, only the mean dietary exposure for consumers only was derived for that Codex commodity code.

b. A cohort is a unique combination of country, age and/or gender and survey year. Within the specified population subgroups, the number of cohorts are: Adults, all (81), Adults, female (88), Children & adolescents (50), Infants and toddler (30)

c. Including carbofuran

Comparison of IEDI and GECDE

When there was a large deviation between the two methods this tended to be due to a particular dietary pattern in a country or small number of countries. For example, the deviation for piperonyl butoxide is largely due to the high consumption of sorghum in Burkina Faso and maize in Zambia. These individual patterns tend to be submerged in the averaging process resulting in the cluster diets.

The inclusion of statistics on the percentage of subpopulation groups within an age-sex class exceeding the ADI helps to inform the likely pattern of exceedances, with a low percentage indicating either marginal exceedance or exceedance due to a specific dietary pattern.

The relationship between the GECDE-mean and GECDE-high also tends to follow a well-behaved pattern with the upper limit of the GECDE-high usually a factor of 2-5 above the upper limit of the GECDE-mean. This ratio would be expected for a high percentile of about 90-95.[4]

Possible refinement when the IEDI exceeds the ADI

The upper end of the range of IEDI did not exceed the ADI for any of the pesticide residues considered.

4.2 Acute dietary exposure

At the current Meeting, an international estimate of short-term intake (IESTI) was calculated for compounds for which an acute reference dose (ARfD) was established. For each relevant food commodity, the highest expected residue (highest residue in the edible portion of a commodity [HR] or highest residue in a processed commodity [HR-P]) and the highest large portion (LP) food consumption value for the general population (all ages) and children (6 years and under) were used for the calculation of the IESTI. The LP data are derived from single-day measures of food consumption, from national dietary surveys. For bulked and blended commodities, the STMR or STMR-P is used as the residue level in the IESTI calculation. A description of the IESTI method is included in EHC 240.

The IESTI results are expressed as a percentage of the ARfD and are summarized in the table below. The spreadsheet application is available at https://cdn.who.int/media/docs/default-source/food-safety/gems-food/iesti_calculation21_model.xlsx?sfvrsn=1dca5616_9.

The detailed calculations of acute dietary exposure are given in Annex 4.

[4] USFDA. 2006. Guidance for Industry: Estimating Dietary Intake of Substances in Food. [cited 9 November 2015]. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food

Summary of acute dietary exposure assessments (IESTI)

CCPR code	Pesticide	ARfD (mg/kg bw)	Range of percentages of ARfD across commodities
246	Acetamiprid	0.1	0-0
145	Carbosulfan [a]	0.02	0-310 310 Mango (Toddler 8–20 months, Netherlands) 210 Eggplant (Children 1–6 yrs, China) 120 Eggplant (General population >1 yrs, China)
238	Clothianidin	0.6	0–1
118	Cypermethrin, zeta	0.04	0–20
135	Deltamethrin	0.05	0–1
224	Difenoconazole	0.3	0–100
255	Dinotefuran	1	0–0
243	Fluopyram	0.5	0–10
111	Iprodione	0.6	0–190 190 Broccoli (Toddler 8-20 months, Netherlands)
334	Isocycloseram	0.5 (general population) 0.08 (women of childbearing age)	0–9
336	Mepiquat Chloride	0.6	0–40
160	Propiconazole	0.3	70–100
063	Pyrethrins	0.2	0–0
245	Thiamethoxam	1	0–1
77	Thiophanate-methyl	1	0–0
337	Tricyclazole	0.05	0–40

ARfD: acute reference dose; bw: body weight; CCPR: Codex Committee on Pesticide Residues; IESTI: international estimate of short-term intake.

a. Including carbofuran

Possible refinement when the IESTI exceeds the ARfD

Iprodione

The Meeting concluded that the estimated acute dietary exposure to residues of iprodione for the consumption of broccoli by children may present a public health concern; 190 percent of the ARfD for consumption of cooked/boiled broccoli for toddlers (Netherlands diet).

As no alternative GAP data were available to the Meeting to estimate lower HR values for these commodities, no refinement of the acute dietary exposure estimates was possible. International estimates of short-term intakes can be refined if alternative GAP data become available in the future. In addition, processing data (cooking/boiling) on broccoli might lead to a refinement of the short-term intakes.

The ARfD of 0.6 mg/kg bw established by the 2023 JMPR was derived from a threshold dose of 60 mg/kg bw for effects (body weight loss and reduced food consumption) observed after 6 days of exposure, the first day these endpoints were measured following the start of treatment, in the developmental study in rabbits. As the study was considered adequate and the LOAEL is just over three times the NOAEL, it is unlikely that the ARfD can be refined significantly.

Carbosulfan

The Meeting concluded that the estimated acute dietary exposure to residues of carbosulfan for the consumption of mango and eggplant by children and of eggplant by the general population may present a public health concern.

As no alternative GAP data were available to the Meeting to estimate lower HR values for these commodities, no refinement of the acute dietary exposure estimates was possible. International estimate of short-term intakes can be refined if alternative GAP data become available in the future.

There is essentially no room for refinement of the health-based guidance values for carbosulfan. The reasons for this are: essentially no new data of any value was submitted by the Sponsor. There was some new toxicokinetic information that was considered in relation to deriving a chemical specific adjustment factors for the health-based guidance values. However, the overall conclusion was that this data was insufficient to derive chemical specific adjustment factors because there was too much remaining uncertainty.

The 2023 evaluation essentially re-confirmed the existing JMPR health-based guidance values while providing some updates in relation to the major metabolites. Essentially, it is not surprising that re-evaluation of the same data results in essentially the same results as the multiple previous JMPR evaluations of carbosulfan.

5. Evaluation of data for acceptable daily intake and acute reference dose for humans, maximum residue levels and supervised trials median residue values

5.1 1,4-Dimethylnaphthalene (331) (T,R)*

TOXICOLOGY

1,4-Dimethylnaphthalene (1,4-DMN) is the common and systematic (IUPAC) name for this compound, Chemical Abstracts Service number 571-58-4. It belongs to the chemical family of alkylated naphthalenes.

1,4-Dimethylnaphthalene acts as a plant growth regulator preventing sprouting of potato tubers. Besides being synthetically produced, it also occurs naturally in different plant species (for example potato, rhubarb, poppy). 1,4-Dimethylnaphthalene acts by enhancing dormancy, a natural event triggered by biochemical substances found within the potato (*solanum tuberosum*).

1,4-Dimethylnaphthalene has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR).

1,4-Dimethylnaphthalene occurs naturally in food with background values up to 60 µg/kg in potato, 0.4 µg/kg in poppy and up to 12 µg/kg in poppy tops. Consistent with other regulatory authorities' reduced data requirements for naturally occurring substances, a reduced data package was submitted to JMPR. All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with current Organisation for Economic Co-operation and Development (OECD) test guidelines unless otherwise specified. A number of additional papers were identified from a literature search that complemented the toxicological information submitted for the current assessment. Based on its evaluation of the data, the current Meeting considered it sufficient for risk assessment.

Biochemical aspects

After oral administration, radiolabelled 1,4-DMN is rapidly and almost completely absorbed, widely distributed, metabolized, and essentially completely excreted within 48 hours, with urine being the primary route of excretion (72 percent of administered radioactivity). After intraperitoneal administration of [^{14}C]1,4-DMN, radioactivity was found in faeces (40.8 percent of administered dose, AD, within 72 hours) which confirms biliary excretion. After intraperitoneal administration of [^{3}H]1,4-DMN the maximum level of radioactivity in plasma (C_{max}= 0.53 KBq/mL) was reached during the fourth hour after administration of the compound ($T_{max,\ plasma}$ = ca 4 hours).

Limited information is available on the distribution of 1,4-DMN after oral administration. However, after intraperitoneal administration, 1,4-DMN and its metabolites were widely and rapidly distributed in rats. The highest concentrations were

observed in adipose tissue, followed by liver, kidneys, spleen and adrenals. After 72 hours tissue levels, including in adipose tissue, were low (less than 2 percent of AD), indicating that neither 1,4-DMN nor its metabolites accumulate.

After a single oral dose of 28.6 mg/kg body weight (bw) 1,4-DMN, it was detected only in trace amounts in urine. After intraperitoneal administration at 28 mg/kg bw, 1,4-DMN and its metabolites were excreted rapidly (plasma half-life of eight hours) and mainly via urine (56.5 percent of AD within 72 hours), but also via faeces (40.8 percent of AD within 72 hours).

After intraperitoneal administration, apart from the unchanged substance (1,4-DMN), the rat urine contained metabolites obtained via three different pathways:

- side chain hydroxylation, forming 1-hydroxymethyl-4-methylnaphtalene (M21; trace amounts in urine) followed by oxygenation to form 4-methyl-1-naphthoic acid (M23; 6 percent in urine) and further metabolism to, for example, 4-methyl-1-naphthoic acid glucuronide (6.1 percent in urine);

- ring hydroxylation;

- the formation of reactive epoxide intermediates, followed by their conjugation with glutathione or other organic xenobiotics that can be cleaved by enzymatic hydrolysis to naphthothiophenols, resulting in cysteine-S-conjugates, which in turn are enzymatically converted to the corresponding thionaphthol by the release of pyruvate and ammonia. In a further step, metabolites with accessible sulfhydryl groups can be subjected to methylation, yielding 1,4-dimethyl-methylthionaphthalene.

From in vitro studies of the metabolism of 1,4-DMN with microsomes, no unique metabolite was identified with human microsomes compared to mice, rats and dogs. It was observed that rat metabolism was slower than metabolism in humans, dogs or mice.

Toxicological data

The acute oral median lethal dose (LD_{50}) of 1,4-DMN was greater than 2000 mg/kg bw and the dermal LD_{50} was greater than 2000 mg/kg bw. The inhalation median lethal concentration (LC_{50}) of 1,4-DMN was greater than 4.15 mg/L. 1,4-Dimethylnaphthalene was slightly to moderately irritating to skin and irritating, but reversibly so, to the eyes in rabbits. It was not skin sensitizing in a local lymph node assay (LLNA).

In repeat-dose toxicity studies on rats the main effects were on the kidney.

In a 90-day dietary toxicity study in rats, 1,4-DMN was administered at concentrations of 0, 500, 2500 or 10 000 ppm (equal to 0, 32, 161 and 677 mg/kg bw per day for males, 0, 38, 186 and 747 mg/kg bw per day for females). The no-observed-adverse-effect level (NOAEL) for 1,4-DMN was 500 ppm (equal to 32 mg/kg bw per day) based on increases in relative kidney weight (by 15 percent), basophilic tubules in the

kidney and a suppression of body weight gain (by 11 percent in males) at 2500 ppm (equal to 161 mg/kg bw per day).

In a 104-week combined chronic toxicity and carcinogenicity study in rats, 1,4-DMN was administered in the diet at concentrations of 0, 150, 500 or 3750 ppm (equal to 0, 8, 27 and 208 mg/kg bw per day for males, 0, 10, 33 and 247 mg/kg bw per day for females). The NOAEL for systemic toxicity was 500 ppm (equal to the 27 mg/kg bw per day) based on reduced body weight and histopathological changes in the kidneys of both sexes at 3750 ppm (equal to 208 mg/kg bw per day). The NOAEL for carcinogenicity was 3750 ppm (equal to 208 mg/kg bw per day), the highest dose tested.

The Meeting concluded that 1,4-DMN is not carcinogenic in rats.

1,4-Dimethylnaphthalene was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The Meeting concluded that 1,4-DMN is unlikely to be genotoxic.

In view of the lack of genotoxicity and the absence of carcinogenicity in rats, the Meeting concluded that 1,4-DMN is unlikely to pose a carcinogenic risk to humans.

In an extended one-generation reproductive toxicity study in rats, 1,4-DMN was administered at dietary concentrations of 0, 500, 2000 or 7500 ppm (equal to 0, 40, 160 and 510 mg/kg bw per day). The NOAEL for parental toxicity was 500 ppm (equal to 40 mg/kg bw per day), based on increased liver weights, increased cholesterol accompanied by increased triglycerides in females at 2000 ppm (equal to 160 mg/kg bw per day). The reproductive NOAEL was 7500 ppm (equal to 510 mg/kg bw per day), the highest dose tested. The offspring/developmental NOAEL was 2000 ppm (equal to 160 mg/kg bw per day), based on delayed vaginal patency and preputial separation, and reduced body weight at 7500 ppm (equal to 510 mg/kg bw per day.

In a developmental toxicity study in rabbits, 1,4-DMN was administered by gavage at dose levels of 0, 25, 80 or 250 mg/kg bw per day. The maternal NOAEL was 80 mg/kg bw per day based on reduced food consumption and body weight gain at the 250 mg/kg bw per day. The embryo/fetal NOAEL was 250 mg/kg bw per day, the highest dose tested.

The Meeting concluded that 1,4-dimethylnaphthalene is not teratogenic.

No specific data were submitted regarding neurotoxicity, but no evidence of neurotoxicity was reported in routine toxicological studies with 1,4-DMN.

The Meeting concluded that 1,4-dimethylnaphthalene is unlikely to be neurotoxic.

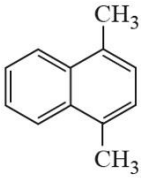
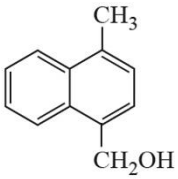
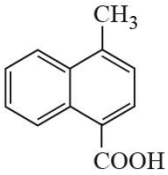
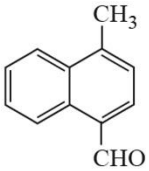
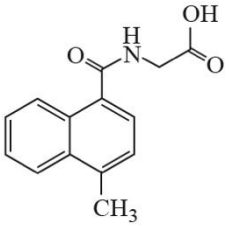
No specific data were submitted regarding immunotoxicity, but no evidence of immunotoxicity was reported in routine toxicological studies with 1,4-DMN.

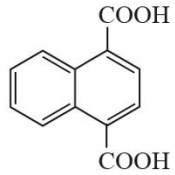
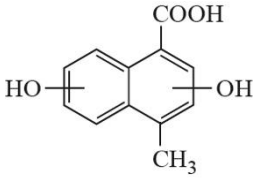
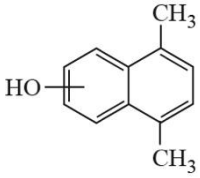
The Meeting concluded that 1,4-dimethylnaphthalene is unlikely to be immunotoxic.

Toxicological data on metabolites and/or degradates

There were in total nine metabolites identified. These were M21 (1-hydroxymethyl-4-methylnaphthalene), M23 (4-methyl-1-naphthoic acid), M01 (4-methyl-1-naphthaldehyde), M02 (glycine conjugate of M23), M03 (α variant) and M04 (δ variant) both of which are ornithine conjugates of M23), M14 (1,4-naphthalenedicarboxylic acid, M06 (dihydroxy-1-methyl-4-naphthoic acid), and
M15 (1,4-dimethylnaphthol). Information on these metabolites is summarized in the table below.

Summary overview of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	**Major rat metabolite** (>10% AD)	**Genotoxicity assessment** (data, QSAR, read-across)	**General toxicity**	**Toxicological reference values**
1,4-Dimethylnaphthalene (1,4-DMN) 	Parent	Not genotoxic (data)	Dataset	ADI 0–0.08 mg/kg bw ARfD: Unnecessary
M21 (1-Hydroxymethyl-4-methylnaphthalene) 	Traces in urine, but >12.1% of AD based on downstream metabolites	Not genotoxic (QSAR)	Covered by parent	Parent ADI
M23 (4-Methyl-1-napthaoic acid) 	6.0% in urine, but >12.1% including downstream metabolites	Not genotoxic (QSAR)	Covered by parent	Parent ADI
M01 (4-Methyl-1-naphthaldehyde) 	M01 is a metabolite of M21 and is metabolized into M23	Not genotoxic (QSAR)	No data	Parent ADI
M02 (Glycine conjugate of 4-methyl-1-napthaoic acid) 	Glycine conjugate of M23	Not genotoxic (QSAR)	No data	Parent ADI
M03 (δ variant) **M04** (α variant) Ornithine conjugates of M23,4-methyl-1-napthaoic acid (two stereoisomers)	Ornithine conjugates of M23	Not genotoxic (QSAR)	No data	Parent ADI

M14 (1,4-naphthalenedicarboxylic acid) 	Not found in rats	Not genotoxic (QSAR)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
M06 (Dihydroxy-1-methyl-4-naphthoic acid) 	Not found in rats	Not genotoxic (QSAR)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
M15 (1,4-dimethylnaphthol) 	Not found in rats	Not genotoxic (QSAR)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day

ADI: Acceptable daily intake;RA: read across; AD: Administered dose; TTC: Threshold of toxicological; concern
QSAR: Quantitative structure–activity relationship

Microbiological aspects

There was no information available in the public domain, and no experimental data was submitted that addressed the possible impact of 1,4-DMN residues on the human intestinal microbiome.

Human data

No exposure-related health effects during manufacture or use of 1,4-DMN are known.

No information on accidental or intentional poisoning in humans was available.

The Meeting concluded that the existing database on 1,4-dimethylnaphthalene was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) for 1,4-dimethylnaphthalene of 0–0.3 mg/kg bw based on the NOAEL of 27 mg/kg bw per day in the 104-week combined chronic toxicity and carcinogenicity study in rats, and using a safety factor of 100. This was supported by the NOAEL of 32 mg/kg bw per day in the 90-day rat dietary study.

The Meeting concluded that it was not necessary to establish an acute reference dose (ARfD) for 1,4-dimethylnaphthalene in view of its low acute oral toxicity and the absence of developmental toxicity or any other toxicological effects likely to be elicited by a single dose.

A toxicological monograph was prepared.

Levels relevant to risk assessment of 1,4-dimethylnaphthalene

Species	Study	Effect	NOAEL	LOAEL
Rat	90-day dietary toxicity study	Toxicity	500 ppm, equal to 32 mg/kg bw per day	2500 ppm, equal to 161 mg/kg bw per day
	104-week combined chronic toxicity and carcinogenicity study [a]	Toxicity	500 ppm, equal to 27 mg/kg bw per day	3750 ppm, equal to 208 mg/kg bw per day
	Extended one-generation reproductive toxicity study [a]	Carcinogenicity	3750ppm, equal to 208mg/kg bw per day [c]	-
		Reproductive toxicity	7500 ppm equal, to 510 mg/kg bw per day [c]	-
		Parental toxicity	500 ppm equal, to 40 mg/kg bw per day	2000 ppm, equal to 160 mg/kg bw per day
		Offspring toxicity	2000 ppm, equal to 160 mg/kg bw per day	7500 ppm, equal to 510 mg/kg bw per day
Rabbit	Developmental toxicity study [b]	Maternal toxicity	80 mg/kg bw per day	250 mg/kg bw per day
		Embryo/fetal toxicity	250 mg/kg bw per day [c]	-

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

ADI applies to 1,4-dimethylnaphthalene, M01, M02, M03, M04, M21 and M23, expressed as 1,4-dimethylnaphthalene

0–0.3 mg/kg bw

Acute reference dose (ARfD)

Unnecessary

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

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

Critical end-points for setting guidance values for exposure to 1,4-dimethylnaphthalene

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; extensive, T_{max} = 4 hours
Dermal absorption	No data
Distribution	Wide; highest concentrations in the adipose tissue and liver
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid and nearly complete via urine and faeces; 99% within 48 hours
Metabolism in animals	Extensively metabolized mainly through hydroxylation on a methyl group, to form M21 and M23, and ring hydroxylation
Toxicologically significant compounds in animals and plants	1,4-Dimethylnaphthalene, metabolites M01, M02, M03, M04, M21, M23
Acute toxicity	
Rat, LD_{50}, oral	>2000 mg/kg bw
Rat, LD_{50}, dermal	>2000 mg/kg bw
Rat, LC_{50}, inhalation	>4.15 mg/L
Rabbit, dermal irritation	Moderately irritating
Rabbit, ocular irritation	Slightly irritating, but reversible
Mouse, dermal sensitization	Not sensitizing (LLNA)
Guinea pig, dermal sensitization	No data
Short-term studies of toxicity	
Target/critical effect	Body weight gain, liver weight, kidney effects
Lowest relevant oral NOAEL	32 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight gain, kidney effects

Lowest relevant NOAEL	27 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Liver weights, cholesterol and triglycerides
Lowest relevant parental NOAEL	40 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	160 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	510mg/kg bw per day, highest dose tested (rat)
Developmental toxicity	
Target/critical effect	Reduced body weight and food consumption
Lowest relevant maternal NOAEL	80mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	250 mg/kg bw per day, highest dose tested (rabbit)
Neurotoxicity	No data
Studies on toxicologically relevant metabolites	
M01, M02, M03, M04, M21, M23	QSAR data only; all negative for genotoxicity
Microbiological data	No data submitted
Human data	No clinical cases or poisoning incidents have been recorded

Summary

	Value	Study	Safety factor
ADI	0– 0.3 mg/kg bw[a]	Two-year study of toxicity and carcinogenicity (rat)	100
ARfD	Unnecessary		

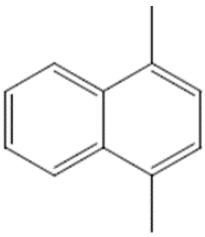
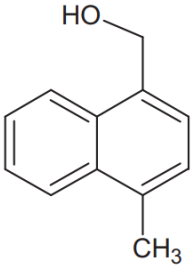
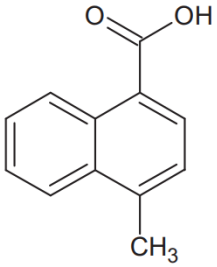
[a] Applies to 1,4-dimethylnaphthalene,. M01, M02, M03, M04, M21 and M23, expressed as 1,4-dimethylnaphthalene

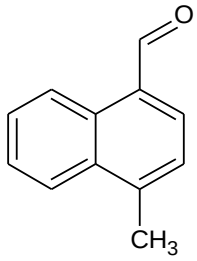
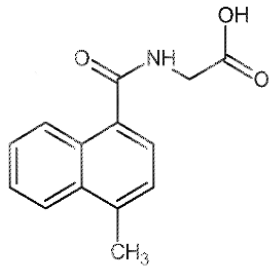
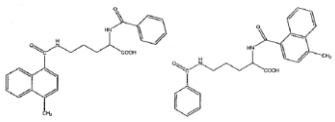
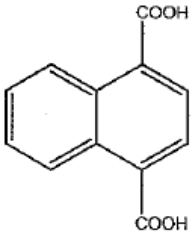
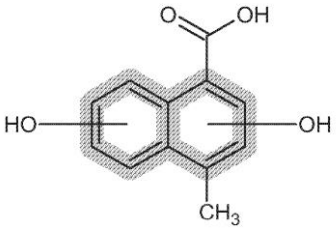
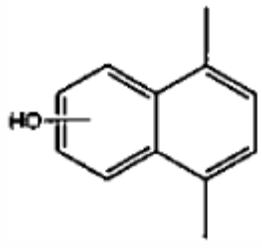
RESIDUE AND ANALYTICAL ASPECTS

1,4-Dimethylnaphthalene (1,4-DMN) acts as a plant growth regulator preventing sprouting of the potato tubers. It is naturally occurring in different plant species (e.g. potato, rhubarb, poppy). 1,4-DMN acts by enhancing dormancy, a natural event triggered by biochemical substances found within the potato (solanum tuberosum). With sufficient levels of dormancy enhancer present in potato tubers, sprouting does not occur. At the Fifty-second Session of the CCPR, 1,4-DMN was originally scheduled for evaluation as a new compound in 2022 and was rescheduled to the 2023 JMPR.

The Meeting received information on identity, physicochemical properties, metabolism (plant and animals), methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials in potato, fate of residues in processing, and livestock feeding studies.

Overview of compounds referred to in the appraisal

Code Names	**Chemical Names (IUPAC)**	**Structure**	**Where found**
1,4-dimethylnaphthalene 1,4-DMN	1,4-dimethylnaphthalene	 Molar mass: 156.2 g/mol	Plants (potato) Ruminants (muscle) Poultry (egg yolk, muscle, fat, liver))
1-hydroxymethyl-4-methylnaphthalene M21	1-hydroxymethyl-4-methylnaphthalene	 Molar mass: 172.2 g/mol	Plants (potato)
4-methyl-1-naphthoic acid M23	4-methyl-1-naphthoic acid	 Molar mass: 186.2 g/mol	Plants (potato) Ruminants (kidney) Poultry (egg white, egg yolk, muscle, liver)

Code Names	Chemical Names (IUPAC)	Structure	Where found
4-methyl-1-naphthaldehyde M-01	4-methyl-1-naphthaldehyde		Processed commodity after hydrolysis (potato)
Glycine conjugate of 4-methyl-1-naphthoic acid Gly-M23 M-02			Ruminants (milk, kidney)
Ornithine conjugate of 4-methyl-1-naphthoic acid Orn-M23 M-03 (Delta variant) & M-04 (α variant)			Poultry (egg yolk, liver)
1,4-naphthalenedicarboxylic acid M14	1,4-naphthalenedicarboxylic acid		Poultry (muscle, liver)
Dihydroxy-1-methyl-4-naphthoic acid M-06	Dihydroxy-1-methyl-4-naphthoic acid		Ruminants (kidney, muscle)
1,4-dimethylnaphthol M15	1,4-dimethylnaphthol		Processed commodity (potato)

Physical and chemical properties

The solubility of 1,4-DMN in organic solvents is high, but fairly low in water. Its $logP_{OW}$ at 20°C is four, suggesting that 1,4-DMN has the potential to partition into fat. Hydrolysis was not tested, but it was suggested that based on the molecules' structure it is hydrolytically stable. Based on a computational estimation, 1,4-DMN is assumed to undergo photodegradation with a half-life of 6.4 h. The vapour pressure indicates that 1,4-DMN is moderately volatile.

Plant metabolism

The metabolic fate in plants was investigated following post-harvest application of ^{14}C-labelled 1,4-DMN by means of volatilization of the compound to potato in specially constructed glass vessels.

In the first study, potatoes stored received six treatments in 30 days intervals at a rate of 21.2 mg/kg. Potatoes were collected at around 30 days after each treatment. In a second study only one application was performed at 20.07 mg/kg and sampling at 1 and 30 days after treatment.

Potato samples were separated in peeled potatoes and potato peels (potatoes from the study receiving one application only received an acetonitrile surface wash prior to peeling), followed by homogenization. Extraction of the homogenized samples was performed with twice with acetonitrile/water (1/1, v/v) and once with acetonitrile.

In potatoes receiving multiple applications, TRRs increased with each application, in potato peels from 16 mg eq/kg at 30 DAT1 to 159 mg eq/kg at 30 DALA, in peeled potatoes from 0.27 mg eq/kg at 30 DAT1 to 6.4 mg eq/kg at 30 DALA and in whole potatoes from 2.9 mg eq/kg at 30 DAT1 to 24 mg eq/kg at 30 DALA. In potatoes receiving one application, TRRs in potato peels were 91 mg eq/kg (1 DAT) and 15 mg eq/kg (30 DAT), in peeled potatoes 1.8 mg eq/kg (1 DAT) and 0.7 mg eq/kg (30 DAT) and in whole potatoes 13 mg eq/kg (1 DAT) and 2.8 mg eq/kg (30 DAT).

The extracted radioactivity in peeled potatoes and peel ranged between 92–99 percent TRR, while 0.4–8 percent TRR remained in the PES.

Parent 1,4-DMN was the major identified residue in potato peels at 34–98 percent TRR (5.2–137 mg/kg), in peeled potato at 2.9–90 percent TRR (0.02–3.6 mg/kg) and in whole potato at 27–97 percent TRR (0.75–20 mg/kg). Additionally, metabolite M21 was identified partially at major proportions in potato peels at 1–41 percent TRR (0.4–8.7 mg eq/kg), in peeled potatoes at 3.9–65 percent TRR (0.046-1.3 mg eq/kg) and in whole potatoes at 1.4–46 percent TRR (0.1–2.2 mg eq/kg). Generally, levels of 1,4-DMN and metabolite M21 depended on the DAT, with the following ratios at 1 DAT vs 30 DAT: 94 vs 0.82 (potato peels); 23 vs 0.04 (peeled potato) and 69 vs 0.59 (whole potatoes). As a minor metabolite M23 was identified in potato peels and whole potatoes accounting for 1.5–2.3 percent TRR (0.06–3.0 mg eq/kg). In addition, an unknown component was detected in peeled potato from 30 DAT at 14.6 percent TRR (0.1 mg eq/kg), but no further attempts to characterize the component were undertaken.

Summary plant metabolism

In potato, parent 1,4-DMN is moderately fast degraded into metabolite M21 via hydroxylation and

further oxidized to metabolite M23. While soon after treatment, parent 1,4-DMN is the major residue, levels of metabolite M21 increase over time.

Animal metabolism

The Meeting received studies on the metabolism of 1,4-DMN in laboratory animals, lactating goats and laying hens. The evaluation of the metabolism studies in laboratory animals was carried out by the WHO Core Assessment Group.

In lactating goats, the metabolic fate of 1,4-DMN was investigated using ^{14}C-labelled 1,4-DMN. The compound was administered orally once daily for 7 consecutive days at 12.5 ppm (0.39 mg/kg bw day).

The majority of the radioactivity was found in urine at 76 percent AR, followed by feces 14 percent AR. In edible tissues radioactivity was highest in liver (0.277 mg eq/kg) and kidney (0.241 mg eq/kg), while it was at least one order in magnitude lower for all other tissues (0.016-0.019 mg eq/kg).

In milk, the total radioactivity from both labels increased rapidly after the first administration and ranged over the course of the study between 0.015–0.060 mg eq/kg. Residue levels reached a plateau after approximately 48 hours.

Milk samples were liquid-liquid partitioned with a mixture of potassium oxalate, ethanol, diethyl ether and hexane, followed by protein precipitation and further treatment with pepsin and protease. Dependent on the matrix, tissue samples were extracted (alone or in combination) with acetonitrile and/or methanol/water (9/1, v/v) and/or methanol/water (1/1, v/v). Extraction with solvents released 76–97 percent TRR from milk, muscle and kidney, but was lower for liver and fat at 47 percent TRR and 57 percent TRR, respectively. PES from liver (41 percent TRR) were further solubilized successively with pepsin, protease and boiling with 6 mol/L hydrochloric acid, releasing an additional 6.1 percent TRR (0.017 mg eq/kg). The PES from fat (53 percent TRR) was not further characterized, due to the low absolute radioactivity (<0.01 mg eq/kg).

Parent 1,4-DMN was only detected in muscle accounting for 4.7 percent TRR (0.001 mg/kg) as a minor component. A major identified metabolite was the glycine conjugate of metabolite M23 (Gly-M23) in milk and kidney at 17–18 percent TRR (0.006-0.046 mg eq/kg). The unconjugated metabolite M23 was also detected in kidney at 1.3 percent TRR (0.004 mg eq/kg). Additionally, dihydroxy-1-methyl-4-naphthoic acid was found in minor amounts in kidney and muscle at 1.3–4.05 TRR (0.001–0.004 mg eq/kg). One unknown component (P3) was detected in kidney at 16 percent TRR (0.044 mg eq/kg).

In laying hens, the metabolic fate of 1,4-DMN was investigated using ^{14}C-labelled 1,4-DMN. The compound was administered orally once daily for 7 consecutive days to ten laying hens, at 10 ppm (0.82 mg/kg bw day). Eggs were collected twice daily, while excreta samples were collected once a day. Samples of breast muscle, thigh muscle, abdominal and subcutaneous fat and liver were collected after sacrifice, which occurred 6 hours after the last dose.

Nearly complete elimination of the radioactivity with excreta (99.3 percent AD) was observed. In edible tissues radioactivity was highest in egg yolk (1.3 mg eq/kg), followed by fat and whole eggs (~0.5 mg eq/kg). In all other tissues the radioactive residues ranged between 0.038–0.19 mg eq/kg.

Egg white and yolk, muscle and liver samples were homogenized twice with

acetonitrile/water (1+1, v/v) and then once with acetonitrile. Fat samples were extracted twice with acetone/hexane (1:4, v/v) then once with acetone. Extraction with solvents released at least 87–98 percent TRR from all matrices.

Parent 1,4-dimethyl-naphthalene was identified in whole egg, egg yolk, fat (subcutaneous & abdominal) and thigh muscle as a major residue ranging between 29–94 percent TRR (0.019–0.47 mg/kg) and as minor residue in breast muscle and liver 1.5–7.9 percent TRR (0.003 mg/kg). As a major metabolite, M23 was identified egg white and yolk, muscle (breast & thigh) and liver at 13–71 percent TRR (0.015-0.11 mg eq/kg). Additionally in egg yolk and liver, the ornithine conjugate of M23 (Orn-M23) was found, accounting for 6.4–16 percent TRR (0.013-0.027 mg eq/kg). As minor metabolites, M14 was found in muscle (breast & thigh) and liver accounting for up to 5.4 percent TRR (0.011 mg eq/kg).

Summary livestock metabolism

Generally, the transfer of radioactivity into livestock was low. In a lactating goat, the highest TRRs were found in liver and kidney, while in laying hens TRRs were highest in fat and egg yolk. Parent 1,4-DMN was only detected in minor amounts in muscle of a lactating goat, demonstrating extensive metabolism in ruminants. On the contrary, parent was detected in poultry as a major residue in egg yolk and fat, indicating a lower rate of transformation. The major identified metabolite was the glycine conjugate of M23 in milk and kidney from a lactating goat and unconjugated M23 or its ornithine conjugate in eggs, muscle and liver from laying hens.

The main transformation of 1,4-DMN was similar in ruminants and poultry. It occurred by carboxylation of one of the methyl groups, resulting in 4-methyl-1-naphthoic acid (M23), which was subsequently conjugated with glycine (ruminant) or ornithine (poultry). As minor routes of metabolism, hydroxylation and dihydroxylation of M23 is postulated for ruminants, while in poultry further oxidation of M23 at its second methyl group resulted in 1,4-naphthalenedicarboxylic acid (M14).

Environmental fate

Since the intended use for 1,4-DMN is post-harvest on potatoes in closed storage facilities, neither investigations on the environmental fate nor on residues on succeeding crops are necessary.

Methods of residue analysis

The Meeting received analytical methods for the determination of 1,4-DMN and metabolites M21 and M23 in plant matrices and for 1,4-DMN and metabolites M21, M23, Gly-M23 and Orn-M23 in animal matrices.

For matrices of plant origin, a method for all analytes based on QuEChERS employed extraction with acetonitrile/water (1/1; v/v) + buffer salts, followed by clean-up using dispersive solid phase extraction (dSPE) with primary secondary amine (PSA). Analytes were determined by GC-MS (1,4-DMN) and LC-MS/MS (M21, M23) with an LOQ of 0.05 mg/kg. One additional residue method employed extraction with acetonitrile + buffer salts, followed by quantitation by HPLC-FLD with an LOQ of 0.05 mg/kg for all analytes.

For matrices of animal origin, the methods employed extraction with acetonitrile or

ethanol. Additional clean-up using SPE was employed for the determination of all analytes in fat and for the determination of Orn-M23 in egg yolk. Final determination was accomplished by HPLC-FLD (1,4-DMN, M21, M23 and Orn-M23), GC-MS/MS (1,4-DMN), LC-MS/MS (M23, Gly-M23, Orn-M23) with LOQs ranging between 0.01–0.06 mg/kg.

The Meeting concluded that suitable methods are available to measure residues of 1,4-DMN and metabolites M21 and M23 in plant matrices (high water content, high oil content, high starch content and high acid content; but not for high protein matrices) as well as 1,4-DMN and metabolites M21, M23, Gly-M23 and Orn-M23 in animal matrices.

Stability of residues in stored analytical samples

The Meeting received information on the storage stability of 1,4-DMN as well as metabolites M21 and M23 in potato and its processing matrices stored under frozen conditions.

Residues of 1,4-DMN and metabolites M21 and M23 were stable in high starch matrices (potato, starch) and high oil matrices (frying oil) for at least 400 days (~13 months).

All samples from field trials were analysed within the tested storage stability time.

For animal matrices, the Meeting received information on the storage stability of 1,4-DMN as well as its metabolites M21, M23 and Gly-M23 in ruminant matrices and of 1,4-DMN as well as its metabolites M21, M23 and Orn-M23 in poultry matrices stored at -20 °C.

Analytes in ruminant matrices were stable for at least 27–29 days (~1 month) in milk (whole milk, skim milk, and cream), egg white, egg yolk, liver, kidney and fat. In muscle, analytes were stable for at least 56 days (~2 month) and in whole eggs for at least 49 days (~1.5 month).

All samples from feeding studies were analysed within the tested storage stability time.

Definition of the residue

The Meeting noted that 1,4-DMN is a naturally occurring component in different plant species. However, no information on the level is available. Therefore, the Meeting concluded to limit their recommendations to potato, only.

In food commodities from plant metabolism studies conducted on potatoes and from a processing study with potatoes using radiolabelled 1,4-DMN, the predominant residue was parent 1,4-DMN, accounting for 27–97 percent TRR in whole potatoes.

Analytical methods are available for monitoring 1,4-DMN in all plant matrices, except high protein content matrices.

The Meeting concluded that parent 1,4-DMN is a major residue and a suitable marker compound for compliance with MRLs.

On deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the metabolites M21 and M23.

Metabolite M21 was detected in metabolism studies with potatoes at major proportions at up to 46 percent TRR. Additionally, the metabolite was detected frequently in whole potatoes from supervised trials above the LOQ at levels slightly lower compared to parent. However, in potato pulp levels were generally about one order in magnitude higher than those of parent 1,4-DMN. The Meeting concluded that metabolite M21 is of no greater toxicity than parent 1,4-DMN

and is covered by the toxicological reference values of the parent. The Meeting decided that M21 adds significantly to the dietary exposure and should be included into the residue definition for risk assessment.

Metabolite M23 was identified in metabolism studies with potatoes as a minor metabolite (<10 percent TRR), at levels approximately 50 times lower than the parent. The metabolite was detected frequently in potatoes from supervised trials, but always about one order in magnitude lower, compared to parent, and at least one order in magnitude lower compared to the sum of parent and M21. The Meeting concluded that metabolite M23 is of no greater toxicity than parent 1,4-DMN and is covered by the toxicological reference values of the parent. The Meeting decided that M23 contributes insignificantly to the dietary exposure and does not need to be included into the residue definition for risk assessment.

The Meeting noted that the sum of 1,4-DMN and metabolite M21 represents the major part of the residues in potato, sufficiently addressing the overall potential dietary exposure and agreed to set the definition of the residue for dietary risk assessment for plant commodities as sum of 1,4-DMN and metabolite M21, expressed as 1,4-DMN.

In animal metabolism studies performed with laying hens, parent 1,4-DMN was detected as a major residue in whole egg, egg yolk, fat (subcutaneous & abdominal) and thigh muscle (29–94 percent TRR). In addition, 1,4-DMN was detected as a minor residue in poultry breast muscle and liver (up to 7.9 percent TRR) and in ruminant muscle (4.7 percent TRR). 1,4-DMN was not detected in ruminant milk, liver, kidney and fat, as well as in egg white. In feeding studies, performed with a mixture of 1,4-DMN, M21 and M23, residues of 1,4-DMN were detected above LOQ at the relevant feeding levels in liver (up to 0.16 mg/kg) and fat (up to 0.36 mg/kg). The Meeting noted that 1,4-DMN is not a suitable marker in all tissues for the residue definition for compliance with the MRLs for animal commodities alone.

In the poultry metabolism, M23 was the major identified metabolite in egg matrices, muscle and liver, accounting for 13–71 percent TRR, while in the ruminant metabolism M23 was not detected except in kidney at 1.3 percent TRR. In feeding studies, performed with a mixture of 1,4-DMN, M21 and M23, residues of M23 were detected above LOQ at the relevant feeding levels in whole egg (up to 0.036 mg/kg), egg white (up to 0.013 mg/kg), egg yolk (up to 0.014 mg/kg), muscle (up to 0.09 mg/kg), liver (up to 0.54 mg/kg), kidney (up to 0.27 mg/kg) and fat (up to 0.08 mg/kg.

In the ruminant metabolism, Gly-M23 was the major identified metabolite in milk and kidney, accounting for 17–18 percent TRR, while in the poultry metabolism Gly-M23 was not detected. In a ruminant feeding study, residues of Gly-M23 were detected above LOQ at the relevant feeding levels in whole milk (up to 0.027 mg/kg), in liver (up to 0. 019 mg/kg), in kidney (up to 0.1 mg/kg) and in fat (up to 0.013 mg/kg).

Analytical methods are available for measuring 1,4-DMN and metabolite M23 in animal matrices, as well as Gly-M23 in milk.

Hence, the Meeting decided to include parent 1,4-DMN as well as metabolite M23 into the residue definition for compliance with the MRLs for animal commodities, except milk. For milk, the Meeting decided to include Gly-M23 into the residue definition for compliance with the MRL.

In muscle and fat tissues of all animals investigated, residue concentrations of the sum of 1,4-DMN and metabolite M23 were ~5–26 times higher in fat compared to muscle. Similarly, levels in egg yolk compared to egg white were ~2–7 times higher. The log P_{ow} of 1,4-DMN is 4.0. The Meeting concluded that residues in animal matrices, except milk, according to the residue

definition are fat-soluble. In milk residue levels of Gly-M23 in skim milk and cream were comparable. Hence, the Meeting concluded that residues of Gly-M23 in milk are not fat-soluble.

On deciding which compounds should be additionally included in the residue definition for risk assessment, the Meeting considered the likely occurrence and toxicological properties for the candidates Orn-M23, M21, and M14.

Metabolite Orn-M23 occurred only in a poultry metabolism study in egg yolk (16 percent TRR), whole egg (12 percent TRR) and liver (6.4 percent TRR), at similar or lower proportions as 1,4-DMN and M23. In a poultry feeding study, residues above LOQ were detected in whole egg (up to 0.039 mg/kg), in egg yolk (up to 0.12 mg/kg), in muscle (up to 0.015 mg/kg), in liver (up to 0.24 mg/kg) and in fat (up to 0.021 mg/kg). However, residues were consistently similar, or below residues of 1,4-DMN and M23. The Meeting concluded that Orn-M23 is covered by the toxicological reference value of the parent and does not significantly contribute to the dietary exposure.

Metabolite M21 was not detected in animal metabolism studies and were in feeding studies mostly <LOQ, except for in egg yolk from the highest treatment group (up to 0.1. mg/kg) and in fat from the intermediate and highest treatment group (up to 0.29 mg/kg). The Meeting concluded that M21 is covered by the toxicological reference value of the parent and does not significantly contribute to the dietary exposure from animal commodities.

Metabolite M14 was identified in a poultry metabolism study in muscle and liver (up to 5.4 percent TRR). Since no genotoxicity was indicated for metabolite M14, the TTC approach for Cramer Class III compounds (1.5 µg/kg bw per day) was applied. Potential long-term exposure to M14 was estimated using the maximum values found in muscle and liver in the metabolism studies and resulted in 0.007 µg/kg bw per day. The Meeting concluded that dietary exposure to this metabolite is unlikely to be of public health concern.

Similar, dihydroxy-1-methyl-4-naphthoic acid was identified in a ruminant metabolism study in muscle and kidney only (up to 4 percent TRR). Since no genotoxicity was indicated for metabolite dihydroxy-1-methyl-4-naphthoic acid, the TTC approach for Cramer Class III compounds (1.5 µg/kg bw per day) was applied. Potential long-term exposure to dihydroxy-1-methyl-4-naphthoic acid was estimated using the maximum values found in muscle and kidney in the metabolism studies and resulted in 0.003 µg/kg bw per day. The Meeting concluded that dietary exposure to this metabolite is unlikely to be of public health concern.

For dietary exposure purposes for animal commodities, based on the results of the animal metabolism and feeding studies, the Meeting decided to include parent 1,4-DMN as well as metabolites M23 and Gly-M23 in the residue definition for animal matrices.

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

1,4-dimethylnaphthalene

Definition of the residue for dietary risk assessment for plant commodities:

sum of 1,4-dimethylnaphthalene and metabolite 1-hydroxymethyl-4-methylnaphthalene (M21), expressed as 1,4-dimethylnaphthalene.

Definition of the residue for compliance with the MRL for animal commodities, except milk:

sum of 1,4-dimethylnaphthalene and metabolite 4-methyl-1-naphthoic acid (M23),

expressed as 1,4-dimethylnaphthalene.

The residue in animal commodities except milk is fat-soluble.

Definition of the residue for compliance with the MRL for milk:

glycine conjugate of 4-methyl-1-naphthoic acid (Gly-M23)

The residue definition in milk is not fat-soluble.

Definition of the residue for dietary risk assessment for animal commodities:

sum of 1,4-dimethylnaphthalene, metabolite 4-methyl-1-naphthoic acid (*M23), and its glycine conjugate 4-methyl-1-naphthoic acid (Gly-M23) expressed as 1,4-dimethylnaphthalene*

Results of supervised residue trials on crops

Supervised trials were available for the use of 1,4-DMN on stored potatoes.

Potatoes

The critical GAP in Germany allows six fogging applications of 1,4-DMN to stored potatoes at 20 ml ai /1000 kg (19.9 g ai/1000 kg) with a RTI of 28–42 days and a PHI of 30 days. Trials with potato conducted in the Kingdom of the Netherlands were performed approximating to GAP (±25 percent).

For estimating maximum residue levels of 1,4-DMN in potato, the ranked order of residues was (n=12): 2.5, 2.9, 3.1, 3.4, 3.7, 4.7, 5.4, 5.7, 6.8, 7.3, 7.5, 7.9 mg/kg.

For dietary risk assessment, the ranked order of the total residue was (n=12): 5.2 (2), 6.7, 7.7, 7.9, 8.6, 8.7, 8.9, 11, 12, 14, 17 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg (Po), an STMR of 8.65 mg/kg and a highest residue of 17 mg/kg for 1,4-DMN in potatoes (VR 0589).

Fate of residues during processing

The fate of 1,4-DMN and its degradation products has not been investigated according to OECD 507 with model systems mimicking pasteurization (90 °C, pH 4), baking, brewing, boiling (100 °C, pH 5), or sterilization (120 °C, pH 6).

Instead, a processing study using potatoes treated with radiolabelled 1,4-DMN and thus exhibiting incurred radiolabelled residues was conducted. A total of five treatments were performed at a nominal rate of 20 mg ai/kg and a 28 day RTI. Potatoes were collected at 28 DALA and processed after 42 DALA to boiled, baked and fried potatoes, reflecting industrial or domestic practices.

Parent 1,4-DMN was the major identified residue accounting for 60 percent TRR (11 mg/kg) the RAC and for 47–58 percent TRR (5.4-7.7 mg/kg) in processed commodities. Metabolite M21 was identified as a major residue in the RAC, accounting for 17 percent TRR (2.9 mg eq/kg) and as a minor residue in processed commodities accounting for 0.5–7.2 percent TRR (0.044–1.2 mg eq/kg). Metabolite M23 was identified as a minor residue accounting for 4.6 percent TRR (0.8 mg eq/kg) in the RAC and for <0.6–5.6 percent TRR (<0.053-0.899 mg eq/kg) in

processed commodities. Additionally, two components accounting for 12–15 percent TRR (1.2-2.4 mg eq/kg) could be identified as glycoside conjugates of M21 and 1,4-dimethylnaphtol.

The Meeting noted that the residue profile of 1,4-DMN in potato processed commodities is similar to that of primary crop commodities (potatoes) with parent 1,4-DMN representing the major residue.

The fate of 1,4-DMN residues has been examined simulating household and commercial processing of potatoes. The Meeting noted that none of the relevant traded processed commodities resulted in PF >1.3 (based on the residue definition for compliance with the MRL) and concluded that these commodities are covered by the MRL for the RAC. For the estimation of dietary intake of processed commodities, processing factors according to the residue definition (*Sum of 1,4-dimethylnaphthalene and metabolite 1-hydroxymethyl-4-methylnaphthalene (M21), expressed as 1,4-dimethylnaphthalene*) are summarized below.

Estimated processing factors for dietary exposure of processed commodities according to the residue definition

Crop	Residue in RAC (mg/kg)	Processed commodity	Individual PF	Median or best estimate PF	Residue in processed commodity (mg/kg)
	STMR				STMR-P
		Baked potato (unpeeled)	0.55, 0.56, 0.62, 0.63	0.59	5.1
		Boiled potato (peeled)	<0.02, <0.02	<0.02	0.17
		Boiled potato (unpeeled)	0.05, 0.06, 0.24, 0.27, 0.4, 0.74	0.26	2.3
		Canned potatoes (unpeeled)	0.23, 0.25, 0.28	0.25	2.2
		Crisps (peeled)	0.12, 0.14, 0.16	0.14	1.2
		Crisps (unpeeled)	0.16, 0.19, 0.20	0.19	1.6
		Dried pulp	3.17, 3.20, 3.28	3.2	28
		Fried potato (unpeeled)	0.6	0.6	5.2
		Fries (chips) (peeled)	<0.05, <0.06	<0.05	0.43
		Fries (chips) (unpeeled)	0.16, 0.18, 0.25	0.18	1.6
		Microwaved potatoes (unpeeled)	0.05, 0.06, 0.17, 0.21, 0.24	0.17	1.5
Potato	8.65	Peeled potato	<0.02, 0.03, 0.20 0.21, 0.26, 0.52, 0.54, 0.72	0.24	2.1
		Potato flakes (flour)	0.08, 0.15, 0.18	0.15	1.3
		Process waste	0.24, 0.29, 0.34	0.29	2.5
		Sliced potato	0.35, 0.45, 0.51	0.45	3.9
		Starch	0.39, 0.45, 0.55	0.45	3.9

Residues in animal commodities

Farm animal feeding studies

The Meeting received feeding studies performed with a mixture of 1,4-DMN, M21 and M23 (reflecting the residue in animal feeds regarding the ratio of analytes) on lactating cows and laying hens.

The study with lactating cows was conducted with 1,4-DMN, M21 and M23 in a 49:47:4 ratio at treatment rates of 39, 118 and 624 ppm. In milk, residues of metabolite Gly-M23 were detected at levels >LOQ from all treatment groups (up to 1.1 mg/kg). Similar levels of Gly-M23 were found in skim milk (up to 0.45 mg/kg) and in cream (up to 0.36 mg/kg).

In tissues, residues of 1,4-DMN were detected at levels >LOQ in flank muscle from the

highest treatment group only (up to 0.011 mg/kg), in liver from all treatment groups (up to 0.267 mg/kg), in kidney from the highest treatment group only (up to 0.018 mg/kg) and in fat from all treatment groups (perirenal & omental) or from the intermediate and highest treatment groups (subcutaneous) (up to 0.36 mg/kg).

Residues of M23 were detected at levels >LOQ in muscle (flank & loin) only from the highest treatment group (up to 0.014 mg/kg), in liver from all treatment groups (up to 4.0 mg/kg), in kidney from all treatment groups (up to 2.2 mg/kg) and in fat from all treatment groups (perirenal) or from the intermediate and highest treatment groups (omental & subcutaneous) (up to 0.23 mg/kg).

The study with laying hens was conducted with 1,4-DMN, M21 and M23 in a 19.5:80:0.5 ratio at treatment rates of 11, 29 and 107 ppm.

Residues of parent 1,4-DMN above LOQ were detected in whole eggs from the intermediate and highest treatment group (up to 0.16 mg/kg). In egg white 1,4-DMN was not detected, while the compound was found in egg yolk at quantifiable levels from all treatment groups (up to 0.158 mg/kg). In tissues, residues of 1,4-DMN were detected at levels >LOQ in muscle and liver from the highest treatment group only (up to 0.033 mg/kg in muscle and up to 0.024 mg/kg in liver) and in fat in all treatment groups (up to 1.01 mg/kg).

Residues of metabolite M23 above LOQ were detected in whole eggs in all treatment groups (up to 0.29 mg/kg). In egg white levels were similar (up to 0.16 mg/kg), compared egg yolk (up to 0.12 mg/kg). In tissues, residues of M23 above LOQ were detected in all treatment groups: muscle (up to 0.25 mg/kg), liver (up to 0.94 mg/kg) fat (up to 0.14 mg/kg).

Estimated maximum and mean dietary burdens of livestock

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the current Meeting (potato culls, potato process waste and dry pulp). The dietary burdens, estimated using the OECD diets listed in appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6. The summary results are shown in the table below.

Estimated livestock dietary burden for the *Sum of 1,4-DMN and metabolite M21, expressed as 1,4-DMN*, ppm of dry matter diet

	US-Canada		**EU**		**Australia**		**Japan**	
	max.	**Mean**	**max.**	**mean**	**max.**	**Mean**	**max.**	**Mean**
Beef cattle	32	19	35❶	22❸	10	5.9	-	-
Dairy cattle	11	6.4	33❷	20❹	10	5.9	-	-
Poultry – broiler	-	-	15❺	11❻	-	-	-	-
Poultry – layer	-	-	13❼	9.1❽	-	-	-	-

❶ Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues
❷ Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk
❸Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.
❹ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.
❺Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.
❻Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.
❼Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.
❽Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

Animal commodities maximum residue levels

For beef and dairy cattle, a maximum and mean dietary burden of 35 ppm and 22 ppm were estimated, respectively. The estimated dietary burdens are evaluated against a lactating cow feeding study conducted at treatment rates of 39, 118 and 624 ppm.

Maximum residue level estimation of 1,4-DMN in cattle commodities

Maximum residue level beef or dairy cattle	Feed level (ppm) for milk residues	Gly-M23 in milk (mg/kg per se)	Feed level (ppm) for tissue residues	Sum of 1,4-DMN + M23 (mg/kg eq)			
				Liver	Kidney	Muscle	Fat
Feeding study	39	0.026	39	0.468	0.236	<0.018	0.028
Dietary burden and highest residue	33	0.022	35	0.420	0.212	<0.016	0.025

The Meeting recommended a maximum residue level for milks at 0.03 mg/kg, edible offal (mammalian) at 0.5 mg/kg and 0.03 mg/kg for meat from mammals (fat) and mammalian fats.

Median estimation of 1,4-DMN in cattle commodities

STMR beef or dairy cattle	Feed level (ppm) for milk residues	Sum of 1,4-DMN + M23 + Gly-M23 in milk (mg/kg eq)	Feed level (ppm) for tissue residues	Sum of 1,4-DMN + M23 + Gly-M23 (mg/kg eq)			
				Liver	Kidney	Muscle	Fat
Feeding study	39	0.030	39	0.39	0.28	<0.025	0.032
Dietary burden and highest residue	20	0.015	22	0.22	0.16	<0.014	0.018

For milk, the calculated mean residue concentration from day ten to 28 was used. The Meeting estimated median values of 0.02 mg/kg in milks, 0.22 mg/kg in edible offal (mammalian), 0.014 mg/kg in muscle from mammals and 0.018 mg/kg in mammalian fats.

For broiler and laying poultry, a maximum and mean dietary burden of 15 ppm and 11 ppm were estimated, respectively. The estimated dietary burdens are evaluated against a laying hen feeding study conducted at treatment rates of 11, 29 and 107 ppm.

For maximum residue level estimation, the maximum dietary burden of 13 ppm (eggs) and 15 ppm (poultry tissues) was evaluated by interpolating between the 11 and 29 ppm dosing levels of the laying hen feeding study.

Maximum residue level estimation of 1,4-DMN in poultry commodities

Maximum residue level broiler or layer poultry	Feed level (ppm) for eggs residues	Sum of 1,4-DMN + M23 in eggs (mg/kg eq)	Feed level (ppm) for tissue residues	Sum of 1,4-DMN + M23 (mg/kg eq)		
				Liver	Muscle	Fat
Feeding study	11	0.022	11	0.15	0.047	0.15
	29	0.049	29	0.28	0.086	0.43
Dietary burden and highest residue	13	0.025	15	0.18	0.056	0.21

The Meeting recommended a maximum residue level of 0.03 mg/kg for eggs, 0.2 mg/kg for poultry edible offal and 0.3 mg/kg for poultry fats and meat.

STMR estimation of 1,4-DMN in poultry commodities

STMR broiler or layer poultry	Feed level (ppm) for eggs	Sum of 1,4-DMN + M23	Feed level (ppm) for tissue	Sum of 1,4-DMN + M23 (mg/kg eq)		
				Liver	Muscle	Fat

	residues	in eggs (mg/kg eq)	residues			
Feeding study	11	0.021	11	0.12	0.043	0.11
Dietary burden and highest residue	9.1	0.017	11	0.12	0.043	0.11

For eggs, the calculated mean residue concentration from day 3 to 24 was used. The Meeting estimated median values of 0.017 mg/kg in eggs, 0.12 mg/kg in poultry edible offal, 0.043 mg/kg poultry muscle as well as 0.11 mg/kg for poultry fats.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for International Estimated Daily Intake (IEDI) and International Estimate for Short-Term Intake (IESTI) assessments.

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

1,4-dimethylnaphthalene

Definition of the residue for dietary risk assessment for plant commodities:

sum of 1,4-dimethylnaphthalene and metabolite 1-hydroxymethyl-4-methylnaphthalene (M21), expressed as 1,4-dimethylnaphthalene

Definition of the residue for compliance with the MRL for animal commodities, except milk:

sum of 1,4-dimethylnaphthalene and metabolite 4-methyl-1-naphthoic acid (M23), expressed as 1,4-dimethylnaphthalene

The residue in animal commodities except milk is fat-soluble.

Definition of the residue for compliance with the MRL for milk:

glycine conjugate of 4-methyl-1-naphthoic acid (Gly-M23)

The residue definition in milk is not fat-soluble

Definition of the residue for dietary risk assessment for animal commodities:

sum of 1,4-dimethylnaphthalene, metabolite 4-methyl-1-naphthoic acid (*M23), and its glycine conjugate 4-methyl-1-naphthoic acid (Gly-M23) expressed as 1,4-dimethylnaphthalene*

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for 1,4-dimethylnaphthalene is 0–0.3 mg/kg bw. The IEDIs for 1,4-dimethylnaphthalene were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 0 to 20 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of 1,4-dimethylnaphthalene from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2023 JMPR decided that an ARfD for 1,4-dimethylnaphthalene was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of 1,4-dimethylnaphthalene from the uses considered is unlikely to present a public health concern.

5.2 Acetamiprid (246) (R)

RESIDUE AND ANALYTICAL ASPECTS

Acetamiprid is a neonicotinoid insecticide with contact and stomach action against a range of Hemiptera, Thysanoptera and Lepidoptera plant pests, acting as an agonist of the nicotinic acetylcholine receptor in the insect central nervous system. It was evaluated for the first time by the 2011 JMPR, where an ADI of 0–0.07 mg/kg bw and an ARfD of 0.1 mg/kg bw were established, followed additional residue evaluations in 2012, 2015 and 2017.

The residue definition for plant commodities, for compliance with MRLs and estimation of dietary exposure, is *acetamiprid*. The residue definition for animal commodities, for compliance with MRLs and estimation of dietary exposure, is the *sum of acetamiprid and desmethyl-acetamiprid, expressed as acetamiprid*.

The residue is not fat-soluble.

At the Fifty-second Session of the CCPR, acetamiprid was originally scheduled for evaluation of new uses in 2022 and was rescheduled for the 2023 JMPR.

The current Meeting received additional analytical methods, storage stability data, GAP information and residue trial data from uses on various pulses.

Methods of analysis

The Meeting received additional information on analytical methods for acetamiprid in various plant matrices.

Methods generally employed the QuEChERS method (buffered or unbuffered) or a modified version thereof, using acetonitrile or acetonitrile/water (9/1, v/v) as extraction solvent. If necessary, phase separation was accomplished by addition of salts and clean-up was performed with primary secondary amine (PSA) alone, or in combination with graphitized carbon black (GCB). The resulting extracts were analysed by LC-MS/MS with an LOQ of 0.01 mg/kg for all methods.

The Meeting concluded that the methods were sufficiently validated and are suitable to measure acetamiprid in dried pulses, as well as in forage and straw.

Stability of pesticides in stored analytical samples

At the 2011 JMPR evaluation, acetamiprid was shown to be stable for up to 12 months for a large range of commodities.

The 2023 Meeting received additional information on storage stability of acetamiprid in high water content, high fat content, high acid content, high protein matrices and bean straw, confirming the previously established a storage stability of at least 12 months. The (frozen) storage intervals between sampling and analysis of the submitted field trials with pulses were mostly within this range, except for the trials with broad beans and chickpeas, which were stored up to ~13 months. The Meeting concluded that any residue degradation during these extended storage intervals would be negligible.

Results of supervised residue trials on crops

Supervised trials were available for the use of acetamiprid on various dry pulses.

Pulses

The critical GAP for the use on winter and summer pulses in Australia allows two foliar applications of acetamiprid at 70 g ai/ha and a PHI of 28 days for mung beans and 42 days for other pulses.

Beans, dry, except mung beans

A total of five field trials with various beans in Australia approximating the GAP (±25 percent) at a PHI of 42 days were conducted.

The Meeting concluded that the number of trials is insufficient to estimate maximum residue levels for acetamiprid in beans, dry, except mung beans. In addition, the Meeting noted that residues in broad beans deviated significantly from other bean species.

Mung beans (dry)

A total of two field trials with mung beans in Australia approximating the GAP (±25 percent) at a PHI of 28 days were conducted.

The Meeting concluded that the number of trials is insufficient to estimate maximum residue levels for acetamiprid in mung beans.

Soya beans (dry)

In one field trial conducted with soya beans in Australia approximating the GAP (±25 percent), the residue of acetamiprid was (n=1): <0.01 mg/kg.

Four additional trials from the Federative Republic of Brazil, performed at higher GAP (3×113 g/ha) resulted in residues of acetamiprid at or below LOQ (0.01 mg/kg).
The Meeting agreed that the trials conducted at higher GAP supported a conclusion that residues in soya beans from trials conducted at GAP were unlikely to exceed 0.01 mg/kg. The Meeting estimated a maximum residue level and an STMR of 0.01 mg/kg for acetamiprid in soya beans

Chickpeas (dry)

A total of one field trial with chickpeas in Australia approximating the GAP (±25 percent) at a PHI of 42 was conducted.

The Meeting concluded that the number of trials is insufficient to estimate maximum residue levels for acetamiprid in chickpeas.

Animal feed

The critical GAP on winter and summer pulses in Australia allows two foliar applications of acetamiprid at 70 g ai/ha and a PHI of 42 days. No grazing or cutting for stock feed allowed for 6 weeks after application.

Bean forage (green)

None of the trials provided matched the GAP.

Soya bean forage (green)

None of the trials provided matched the GAP.

Pea vines (green)

None of the trials provided matched the GAP.

Bean, hay and/or straw

A total of five field trials with beans in Australia approximating the GAP (±25 percent) were conducted:

In one field trial with navy beans, residues of acetamiprid in straw were <0.01 mg/kg, as received.

In two field trials with mung beans, residues of acetamiprid in straw were <0.01, 0.11 mg/kg, as received.

In two field trials with broad beans, residues of acetamiprid in straw were 0.57, 0.60 mg/kg, as received.

The Meeting noted that residues were different and could not be combined. Hence, the Meeting concluded that no maximum residue level could be estimated for acetamiprid in bean hay and/or straw.

Soya bean, hay and/or straw

In field trials conducted with soya beans in Australia approximating the GAP (±25 percent), the ranked order of acetamiprid residues in soya bean straw was (n=1): <0.01 mg/kg.

The Meeting concluded that the number of trials is insufficient to estimate maximum residue levels for acetamiprid in soya bean, hay and/or straw.

Chick pea, hay and/or straw

In field trials conducted with chickpeas in Australia approximating the GAP (±25 percent), the ranked order of acetamiprid residues in straw was (n=1): 0.025 mg/kg.

The Meeting concluded that the number of trials is insufficient to estimate maximum residue levels for acetamiprid in chickpea, hay and/or straw.

Residues in animal commodities

Estimated maximum and mean dietary burdens of livestock

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR in 2011, 2015 and the current Meeting. The dietary burdens, estimated using the OECD diets listed in appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6.

Previous evaluations included the following potential feed items: sweet corn forage &

stover, cabbage and processing fractions (almond hulls, apple pomace, citrus dried pulp, cotton meal, cotton hulls and cotton gin trash). Additionally, the current Meeting considered soya bean seed. The summary results are shown in Table 3.

The estimation of residues of acetamiprid in the crops considered by the current Meeting does not impact on the previous recommendations for residues in animal commodities made by the 2011 JMPR (poultry) and 2015 JMPR (cattle).

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDIs and IESTIs assessments.

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

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of acetamiprid and desmethyl-acetamiprid, expressed as acetamiprid*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for acetamiprid is 0–0.07 mg/kg bw. The IEDIs for acetamiprid were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR report.

The IEDIs ranged from 0 to 3 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of acetamiprid from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for acetamiprid is 0.1 mg/kg bw. The IESTIs for acetamiprid were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR report.

The IESTIs ranged from 0 to 0 percent of the ARfD for children and 0 to 0 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of acetamiprid from uses considered by the present Meeting is unlikey to present a public health concern.

5.3 Boscalid (221) (R)

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. The extra JMPR 2019 concluded that the metabolite M510F47 should be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day). Since this metabolite was not identified in food or feed commodities, the Meeting concluded that it is unlikely to present a public health concern and will not be considered in future assessments.

Definition of the residue for compliance with the MRL in plant and animal commodities and for the estimation of the dietary exposure in plant commodities: *boscalid*.

Definition of the residue for the estimation of the dietary exposure in animal commodities: *sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide (M510F01) including its conjugate, expressed as boscalid*

The residue is fat-soluble.

Boscalid was considered by the 2023 JMPR Meeting as substitute for another compound not supported in the call for data.

The current Meeting received new information on use patterns and supervised field trials for boscalid in pomegranates.

Methods of analysis

The current Meeting received additional concurrent recovery data based on the LC-MS/MS method L0076/01 for boscalid. This method was already evaluated and described by the 2019 Extra JMPR Meeting. Newly submitted data demonstrated the method to be fit for purpose for the analysis of boscalid in pomegranate matrices with a LOQ of 0.01 mg/kg.

Storage stability

The current Meeting did not receive additional information on the storage stability of boscalid.

The 2006 Meeting evaluated the storage stability of boscalid and concluded that it is stable for at least 24 months in all plant commodity categories. Field trial samples of pomegranates were analysed within this interval.

Results of supervised residue trials on crops

The Meeting received information on use patterns and supervised residue trials for pomegranates from the several countries.

Pomegranates

The critical GAP for boscalid is from the Hellenic Republic and the Republic of Italy involving two foliar sprays of 0.5 kg ai/ha each (5 day retreatment interval - RTI) and a PHI of 7 days.

Supervised field trials conducted in Greece, Italy and the Kingdom of Spain approximated the cGAP.

Residues of boscalid in pomegranates, whole fruits, were (n=4): 0.37, 0.46, 0.53 and 0.82 mg/kg.

Residues of boscalid in pomegranates, flesh and seeds, were (n=4): <0.01, <0.01, 0.072 and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg (based on whole fruits) and a STMR value of 0.041 mg/kg (based on the edible portion), for boscalid in pomegranates.

Residues in animal commodities

Pomegranates are not utilized as animal feed. Therefore, consideration of residues in animal commodities is unnecessary.

RECOMMENDATIONS

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

Definition of the residue for dietary risk assessment 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.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for boscalid is 0–0.04 mg/kg bw. IEDIs for boscalid were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 10 to 60 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of boscalid from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2006 JMPR decided that an ARfD for boscalid was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of boscalid from the uses considered is unlikely to present a public health concern.

5.4 Carbendazim (072) (T, R)**

TOXICOLOGY

The present Meeting was asked by the CCPR to re-evaluate carbendazim under the periodic review programme. However, insufficient toxicological information was submitted to allow a re-evaluation of this substance to confirm or amend the reference values established in 1995 (ADI) and 2005 (ARfD). On this basis, the WHO Core Assessment Group withdraws the current ADI and ARfD values.

Recommendations for maximum residue levels for carbendazim are reported under thiophanate-methyl.

5.5 Carbofuran (96) (T,R)**

TOXICOLOGY

Carbofuran is the ISO-approved common name for 2,3-dihydro-2,2-dimethylbenzofuran-7-yl-*N*-methylcarbamate, which has the Chemical Abstracts Service number 1563-66-2. Carbofuran is a carbamate insecticide that acts by reversibly inhibiting the activity of acetylcholinesterase (AChE) thus inhibiting the breakdown of the neurotransmitter acetylcholine (ACh). This results in an increase of both the level and duration of the neurotransmitter action at ACh receptors.

Carbofuran has been previously evaluated by the Joint FAO/WHO Meeting on Pesticide Residue (JMPR) in 1976, 1979, 1980, 1982, 1996, 2002 and 2008. Carbofuran was evaluated at the present Meeting as part of the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). At JMPR 2008 the Meeting established an ADI of 0–0.001 mg/kg body weight (bw) and an ARfD of 0.001 mg/kg bw.

Many of the submitted studies were not conducted in accordance with current national or international test guidelines. Only those studies considered to be of acceptable quality and regulatory value are included in this report. Unless otherwise stated, all critical studies were conducted in compliance with good laboratory practice (GLP) and statements of quality assurance were provided. Relevant peer reviewed published scientific papers were identified and evaluated.

Overall, the Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

No new results from mass balance studies were supplied. Based on rat data previously evaluated by JMPR, carbofuran is rapidly absorbed and subsequently metabolized by hydroxylation, hydrolysis and conjugation.

Radioactivity derived from carbofuran is mostly excreted in urine (up to 92 percent of the administered radioactivity, with most being eliminated within 24 hours following dosing).

Based on the mass balance of radioactivity derived from carbofuran, oral absorption is up to 92 percent; carbofuran is unlikely to persist in the body. The major urinary metabolites found in rats following oral dosing were 3-hydroxy-carbofuran, 3-keto-7-phenol-carbofuran, 3-hydroxy-*N*-hydroxymethyl-carbofuran, 3-hydroxymethyl-carbofuran, and carbofuran-phenol.

Based on in vitro data the predominant catalyst for the detoxification of carbofuran is CYP3A4. The hepatic microsomal metabolism of carbofuran in humans, rabbits and mice was slower than that in rats and dogs when they were compared.

Toxicological data

In male and female rats, the acute oral median lethal dose (LD_{50}) of pure carbofuran ranged from 5.2 to 14.9 mg/kg body weight (bw). The LD_{50} in neonatal and weanling rats was 7.3–8.1 mg/kg bw. Under occlusive conditions, the dermal LD_{50} values for pure carbofuran in male and female rabbits were ca 2700 and ca 2000 mg/kg bw respectively when tested with abraded skin, whilst in males with intact skin the LD_{50} was ca 4400 mg/kg bw. No acute inhalation toxicity or dermal irritation studies were supplied. A single instillation of 5 mg of technical grade carbofuran per rabbit eye was minimally irritant and induced a systemic cholinergic toxicity. Carbofuran was not a skin sensitizer in the Guinea pig and was not a skin irritant in the study submitted.

In repeat-dose toxicity studies on mice, rats, rabbits and dogs, the main effect was the inhibition of AChE activity, clinical signs consistent with the AChE inhibition and decreased body weight.

In a 13-week dietary toxicity study in dogs carbofuran was administered at concentrations of 0, 10, 70 or 500/250 ppm (equal to 0, 0.43, 3.1 and 11 mg/kg bw per day for males and females combined). A no-observed-adverse-effect level (NOAEL) was not identified. The lowest-observed-adverse-effect level (LOAEL) was 10 ppm (equal to 0.43 mg/kg bw per day), the lowest dose tested, due to inhibition of erythrocyte AChE activity, excessive salivation and hyperaemia.

In a 1-year dietary toxicity study in dogs (not GLP), carbofuran was administered at dietary concentrations of 0, 10, 20 or 500 ppm (equivalent to 0, 0.25, 0.5 and 12 mg/kg bw per day). The NOAEL was 20 ppm (equivalent to 0.5 mg/kg bw per day) based on inhibition of erythrocyte AChE activity at 500 ppm (equivalent to 12 mg/kg bw per day).

In a 2-year combined carcinogenicity and toxicity study in mice (not GLP), carbofuran (purity 95.6 percent) was administered at dietary concentrations of 0, 20, 125 or 500 ppm (equal to 0, 2.8, 18, and 70 mg/kg bw per day). The NOAEL for toxicity was 20 ppm (equal to 2.8 mg/kg bw per day) based on inhibition of brain AChE activity at 125 ppm (equal to 18 mg/kg bw per day). The NOAEL for carcinogenicity was 500 ppm (equal to 70 mg/kg bw per day), the highest dose tested.

In a 2-year combined carcinogenicity and toxicity study in rats (not GLP), carbofuran (purity 95.6 percent) was administered at dietary concentrations of 0, 10, 20 or 100 ppm (equivalent to 0, 0.5, 1 and 5 mg/kg bw per day). The NOAEL for toxicity was 20 ppm (equivalent to 1 mg/kg bw per day), based on inhibition of brain and erythrocyte AChE activity at 100 ppm (equivalent to 5 mg/kg bw per day). The NOAEL for carcinogenicity was 100 ppm (equivalent to 5 mg/kg bw per day), the highest dose tested.

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

Carbofuran was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found with high (99.8 percent) purity carbofuran. Some lower purity carbofuran batches (purity 99 percent or less) were genotoxic. The US EPA has reported the presence of genotoxic impurities in carbofuran. No data on genotoxic impurities in carbofuran was supplied.

The Meeting concluded that high purity carbofuran (purity 99.8 percent) is unlikely to be genotoxic. However, some batches of lower purity technical grade carbofuran (purity less than 99.8 percent) were genotoxic.

In view of the lack of genotoxicity of high purity carbofuran (purity 99.8 percent), and the absence of carcinogenicity in mice and rats, the Meeting concluded that high purity carbofuran (purity 99.8 percent) is unlikely to be carcinogenic to humans.

In a three-generation reproductive toxicity study in rats (not GLP), carbofuran was administered at dietary concentrations of 0, 20 or 100 ppm (equal to 0, 1.2 and 6 mg/kg bw per day for males, 0, 1.9, and 9.7 mg/kg bw per day for females). The NOAEL for reproductive toxicity was 100 ppm (equal to 6 mg/kg bw per day), the highest dose tested. The offspring NOAEL was 20 ppm (equal to 1.2 mg/kg bw per day), based on reduced growth and survival of pups at 100 ppm (equal to 6 mg/kg bw per day). The parental NOAEL was 100 ppm (equal to 6 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats (not GLP), carbofuran was administered by gavage at dose levels of 0, 0.1, 0.3 or 1.0 mg/kg bw per day. The maternal NOAEL was 0.1 mg/kg bw per day, based on increased incidence of cholinergic clinical signs at 0.3 mg/kg bw per day. The embryo/fetal NOAEL was 1 mg/kg bw per day, the highest dose tested.

In a second developmental toxicity study in rats (not GLP), carbofuran was administered by gavage at dose levels of 0, 0.25, 0.50 or 1.20 mg/kg bw per day. The maternal and embryo/fetal NOAEL was 1.20 mg/kg bw per day, the highest dose tested.

In a third developmental toxicity study in rats (not GLP), carbofuran was administered at dietary concentrations of 0, 20, 60 or 160 ppm (equal to 0, 1.5, 4.4 and 11 mg/kg bw per day). The maternal NOAEL was 20 ppm (equal to 1.5 mg/kg bw per day), based on reduced body weight gain at 60 ppm (equal to 4.4 mg/kg bw per day). The embryo/fetal NOAEL was 60 ppm (equal to 4.4 mg/kg bw per day) based on reduced weight of pups at 160 ppm (equal to 11 mg/kg bw per day).

In a developmental toxicity study in rabbits, carbofuran was administered by gavage at dose levels of 0, 0.2, 0.6 or 2 mg/kg bw per day. The maternal NOAEL was 0.6 mg/kg bw per day, based on clinical signs consistent with cholinergic toxicity at 2 mg/kg bw per day. The embryo/fetal NOAEL was 2 mg/kg bw per day, the highest dose tested.

The Meeting concluded that carbofuran is not teratogenic.

In a 13-week neurotoxicity study in rats, carbofuran was administered at dietary concentrations of 0, 50, 500 or 1000 ppm (equal to 0, 2.4, 27.3 and 55.3 mg/kg bw per day for males, 0, 3.1, 35.3, and 64.4 mg/kg bw per day for females). No NOAELs were identified. The LOAEL for neurotoxicity was 50 ppm, (equal to 3.1 mg/kg bw per day) the lowest dose tested, based on increased landing foot splay in females. The LOAEL for systemic toxicity was 50 ppm (equal to 2.4 mg/kg bw per day) the lowest dose tested, based on reduced body weight gain.

In a developmental neurotoxicity study in rats, carbofuran (purity 99.1 percent) was administered at dietary concentrations of 0, 20, 75 or 300 ppm (equal to 0, 1.7, 5.0 and 8.6 mg/kg bw per day). The maternal NOAEL was 20 ppm (equal to 1.7 mg/kg bw per day) based on adverse reduction in body weight parameters at 75 ppm (equal to 5.0 mg/kg bw per day). The developmental NOAEL was 20 ppm (equal to 1.7 mg/kg bw per day), based on adverse effects on pup body weight parameters, pup viability and weaning indices, and pup developmental delay at 75 ppm (equal to 5.0 mg/kg bw per day).

To evaluate possible life stage-related differences in susceptibility to acute neurotoxicity, carbofuran was administered by gavage at dose levels of 0, 0.3, 0.6 or 1.0 mg/kg bw to rat pups on postnatal day (PND) 11 and to adult rats. The LOAEL was 0.3 mg/kg bw, the lowest dose tested, based on inhibition of brain AChE activity in pups and adults.

In a second study, carbofuran was administered by gavage at dose levels of 0, 0.03, 0.1 or 0.3 mg/kg bw to pups on PND 11. The NOAEL was 0.03 mg/kg bw, due to inhibition of brain AChE activity at 0.1 mg/kg bw. In a third study, carbofuran was administered by gavage at dose levels of 0, 0.03, 0.1 or 0.3 mg/kg bw to pups on PND 11 and to adult rats. The NOAEL for adults was 0.03 mg/kg bw due to inhibition of erythrocyte and brain AChE at 0.1 mg/kg bw 30 minutes after dosing. The NOAEL for pups was 0.03 mg/kg bw due to inhibition of brain AChE at 0.1 mg/kg bw. In an acute toxicity study in young rats (not GLP), carbofuran was administered by gavage to male pups on PND 17, at dose levels of 0, 0.1, 0.3, 0.6 or 1.0 mg/kg bw, and to adult males at 0, 0.1, 0.3, 0.5, 0.75 or 1.5 mg/kg bw. In pups the LOAEL was 0.1 mg/kg bw, the lowest dose tested, based on inhibition of brain AChE. Re-evaluation of this study and the similar one reported in the previous paragraph supported JMPR's 2008 value for a combined lower confidence limit benchmark dose at 10 percent response (BMDL10) for rat pups of 0.03 mg/kg bw, which is equal to the lowest NOAEL of 0.03 mg/kg bw for both adults and pups, proposed in the study reported here.

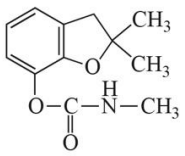
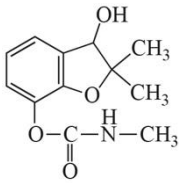
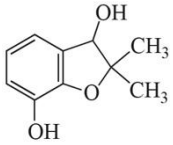
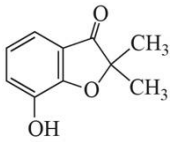
The Meeting concluded that carbofuran is neurotoxic. No studies on delayed neurotoxic potential were submitted. However, experimental data with several carbamates showed that their interaction with the target for delayed polyneuropathy (neuropathy target esterase) protects from, rather than causes, any such neurotoxic effect.

Based on the results of a combined in vitro and in vivo endocrine disruption screening study battery, carbofuran is unlikely to cause toxicity via effects on testosterone/estradiol synthesis, androgen/estrogen receptor binding, aromatase, androgen/estrogen effects on end-

organs and tissues, or effects on the thyroid at the levels of exposure that are likely to occur in the human diet.

Toxicological data on metabolites and/or degradates

Summary of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	Major rat metabolites (>10% AD)[a]	Genotoxicity assessment (data, QSAR, read across)	General toxicity	Toxicological reference values
Carbofuran 	Parent	Not genotoxic provided purity ≥99.8%	Full dataset	ADI [b]: 0–0.001 mg/kg bw ARfD [b]: 0.001 mg/kg bw
3-Hydroxy-carbofuran 	Uncertain	Not genotoxic in vitroc	Covered by parent Rat oral LD_{50} 17.9 to 21.9 mg/kg bw [d] Acts as an anticholinesterase with similar potency to parent, based on acute toxicity	Parent ADI and ARfD
3-Hydroxy-7-phenol-carbofuran 	Uncertain	Negative QSAR	Covered by parent Rat oral LD_{50} for 20% 3-hydroxy-7-phenol was 1654 mg/kg bw There was no evidence of clinical signs consistent with anticholinesterase effects in the acute toxicology studies in rats	Parent ADI and ARfD
3-Keto-7-phenol-carbofuran 	Uncertain	Negative QSAR	Covered by parent Acute oral LD_{50} of 5% (w/w) 3-keto-7-phenol-CF in SD rats was 295.1 mg/kg bw Acute oral LD_{50} of 10% (w/w) 3-keto-7-phenol-CF in SD rats was >800 mg/kg bw NOAEL for parental and offspring toxicity in a one-generation reproduction study was 2.5 mg/kg bw per day, the highest dose tested. No evidence of toxicity associated with the inhibition of AChE was observed.	Parent ADI and ARfD

AChE: Acetylycholinesterase; QSAR: Quantitative structure–activity relationship; ADI: Acceptable daily intake;

ARfD: Acute reference dose;

[a] Based on JMPR, 1996

[b] Applies only to sources of carbofuran of purity 99.8% or greater

[c] 3-Hydroxy-carbofuran (purity 99.1 percent) was not genotoxic in a bacterial reverse mutation assay, did not induce forward mutations in the Chinese hamster ovary HPRT test, and did not induce micronuclei in human peripheral blood lymphocytes in vitro

[d] In male and female rats, the LD_{50} values for 3-hydroxy-carbofuran (purity not stated and/or 96% pure) ranged from 8.3 to 21.9 mg/kg bw, with clinical signs consistent with a cholinergic crisis.

Considering the available data and the structure of the metabolites, as a conservative approach the Meeting considered that the ADI and ARfD for the parent should also apply to 3-hydroxy-carbofuran,3-hydroxy-7-phenol-carbofuran and 3-keto-7-phenol-carbofuran.

Microbiological aspects

No information was available in the public domain and no experimental data were submitted that addressed the possible impact of carbofuran residues on the human intestinal microbiome.

Human data

No workplace surveillance and/or poisoning reports were submitted.

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

Toxicological evaluation

The Meeting re-affirmed JMPR's current ADI of 0–0.001 mg/kg bw, based on the overall NOAEL of 0.03 mg/kg bw per day from acute neurotoxicity studies in rats and using a safety factor of 25. This ADI only applies to sources of carbofuran that have a purity of 99.8 percent or greater.
The Meeting re-affirmed JMPR's current ARfD of 0.001 mg/kg bw, based on the overall NOAEL of 0.03 mg/kg bw per day from acute neurotoxicity studies in rats, and using a safety factor of 25. This ARfD only applies to sources of carbofuran that have a purity of 99.8 percent or greater.

A toxicological monograph was prepared.

Levels relevant to risk assessment of carbofuran

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity[a]	Toxicity	20 ppm, equal to 2.8 mg/kg bw per day	125 ppm, equal to 18 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 70 mg/kg bw per day[b]	-
Rat	Acute neurotoxicity studies in pups and adults[d, e]	Neurotoxicity	0.03 mg/kg bw	0.1 mg/kg bw
	13-week study of neurotoxicity[a]	Neurotoxicity	-	50 ppm equal to 3.1 mg/kg bw per day (females)[c]
		Systemic toxicity	-	50 ppm equal to 2.4 mg/kg bw per day (males)[c]
	Developmental neurotoxicity study[a]	Maternal toxicity	20 ppm, equal to 1.7 mg/kg bw per day	75 ppm, equal to 5.0 mg/kg bw per day
		Embryo/fetal toxicity	20 ppm, equal to 1.7 mg/kg bw per day	75 ppm, equal to 5.0 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity[a]	Toxicity	20 ppm, equivalent to 1 mg/kg bw per day	100 ppm, equivalent to 5 mg/kg bw per day
		Carcinogenicity	100 ppm, equivalent to 5 mg/kg bw per day[b]	-
	Three-generation study of reproductive toxicity[a]	Reproductive toxicity	100 ppm, equal to 6 mg/kg bw per day[b]	-
		Parental toxicity	100 ppm, equal to 6 mg/kg bw per day[b]	-
		Offspring toxicity	20 ppm, equal to 1.2 mg/kg bw per day	100 ppm, equal to 6 mg/kg bw per day
	Developmental toxicity study[d]	Maternal toxicity	0.1 mg/kg bw per day	0.3 mg/kg bw per day
		Embryo/fetal toxicity	1 mg/kg bw per day[b]	-
	Developmental toxicity study[d]	Maternal toxicity	1.2 mg/kg bw per day[b]	-
		Embryo/fetal toxicity	1.2 mg/kg bw per day[b]	-

Species	Study	Effect	NOAEL	LOAEL
	Developmental toxicity study[a]	Maternal toxicity	20 ppm, equal to 1.5 mg/kg bw per day	60 ppm, equal to 4.4 mg/kg bw per day
		Embryo/fetal toxicity	60 ppm, equal to 4.4 mg/kg bw per day	160 ppm, equal to 11 mg/kg bw per day
Rabbit	Developmental toxicity study[d]	Maternal toxicity	0.6 mg/kg bw per day	2 mg/kg bw per day
		Embryo/fetal toxicity	2 mg/kg bw per day[b]	-
Dog	13-week study of toxicity[a]	Toxicity	-	10 ppm equal to 0.43 mg/kg bw per day[c]
	One-year study of toxicity[a]	Toxicity	20 ppm, equivalent to 0.5 mg/kg bw per day	500 ppm, equivalent to 12 mg/kg bw per day
3-Keto-7-phenol-carbofuran				
Rat	One-generation study of reproductive toxicity[a]	Reproductive toxicity	50 ppm, equivalent to 2.5 mg/kg bw per day[b]	-
		Parental toxicity	50 ppm, equivalent to 2.5 mg/kg bw per day[b]	-
		Offspring toxicity	50 ppm, equivalent to 2.5 mg/kg bw per day[b]	-

[a] Dietary administration;
[b] Highest dose tested;
[c] Lowest dose tested;
[d] Gavage administration;
[e]Two or more studies combined

Acceptable daily intake (ADI) for carbofuran*
0–0.001 mg/kg bw

Acute reference dose (ARfD) for carbofuran*
0.001 mg/kg bw

* Applies to carbofuran plus 3-hydroxy-carbofuran, 3-hydroxy-7-phenol-carbofuran and 3-keto-7-phenol-carbofuran, expressed as carbofuran. The ADI and ARfD apply only to sources of carbofuran of purity 99.8% or greater.

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 carbofuran	
Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and extensive
Dermal absorption	No data
Distribution	Wide; highest concentration in liver
Potential for accumulation	Low
Rate and extent of excretion	Rapid with majority of the absorbed radiolabel being excreted in urine within 24 hours
Metabolism in animals	Primarily by CYP3A4-mediated hydroxylation and hydrolysis with subsequent conjugation 3-Hydroxy-carbofuran, 3-keto-carbofuran phenol, 3-hydroxy-N-hydroxymethyl-carbofuran, 3-hydroxymethyl-carbofuran, and carbofuran-phenol were the major metabolites in urine.
Toxicologically significant compounds in animals and plants	Carbofuran, 3-hydroxy-carbofuran, 3-hydroxy-7-phenol-carbofuran and 3-keto-7-phenol-carbofuran
Acute toxicity	
Rat, LD_{50}, oral	5.2 to 14.9 mg/kg bw
Rat, LD_{50}, dermal	No data
Rabbit, LD_{50}, dermal	ca 4400 mg/kg bw (occlusive, intact skin) >2000 mg/kg bw (occlusive, abraded skin)
Rat, LC_{50}, inhalation	No data
Rabbit, dermal irritation	No data
Rabbit, ocular irritation	Minimally irritant (at 5 mg/eye; expected to be lethal at higher, untested doses)
Mouse, dermal sensitization	No data
Guinea pig, dermal sensitization	Not sensitizing (Draize)
Short-term studies of toxicity	
Target/critical effect	Inhibition of AChE activity (rabbit, dog)

Lowest relevant oral LOAEL	0.43 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day, highest dose tested (rabbit)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Inhibition of AChE (mice, rats and dogs), clinical signs of cholinergic toxicity (rats, rabbits), decreased body weight /body weight gain (rats)
Lowest relevant NOAEL	1 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic[a]
Genotoxicity	Unlikely to be genotoxic if purity is $\geq$ 99.8% [a]
Reproductive toxicity	
Target/critical effect	Reduced pup growth and survival (rat)
Lowest relevant parental NOAEL	6 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	1.2 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	6 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	Reduced maternal body weight gain and reduced fetal body weight (rat), maternal signs of cholinergic crisis (rat and rabbit)
Lowest relevant maternal NOAEL	0.1 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	1 mg/kg bw per day (rat)
Neurotoxicity	
Acute neurotoxicity NOAEL	0.03 mg/kg bw (rat, adults and pups 11–17 days old)
Subchronic neurotoxicity LOAEL	3.1 mg/kg bw per day[b] (rat)
Developmental neurotoxicity NOAEL	1.7 mg/kg bw per day (rat)
Other toxicological studies	
Immunotoxicity	No data; unlikely to be immunotoxic
Studies on toxicologically relevant metabolites	

3-Hydroxycarbofuran	Acute oral LD_{50}: 8.3 to 21.9 mg/kg bw (rat) Not genotoxic in in vitro assays Acts as an cholinesterase inhibitor (potency likely similar to parent)
Microbiological data	No data submitted
Human data	No clinical cases or poisoning incidents have been submitted

[a] Unlikely to pose a carcinogenic risk to humans via exposure from the diet
[b] Lowest dose tested

Summary

	Value	Study	Safety factor
ADI	0–0.001 mg/kg bw [a]	Acute neurotoxicity studies (rat)	25
ARfD	0.001 mg/kg bw [a]	Acute neurotoxicity studies (rat)	25

[a] Applies to carbofuran, 3-hydroxy-carbofuran, 3-hydroxy-7-phenol-carbofuran and 3-keto-7-phenol-carbofuran,expressed as carbofuran.

5.6 Carbosulfan (145) (T,R)**

TOXICOLOGY

Carbosulfan is the International Organization for Standardization (ISO-approved common name for (2,2-dimethyl-*3H*-1-benzofuran-7-yl) *N*-(dibutylamino)sulfanyl-*N*-methylcarbamate, which has the Chemical Abstracts Service number 55285-14-8. Carbosulfan is a procarbamate insecticide that, when converted to carbofuran, acts by reversibly inhibiting the activity of acetylcholinesterase (AChE) thus, inhibiting the breakdown of the neurotransmitter acetylcholine (ACh). This results in increasing both the level and duration of the neurotransmitter action at ACh receptors.

Carbosulfan has been previously evaluated by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 1984, 1986 and 2003. In 2003 JMPR established an ADI for carbosulfan of 0–0.01 mg/kg body weight (bw). In 2003 JMPR established an ARfD for carbosulfan of 0.02 mg/kg bw. Carbosulfan was reviewed by the present Meeting at the request of Codex Committee on Pesticide Residues (CCPR) as part of their periodic review programme.

Most critical studies contained statements of compliance with good laboratory practice (GLP) unless otherwise stated, and generally complied with currently accepted test methods. Relevant peer-reviewed published scientific papers were identified and evaluated.

Overall, the Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

Following oral dosing, carbosulfan undergoes substantial presystemic degradation resulting in a lower acute oral toxicity compared with carbofuran. Oral uptake is rapid. Based on the elimination fraction of carbosulfan-derived radiolabel in mass balance studies, estimated oral absorption in rats was up to 91.4 percent of administered dose (AD). Radioactivity derived from carbosulfan was widely distributed in rats. In rats carbosulfan was rapidly metabolized and excreted, predominantly in urine (up to 91.4 percent of AD). Excretion is largely complete by 48 hours following dosing. In rats the rate of excretion is increased following repeated dosing.

Two hepatic metabolic pathways were identified: the sulphur oxidation (detoxification) pathway, and the carbofuran (toxication) pathway. In vitro, human biomaterials detoxified carbosulfan more extensively than with comparable rodent biomaterials. Enzymes in the CYP3A subfamily were the major in vitro catalysts of carbosulfan metabolism.

In rats the major urinary metabolites were 3-hydroxy-carbofuran, 3-keto-7-phenol-carbofuran, 3-hydroxy-7-phenol-carbofuran, 7-phenol-carbofuran and dibutylamine. The major faecal metabolites were 3-hydroxy-carbofuran and carbofuran.

Toxicological data

Values for the acute oral median lethal dose (LD_{50}) of carbosulfan in rats ranged from 7.9 to 300 mg/kg bw. The dermal LD_{50} was greater than 2000 mg/kg bw. The inhalation median lethal concentration (LC_{50}) of carbosulfan (4 hours, nose only) ranged from 0.05 to 0.38 mg/L.

Stabilized carbosulfan was not irritating to rabbits' skin. Carbosulfan was slightly to mildly irritating to the eyes of rabbits and was not skin sensitizing in a Guinea pig maximization test.

In general, in short-term and long-term studies of toxicity, the most sensitive effect of oral administration of carbosulfan was the inhibition of AChE activity, accompanied at the same or higher doses, by clinical signs indicative of a cholinergic toxidrome.

In a 90-day oral toxicity study in rats (not GLP), carbosulfan was administered at dietary concentrations of 0, 10, 20 or 500 ppm (equal to 0, 0.25, 0.50 and 13.6 mg/kg bw per day for males, 0, 0.19, 0.38 and 9.8 mg/kg bw per day for females). The no-observed-adverse-effect level (NOAEL) was 20 ppm (equal to 0.38 mg/kg bw per day, due to inhibition of brain AChE at 500 ppm (equal to 9.8 mg/kg bw per day).

In a 24-month combined chronic oral toxicity and carcinogenicity study in mice, carbosulfan was administered at dietary concentrations of 0, 10, 20, 500 or 2500 ppm (equal to 0, 1.3, 2.5, 62 and 320 mg/kg bw per day for males, 0, 1.5, 3.1, 72 and 337 mg/kg bw per day for females). The NOAEL for toxicity was 20 ppm (equal to 2.5 mg/kg bw per day), due to reduced brain AChE activity at 500 ppm (equal to 62 mg/kg bw per day). The NOAEL for carcinogenicity was 2500 ppm (equal to 320 mg/kg bw per day), the highest dose tested.

In a 104-week combined chronic oral toxicity and carcinogenicity study in rats, carbosulfan was administered at dietary concentrations of 0, 10, 20, 500 or 2500 ppm (equal to 0, 0.5, 1.0, 26.8 and 152.8 mg/kg bw per day for males, 0, 0.6, 1.2, 34.7 and 213.3 mg/kg bw per day for females). The NOAEL for toxicity was 20 ppm (equal to 1.0 mg/kg bw per day) due to reduced brain AChE activity, increased incidence of focal iris atrophy and decreased body weight, at 500 ppm (equal to 26.8 mg/kg bw per day). The NOAEL for carcinogenicity was 2500 ppm (equal to 152.8 mg/kg bw per day), the highest dose tested.

Overall, the Meeting concluded that carbosulfan is not carcinogenic in mice or rats.

Carbosulfan was evaluated for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The Meeting concluded that carbosulfan is unlikely to be genotoxic.

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

In a three-generation reproductive toxicity study in rats, carbosulfan was administered at dietary concentrations of 0, 10, 20 or 250 ppm (equivalent to 0, 0.67, 1.3 and 16.7 mg/kg bw per day). Cholinesterase activities were not determined in this study. The NOAEL for parental effects was 20 ppm (equivalent to 1.3 mg/kg bw per day), based on decreased body weight at 250 ppm equivalent to 16.7 mg/kg bw per day. The NOAEL for reproductive toxicity was 20 ppm (equivalent to 1.3 mg/kg bw per day) due to effects on litter size at the next highest dietary concentration of 250 ppm (equivalent to 16.7 mg/kg bw per day). The NOAEL for offspring toxicity was 20 ppm (equivalent to 1.3 mg/kg bw per day) based on reductions in pup weight and pup weight gain at 250 ppm (equivalent to 16.7 mg/kg bw per day).

In a developmental toxicity study in rats, carbosulfan was administered by gavage at dose levels of 0, 2, 10 or 20 mg/kg bw per day. Cholinesterase activities were not measured in this study. The maternal NOAEL was 2 mg/kg bw per day based on an increased incidence of oral discharge (consistent with cholinergic toxicity) at 10 mg/kg bw per day. The embryo/fetal NOAEL was 2 mg/kg bw per day based on a reduction in fetal weight at 10 mg/kg bw per day.

In a developmental toxicity study in rabbits, carbosulfan was administered by gavage at dose levels of 0, 2, 5 ord 10 mg/kg bw per day. The maternal and embryo/fetal NOAEL was 10 mg/kg bw per day, the highest dose tested. Cholinesterase activities were not measured in this study.

Overall, the Meeting concluded that carbosulfan is not teratogenic.

In an acute neurotoxicity study in rats, carbosulfan was administered by gavage at doses of 0, 0.5, 5 or 30 mg/kg bw. The NOAEL was 0.5 mg/kg bw, based on decreased AChE activity in the brain and erythrocytes at 5 mg/kg bw.

In a 13-week neurotoxicity study in rats, carbosulfan was administered at dietary concentrations of 0, 20, 1000 or 2000 ppm (equal to 0, 1.2, 65 and 131 mg/kg bw per day for males, 0, 1.4, 79 and 152 mg/kg bw per day for females). Measurements of AChE activity were not included in this study. The NOAEL was 20 ppm (equal to 1.2 mg/kg bw per day), based on tremors, reduced motor activity, decreased food consumption and decreased body weight and body weight gain at 1000 ppm (equal to 65 mg/kg bw per day).

In a delayed neurotoxicity study in hens, carbosulfan was administered orally as a single 500 mg/kg bw dose. Neuropathy target esterase measurements were not performed. Neither were neurobehavioural signs, or microscopic anatomic pathology evidence of delayed neurotoxicity observed.

The Meeting concluded that carbosulfan is neurotoxic but does not induce delayed neurotoxicity.

No immunotoxicity studies were submitted, but no evidence of immunotoxicity was observed in repeat-dose studies of toxicity.

Based on the available data the Meeting concluded that carbosulfan is unlikely to be immunotoxic.

Toxicological data on metabolites and/or degradates

The conversion of carbosulfan to carbofuran involves the formation of dibutylamine. The major metabolites present in carbosulfan dietary residues, except for dibutylamine, are derived from the metabolism of carbofuran (see above report item, 5.05 Carbofuran).

While dibutylamine is a major metabolite of carbosulfan occurring in rats, it is unlikely to have any anticholinesterase effects. There is insufficient data to derive a potency factor. The Meeting concluded that dibutylamine is toxicologically relevant but can be covered by the health-based guidance values (HBGVs) for carbosulfan.

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of carbosulfan residues on the human intestinal microbiome.

Human data

In reports on manufacturing plant personnel for 2017 and 2018 no adverse health effects were noted.

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

Toxicological evaluation

The Meeting re-affirmed an ADI of 0–0.01 mg/kg bw, based on a combined point of departure of 1.3 mg/kg bw per day derived from the NOAEL values of 1.2 mg/kg bw per day in the 13-week neurotoxicity study in rats, 1 mg/kg bw per day for toxicity in the 104-week study of toxicity and carcinogenicity in rats, and 1.3 mg mg/kg bw per day for parental and offspring toxicity in the three-generation reproductive toxicity study in rats. The NOAEL of 0.38 mg/kg bw per day in the 90-day rat study was not considered appropriate to derive the ADI because of the wide dose spacing, with the least-observed-adverse-effect level (LOAEL) of 9.8 mg/kg bw per day. A safety factor of 100 was used.

The Meeting re-affirmed an ARfD for the general population of 0.02 mg/kg bw, based on the NOAEL of 0.5 mg/kg bw in the acute neurotoxicity study in rats. The Meeting noted the wide dose range between the NOAEL of 0.5 mg/kg bw and the LOAEL of 5 mg/kg bw, and what is likely to be the higher C_{max} associated with gavage dosing compared to dietary exposure. For these reasons the NOAEL for the acute neurotoxicity study was not used as the point of departure for the ADI. A safety factor of 25 was considered appropriate because the acute toxic effects of carbofuran are dependent on C_{max} rather than the area under the concentration–time curve (AUC). Also, data indicated that the sensitivities of humans and laboratory animals (rats, dogs) to inhibition of AChE activity by carbofuran were similar. A full justification for the use of a total uncertainty factor of 25 was provided at JMPR, 2008.

A toxicological monograph was prepared.

Levels relevant to risk assessment of carbosulfan

Species	Study	Effect	NOAEL	LOAEL
Mouse	24-month combined study of toxicity and carcinogenicity[a]	Toxicity	20 ppm, equal to 2.5 mg/kg bw per day	500 ppm, equal to 62 mg/kg bw per day
		Carcinogenicity	2500 ppm, equal to 320 mg/kg bw per day[c]	-
Rat	Acute neurotoxicity study[b]	Neurotoxicity	0.5 mg/kg bw	5 mg/kg bw
	13-week study of neurotoxicity [a]	Neurotoxicity	20 ppm, equal to 1.2 mg/kg bw per day	1000 ppm, equal to 65 mg/kg bw per day
	104-week study of toxicity and carcinogenicity[a]	Toxicity	20 ppm, equal to 1.0 mg/kg bw per day	500 ppm, equal to 26.8 mg/kg bw per day
		Carcinogenicity	2500 ppm, equal to 152.8 mg/kg bw per day[c]	-
	Three-generation study of reproductive toxicity[a]	Reproductive toxicity	20 ppm, equivalent to 1.3 mg/kg bw per day	250 ppm, equivalent to 16.7 mg/kg bw per day
		Parental toxicity	20 ppm, equivalent to 1.3 mg/kg bw per day	250 ppm, equivalent to 16.7 mg/kg bw per day
		Offspring toxicity	20 ppm, equivalent to 1.3 mg/kg bw per day	250 ppm, equivalent to 16.7 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	2 mg/kg bw per day	10 mg/kg bw per day
		Embryo/fetal toxicity	2 mg/kg bw per day	10 mg/kg bw per day
Rabbit	Developmental toxicity study[b]	Maternal toxicity	10 mg/kg bw per day[c]	-
		Embryo/fetal toxicity	10 mg/kg bw per day[c]	-
Metabolites: see above report item 5.05 Carbofuran				

a Dietary administration b Gavage administration c Highest dose tested

*Acceptable daily intake (ADI) applies to carbosulfan**

0–0.01 mg/kg bw

*Acute reference dose (ARfD) applies to carbosulfan***

0.02 mg/kg bw

*Applies to carbosulfan and dibutylamine expressed as carbosulfan, plus ten times carbofuran and metabolites (see 5.05 Carbofuran above)

**Applies to carbosulfan and dibutylamine expressed as carbosulfan, plus 20 times carbofuran and metabolites (see 5.05 Carbofuran above)

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

Clarification of the level of carbofuran in the carbosulfan test articles used in the toxicology studies. Results from epidemiological, occupational health and other such observational studies of human exposure.

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

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapid and extensive (up to 91%)
Dermal absorption	No data Rabbit: reduction in brain cholinesterase activity at 50 mg/kg bw per day Rat: substantial conversion of carbosulfan to carbofuran occurred in rat skin in vitro
Distribution	Wide; highest concentrations in gastrointestinal tract, liver, kidney, fat, thymus and central nervous system
Potential for accumulation	Low
Rate and extent of excretion	Rapid; >70% dose eliminated within 24 hours and nearly complete within 120 hours; Mainly via urine (65 to >90% dose)
Metabolism in animals	3-Hydroxy-carbofuran, 3-keto-7-phenol-carbofuran, 3-hydroxy-7-phenol-carbofuran and 7-phenol-carbofuran
Toxicologically significant compounds in animals and plants	Carbosulfan, dibutylamine, carbofuran and its metabolites (see above, 5.05 Carbofuran)

Acute toxicity

Rat, LD_{50}, oral	≤7.9 to < 300 mg/kg bw
Rat, LD_{50}, dermal	>4000 mg/kg bw
Rat, LC_{50}, inhalationa	0.05 to 0.38 mg/L
Rabbit, dermal irritation	Stabilized carbosulfan: not irritating
Rabbit, ocular irritation	Slightly irritating
Mouse, dermal sensitization	No data
Guinea pig, dermal sensitization	Not a sensitizer (Magnussen & Kligman)

Short-term studies of toxicity

Target/critical effect	Inhibition of cholinesterase activity (rat, rabbit)
Lowest relevant oral NOAEL	1.2 mg/kg bw per day (rat)

Lowest relevant dermal NOAEL	5 mg/kg bw per day (rabbit)
Lowest relevant inhalation NOAEC	0.65 µg/L (rat)

Long-term studies of toxicity and carcinogenicity

Target/critical effect	Inhibition of cholinesterase activity (mouse and rat), Increased incidence of focal iris atrophy (rat), Decreased bodyweight (rat)
Lowest relevant NOAEL	1 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic
Genotoxicity	Unlikely to be genotoxic

Reproductive toxicity

Target/critical effect	Reduced fetal and maternal body weights
Lowest relevant parental NOAEL	1.3 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	1.3 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	1.3 mg/kg bw per day (rat)

Developmental toxicity

Target/critical effect	Decreased maternal and embryo/fetal body weight (rat)
Lowest relevant maternal NOAEL	2 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	2 mg/kg bw per day (rat)

Neurotoxicity

Acute neurotoxicity NOAEL	0.5 mg/kg bw (rat)
Subchronic neurotoxicity NOAEL	1.2 mg/kg bw per day (rat, AChE activity not assessed)
Developmental neurotoxicity NOAEL	No data
Delayed neurotoxicity	Negative

Other toxicological studies

Immunotoxicity	No specific data; unlikely to be immunotoxic based on the available data

Studies on toxicologically relevant metabolites

Dibutylamine, carbofuran and its metabolites	(see 5.05 Carbofuran, above)
Microbiological data	No data submitted
Human data	In reports on manufacturing plant personnel, no adverse health effects were noted

Summary

	Value	Study	Safety factor
ADI	0–0.01 mg/kg bw [a]	13-week neurotoxicity study, the 104-week study of toxicity and carcinogenicity, and the three-generation reproductive toxicity study (all rat)	100
ARfD	0.02 mg/kg bw [b]	Acute neurotoxicity study (rat)	25

[a] Applies to carbosulfan and dibutylamine expressed as carbosulfan, plus ten times carbofuran and its metabolites (see 5.05 Carbofuran above)

[b] Applies to carbosulfan and dibutylamine expressed as carbosulfan, plus 20 times carbofuran and metabolites (see 5.05 Carbofuran above)

RESIDUE AND ANALYTICAL ASPECTS

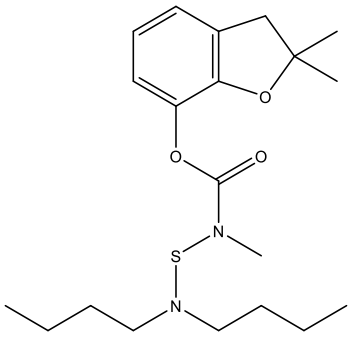
Carbosulfan is a broad spectrum carbamate insecticide, acting by inhibiting the activity of acetylcholinesterase and used for the control of a number of soil and foliar insects. Carbosulfan was first evaluated by the 1984 JMPR, periodically evaluated for residues by the JMPR in 1997 and new uses were considered by the 2002 and 2003 JMPRs.

Carbofuran (096) is the biologically active metabolite of carbosulfan. It is also a pesticide in its own right, and a metabolite of furathiocarb and benfuracarb. JMPR has previously recommended maximum residue levels for carbofuran based on the use of carbofuran and of carbosulfan.

Carbosulfan and carbofuran were scheduled at the Fiftieth Session of the CCPR for Periodic Re-evaluation for residues and toxicology by 2019 JMPR but this was postponed until additional genotoxicity information was available. The Meeting was informed that carbofuran was no longer being supported and received information on identity, physical-chemical properties, metabolism of carbosulfan in crops, metabolism in livestock, environmental fate in soil and water, residue analysis, stability in stored analytical samples, use patterns, supervised residue trials, fate of residue during processing, and livestock feeding studies.

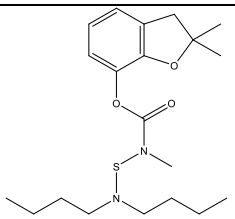
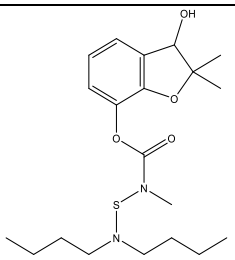
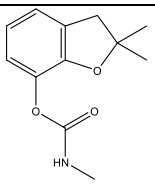
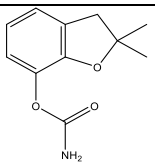
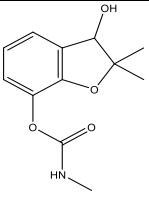
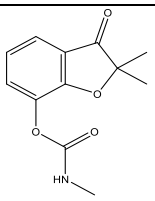
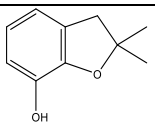
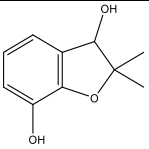
FAO specifications for carbosulfan were published by the Joint Meeting on Pesticide Specifications in 1995 (AGP.CP/315).

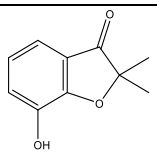
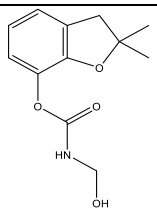
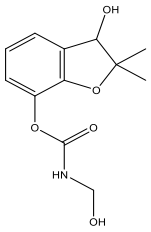
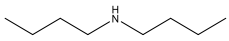
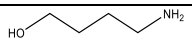
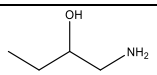
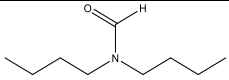
Carbosulfan is 2,3-Dihydro-2,2-dimethylbenzofuran-7-yl (dibutylaminothio)methylcarbamate.



The following abbreviations are used for the major metabolites discussed below.

Major carbosulfan metabolites identified in plant and animal matrices

Common or abbreviated name	Chemical name	Chemical structure
Carbosulfan	2,3-dihydro-2,2-dimethylbenzofuran-7-yl (dibutylaminothio)methylcarbamate MW 380.55	
3-hydroxy-carbosulfan	3-hydroxy-2,2-dimethyl-2,3-dihydrobenzofuran-7-yl ((dibutylamino)thio)(methyl)carbamate	
Carbofuran FMC 10242	2,3-dihydro-2,2-dimethylbenzofurany-7-yl methylcarbamate MW 221.26	
Desmethyl-carbofuran	2,2-dimethyl-2,3-dihydrobenzofuran-7-yl carbamate	
3-hydroxy-carbofuran FMC 18209	2,3-dihydro-3-hydroxy-2,2-dimethylbenzofuran-7-yl methylcarbamate MW 237.25	
3-keto carbofuran	2,2-dimethyl-3-oxo-2,3-dihydrobenzofuran-7-yl methylcarbamate MW 235.24	
7-phenol FMC 10272	2,3-dihydro-2,2-dimethylbenzofuran-7-ol MW 164.2	
3-hydroxy-7-phenol FMC 16497	2,3-dihydro-2,2-dimethylbenzofuran-3,7-diol MW 180.2	

Common or abbreviated name	Chemical name	Chemical structure
3-keto-7-phenol FMC 16490	2,3-dihydro-2,2-dimethyl-3-oxobenzofuran-7-ol MW 178.18	
N-hydroxymethyl carbofuran	2,2-dimethyl-2,3-dihydrobenzofuran-7-yl (hydroxymethyl)carbamate	
3-Hydroxy-N-hydroxymethyl carbofuran N-Hydroxy-methyl-3-hydroxy carbofuran	3-hydroxy-2,2-dimethyl-2,3-dihydrobenzofuran-7-yl (hydroxymethyl)carbamate	
Dibutylamine DBA FMC 65387	Dibutylamine MW 129.3	
4-amino-butanol	4-aminobutan-1-ol	
1-amino-2-butanol	1-aminobutan-2-ol	
N-formyl dibutylamine	N,N-dibutylformamide	

Physical and chemical properties

Carbosulfan is not volatile (3.58×10^{-8} mm Hg at 25 °C), low solubility in water (0.33 mg/L at pH 6.91, 3 mg/L at pH 9) but readily dissolves in organic solvents (miscible in all proportions with acetone, acetonitrile, toluene, hexane and methanol). It is rapidly hydrolized to carbofuran and dibutylamine especially under acidic contitions with DT_{50} values ranging from 0.2 hours (pH 5.0) to 7 days (pH 9.0) at 25° C. The octanol/water partition coefficient (log K_{ow}) of 5.4 suggests that carbosulfan could be fat-soluble.

Plant metabolism

The Meeting received studies on metabolism of carbosulfan in orange, maize, rice, sugar beet, alfalfa and soya bean, using carbosulfan radiolabelled (^{14}C) in the phenyl ring (phenyl label) or the C1 position of the dibutylamine chain (DBA label).

<u>Orange (foliar treatment)</u>

Navel orange trees in the field were treated with foliar applications of phenyl or DBA-labelled ^{14}C-carbosulfan at a spray concentration of 0.5 g ai/L (estimated 0.615 kg ai/ha). Orange fruits were

sampled at 0, 7, 15 and 30 days after treatment and leaves were sampled at 0 and 30 days after treatment. Oranges were rinsed with methanol:dichloromethane (1:1 v/v) and samples of peel rinse, peel, pulp and juice were stored for up to 11 months before analysis by HPLC-MS, TLC, GC-MS and LSC.

The majority of the radioactivity (99 percent TRR) was recovered initially as a surface rinse (94–96 percent TRR) or peel residue (4–6 percent TRR), with peel accounting for 42–46 percent TRR after 30 days (with the surface rinse decreasing to 54–58 percent TRR). Only trace levels (up to 0.3 percent TRR) were recovered in the juice or flesh at any sampling interval. Calculated whole fruit residues were 0.78–0.85 mg eq/kg (phenyl label) and 0.56–0.7 mg eq/kg (DBA label).

In the leaves, TRRs were 16 mg eq/kg and 13 mg eq/kg after 0 and 30 days respectively from the phenyl label samples and 9.3 and 4.6 mg eq/kg from the DBA label samples.

Surface rinse samples were extracted with methanol:dichloromethane and peel samples were extracted with methanol:phosphate buffer, with conjugated residues in the phenyl label aqueous fractions released by refluxing in 0.25 mol/L HCl for 1 hour. The DBA label aqueous fractions were adjusted to pH 14 (NaOH) and hydrolysed to release conjugates. Unextracted residues not exceeding 3.7 percent TRR.

In the surface rinses for fruit, about 94–96 percent TRR was characterized in the 0-day samples, mostly being parent compound (about 88–91 percent TRR). For 30-DALA samples, parent compound accounted for 27.7–37.4 percent TRR and dibutylamine 25 percent TRR. All other identified and characterized metabolites each did not exceed 5 percent TRR.

In whole fruit (based on radioactivity in the surface wash, peel, flesh and juice), between 90 percent and 98 percent TRR was identified at any given sampling interval. In the 15- and 30-DALA samples respectively, the major phenyl label components were carbosulfan (62.9 percent TRR, 0.51 mg/kg and 40.1 percent TRR, 0.31 mg/kg) and carbofuran (16.8 percent TRR, 0.135 mg eq/kg and 33.9 percentTRR, 0.26 mg eq/kg). The major DBA label components in the 15-DAT samples were carbosulfan (64.4 percent TRR, 0.36 mg/kg) and free and conjugated dibutylamine (26.7 percent TRR, 0.15 mg eq/kg), with the carbosulfan residues decreasing to 31.2 percent TRR (0.18 mg/kg) in the 30-DALA samples and the total dibutylamine residues increasing accordingly to 58.2 percent TRR, 0.34 mg eq/kg (22.6 percent TRR as DBA-conjugates)

Other identified or characterized metabolites present in whole fruit did not exceed 3.6 percent TRR or 0.03 mg eq/kg.

Alfalfa (foliar treatment)

Phenyl or DBA-labelled carbosulfan was applied once as a foliar spray to mature alfalfa at a rate of 0.5 kg ai/ha. Plant samples were taken 7 and 14 days after application. Only the percentages of radioactive residues were reported.

Samples were extracted with methanol:phosphate buffer, partitioned with dichloromethane and conjugated residues in the aqueous fractions released by refluxing in 0.25 mol/L HCl for 1 hour. Unextracted residues accounted for 11.2 percent TRR.

From the phenyl label study, 44.2 percent and 33.4 percent TRR were organosoluble non-conjugated residues, 44.6 percent and 50.4 percent were metabolite conjugates, and unextracted residues were 11.2 percent and 16.2 percent in 7 and 14 day plants respectively. Carbosulfan accounted for 14 percent TRR in alfalfa (7-DALA) and 5.9 percent TRR (14-DALA). Carbofuran (10–15 percent TRR; mostly non-conjugated) and 3-hydroxy carbofuran (15–28 percent TRR -

free and conjugated) were the principal metabolites. Other carbofuran-related metabolites did not exceed four percent TRR (3-keto carbofuran) and carbosulfan-related metabolites were less than 1.6 percent TRR (carbosulfan sulfone).

In the DBA label samples, the major residues were carbosulfan, making up 46.8 percent TRR (7-DALA) and 26.3 percent TRR (14-DALA) and dibutylamine, increasing as a proportion from 14.3 percent TRR (7-DALA) to 38 percent TRR (14-DALA). Minor carbosulfan-related metabolites did not exceed 1.5 percent TRR (3-hydroxy carbosulfan).

Sugar beet (foliar or soil treatment)

Phenyl or DBA-labelled carbosulfan was applied to 51-day old sugar beet plants under greenhouse conditions, either as a soil or foliar treament. For the foliar applications, ^{14}C-carbosulfan solutions were uniformly sprayed onto the plants using an atomizer (1.0 kg ai/ha). For the soil treatments, the applications were to the soil surrounding the plants (1.1 kg ai/ha). Samples were taken at 30, 60 and 130 days after application and plants were separated into leaf and root portions. Root samples were gently washed with distilled water and dried before analysis. Sample frozen storage periods were not reported.

In the foliar-treated plants, highest residues were found in tops, declining from 37.2 to 21.5 mg eq/kg in immature tops (30 DALA) to 0.06—0.01 mg eq/kg at maturity (130 DALA). In mature roots, residues did not exceed 0.17 mg eq/kg.

After extraction with hexane and methanol (with conjugated residues released by acid refluxing, in 6 mol/L HCl for 1 hour), unextracted residues in tops were up to 25.2 percent TRR for the phenyl label and up to 9.4 percent TRR for the DBA label experiment. In roots, unextracted residues were up to 54.9 percent TRR (phenyl label) and up to 48 percent TRR (DBA label). The phenyl label mature roots and tops (130 DAT) were not extracted. More aggressive acid and base extraction released about 31 percent of the tops PES and 39 percent of the roots PES, with no further identification.

In the phenyl label samples, the predominant residues in immature sugar beet tops were 3-keto-7-phenol (16–22.6 percent TRR), 3-hydroxy carbofuran (15–16.8 percent TRR), and 3 hydroxy-7-phenol (10.6–13.6 percent TRR), mostly present as conjugates. Carbosulfan and its sulphone, 3-hydroxy- and 3-keto- metabolites were present at low levels (0.2–0.6 percent TRR), carbofuran residues were 1.2–2.1 percent TRR and its desmethyl, keto- and 3-hydroxy-N-hydroxymethyl derivatives each made up 0.5-4.5 percent TRR.

In the DBA label immature sugar beet tops, the predominant residues were dibutylamine (19.9–46.9 percent TRR) and N-formyl dibutylamine (13.9–30.8 percent TRR) and in immature roots, N-formyl dibutylamine (12.1 percentTRR) was the major residue, with dibutylamine making up 3.9 percent TRR. Residues in mature tops and roots were too low to identify.

Following soil treatment, unextracted residues in the phenyl label 60-DALA roots were 65.5 percent TRR and were 33.9 percent TRR in the 30-DALA tops. The DBA label samples were not extracted. Samples of phenyl label mature roots and tops (130 DAT) were also not extracted. Residues in tops decreased from 1.53 mg eq/kg (30 DALA) to 0.02-0.08 mg eq/kg at maturity. In the 60-DALA roots, residues did not exceed 0.08 mg eq/kg. For the 30-DALA tops, the acid-hydrolysed organosoluble extract (containing 15.9 percent TRR,) was the only fraction analysed, with major metabolites being the 3-hydroxy-7-phenol conjugates (3.9 percent TRR, 0.06 mg eq/kg), 3-hydroxy carbofuran (3.1 percent TRR) and 3-keto-7-phenol (2.5 percent TRR) and desmethyl carbofuran (0.9 percent TRR). Residues in other extracts were not investigated further.

For the 60-DALA roots, the acid-hydrolysed organosoluble extract (containing 7.2 percent TRR), carbofuran (1 percent TRR, 0.07 mg eq/kg) was the predominant residue, with other carbamate and phenol components each <0.4 percent TRR. Residues in other extracts and in mature tops and roots were not investigated further.

Maize (soil treatment)

Phenyl- or DBA-labelled ^{14}C-carbosulfan was sprayed over the furrow at the time of sowing in a sandy loam soil at a rate of 3.36 kg ai/ha under greenhouse conditions. Immature plants were sampled 31 and 60 days after application and at the silage stage (110 days), with grain, husks and stalks/leaves sampled at maturity (136 days).

From the phenyl label study, the TRRs were 20 mg eq/kg in 31-DAT plants, 6.3 mg eq/kg in 60-DAT plants, 4.4 mg eq/kg in silage (110 DAT), 25 mg eq/kg and 1.8 mg eq/kg in stalks/leaves respectively, and 1.1 mg eq/kg in husks and grain. Methanol:phosphate buffer extraction was able to extract more than 80 percent TRR in plants, silage and stalks/leaves and 74–79 percent TRR in husks and grain.

Parent carbosulfan was only identified in immature (31 DAT) plants at a very low-level (0.2 percent TRR, 0.04 mg/kg). The 3-OH-carbofuran (25 percent TRR, 3.2 mg eq/kg) and carbofuran (24 percent TRR, 2.8 mg eq/kg) metabolites were the major components in 31 DAT and 60 DAT plants. The 3-OH-carbofuran was also the major metabolite in silage (14 percent TRR, 0.37 mg eq/kg) and stalks/leaves (12 percent TRR). The other significant metabolites included 3-keto-7-phenol (15 percent TRR in 60 DAT plants, 11 percent TRR in silage, 9.7 percent TRR in stalks/leaves, 6.7 percent TRR in husks), 3-OH-7-phenol (9.8 percent TRR in husks). Other minor metabolites (<5 percent TRR) included 3-keto carbofuran (3.1-3.2 percent TRR), 7-phenol (0.5–3.2 percent TRR), 3-keto-carbofuran sulfone (0.2 percent TRR) and carbosulfan sulfone (0.1 percent TRR). The low residues in grain were not characterized and identified.

From the DBA label study, the TRRs were 3.6 mg eq/kg in the 31-DAT plants, 1.3 mg eq/kg in the 60-DAT plants, 1.2 mg/kg in silage, 2.4 mg eq/kg in stalks/leaves and 1.2 mg eq/kg in both the husks and grain. From 65 to 79 percent TRR was extracted in maize plants, 51 percent TRR in silage, 68 percent TRR in stalks/leaves, 51 percent TRR in husk and 84 percent TRR in grain. Carbosulfan was only identified in 31 day plants at very low-level (0.3 percent TRR, 0.01 mg/kg). DBA was the major metabolite in all samples, decreasing from 30.6 percent TRR in the 31-DAT plants to 9.3 percent TRR in silage and 7.8 percent TRR in stalks/leaves. No other metabolites exceeded five percent TRR. Residues in grain were too low for characterization and identification.

Rice (soil treatment)

Phenyl or DBA-labelled carbosulfan was applied to sandy loam soil at a rate of 1.1 kg ai/ha and two-week old rice plants were transplanted about an hour after application. The soil was then flooded and remained flooded during the study period. Immature plants were harvested 11 and 30 days after application and the mature rice grain was sampled 148 days after application.

Only the percentages of radioactive residues in immature plants were reported. In grain, low levels of radioactivity (0.3–0.43 mg eq/kg) were found, 92–95 percent of which were not able to be extracted with hexane.

For the phenyl label, 60–83 percent TRR was extracted with hexane from samples of 11 and 30 DALA plants and less than 6 percent TRR was extracted from the mature grain. Carbosulfan was only a minor component of the radioactivity (0.2 percent TRR) in the 30-DAT

plants. In the 11-DAT plants, carbofuran (45.3 percent TRR) and 3-hydroxy carbofuran (20.2 percent TRR) were the major metabolites, and other metabolites were <3.5 percent TRR. In 30-DAT plants, the major metabolites included carbofuran (12 percent TRR), 3-OH-carbofuran (9.4 percent TRR), 7-phenol (14 percent TRR) and 3-keto-7-phenol (7.6 percent TRR). Other minor metabolites were less than 4 percent TRR.

From the DBA label study, 19–24 percent TRR was extracted in rice plants and 8 percent TRR extracted from grain. The parent carbosulfan was only identified in 30-DAT plants as a minor component of the radioactivity (0.7 percent TRR). DBA was a minor component (2.5–3.3 percent TRR) in all plant samples, and no other metabolites identified in 30 DAT plants exceeded 1 percent TRR.

As a separate experiment, grain heads on each of the five soil-treated plants were also treated with 14C-carbosulfan and the grain was harvested 30–45 days later. The major residues in mature rice grains samples 45 days after the phenyl label treatment were carbofuran (29 percent TRR), 3-hydroxy carbofuran (7.7 percent TRR), carbosulfan (5.7 percent TRR) and 3-keto-7-phenol (4.3 percent TRR) and 30 days after the DBA label treatment the major residues were carbosulfan (15.6 percent TRR) and dibutylamine (29.6 percent TRR). No other metabolites exceeded 3 percent TRR.

Soya bean (soil treatment)

Phenyl or DBA label carbosulfan were applied as a soil application at a rate of 2.2 kg ai/ha immediately after sowing soya beans. Immature samples were harvested 30 and 60 days after application, and mature soya bean seeds were harvested 123 days after application.

TRRs in phenyl label samples ranged from approximately 480 mg eq/kg in immature plants (30-DAT) to 3.3 mg eq/kg in mature bean seeds, while TRRs in the DBA label immature plants were 7.5 mg eq/kg (30-DAT) and 2.4 mg eq/kg (60-DAT), with residues in mature bean seeds being 2.0 mg eq/kg.

Plant samples were extracted with methanol/phosphate buffer (plants) or hexane (soya bean seeds). For the phenyl label and DBA label samples, the respective unextracted radioactivity was 15.7–34 percent TRR in the 30 DALA plants and 25.8–27.9 percent TRR in the 60 DALA plants.

Bean seeds were extracted with hexane and saponified by refluxing with KOH:methanol for 3 hours and the soap extracted with diethyl ether. Unextracted radioactivity accounted for 28.5 percent TRR (phenyl label) and 34.1 percent TRR (DBA label).

Major metabolites in immature phenyl label plants(30 or 60 DALA) included carbofuran (up to 27.7 percent TRR), 3-hydroxy carbofuran (up to 20.1 percent TRR) and 3-keto-7-phenol (up to 24.2 percent TRR). Other carbofuran-related metabolites containing the carbamate moiety (free and conjugated) accounted for up to 2.1 percent TRR, phenol-related carbofuran metabolites (free and conjugated) were found at up to 7.3 percent TRR and up to 12 unidentified components were also present, none of which exceeded 3.2 percent TRR. Unextracted residues accounted for up to 25.8 percent TRR.

In the DBA label plants, the only identified residues found were carbosulfan, present only in immature plants (0.2 percent TRR at 30 days and 0.02 percent TRR at 60 days) and 3-keto carbosulfan sulfone (4.0 percent TRR in the 30-DAT plants).

In mature phenyl label bean seeds, low levels of 3-keto-7-phenol (4.3 percent TRR, 0.14 mg eq/kg) and 3-hydroxy-7-phenol (2.1 percent TRR, 0.07 mg eq/kg) were detected, mostly

released from the PES, with free and conjugated 3-hydroxy carbofuran and 7-phenol both present at low levels (0.5 percent TRR, 0.017 mg eq/kg). Up to five unidentified components were also present, each not exceeding 2.8 percent TRR and unextracted residues accounted for 24.5 percent TRR. In mature DBA label bean seeds, no identified metabolites were detected, with up to five unidentified components present, none of which exceeded 2.8 percent TRR. Unextracted residues accounted for up to 34.1 percent TRR.

Conclusions

Carbosulfan was rapidly metabolized in citrus, maize, rice, sugar beet, alfalfa, soybean following either foliar or soil treatment. The metabolism pathways of carbosulfan in crops are similar, involving hydrolysis of the parent molecule to form carbofuran and dibutylamine or oxidation to carbosulfan sulfone. Carbofuran is then either oxidized to the 7-phenol metabolite (and the subsequent formation of 3-hydroxy-7-phenol and 3-keto-7-phenol metabolites) or the intact carbamate moiety is retained and carbofuran is oxidized to N-hydroxymethyl carbofuran or hydroxylated to 3-hydroxy carbofuran and 3-keto carbofuran. Metabolites are present in conjugated and non-conjugated forms, with an acid hydrolysis step required to release conjugated metabolites.

Carbosulfan, carbofuran and dibutylamine were the major residues following foliar applications. Following soil applications, the major residues at the early sampling times were carbofuran and 3-hydroxy carbofuran, with concentrations of phenol-derivatives increasing at later sampling times. Dibutylamine was a major metabolite in immature plants, decreasing slowly with time. Total residues in mature sugar beet roots, maize grain and rice grain were too low to identify. Low levels of 3-hydroxy carbofuran and the phenol-derivatives were found in mature soya beans and maize stover.

Animal metabolism

The Meeting received studies on metabolism of carbosulfan in rats, lactating goat and laying hens where animals were dosed with phenyl label or DBA label ^{14}C carbosulfan. The Meeting noted that sample storage stability studies indicate that residues of carbosulfan are not stable in stored frozen samples of cow milk, muscle or liver, and that this may have some impact on the results of the metabolism studies.

Rats

The metabolism of carbosulfan in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the current JMPR.

Goats

The Meeting received two metabolism studies in goats from 1979 to 1982 and 1996. Three additional studies were also provided, but these only reported TRR distributions in milk and tissues, and were not evaluated further.

In the 1996 study, lactating goats were dosed orally once daily with either phenyl- or DBA-labelled carbosulfan for 7 days at the equivalent of 23–25 ppm in the diet. Urine and faeces were collected daily and milk collected in the afternoon and in the morning before dosing. Animals were sacrificed at 22 hours after the final dose. Samples of omental and peripheral fat, liver, kidney and leg and lumbar muscle were stored for up to 6 months before extraction and analysis. About 83 percent of the phenyl label and 68 percent of the DBA label was eliminated in the urine and about 7 percent TRR (phenyl label) and 3.3 percent TRR (DBA label) was eliminate in faeces.

TRRs in milk reached a plateau by day 2 with maximum residues of 0.09 mg eq/kg for the phenyl label-treated goats and 0.94 mg eq/kg for the DBA label-treated goats.

From the phenyl label-treated goats, the TRRs were 0.06 mg eq/kg in liver, 0.18 mg eq/kg in kidney, and <0.01 mg eq/kg in muscle and fat. About 97 percent TRR from milk, 87 percent from liver and 98 percent from kidney were extracted with acetone/acetonitrile (milk), hexane (omental fat), or methanol/buffer (liver, kidney). Polar residues (>0.05 mg/kg) remaining in the aqueous fraction were subjected to enzymatic or mild acid hydrolysis. Lipid-containing fractions of the milk and omental fat were saponified to release the fatty acids. The unextracted residues in the liver, kidney, and DBA label lumbar muscle and milk were fractionated using enzymatic and/or acid hydrolyses.

Metabolites found at concentrations above 0.01 mg eq/kg were 3-hydroxy carbofuran (34 percent TRR, 0.031 mg eq/kg in milk and 22 percent TRR, 0.033 mg eq/kg in kidney), 3-keto-7-phenol (30 percent TRR, 0.027 mg eq/kg in milk), 3-hydroxy-7-phenol (21 percent TRR, 0.019 mg eq/kg in milk and 13 percent TRR, 0.02 mg eq/kg in kidney) and 7-phenol (8.9 percent TRR, 0.014 mg eq/kg in kidney).

Low levels (<0.01 mg eq/kg) of 3-hydroxy carbofuran (ten percent TRR in liver), 3-hydroxy-7-phenol (16 percent TRR in liver) and 7-phenol (9.2 percent TRR in milk) were also identified. Carbofuran residues were present at low levels in kidney (0.8 percent TRR, 0.0012 mg eq/kg) and 3-keto-carbofuran residues in kidney were <4 percent TRR (0.006 mg eq/kg).

From the DBA label-treated goats, the TRRs were 0.68 mg eq/kg in milk, 1.0 mg eq/kg in liver, 0.82 mg eq/kg in kidney, 0.19 mg eq/kg in muscle and 1.3 mg eq/kg in fat. About 97 percent TRR from milk, 93 percent TRR from liver and 96 percent TRR from kidney, 90 percent TRR in muscle and 89 percent TRR in fat were extracted.

The major metabolites identified were aminobutanols (4-amino-1-butanol and 1-amino-2-butanol isomers), making up about 30 percent TRR (0.2 mg eq/kg) in milk, 8.1 percentTRR (0.08 mg eq/kg) in liver and 12 percent TRR in kidney (0.098 mg eq/kg), with dibutylamine and related compounds present at 6.7 percent TRR in milk, 13 percent TRR in liver, 11 percent TRR in kidney and 9.6 percent TRR in muscle.

Much of the DBA label radioactivity consisted of radiocarbon fragments incorporated into natural products (fatty acids, triglycerides, carbohydrates and amino acids), totalling 87.3 percent TRR in fat, 29–32 percent TRR each in milk, liver, muscle and 13.8 percent TRR in kidney. Characterized constituents (non-conjugated amines, conjugated or bound amines, lipophilic metabolites and polar aqueous metabolites) comprised 30.5 percent TRR in the milk, 0.7 percent TRR in the fat, 42.2 percent TRR in the liver, 59.6 percent TRR in the kidney and 48.3 percent TRR in muscle.

In the earlier study, conducted between 1979 and 1981, lactating goats were dosed orally once daily for 7 days with phenyl-labelled carbosulfan at the equivalent of 4.4 ppm or 11.4 ppm in the diet. Urine and faeces were collected daily and milk in the afternoon and in the morning before dosing. Animals were sacrificed 12 hours after the final dose. Samples of omental fat, liver, kidney and muscle were taken for analysis. About 80 percent TRR was eliminated in the urine and 2.5 percent TRR in faeces.

TRRs in milk reached a plateau by day 2 with average residues in whole milk, skim milk and cream of 0.015–0.022 mg eq/kg from the 4.4 ppm dose group and 0.043–0.056 mg eq/kg from the 11.4 ppm dose group.

From the 4.4 ppm dose group, the TRRs were 0.03 mg eq/kg in liver, 0.049 mg eq/kg in kidney, and less than 0.01 mg eq/kg in muscle and fat. In the 11.4 ppm dose group, TRRs were 0.11 mg eq/kg in liver, 0.12 mg eq/kg in kidney, up to 0.023 mg eq/kg in muscle and less than 0.01 mg eq/kg in fat.

About 33—52 percent TRR from milk, 47–57 percent TRR from liver and 73 percent TRR from kidney were extracted and characterized. The only metabolite found above 0.01 mg eq/kg was the 7-phenol (conjugated), present at 24.5 percent TRR, 0.012 mg eq/kg in kidney from the 4.4 ppm dose group but making up 7.4 percent TRR (0.009 mg eq/kg) in the 11.4 ppm kidney.

Laying hens

The laying hen metabolism studies were conducted using pheny-labelled or DBA-labelled carbosulfan. White Leghorn hens were orally dosed once per day by capsule for 14 days at rates equivalent to 0.6, 1.8 and 6.0 ppm in the diet. Eggs were collected daily throughout the dosing period and for a further 12 days depuration period. Hens were sacrificed a within 6 hours of the final dose, or after 7 and 14 days of depuration. The tissue samples of gizzard, breast muscle, thigh muscle, fat, skin, liver, heart and blood were collected from each bird at sacrifice. No information was provided on the frozen sample storage periods.

TRRs in tissues from the 6 ppm phenyl label dose group were 0.081 mg eq/kg in fat, 0.145 mg eq/kg in skin, 0.11 mg eq/kg in muscle and 0.281 mg eq/kg in liver. Residues declined to 0.002 mg eq/kg or less after 7 days depuration. In DBA label dose group, TRRs were 1.35 mg eq/kg in liver, 0.3 mg eq/kg in fat, up to 0.16 mg eq/kg in muscle and 0.12 mg eq/kg in skin. After 14-days depuration, residues declined to 0.04 mg eq/kg and 0.02 mg eq/kg in muscle and liver but were stable, or slightly increased in skin and fat.

Tissues and eggs were extracted with ethanol/ether/hexane, with unextracted residues of 18.6 percent in liver and 1.6 percent TRR in muscle. Acid hydrolysis was also used on the post extraction solids and on the polar aqueous fractions of thigh muscle and liver for additional release of conjugated metabolites. Fat fractions from egg yolk and fat tissues were saponified with alcoholic KOH to release the fatty acids.

In the phenyl label dose group, the predominant residues in muscle were 3-hydroxy carbofuran (36.9 percent TTR, 0.026 mg eq/kg) and 3-hydroxy-N-hydroxy carbofuran (9.3 percent TRR, 0.007 mg eq/kg) and in liver, the major metabolite was 3-OH-7-phenol (16 percent TRR, 0.021 mg eq/kg, with the carbofuran-related metabolites making up 1.1–2.1 percent TRR. No other single residue (including those identified in the liver PES and the polar aqueous liver and muscle fraction) was present above 7.1 percent TRR and 0.004 mg/kg.

In the DBA label dose group, most of the residues were unidentified, with dibutylamine the only measurable residue in liver (37 percent TRR, 0.5 mg eq/kg) muscle (22.5 percent TRR, 0.036 mg eq/kg) and fat (3.1 percent TRR, 0.009 mg eq/kg). Most of the radioactivity in fat was shown to be incorporated into natural fatty acids (palmitic - 33.3 percent TRR, oleic – 37 percent TRR, stearic – 7.7 percent TRR and linoleic – 6.2 percent TRR).

In eggs, TRRs from the 6 ppm phenyl label dose group plateaued in both yolks and egg whites after 5 days, with maximum concentrations of 0.026 and 0.009 mg eg/kg respectively. After the final dose, residues steadily declined to below the the limit of detection after 7 days depuration (whites) and 12 days for yolks. The total residue levels found were too low for metabolite analysis.

In the DBA label dose group, TRRs in eggs also plateaued at 5 days with maximum levels of 1.9 mg eq/kg in yolks and 0.12 mg eq/kg in whites. After the final dose, residues in egg whites

depleted rapidly to <0.002 mg eg/kg by day 11, while residues in yolk were still present after 14 days of depuration (0.055 mg eq/kg). In composite (dosing days 9–12) samples of yolks and egg whites, dibutylamine was the only measurable metabolite, 3.8–4.2 percent TRR and 0.066 mg eq/kg in yolks and 0.0033 mg eq/kg in whites.

Conclusions

Carbosulfan is rapidly metabolized and excreted in animals, and if detected, found only at very low levels (<2 percent TRR). The predominant metabolites are 3-hydroxy-carbofuran (poultry muscle, milk and kidney) and dibutylamine (poultry muscle and liver). Carbofuran is only a minor component in all matrices.

The proposed metabolic pathway for carbosulfan in goats involves hydrolytic cleavage of the N-S bond to form dibutylamine and carbofuran, with the subsequent formation of carbamate derivatives or the loss of the carbamate group to form the phenolic carbofuran derivatives. The dibutylamine moiety is oxidized into compounds containing the amine fragment. Dibutylamine may be oxidized to 4-(n-butylamino)-1-butanol and further to the corresponding butanoic acid or undergo a series of reactions to form butylamines and butanols which can then be incorporated into natural products such as fatty acids, triglycerides, carbohydrates and proteins. The main metabolic routes are similar to those in rats.

Environmental fate

The Meeting received information on the hydrolytic stability, photochemical and aerobic soil degradation and water/sediment studies of carbosulfan and its metabolite carbofuran.

Hydrolysis

Carbosulfan decomposed to carbofuran and dibutylamine in aqueous media with a much faster decomposition rate seen under acid conditions than at neutral or basic pH. The first order DT_{50} values (25° C) for carbosulfan were 0.2 hours (pH 5.0, buffered), 11.4 hours (pH 7, buffered), 18.2 hours (pH 7.3, distilled water) and 7.2 days pH 9, buffered). The major degradation product, carbofuran, was stable at acidic and neutral pH but decomposed to 7-phenol under basic conditions with a first order DT_{50} of 2.3 hours at buffered pH 9.9. In pH 6.2 buffer solutions, carbofuran half-lives were <10 months at 25° C, about 2 months at 35° C and 13 days at 45° C.

Photochemical degradation

Carbosulfan is more rapidly degraded in irradiated aqueous solutions (DT_{50} of 1.3 days in pH 7 buffer solution) than in the dark (DT_{50} of 7.5 days). It is also rapidly degraded in dry soil, irrespective of irradiation (DT_{50} of less than 10 minutes), with carbofuran and dibutylamine being the major degradates. Soil degradation rates for carbofuran and dibutylamine in irradiated and dark control samples were similar, and the Meeting concluded that photolysis is not a major degradation route in soil.

Aerobic soil metabolism

The route and range of degradation of carbosulfan in soil was investigated in four aerobic soils in darkness.

Carbosulfan rapidly degrades in soils under aerobic conditions. Overall a DT_{50} value of 17.5 days was determined for the aerobic degradation according to first order kinetics. Carbofuran was the major metabolite appearing from the first day and reaching a maximum level of 48.7 percent AR at day 7. The carbofuran DT_{50} and DT_{90} values were 24.5 days and 81.3 days, respectively (single first order). The metabolites 3-keto carbofuran and dibutylamine were minor

metabolites with respective maximum values of 5.3 percent (14-DAT) and 3.1 percent (4-DAT) of the applied dose. Bound residues increased during the course of this study reaching levels of >84 percent in Speyer 2.2 soil (28-DAT).

Carbosulfan DT_{50} values ranged from 2 to 3.1 days and DT_{90} values were 3 to 76 days. Carbofuran also degraded in the test soils, with DT_{50} values between 7.9 and 24.5 days, and DT_{90} values between 26 and 81 days.

Water/sediment studies

The degradation of phenyl label [^{14}C]carbosulfan was investigated in two aquatic systems treated with the equivalent of 0.5 kg ai/ha and 1.0 kg ai/ha and incubated at 10°C or 20°C.

Carbosulfan residues declined rapidly, degrading to carbofuran (up to ≈35 percent AR in surface water and up to ≈13 percent AR in sediment). The 7-phenol metabolite was also detected in the surface water of all test systems, accounting for up to ≈12 percent AR in surface water and ≈1 percent AR in sediment and trace levels (< 1 percent) of 3-hydroxy carbosulfan, 3-keto-7-phenol and carbosulfan sulfone were found in all test systems.

Half-lives for carbosulfan in the surface waters ranged from 1.3 days to 10.1 days in the four systems, with whole-system half-lives of 4.2–10 days.

Conclusions

Carbosulfan is readily hydrolysed in aqueous solutions, more rapidly at higher temperatures and lower pHs. The aqueous half life at pH 7 was 11.4 hours. Soil degradation under aerobic conditions is rapid with half-lives of 3-5.9 days. Photolysis is not considered to be a major degradation route. In water/sediment systems, carbosulfan degrade rapidly, with whole-system half-lives of 4.2–10 days.

Rotational crop metabolism

Confined rotational crop studies

Carbosulfan is readily degraded in soil, and not expected to be taken up in rotational crops. However, since carbofuran is the primary soil degradate of carbosulfan, the Meeting evaluated three carbofuran rotational crop studies to estimate potential residues in succeeding crops following the application of carbosulfan to primary crops.

In a confined rotational crop study, a bare clay loam soil was treated with the equivalent of 0.6 kg ai/ha and spinach, radish and maize/wheat crops were planted 24 days and 64 days after treatment, TRRs were below <0.01 mg eq/kg in all food commodities except the 24 day PBI spinach, where TRRs of 0.031–0.036 mg eq/kg were found at all three sampling intervals. In livestock feed commodities, TRRs were all <0.05 mg eq/kg. No further characterization was conducted.

In a further confined study, a bare silty loam soil was treated with the equivalent of 3.4 kg ai/ha carbofuran, sweet corn was planted as a primary crop and after harvest the soil was tilled and wheat, soya bean and sugar beet crops were planted 4 months and 12 months after treatment.

In the 4-month PBI samples, about half the radioactivity was either unextracted or unidentified conjugated residues, these increasing to about 70–80 percent of the radioactivity in the 12-month PBI samples.

In the 4-month PBI food commodities, TRRs in wheat grain (0.6 mg eq/kg) and soya bean seeds (1.0 mg eq/kg) were not investigated further. In sugar beet roots (TRR of 0.2 mg eq/kg), the 7-phenol metabolite was the highest identified metabolite (2.6 percent TRR, 0.005 mg eq/kg).

In the 12-month PBI food crops, TRRs were 0.04 mg eq/kg (wheat grain), 0.08 mg eq/kg (soya bean) and 0.05 mg eq/kg (sugar beet roots).

In the 4-month PBI feed commodities, the phenolic metabolites were the principal degradation products, with 3-hydroxy-7-phenol being the predominant residue in wheat straw (14.3 percent TRR, 7.7 mg eq/kg), 7-phenol being a major residue in soya bean stems (0.15 mg eq/kg) and sugar beet tops (<0.05 mg eq/kg) and 3-keto-7-phenol a major residue in sugar beet tops (18.9 percent TRR, <0.08 mg eq/kg). For the carbamate derivatives, 3-hydroxy carbofuran was the major residue in wheat straw 7.8 percent TRR, 4.2 mg eq/kg) and immature soya bean leaves (9.1 percent TRR, 3.9 mg eq/kg).

In the 12-month PBI samples, highest residues were in immature wheat forage (1.4 mg eq/kg) and mature soya bean stems (0.7 mg eq/kg). The principal degradation products were 3-keto-7-phenol and 7-phenol, each making up about 11 percent TRR (0.055 mg eq/kg). Trace levels of 3-hydroxy carbofuran were detected (up to 2.5 percent TRR, 0.035 mg eq/kg in wheat forage).

In an outdoor study, a loam soil plots were treated with the equivalent of at 1.1, 3.4 or 6.7 kg ai/ha phenyl-labelled carbofuran and sorghum was planted as a primary crop and 120 days later a wheat was planted as a second cover crop. After the wheat crop was harvested and the soil hand-tilled, wheat, soya bean, sugar beet, sorghum, lettuce and cabbage were planted 11 months after treatment as rotational crops. TRRs in food commodities from all treatment rates were below the reported limits of detection (0.008 – 0.1 mg eq/kg) except for cabbage (0.01 mg eq/kg at the highest treatment rate). In animal feed commodities, residues were also below the reported limits of detection (0.008 – 0.065 mg eq/kg) at all treatment rates except for wheat straw (0.21 mg eq/kg) and soya bean stems 0.63 mg eq/kg) from the 6.7 kg ai/ha treatment plots.

Conclusions

Carbosulfan residues are not expected in rotational crops. However, based on studies with carbofuran, at treatment rates scaled to reflect the maximum carbosulfan seasonal application rates of about 3 kg ai/ha/year (equivalent to about 1.8 kg ai carbofuran/year), in food commodities (4-month PBI), TRRs of 0.3–0.5 mg eq/kg could be expected in wheat grain and soya bean seed.

In the carbosulfan metabolism study on soil-treated soya bean (approximating a 0-day PBI), where 3.3 mg eq/kg were found in mature soya bean seeds, 3-keto-7-phenol (4.3 percent TRR) and 3-hydroxy-7-phenol (2.1 percent TRR) were the main metabolites.

In the carbosulfan soil-treated rice metabolism study (also approximating a 0-day PBI), TRRs in mature rice grain were about the same as the above expected TRRs in grain from the rotated wheat crop, with about 2 percent of this TRR abel to be extracted and categorized as containing conjugated residues.

These studies provide some indication of what metabolites and their relative proportions might be expected in soya beans and wheat grown as rotational crops.

In sugar beet roots residues of the 7-phenol metabolite (the highest identified metabolite – 2.6 percent TRR) could reach 0.0025 mg eq/kg and the carbamate derivatives (carbofuran, 3-hydroxy carbofuran and 3-keto-carbofuran) shoud not exceed 0.005 mg eq/kg. In feed commodities (wheat straw), 3-hydroxy-7-phenol residues could be present at up to about 4 mg eq/kg, and levels of 3-hydroxy carbofuran could reach 2 mg eq/kg.

The Meeting concluded that in rotational crops, significant residues of carbosulfan metabolites are not expected in food commodities but there is a potential for metabolite residues to be taken up in feed commodities.

Methods of analysis

The Meeting received analytical method descriptions and validation data for carbosulfan and its carbamate metabolites in plant and animal matrices.

For plant and animal matrices, the earlier analytical methods developed between 1980 and 1995 for measuring residues of carbosulfan, carbofuran (and 3-hydroxy carbofuran, 3-keto carbofuran residues in some methods), involved hexane:acetone, hexane:propanol or dichloromethane extraction, one or more SPE clean-up and partitioning steps, with residues being measured by GC-NPD or GC-MS. In most of these methods, an additional acid hydrolysis step (refluxing for 1 hour in 0.25 M HCl) and was used to release conjugated 3-hydroxy carbofuran residues which were measured (after ethoxylation) by GC-NPD or by HPLC (with post-column derivatization).

Most of these methods (used in some of the field trials, the storage stability studies and the citrus processing study) did not meet the current validation requirements, although concurrent recovery rates were within the acceptable range of 70–120 percent. Reported LOQs ranged from 0.05 to 0.1 mg/kg, but were higher (up to 20 mg/kg) in some matrices.

In the more recent methods, carbosulfan residues were measured following ethyl acetate or acetone:dichloromethane extraction, Florisil or GPC clean-up and GC-MS or LC-MS/MS analysis. In methods developed for measuring carbosulfan, carbofuran and 3-hydroxy carbofuran residues, samples were extracted with acetonitrile or hexane:acetone and the filter cake hydrolysed by refluxing in 0.25 mol/L HCl before SPE clean-up and the combined extracts analysed by LC-MS/MS.

These methods, used in the more recent supervised field trials and in the lactating cow studies met current validation criteria, with LOQs of 0.005–0.05 mg/kg.

Conclusions

For the plant and animal commodities under consideration, validated GC-MS and LC-MS/MS methods are available for determining residues of carbosulfan, carbofuran, 3-hydroxy carbofuran and 3-keto carbofuran (animal commodites). Methods that include an acid hydrolysis step to release bound residues are also suitable for measuring 3-hydroxy carbofuran and 3-keto carbofuran. The LOQs for these methods are 0.01-0.05 mg/kg. A number of published multi-residue methods are able to detect carbosulfan and carbofuran residues, with LOQs of 0.01–0.05 mg/kg.

Stability of pesticide residues in stored analytical samples

Plant commodities

Residues of carbosulfan in frozen stored samples are susceptible to degradation via hydrolysis in orange juice, molasses and oil, in mango and sugar beet roots. In mango, analysis for both carbosulfan and carbofuran in samples fortified with carbosulfan alone, indicated that the

combined residues of carbosulfan and carbofuran (expressed as carbosulfan) were stable for up to 3 months.

Residues of carbosulfan are stable on frozen storage for at least 6 months in soya bean, 12 months in alfalfa (hay and forage), orange fruit and dry pulp, 14 months in sugar cane and 15 months in maize grain.

Carbofuran and 3-hydroxy carbofuran residues are stable on frozen storage for at least 3 months in mango, 6 months in soya beans, 12 months in processed orange commodities (dried pulp, juice, molasses and oil), 14 months in sugar cane, 15 months in maize grain, 24 months in orange fruit, peanut nutmeat and hulls and at least 26 months in alfalfa forage and hay, sugar beet tops and roots, maize grain and silage, potato tubers and sorghum stalks.

Residues of 3-keto carbofuran are not stable on frozen storage in mango or sugar beet tops, but stable for at least 12 months in processed orange commodities (dried pulp, juice, molasses and oil), 24 months in orange fruit, peanut nutmeat and hulls and at least 26 months in sugar beet roots, maize grain and silage, alfalfa hay and forage, potato tubers and sorghum stalks.

Dibutylamine residues are not stable on frozen storage in orange oil but stable for at least 18 months in orange juice, 19 months in orange fruit and 24 months in orange molasses.

Animal commodities

Residues of carbosulfan were not stable in stored frozen samples of cow milk, muscle or liver. Residues of dibutylamine (DBA) were stable for at least 6 months in both milk and tissues (muscle and liver). Residues of carbofuran, 3-hydroxy carbofuran and 3-keto carbofuran were stable on frozen storage in milk for up to 24 months and stable for up to 23 months cow muscle (7 months for 3-hydroxy carbofuran). No information on the freezer storage stability of residues in poulty tissues or eggs were received.

Conclusions

Residues of carbosulfan are not stable in orange juice, molasses and oil, mango, sugar beet roots, milk and ruminant tissues (muscle and liver) and 3-keto carbofuran residues are not stable in sugar beet tops. Based on a storage stability study for mango, the combined residues of carbosulfan and carbofuran are stable for at least 3 months.

With the exception of the citrus processing study, the storage intervals in the supervised trials were within these demonstrated periods of frozen storage.

Definition of the residue

Plant commodities

The Meeting received studies on metabolism of carbosulfan following foliar treatments in orange, alfalfa and immature sugar beet, and following soil treatments in immature sugar beet, maize, paddy rice and soya bean.

In plants, carbosulfan is rapidly hydrolysed to carbofuran and dibutylamine or oxidized to carbosulfan sulfone. Carbofuran is then either oxidized to the 7-phenol metabolite (and the subsequent formation of 3-hydroxy-7-phenol and 3-keto-7-phenol metabolites) or the intact carbamate moiety is retained and carbofuran is hydroxylated to 3-hydroxy carbofuran and 3-keto carbofuran or oxidized to N-hydroxymethyl carbofuran. Metabolites are present in conjugated and non-conjugated forms.

In food commodities, following mid-late season foliar applications (orange, rice grain heads), carbosulfan, carbofuran and dibutylamine were the predominant residues. In orange fruit, carbosulfan residues were 31–63 percent TRR, carbofuran residues were 17–34 percent TRR and dibutylamine residues were 27–58 percent TRR. In rice grain, carbofuran (29 percent TRR), dibutylamine (30 percent TRR) and carbosulfan (up to 16 percent TRR) were the major metabolites. The 3-hydroxy carbofuran metabolite made up 1–2 percent TRR in orange fruit and 7.7 percent TRR in rice. Other carbamate derivatives each did not exceed 3.6 percent TRR in orange fruit and 2.3 percent TRR in rice grain and the phenol-derivatives were each less than 0.4 percent TRR in orange fruit and 4.3 percent TRR in rice grain.

Following an early season soil treatment, radioactivity in maize (1.1-1.2 mg eq/kg), rice (0.3-0.43 mg eq/kg), and sugar beet roots (0.08 mg eq/kg) were not identified and in soya bean, low levels of 3-hydroxy carbofuran (0.5 percent TRR, 0.016 mg eq/kg) were observed and the phenol-derivatives made up 0.5–4.3 percent TRR (up to 0.14 mg eq/kg).

In alfalfa, following a mid-late season foliar application, carbosulfan residues reached 14 percent TRR, carbofuran residues were up to 14.6 percent TRR, 3-hydroxy carbofuran residues were up to 28 percent TRR and dibutylamine residues were about 47 percent TRR. Other carbamate-derived metabolites each were present at up to 4.2 percent TRR and the phenol-derived metabolites made up less than 6 percent TRR. The TRRs in mature sugar beet tops were not identified.

In maize, following a soil treatment at sowing, carbosulfan was not detected in silage or stover, with the predominant residue being 3-hydroxy carbofuran (about 14 percent TRR, 0.37 mg eq/kg in silage and up to 12 percent TRR, 1.9 mg eq/kg in stover). Carbofuran residues made up 2.8 percent TRR (<0.1 mg eq/kg) in silage and about 1.6 percent TRR (up to 0.35 mg eq/kg) in stover. The phenol carbofuran derivatives (3-hydroxy-7-phenol and 3-keto-7-phenol) made up 12 percent TRR or less in silage and stover. The TRRs in mature sugar beet tops were not identified.

In rotational crops, significant residues of carbosulfan metabolites are not expected in food commodities but there is a potential for metabolite residues to be taken up in feed commodities.

For MRL-compliance, based on the metabolism studies and in the field trials involving foliar applications (where residues are expected), carbosulfan and carbofuran are both detected and are suitable marker residues. Validated methods of analysis are available for their determination.

Carbosulfan itself, is not stable in some high water content matrices when stored under frozen conditions, but the combined residues of carbosulfan and carbofuran are stable in mango for up to 3 months.

The Meeting therefore considered that to accommodate this potential degradation, the residue definition for MRL-compliance should be the sum of carbosulfan and carbofuran expressed as carbosulfan.

For risk assessment, in deciding which metabolites should be included in the residue definition for plant commodities, the Meeting considered the likely occurence and toxicological significance of the metabolites present in food commodities at more than ten percent of the carbosulfan and carbofuran concentrations (taking into account the relative toxicities of carbofuran and carbosulfan). Compounds considered were: carbofuran, 3-hydroxy carbofuran, dibutylamine and the 3-hydroxy-7-phenol and 3-keto-7-phenol carbofuran metabolites.

Carbofuran has the same toxicological mode of action as carbosulfan, with an ADI 10-fold lower and an ARfD 20-fold lower than carbosulfan. In the metabolism studies it is a major residue in foliar-treated orange fruit and in the supervised field trials involving foliar applications, it is the major residue in citrus fruit and a significant residue in mango, eggplant and asparagus.

The Meeting considered that carbofuran should be included in the residue definition for risk assessment.

3-hydroxy carbofuran (free and conjugated) is a major metabolite in the carbosulfan rat metabolism study and is covered by the HBGVs for carbofuran. Where food commodities in the plant metabolism studies were analysed, following mid-late season foliar treatments, 3-hydroxy carbofuran was present at low levels in orange fruit (0.016 mg eq/kg), rice grain (0.033 mg.kg) and contributed less than 3 percent to the residues of concern. However, in sugar beet tops and alfalfa (surrogates for leafy crops), the residue contributon ranged from 15 to 28 percent. Where 3-hydroxy carbofuran was measured In field trials, residues were present at up to 13 percent in citrus, up to 26 percent in mango and up to 22 percent in eggplant.

Following soil applications, 3-hydroxy carbofuran residues made up 0.5 percent TRR in soya bean seed and contributed about 4 percent to the residues of concern in immature (60 DAT) sugar beet roots (a surrogate for root crops). Information on other food commodities was not available.

The Meeting considered that 3-hydroxy carbofuran (free and conjugated) should be included in the residue definition for risk assessment.

3-hydroxy-7-phenol is a major metabolite in the carbosulfan rat metabolism study and is covered by the HBGVs for carbofuran. Where food commodities in the plant metabolism studies were analysed, 3-hydroxy-7-phenol was not found in foliar-treated orange fruit, but was present at 1.8 percent TRR (0.008 mg eq/kg) in foliar-treated rice. In sugar beet tops, residues were 11-14 percent TRR and were lower (1.5 percent TTR) in alfalfa.

Following soil treatments, 3-hydroxy-7-phenol residues in immature sugar beet roots (a surrogate for root crops), the residue contribution decreased to less than 3 percent in the 60 DAT roots. In soya bean seeds, residues were about 2 percent TRR (0.069 mg eq/kg). Information on other food commodities was not available.

The Meeting considered that 3-hydroxy-7-phenol should be included in the residue definition for risk assessment.

3-keto-7-phenol a major metabolite in the carbosulfan rat metabolism study and is covered by the HBGVs for carbofuran. Where food commodities in the plant metabolism studies were analysed, 3-keto-7-phenol was not found in foliar-treated orange fruit, and was present at 4.3 percent TRR (0.018 mg eq/kg) in foliar-treated rice, contributing less than 2 percent to the residues of concern. In foliar-treated sugar beet tops, 3-keto-7-phenol contributed 16–22 percent and alfalfa contributed up to 6 percent to the dietary risk.

Following soil treatments, 3-keto-7-phenol residues in immature sugar beet roots (a surrogate for root crops), the residue contribution decreased to about 4 percent in the 60 DAT roots. In soya bean seeds, residues were 4.3 percent TRR (0.14 mg eq/kg). Information on other food commodities was not available.

The Meeting considered that 3-hydroxy-7-phenol should be included in the residue definition for risk assessment.

Dibutylamine (free and conjugated) is a major metabolite in the carbosulfan rat metabolism study and is covered by the HBGVs for carbosulfan. In the plant metabolism studies involving foliar treatments, dibutylamine is a significant metabolite in foliar-treated orange fruit (up to 58 percent TRR), rice grain (30 percent TRR), sugar beet tops (20-47 percentTRR) and alfalfa (38 percent TRR) following foliar treatments.

Dibutylamine and carbofuran are the cleavage products formed by hydrolysis of carbosulfan. In the plant metabolism studies, where the treatment rates for the phenyl label and the DBA label studies were similar, residues of dibutylamine in the DBA label samples were found at lower concentrations than the carbofuran-derived residues of concern (i.e. they were 1.2 percent in rice grain, <1 percent in orange fruit and 14 percent, decreasing to 1.5 percent in sugar beet tops).

The Meeting noted that if residues are expressed in terms of parent equivalents (carbosulfan) the dietary risk from residues of dibutylamine are indirectly taken into account in the assessment of the phenol-label metabolites and considered that dibutylamine should not be included in the residue definition for risk assessment.

Since carbofuran has a lower ADI of 0.001 mg/kg bw and a lower ARfD of 0.001 mg/kg bw than carbosulfan and these HBGVs also apply to 3-hydroxy carbofuran, 3-hydroxy-7-phenol and 3-keto-7-phenol, the Meeting considered that the residue definition for dietary risk assessment should be carbosulfan plus 10×(sum of carbofuran, 3-hydroxy carbofuran, 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan for long-term dietary intake and carbosulfan plus 20×(sum of carbofuran, 3-hydroxy carbofuran, 3-hydroxy-7-phenol and 3-keto-7-phenol) expressed as carbosulfan for acute dietary exposure.

Animal commodities

Carbosulfan is rapidly metabolized and excreted in animals, and if detected, found only at very low levels (<2 percent TRR). The predominant metabolites present at concentrations above 10 percent TRR and 0.01 mg eq/kg are conjugated 3-hydroxy carbofuran (10–37 percent TRR in poultry muscle, milk, kidney and liver), dibutylamine (22–37 percent TRR in poultry muscle and liver), 3-keto-7-phenol (30 percent TRR in milk), 3-hydroxy-7-phenol (13–21 percent TRR in kidney, liver and milk) and aminobutanols (12–30 percent TRR in kidney and milk).

In the storage stability studies, the Meeting noted that carbosulfan residues were not stable in frozen samples of cows milk, muscle or liver.

In the lactating goat metabolism study, samples were stored at ≈ -20° C for up to 6 months before analysis and in both the lactating cow feeding studies, samples were stored for more than 3 months. The storage intervals for poultry commodities were not reported.

The Meeting agreed that the results of the metabolism and feeding studies could not be used to estimate residue definitions for animal commodities.

Conclusion

The Meeting recommended the following residue definitions:

Definition of the residue for plant commodities (for compliance with the MRL): *sum of carbosulfan and carbofuran expressed as carbosulfan*.

Definition of the residue for plant commodities (for estimation of dietary intake): *carbosulfan plus 10× (sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan* for long-term dietary intake.

- Carbosulfan plus 20× (sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan for acute dietary exposure.

Results of supervised residue trials on crops

The Meeting evaluated supervised trials on the use of carbosulfan on mandarins, oranges, mango, eggplant, asparagus, soya bean, rice, maize, sorghum, sugar cane and cotton seed. Product labels were provided from Brazil, the People's Republic of China, the Republic of Indonesia and the United Mexican States and authorized GAP information from the Republic of Thailand was also submitted.

In the evaluation, residues and application rates have generally been rounded to two significant digits and where duplicate samples were analysed, mean values have been calculated from unrounded individual values and reported in brackets.

For MRL estimation, the residue definion is sum of carbosulfan and carbosulfan, expressed as carbosulfan. Carbofuran was adjusted to carbosulfan equivalents based on molecular weights (carbosulfan MW 380.55, carbofuran MW 221.3, resulting in a multiplication factor of 1.72 for carbofuran). Where residues were reported below the LOQ, the following conventions were adopted for summing residues (using an LOQ of 0.01 mg/kg as an example):

Convention adopted for summing of residues for MRL estimation:

Carbosulfan (mg/kg)	Carbofuran (mg/kg)	Sum of carbosulfan and carbofuran (expressed as carbosulfan)
<0.01	<0.01	<0.027
0.01	0.02	0.044

For dietary exposure assessment, in order to estimate STMR and HR values the relative toxicity of carbosulfan and carbofuran must be taken into account. In line with the approach taken by previous Meetings, the toxicologically significant residues were estimated by adding the carbosulfan and carbofuran residues after scaling the carbofuran residues to carbosulfan toxicity equivalents - based on the ratio of the carbosulfan to carbofuran maximum ADIs for STMR estimation and acute RfDs for HR estimation.

For long-term dietary exposure estimation, carbosulfan toxic equivalent residues (mg teq/kg) = carbosulfan + 10×(sum of carbofuran plus free and conjugated 3-hydroxy-carbofuran plus 3-hydroxy-7-phenol plus 3-keto-7-phenol).

For short-term dietary exposure estimation, carbosulfan toxic equivalent residues (mg teq/kg) = carbosulfan + 20×(sum of carbofuran plus free and conjugated 3-hydroxy-carbofuran plus 3-hydroxy-7-phenol plus 3-keto-7-phenol).

For acute dietary exposure estimation, the highest individual total residue values from the trials have been used to derive the highest residues.

Convention adopted for summing of residues (mg carbosulfan teq/kg) for dietary exposure assessment:

Carbosulfan (mg/kg)	Carbofuran (mg/kg)	3-hydroxy-carbofuran (free and conjugated) (mg/kg)	3-hydroxy-7-phenol (mg/kg)	3-keto-7-phenol (mg/kg)	Sum for long-term dietary exposure	Sum for short-term dietary exposure
<0.01	<0.01	<0.01	ND	ND	<0.21	<0.41
0.01	0.02	0.01	ND	ND	0.31	0.61
0.01	0.02	0.01	<0.01	<0.01	<0.51	<1.0
0.02	0.05	0.02	0.02	0.01	1.0	2.0

The Meeting agreed to withdraw all previous recommendations (sugarbeet; spices, fruits and berries; spices, roots and rhizomes; rice straw and fodder; dry; potato; rice; milks; sugar beet leaves and tops; and maize forage), meat (from mammals other than marine mammals); edible offal (mammalian; milks; eggs; poultry meat and poultry edible offal.

Citrus

The critical GAP for citrus in Indonesia is for an unspecified number of foliar applications of 60 g ai/hL when the pest threshold is reached. Retreatment intervals and the PHI are not specified.

The Meeting received trials from Spain on oranges, mandarins, and clementines, involving two foliar applications of 31–37.5 g ai/hL, applied between BBCH 70 and BBCH 75 (up to 40 percent or 50 percent fruit size).

As none of the trials match cGAP, the Meeting did not estimate a maximum residue limit for citrus.

The Meeting agreed to withdraw the previous recommendations for citrus pulp, dry, mandarin, and oranges, sweet, sour (subgroup).

Mango

The critical GAP in Thailand for mango is for three foliar applications of 60 g ai/hL (approximately 0.84-0.92 kg/ai/ha) with a 7-day retreatment interval and a 14-day PHI.

Three independent trials matched this GAP. A further three trials used two applications but otherwise matched the GAP. The Meeting decided that the initial application would not contribute significantly to residues based on the decline seen over 14 days, and that these trials therefore approximated GAP.

Carbosulfan residues in whole mangos were <0.01, 0.01, 0.015, 0.02, 0.03 and 0.03 mg/kg and carbofuran residues were <0.01 (2) and 0.01 (4) mg/kg.

For maximum residue level estimation, the combined residues of carbosulfan and carbofuran (expressed as carbosulfan) are <0.027, <0.027, 0.032, 0.037, 0.047 and 0.047 mg/kg (n=6).

For dietary exposure estimation, residues of 3-hydroxy carbofuran (free) residues in the field trials were <0.01 (2), 0.01 (2) and 0.035 (2) mg/kg (n=6). After adjustment using a factor of 1.5 to account for conjugated residues (based on the ratio of free:conjugated 3-hydroxy carbofuran seen in the citrus metabolism study), 3-hydroxy carbofuran (free and conjugated) residues were: <0.015 (2), 0.015 (2) and 0.0525 (2) mg/kg (n=6).

Although metabolites 3-hydroxy-7-phenol and 3-keto-7-phenol were not measured in the field trials, they were not detected in the metabolism study on foliar-treated orange. The Meeting agreed that no adjustment was needed to account for residues of these metabolites in mango.

For assessing long-term dietary exposure from mango, the carbosulfan toxic equivalent residues were: <0.26, 0.26, 0.26, 0.27, 0.66 and 0.66 mg teq/kg (n=6).

For assessing acute dietary exposure from mango, the carbosulfan toxic equivalent residues were: <0.51, 0.51, 0.52, 0.52, 1.3 and 1.3 mg teq/kg (n=6).

The Meeting estimated a maximum residue level of 0.1 mg/kg, an $STMR_{chronic}$ of 0.265 mg teq/kg, an $STMR_{acute}$ of 0.52 and a $HR_{(acute)}$ of 1.3 mg/kg for mango.

The IESTI for carbosulfan is 310 percent of the ARfD for toddlers and for toddlers, eight-20 months. No alternative GAP is available.

Eggplant

The critical GAP in Thailand for eggplant is three foliar applications of 60 g ai/hL at 7 day intervals with a PHI of 9 days.

In six independent trials which matched this GAP, carbosulfan residues in eggplant were: <0.01 (5) and 0.03 mg/kg and carbofuran residues were <0.01 (2), 0.02 (3) and 0.03 mg/kg.

For maximum residue level estimation, the combined residues of carbosulfan and carbofuran (expressed as carbosulfan) are <0.027, <0.027, 0.044, 0.044, 0.062 and 0.064 mg/kg (n=6).

For dietary exposure estimation, residues of 3-hydroxy carbofuran (free) residues in the field trials were <0.01 (4), 0.01 and 0.01 mg/kg (n=6). After adjustment using a factor of 1.5 to account for conjugated residues (based on the ratio of free:conjugated 3-hydroxy carbofuran seen in the citrus metabolism study), 3-hydroxy carbofuran (free and conjugated) residues were: <0.015 (4), 0.015 and 0.015 mg/kg (n=6).

Although metabolites 3-hydroxy-7-phenol and 3-keto-7-phenol were not measured in the field trials, they were not detected in the metabolism study on foliar-treated orange. The Meeting agreed that no adjustment was needed to account for residues of these metabolites in mango.

For assessing long-term dietary exposure from eggplant, the carbosulfan toxic equivalent residues were: <0.26, 0.26, 0.36, 0.36, 0.38 and 0.46 mg teq/kg (n=6).

For assessing acute dietary exposure from eggplant, the carbosulfan toxic equivalent residues were: <0.51, 0.51, 0.71, 0.71, 0.73, and 0.91 mg teq/kg (n=6).

The Meeting estimated a maximum residue level of 0.15 mg/kg, an $STMR_{chronic}$ of 0.36 mg teq/kg, an $STMR_{(acute)}$ of 0.71 mg/kg and a $HR_{(acute)}$ of 0.91 mg/kg for eggplant.

The IESTI for carbosulfan is 210 percent of the ARfD for children (1–6 yrs) and 120 percent for the general population. No alternative GAP is available.

Asparagus

Four independent trials were submitted from Thailand matching the critical GAP of four foliar applications of 50 g ai/hL at 7 day intervals with a PHI of 7 days.

Residues of carbosulfan in these trials matching cGAP were (n=4): <0.01 (4) mg/kg and residues of carbofuran matching cGAP were (n=4): <0.01 (2) and 0.05 (2) mg/kg.

For maximum residue level estimation, the combined residues of carbosulfan and carbofuran (expressed as carbosulfan) were (n=4): <0.027 (2) and 0.096 (2) mg/kg (n=4).

For dietary exposure estimation, metabolites 3-hydroxy carbofuran, 3-hydroxy-7-phenol and 3-keto-7-phenol were not measured in the field trials, and the metabolism studies did not have sufficient information to estimate residues of these metabolites in asparagus.

The Meeting estimated a maximum residue level of 0.3 mg/kg but could not estimate STMRs or a HR for asparagus.

Soya bean (dry)

The critical GAP in Brazil for soya bean is for a single foliar application of 0.19 kg ai/ha, with a 20-day PHI.

In eight independent trials matching this GAP, carbosulfan residues in soya bean seed were: <0.01 (7) and 0.0165 mg/kg (n=8) and carbofuran residues were <0.01 mg/kg (n=8).

For maximum residue level estimation, the combined residues of carbosulfan and carbofuran (expressed as carbosulfan) are <0.027 (7) and 0.034 mg/kg (n=8).

For dietary exposure estimation, residues of conjugated 3-hydroxy carbofuran, 3-hydroxy-7-phenol and 3-keto-7-phenol were not measured in the field trials, and the metabolism studies did not have sufficient information to estimate residues of these metabolites in soy bean.

The Meeting estimated a maximum residue level of 0.04 mg/kg but could not estimate STMRs for soy bean (dry).

Rice

The critical GAP in China for rice is for a single seed application of 8 g ai/kg seed applied pre-planting.

In four independent trials matching this GAP, carbosulfan residues in rice grain were <0.05 (4) mg/kg and carbofuran residues were <0.05 (4) mg/kg (n=4).

Due to the insufficient number of trials, the Meeting did not estimate a maximum residue level for rice.

Sorghum

The critical GAP submitted for sorghum in Mexico is for a single soil application of 0.3 kg ai/ha as a band spray to root zone, with a PHI of 30 days.

The Meeting received ten trials from the United States on sorghum, involving one pre-plant in-furrow treatment of carbofuran followed by three foliar treatments of carbosulfan, at the pre-boot, boot and milk growth stages.

As these trials did not match cGAP, the Meeting could not estimate a maximum residue level for sorghum.

Maize

The critical GAP in Brazil in maize is for two foliar applications of 0.11 kg ai/ha, applied 5 days apart, with a 20-day PHI.

In eight independent trials matching this GAP, carbosulfan residues in maize kernels were <0.01 (8) mg/kg and carbofuran residues were <0.01 (8) mg/kg.

For maximum residue level estimation, the combined residues of carbosulfan and carbofuran (expressed as carbosulfan) are <0.027 (8) mg/kg (n=8).

For dietary exposure estimation, residues of conjugated 3-hydroxy carbofuran, 3-hydroxy-7-phenol and 3-keto-7-phenol were not measured in the field trials, and the metabolism studies did not have sufficient information to estimate residues of these metabolites in maize.

The Meeting estimated a maximum residue level of 0.03 (*) mg/kg for maize to replace the existing recommendation but could not estimate STMRs for maize.

Sugar cane

The critical GAP in Mexico in sugar cane is for a single soil application of 0.3 kg ai/ha applied to the root zone with a 30 day PHI.

No trials matched this GAP.

The critical GAP in Brazil in sugar cane is for a single post-emergent soil application of 3.15 kg ai/ha applied at planting or sprouting.

In four independent trials matching this GAP, carbosulfan residues in sugar cane stalks were <0.01 (4) mg/kg and carbofuran residues were <0.01 (4) mg/kg.

Due to the insufficient number of trials, the Meeting did not estimate a maximum residue level for sugar cane.

Cotton seed

The critical GAP in Brazil for cotton seed is for three foliar applications of 1.1 kg ai/ha when pest thresholds are reached, with a PHI of 60 days.

In four independent trials matching this GAP, carbosulfan residues in cotton seed were: <0.01 (4) mg/kg and carbofuran residues were <0.01 (4) mg/kg.

For maximum residue level estimation, the combined residues of carbosulfan and carbofuran (expressed as carbosulfan) are <0.027 (4) mg/kg (n=4).

For dietary exposure estimation, residues of conjugated 3-hydroxy carbofuran, 3-hydroxy-7-phenol and 3-keto-7-phenol were not measured in the field trials, and the metabolism studies did not have sufficient information to estimate residues of these metabolites in maize.

The Meeting estimated a maximum residue level of 0.03 (*) mg/kg for cotton seed to replace the previous recommendation but could not estimate STMRs for cotton seed.

Fate of residues during processing

Residues in processed commodities

The Meeting received no information on the fate of carbosulfan residues following hydrolysis under conditions simulating commerical processing.

The Meeting considered processing studies for carbofuran on maize. For maize commodities, the Meeting could not derive processing factors for processed fractions because residues were all <LOQ.

Residues in animal commodities

Farm animal feeding studies

Lactating cow

The Meeting received two studies investigating the magnitude of carbosulfan and its degradation products in milk, kidney, liver, fat (peritoneal and subcutaneous) and muscle (adductor, cardial and pectorial) of lactating cows.

In these studies, animals were orally dosed daily with carbosulfan, mixtures of carbosulfan:dibutylamine, or with dibutylamine. Samples were stored for up to 3–5 months.

Because samples from both trials were stored for longer than the maximum period of demonstrated stability, the Meeting agreed that the feeding studies could not be used to estimate residues in animal commodities.

Laying hen

The Meeting received a study investigating the magnitude of carbosulfan and its degradation products in eggs, liver, fat and muscle of laying hens orally dosed with carbosulfan, mixtures of carbosulfan:dibutylamine, or with dibutylamine.

However, as no information was received on storage stability in poultry tissues or eggs, the Meeting agreed that feeding studies could not be used to estimate residues in poultry commodities.

Farm animal dietary burden

Maize grain is the only animal feed considered by the Meeting. Residues of carbosulfan and carbofuran in maize grain are both <0.01 mg/kg and the Meeting did not calculate livestock dietary burden.

Animal commodity maximum residue levels

Because no residue definitions could be established for animal commodities, the Meeting withdrew its previous recommendations for meat (from mammals other than marine mammals), edible offal (mammalian), eggs, poultry meat, poultry edible offal.

RECOMMENDATIONS

Definition of the residue for compliance with the MRL for plant commodities: *carbosulfan plus carbofuran (expressed as carbosulfan)*.

Definition of the residue for dietary risk assessment for plant commodities: *carbosulfan plus 10×(sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan* for long-term dietary exposure and *carbosulfan plus 20×(sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan* for acute dietary exposure.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *not established*.

DIETARY RISK ASSESSMENT

The Meeting considered how to best approach the dietary risk assessment of mixed residues of carbosulfan, carbofuran, 3-hydroxy carbofuran, *3-hydroxy-7-phenol and 3-keto-7-phenol* and decided that an appropriately conservative approach would be to sum them after first scaling the carbofuran, 3-hydroxy carbofuran, *3-hydroxy-7-phenol and 3-keto-7-phenol* residues to account for the differences in toxicity. The relevant factors for chronic and short-term intake were derived from the ratios of the carbosulfan and carbofuran maximum ADI and acute RfD values and are 10× and 20× respectively.

Dietary intake estimates for the combined adjusted residues were compared with the carbosulfan maximum ADI and ARfD.

Long-term dietary exposure

The ADI for carbosulfan is 0–0.01 mg/kg bw. The IEDIs for carbosulfan (including carbofuran) were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2022 JMPR Report.

The IEDIs ranged from 0 to 2 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of carbosulfan (including carbofuran) from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for carbosulfan is 0.02 mg/kg bw. The IESTIs for carbosulfan (including carbofuran) were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs varied from 0 to 310 percent of the ARfD for children and from 0 to 120 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of carbosulfan from uses considered by the present Meeting may present a public health concern for children (mango and eggplant) and for the general population (eggplant).

The Meeting considered that a possible refinement of the acute reference dose might be to assess the potency of the metabolites of carbofuran as cholinesterase inhibitors.

5.7 Clothianidin (238) (R)

RESIDUE AND ANALYTICAL ASPECTS

Clothianidin (ISO common name) is a broad-spectrum, neonicotinoid insecticide with registered uses on multiple crops. Clothianidin is a major metabolite of thiamethoxam (245). Thiamethoxam was scheduled at the Fifty-second Session of the CCPR for the evaluation of additional MRLs in 2022 and rescheduled to the 2023 JMPR: therefore, the Meeting also considered residues of clothianidin arising from the uses of thiamethoxam.

The current Meeting received information on analytical methods, storage stability, field trials and processing studies to support new MRLs in commodities of tree nuts, bulb vegetables, goji berry and stems and petioles. The Meeting also received monitoring data from the Republic of India for cumin seed from 2018 to 2023.

Clothianidin was evaluated for the first time by JMPR 2010, which established an ADI of 0—0.1 mg/kg bw and an ARfD of 0.6 mg/kg bw. Clothianidin underwent subsequent evaluations by the JMPR in 2011, 2012, 2014 and 2021.

The definition of the residue for compliance with MRLs and for dietary risk assessment for animal and plant commodities is clothianidin. The residue is not fat-soluble.

Methods of residue analysis

The Meeting received new recovery data for the use of Method AG-765 (reviewed by the 2010 JMPR) and validation data for method R20013B, used for goji berry, and the method used for cumin seeds. Method AG-765 and R20013B were demonstrated to have adequate performance for recovery of clothianidin, with an LOQ of 0.01 mg/kg. The method for cumin seeds was validated with an LOQ of 0.1 mg/kg for clothianidin.

Storage stability

The 2010 JMPR had determined that residues of clothianidin are stable for 1-2 years under frozen (-18°C) conditions for a large range of commodities, including for 2 years in high-water and high-oil commodities considered by the current Meeting. New storage stability data were submitted to the Meeting for fresh and dried goji berries. The 2023 JMPR concluded that clothianidin is stable in fresh and dried goji berries for at least 13 months. The stability of residues in crops under consideration by the present Meeting is considered to be adequately demonstrated for the periods that field trials samples had been stored prior to analysis.

Results of supervised residue trials on crops

The Meeting received data from supervised residue trials and GAP information on bulb onions, goji berry, celery and almonds. Monitoring data were also provided to the Meeting for cumin seeds.

Bulb onion

The critical thiamethoxam GAP for bulb onions is from the United States and is a seed treatment consisting of one application of 0.2 mg ai/seed.
Residues of clothianidin in independent trials provided to the current Meeting approximating the critical GAP were (n=7): <0.01 (7) mg/kg.
The Meeting estimated a maximum residue level of 0.01* mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for bulb onion.

Goji berry

Goji berries are in the Codex crop group of fruiting vegetables, other than cucurbits. The 2010 JMPR recommended a maximum residue level of 0.05 mg/kg for fruiting vegetables, other than cucurbits, for a critical GAP for thiamethoxam of two applications of 0.1 kg ai/ha, a RTI of 7 days and a PHI of 3 days.

The critical GAP for thiamethoxam from China for goji berry is different from the GAP considered by the 2010 JMPR for fruiting vegetables other that cucurbits and consists of one application of 0.01 kg ai/hL with a PHI of 5 days.
Residues of clothianidin in independent trials provided to the current Meeting approximating the critical GAP were (n=5): <0.01 (3), 0.019, 0.032 mg/kg. The highest single analytical result was 0.034 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.034 mg/kg for goji berry.

The Meeting withdrew its previous recommendation of a maximum residue level of 0.05 mg/kg for fruiting vegetables other that cucurbits and recommended a new maximum residue level of 0.05 mg/kg, an STMR of 0.02 mg/kg and a HR of 0.03 mg/kg for fruiting vegetables other than cucurbits except goji berry.

Stems and petioles

Celery is in the Codex subgroup of stems and petioles. The 2010 JMPR estimated a maximum residue level of 0.04 mg/kg for celery, using the NAFTA calculator and based on the same critical GAP for thiamethoxam for stems and petioles considered by the current Meeting. The critical GAP for the United States consists of two applications of 96.25 g ai/ha with a RTI of 7 days and a PHI of 7 days.

Residues of clothianidin in celery in independent trials provided to the current Meeting approximating the critical GAP were (n=4): <0.01 (2), 0.01 and 0.02 mg/kg.
The Meeting recommendation of a maximum residue level of 0.04 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.02 mg/kg for the subgroup stems and petioles.
The Meeting withdrew its previous recommendation of a maximum residue level of 0.04 mg/kg for celery.

Tree nuts

The critical thiamethoxam GAP for tree nuts is from the United States and consists of two applications of 70 g ai/ha with a RTI of 7 days and a PHI of 14 days.

Residues of clothianidin in pecan in independent trials from the 2010 JMPR approximating the critical GAP were (n=5): <0.01 (5) mg/kg.

Residues of clothianidin in almonds in independent trials provided to the current Meeting approximating the critical GAP were (n=5): <0.01(5) mg/kg.

Based on the data for pecan and almond the Meeting estimated a maximum residue level, STMR and HR of 0.01* mg/kg for tree nuts. The Meeting decided to withdraw the maximum residue level for pecan of 0.01* mg/kg and to recommend a maximum residue level of 0.01* mg/kg for the group of tree nuts.

Cumin seeds

No GAP information or residue trials for the use of thiamethoxam or clothianidin on cumin seed was provided to the Meeting. The Meeting received monitoring data from India and of the 1089 samples analysed, 328 samples contained quantified residues. The residues of clothianidin were:
0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.11, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.14, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.18, 0.18, 0.18, 0.18, 0.18, 0.18, 0.18, 0.18, 0.19, 0.19, 0.19, 0.19, 0.19, 0.19, 0.19, 0.19, 0.20, 0.20, 0.20, 0.20, 0.20, 0.20, 0.20, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.23, 0.23, 0.23, 0.23, 0.23, 0.23, 0.24, 0.24, 0.24, 0.24, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.26, 0.26, 0.26, 0.26, 0.26, 0.26, 0.26, 0.26, 0.26, 0.26, 0.27, 0.27, 0.27, 0.27, 0.27, 0.27, 0.27, 0.27, 0.28, 0.28, 0.28, 0.28, 0.28, 0.28, 0.29, 0.29, 0.29, 0.29, 0.29, 0.29, 0.29, 0.30, 0.30, 0.30, 0.30, 0.30, 0.30, 0.30, 0.30, 0.31, 0.31, 0.31, 0.31, 0.31, 0.32, 0.32, 0.32, 0.33, 0.33, 0.33, 0.34, 0.34, 0.34, 0.34, 0.35, 0.35, 0.35, 0.35, 0.36, 0.36, 0.36, 0.36, 0.37, 0.37, 0.37, 0.38, 0.38, 0.38, 0.38, 0.38, 0.39, 0.40, 0.40, 0.40, 0.40, 0.41, 0.41, 0.41, 0.41, 0.42, 0.42, 0.42, 0.42, 0.43, 0.43, 0.43, 0.43, 0.43, 0.44, 0.44, 0.44, 0.44, 0.44, 0.46, 0.46, 0.46, 0.47, 0.47, 0.47, 0.48, 0.48, 0.48, 0.48, 0.48, 0.49, 0.50, 0.52, 0.52, 0.52, 0.52, 0.52, 0.53, 0.53, 0.55, 0.56, 0.57, 0.58, 0.58, 0.58, 0.58, 0.59, 0.61, 0.61, 0.62, 0.63, 0.63, 0.63, 0.63, 0.64, 0.64, 0.66, 0.66, 0.67, 0.69, 0.74, 0.78, 0.78, 0.80, 0.81, 0.89, 0.89, 0.90, 0.92, 0.96, 0.97, 0.98, 1.00, 1.00, 1.06, 1.07, 1.09, 1.17, 1.51 and 5.57 mg/kg.
According to the current procedure (2015 JMPR) sufficient data of detected residues are available to estimate a maximum residue level. The upper 95 percent one tailed confidence limit of the 95th percentile of the detected residues is 0.97 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg and a median residue of 0.25 mg/kg.

Animal feeds

Almond hulls

The critical thiamethoxam GAP for tree nuts is from the United States and consists of two applications of 70 g ai/ha with a RTI of 7 days and a PHI of 14 days.

Residues of clothianidin in independent trials provided to the current Meeting approximating the critical GAP were (n=5): <0.01, 0.01, 0.02, 2 x 0.04 mg/kg on an as received basis.

The Meeting estimated a maximum residue level of 0.1 mg/kg (on a dry weight basis using a DM content of 90 percent), a median residue of 0.02 mg/kg and highest residue of 0.04 mg/kg for almond hulls.

Fate of residues during processing

The current Meeting considered data on the nature of the residue for clothianidin under simulated processing conditions. Clothianidin is stable under conditions simulating pasteurization, baking/boiling/brewing and sterilization.
The Meeting received data showing the effect of drying on the magnitude of the residue in goji berry. Residues of clothianidin in dried goji berry from independent trials approximating the GAP were:

Sun dried goji berries(n=5): 0.01, 0.011, 0.043, 0.0695 and 0.0845 mg/kg.

Hot air-dried goji berries (n=5):0.0105, 0.013, 0.058, 0.1 and 0.18 mg/kg.

The Meeting noted that residues in sun dried and hot air-dried goji berries were similar and estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.051 mg/kg and a HR of 0.18 mg/kg for dried goji berry using the combined dataset.

Processing factors for dried goji berry were estimated by the Meeting and are summarized in table 1. The Meeting noted that the individual Pf for sun dried and hot air-dried goji berries were similar and decided to estimate a Pf on the basis of all the data.

Processing factors and residue estimates for clothianidin in goji berry

		Processing Factors	
Raw commodity	Processed commodity	Individual levels	Best estimate (combined dataset)
Goji berry	Sun dried goji berry	4.55, 5.23	4.9
	Hot air dried goji berry	3.85, 6.3	

Residues in animal commodities

The Meeting added the residue levels for almond hulls to the dietary burden calculation used by the 2021 JMPR Meeting. Dietary burden calculations are provided in Annex 6. The dietary burden estimates remain unchanged from the JMPR 2021 and the Meeting confirmed the previous recommendations of maximum residue levels in animal products.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for International Estimated Daily Intakes (IEDI) and International Estimate of Short-Term Intakes (IESTI) assessments.

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

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for clothianidin is 0–0.1 mg/kg bw. The IEDIs for clothianidin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 0 to 2 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of clothianidin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for clothianidin is 0.6 mg/kg bw. The IESTIs for clothianidin were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs were < 1 percent of the ARfD for children and for the general population. The Meeting concluded that acute dietary exposure to residues of clothianidin from uses considered by the present Meeting is unlikely to present a public health concern.

5.8 Cyantraniliprole (263) (R)

TOXICOLOGY

Cyantraniliprole is the ISO-approved common name for 3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide (IUPAC), with the Chemical Abstracts Service number 736994-63-1. It is a ryanoid insecticide that upregulates ryanodine receptors in the endoplasmic/sarcoplasmic reticulum membrane, increasing calcium-induced calcium release, depleting calcium stores and thus leading to muscular paralysis and ultimately death.

Cyantraniliprole was previously evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2013, when an ADI of 0–0.03 mg/kg body weight (bw) per day was established based on adverse liver effects in dogs. An ARfD was not considered necessary. At the time of the previous evaluation some studies were available and evaluated for the metabolites IN-JSE76, IN-F6L99 and IN-N5M09. Additional studies performed with the metabolites IN-M2G89, IN-K5A78, IN-K5A79, IN-F6L99, IN-N5M09 and IN-JSE76 were reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR). There was no other new information on the toxicology of cyantraniliprole.

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with current test guidelines, unless otherwise specified. No additional information from a literature search was identified that complementedthe toxicological information submitted for the current assessment.

Biochemical aspects

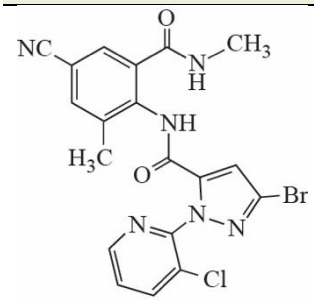
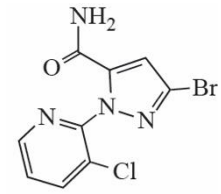
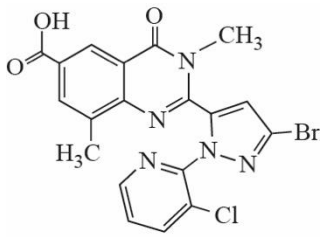
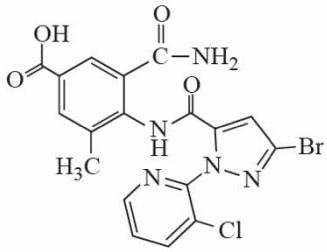
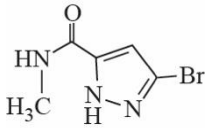
None of the metabolites were detected in urine, faeces or bile, nor were they part of the metabolic pathways proposed for rats.

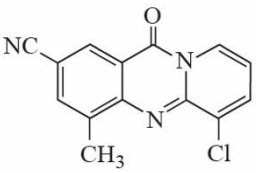
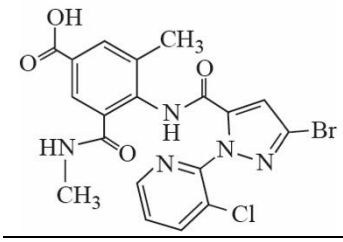
Toxicological data on metabolites and/or degradates

A toxicological evaluation was performed for the metabolites shown in the table below, which shows an overall summary of the toxicological characterization of the metabolites requested for consideration in the residue definition.

Summary of the toxicological characterization of plant/livestock metabolites of cyantraniliprole

Compound, codes and structure	**Major rat metabolite** (>10% AD)	**Genotoxicity assessment** (data, QSAR, read-across)	**General toxicity**	**Toxicological reference values**
Cyantraniliprole	Parent	Not genotoxic (in vitro and in vivo data)	Full dataset	ADI: 0.03 mg/kg bw per day ARfD: not required

Compound, codes and structure	Major rat metabolite (>10% AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Toxicological reference values
				
IN-M2G89 3-Bromo-1-(3-chloropyridin-2-yl)-*1H*-pyrazole-5-carboxamide 	No	Not genotoxic (in vitro data)	Rat LD_{50}, oral: 175 mg/kg bw Rat 28-day repeat dose, oral: No NOAEL. Reduced body weight, body weight gain, damage to olfactory epithelium at the lowest dose tested, 12 mg/kg bw per day	ADI: 10 times more toxic than parent ARfD: 0.1 mg/kg bw per day
IN-K5A78 2-[3-Bromo-1-(3-chloropyridin-2-yl)-*1H*-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carboxylic acid 	No	Not genotoxic (in vitro data)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
IN-K5A79 4-({[3-Bromo-1-(3-chloropyridin-2-yl)-*1H*-pyrazol-5-yl] carbonyl} amino)-3-carbamoyl-5-methylbenzoic acid 	No	Not genotoxic (in vitro data)	Rat LD_{50}, oral: >5000 mg/kg bw Rat 28-day repeat dose, oral NOAEL: 1912 mg/kg bw per day (highest dose tested)	Parent ADI
IN-F6L99 3-Bromo-*N*-methyl-*1H*-pyrazole-5-carboxamide 	No	Not genotoxic (in vitro data)	Mouse LD_{50}, oral: >2000 mg/kg bw a	TTC Cramer class III value: 1.5 µg/kg bw per day

Compound, codes and structure	Major rat metabolite (>10% AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Toxicological reference values
IN-N5M09 6-chloro-4-methyl-11-oxo-11Hpyrido[2,1-b]quinazoline-2-carbonitrile 	No	Not genotoxic (in vitro data)	Mouse LD_{50}, oral: >5000 mg/kg bw [a]	TTC Cramer class III value: 1.5 µg/kg bw per day
IN-JSE76 4-[[[3-Bromo-1-(3-chloro-2-pyridinyl)-*1H*-pyrazol-5-yl]carbonyl]amino]-3-methyl-5-[(methylamino)-carbonyl]benzoic acid 	No	Not genotoxic (in vitro data)	Rat LD_{50}, oral: >5000 mg/kg bw a Rat 28-day repeat-dose, oral NOAEL: 1454 mg/kg bw per day (highest dose tested)[a]	Parent ADI

[a] Previously evaluated by JMPR 2013 (see resulting monograph from this meeting), but included here for completeness

The Meeting concluded that IN-M2G89 is toxicologically relevant and estimated to be 10-fold more potent than the parent based on the 28-day rat studies. The Meeting concluded that IN-K5A78, IN-K5A79, IN-F6L99, IN-N5M09 and IN-JSE76 are not toxicologically relevant.

Toxicological evaluation

The Meeting re-affirmed the ADI of 0–0.03 mg/kg bw for cyantraniliprole, established by the JMPR 2013 Meeting. The current Meeting concluded that the parent ADI applies also to metabolites IN-K5A79 and IN-JSE76 and to 10 times IN-M2G98.

The Cramer class III value of 1.5 µg/kg bw per day applies to IN-K5A78, IN-F6L99 and IN-N5M09.

The current Meeting re-affirmed the conclusion of the 2013 Meeting that it was not necessary to establish an ARfD for cyantraniliprole. The current Meeting established an ARfD of 0.1 mg/kg bw for metabolite IN-M2G98 based on a LOAEL of 12 mg/kg bw per day in the 28-day oral study in rats, and applying a safety factor of 100. Given the lack of toxicity at 55 mg/kg bw in the acute toxicity study, an additional safety factor on the LOAEL was not judged necessary.

An addendum to the toxicological monograph was prepared.

Critical end-points for setting guidance values for exposure to cyantraniliprole (addendum)

Studies on toxicologically relevant metabolites

IN-M2G98	Acute oral LD_{50}: ca 175 mg/kg bw (rat) 28-day LOAEL: 12 mg/kg bw per day (rat) Not genotoxic (Ames, in vitro micronucleus, in vitro chromosomal aberration, in vitro cell mutation)
IN-K5A78	Not genotoxic (Ames, in vitro micronucleus, in vitro cell mutation)
IN-K5A79	Acute oral LD_{50}: >5000 mg/kg bw (rat) 28-day NOAEL: 1912 mg/kg bw per day (rat) Not genotoxic (Ames, in vitro micronucleus, in vitro chromosome aberration assay, in vitro cell mutation)
IN-F6L99	Acute oral LD_{50}: >2000 mg/kg bw (mouse)[a] Not genotoxic (Ames, in vitro micronucleus, in vitro chromosome aberration assay)
IN-N5M09	Acute oral LD_{50}: >5000 mg/kg bw (mouse)[a] Not genotoxic (Ames, in vitro micronucleus, in vitro chromosome aberration assay)
IN-JSE76	Acute oral LD_{50}: >5000 mg/kg (rat)[a] 28-day NOAEL: 1454 mg/kg bw per day (rat)[a] Not genotoxic (Amesa, in vitro micronucleus, in vitro chromosome aberration assaya, in vitro cell mutation[a])

[a] Previously evaluation by JMPR in 2013

Acceptable daily intake (ADI) applies to cyantraniliprole, IN-K5A79, IN-JSE76, and 10 × IN-M2G98

0–0.03 mg/kg bw

Acute reference dose (ARfD) applies to IN-M2G98

0.1 mg/kg bw

Acute reference dose (ARfD) unnecessary for cyantraniliprole, IN-K5A79 and IN-JSE76.

Summary

	Value	Study	Safety factor
ADI [a]	0–0.03 mg/kg bw	Ninety-day and one-year toxicity studies (dog)	100
ARfD for IN-M2G98	0.1 mg/kg bw	28-day study (rat)	100
ARfD for parent, *IN-K5A79 and IN-JSE76*	Unnecessary		

[a] Applies to metabolites IN-K5A79 and IN-JSE76 and 10 × IN-M2G98

RESIDUE AND ANALYTICAL ASPECTS

Cyantraniliprole is a diamide insecticide with a ryanodine receptor activation mode of action. It has root systemic activity with some translaminar movement and is effective against the larval stages of lepidopteran insects; and also on thrips, aphids, and some other chewing and sucking

insects. It was first evaluated for toxicology and residues by the JMPR in 2013 and an ADI of 0–0.03 mg/kg bw was established. An ARfD was considered to be unnecessary. Additional use patterns were evaluated by the 2015 and 2018 JMPR. The established residue definitions are:

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

Definition of the residue for dietary risk assessment for unprocessed plant commodities: *cyantraniliprole*.

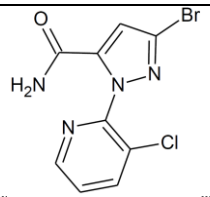
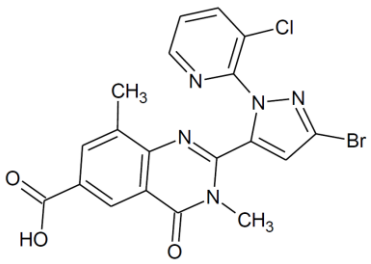
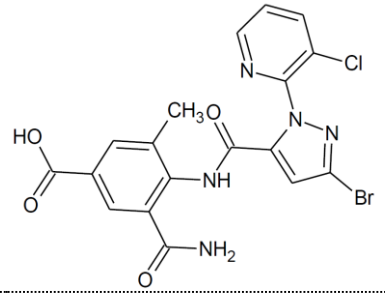
Definition of the residue for dietary risk assessment for processed plant commodities: *sum of **cyantraniliprole** and 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile **[IN-J9Z38]**, expressed as cyantraniliprole.*

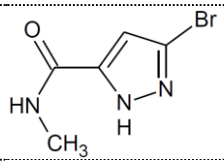
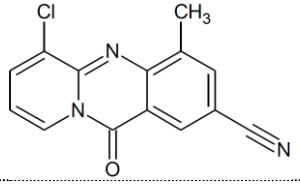
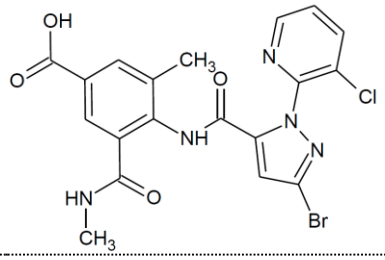
Definition of the residue for dietary risk assessment for animal commodities: *sum of **cyantraniliprole**, 2-[3-bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile **[IN-J9Z38]**, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile **[IN-MLA84]**, 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide **[IN-N7B69]** and 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide **[IN-MYX98]**, expressed as cyantraniliprole*.

The residue is not fat-soluble.

Cyantraniliprole was scheduled at the Fifty-Second Session (2021) of the CCPR for the evaluation of additional uses by the 2022 JMPR and rescheduled for the 2023 JMPR.

The following abbreviations are used for the major metabolites discussed below:

Chemical Name	Chemical Structure
IN-M2G98	
IN-K5A78	
IN-K5A79	

IN-F6L99	
IN-N5M09	
IN-JSE76	

Methods of analysis

The Meeting received method validation and concurrent recovery data for Method DuPont-15736, which was evaluated by the 2013 and 2015 JMPRs. Extraction is by aqueous acetonitrile and analysis by LC-MS/MS. This method was determined to be suitable for analysis of cyantraniliprole and its metabolites in a variety of plant matrices, with an LOQ of 0.01 mg/kg in all cases.

The Meeting also received data on the performance of Method DuPont-30771, which had not been previously reviewed by the Meeting. This method is similar to DuPont-15736, and validation and concurrent recoveries demonstrate that it is suitable for analysis of residues in plant matrices, with a validated LOQ of 0.01 mg/kg each for cyantraniliprole and its metabolites IN-J9Z38, IN-JCZ38, IN-K7H19, IN-MLA84, IN-MYX98, and IN-N7B69.

Two additional methods were submitted for the analysis of cyantraniliprole residues in tea leaves and tea infusion. The first of these methods is similar to DuPont-15736 but adds cleanup by C_{18}, SCX, and SAX columns. This method was validated to an LOQ of 0.01 mg/kg cyantraniliprole in both matrices; analysis of metabolites was not reported. The second method for tea involves acetonitrile extraction of water-soaked leaves and cleanup by partitioning with hexane and with ethyl acetate, coagulation, and column chromatography; analysis of cyantraniliprole, IN-J9Z38 and IN-NXX70 is by LC-MS/MS. The validated LOQ for this method is 0.04 mg/kg in tea leaves for the three analytes.

Stability of residues in stored samples

No specific storage stability studies were submitted to the current Meeting. The 2013 Meeting concluded that residues of cyantraniliprole and metabolites IN-F6L99, IN-J9Z38, IN-JCZ38, INK7H19, IN-MLA84, IN-MYX98, IN-N5M09 and IN-N7B69 are stable for at least 24 months in high-water, high-acid, high-starch, and high-protein commodities. Similarly, residues of cyantraniliprole and metabolites IN-F6L99, IN-J9Z38, IN-MLA84, IN-MYX98, and IN-N5M09 were stable for at least 24 months in high-oil commodities; however, reduced recoveries were observed at all storage intervals for IN-JCZ38, IN-K7H19, and IN-N7B69.

Residue definition

The WHO Core Assessment Group provided conclusions on the following cyantraniliprole metabolites: IN-M2G98, IN-K5A79, IN-JSE76, IN-K5A78, IN-F6L99, and IN-N5M09.

The Meeting re-examined the residue definitions for risk assessment for plants and animals in light of the new information on the above metabolites.

IN-M2G98: the Meeting included this metabolite in the parent ADI with a relative potency of 10 and established an ARfD of 0.1 mg/kg bw. This compound was observed only as a minor soil metabolite and not identified in any primary or rotational food or feed commodities in metabolism studies. The Meeting concluded that IN-M2G98 does not need to be considered further for risk assessment.

The Meeting concluded that the ADI for cyantraniliprole applies to the metabolites **IN-K5A79** and **IN-JSE76**. For both plant and animal commodities, these two metabolites were characterized as occurring only sporadically in the residue profiles and when they were observed, their occurrence was at less than 10 percent of the residues of concern for risk assessment. The Meeting concluded that IN-K5A79 and IN-JSE76 do not need to be included in the residue definitions for risk assessment for plants or animals.

Metabolites IN-K5A78, IN-F6L99, and IN-N5M09 had no indications for genotoxicity and may be assessed using the Cramer Class III threshold of 1.5 µg/kg per day. These metabolites were not assayed in field trials or feeding studies; therefore, the Meeting used ratios from metabolism studies to estimate residues.

IN-K5A78: this residue was observed in the goat milk and liver, rice grain, rotational beet foliage, and rotational animal feeds from wheat and soya bean. Residues in rotational crops were <4 percent of the parent compound in those rotational crops. Since the Meeting has already concluded that carryover of parent compound into rotational crops is not expected (2013 JMPR), the Meeting agreed that IN-K5A78 would also not occur in rotational crops. For animal and primary crop commodities, the Meeting agreed to use ratios of the concentration of IN-K5A78 from metabolism studies to the concentration of residues of concern for plants and animals to derive residue levels for the commodities with recommendations from previous and current Meetings:

Milk = 0.017

Goat Liver = 0.10 (extrapolate to mammalian edible offal)

Rice grain = 0.034 (extrapolate to maize).

IN-K5A78 was not observed in metabolism studies with lettuce, tomato, or cotton following foliar or soil treatments. The Meeting agreed that based on the available data, exposure to IN-K5A78 from foods other than milk, mammalian edible offal, rice, and maize would be insignificant.

IN-F6L99: residues of IN-F6L99 were observed in the high-temperature hydrolysis study under conditions similar to baking, brewing, and boiling, where it occurred at approximately 5 percent of cyantraniliprole + IN-J9Z38 (residue definition for processed plant commodities). In processing studies with apple and tomato, residues were <0.01 mg/kg or not detected in nearly all processed commodity samples. Where quantified residues were found, they were <2 percent of parent + IN-J9Z38. The Meeting agreed to use a factor of 0.05 to account for residues of IN-F6L99 in processed commodities that undergo baking, brewing, or boiling.

IN-N5M09: similar to IN-F6L99, this metabolite was observed in the high-temperature hydrolysis study under conditions similar to baking, brewing, and boiling, where it occurred at approximately 9 percent of cyantraniliprole + IN-J9Z38. Residues of IN-N5M09 were <0.01 mg/kg or not detected in all processed tomato and apple commodities, except apple sauce (maximum factor = 0.099); it was also observed in one sample of cooked spinach (factor = 0.009). The Meeting agreed to use a factor of 0.1 to account for residues of IN-N5M09 in cooked processed fruit commodities such as apple sauce and a factor of 0.01 for cooked vegetables.

Conclusion

The Meeting confirmed its previous residue definitions for cyantraniliprole:

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

Definition of residue for estimation of dietary intake for unprocessed plant commodities: *cyantraniliprole*.

Definition of residue for estimation of dietary intake for processed plant commodities: *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole*.

Definition of residue for estimation of dietary intake for animal commodities: *sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide [IN-MYX98], expressed a cyantraniliprole*.

The residue is not fat-soluble.

Note: metabolites IN-K5A78, IN-F6L99, and IN-N5M09 are assessed using Cramer Class III threshold of 1.5 µg/kg per day.

Residues in supervised trials on crops

The Meeting received supervised trial data for residues of cyantraniliprole in cane berries, grapes, olives, avocado, tomato, and tea. Data for peppers and potato were also submitted, but these, along with data on tomato, were reviewed by the 2013 Meeting; data for pulses were reviewed by the 2015 Meeting.

Residues in raw commodities reported as <LOQ or ND were assumed to be at the LOQ for calculation purposes.

Subgroup of cane berries

The critical GAP for cane berries is from Canada and consists of three applications, each at 150 g ai/ha on a 5-day retreatment interval, with a 1-day PHI.

In trials approximating the critical GAP, residues of cyantraniliprole in blackberries were (n=4): 0.64, 1.0, 1.4, and 1.7 mg/kg, and residues in raspberries were (n=5): 0.55, 0.65, 1.0, and 1.3, and 2.5 mg/kg.

As the residues are from similar populations (Mann-Whitney), the Meeting agreed to combine the data from blackberries and raspberries to make a recommendation for the Subgroup

of Cane berries. Residues in rank order were (n=9): 0.55, 0.64, 0.65, 1.0 (2), 1.3, 1.4, 1.7, and 2.5 mg/kg.

The Meeting estimated a maximum residue level of 4 mg/kg and an STMR of 1 mg/kg for cyantraniliprole in cane berries.

Grapes

A Codex MRL is established for residues of cyantraniliprole in wine grapes at 1 mg/kg.

The Meeting received labels from Japan, Chile, and Poland with use directions for grapes. Based on use parameters, the Meeting agreed that the label from Japan reflects the critical GAP: 3 applications of a 2500-fold dilution (4 g ai/hL) applied at 7000 L/ha with a 1-day PHI; no retreatment interval is listed.

No trials approximated the critical GAP. The next-most critical GAP is from Chile for use on table and wine grapes. This GAP consists of two applications of a 10 g ai/hL solution applied as a 1500-L/ha spray on a 21-day retreatment interval. Trials were conducted in Chile with three applications at the GAP spray concentration and rate, with the first application made at BBCH 65 (before fruits were present and 62-81 days before the second application) and with a 21-day retreatment interval between the second and third applications. The Meeting agreed that the first application would not contribute significantly to residues in grapes at harvest and that the trials from Chile were suitable for making residue recommendations.

In trials from Chile approximating the GAP, residues of cyantraniliprole in table grapes were (n=9): 0.39 (2), 0.47, 0.54, 0.56, 0.59, 0.71, 0.89, and 0.97 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and an STMR of 0.56 mg/kg for cyantraniliprole in table grapes and, noting that the registration covers both table and wine grapes, agreed to extrapolate the data for table grapes to wine grapes. The Meeting withdrew its previous recommendation.

Olives

The critical GAP for olives is from Malta and consists of three applications, each at 7.5 g ai/ha on a 7-day retreatment interval, with a 7-day PHI. The GAP specifies spraying only to one side of the tree row.

Field trials were conducted with application rate of 15 g ai/ha, with application to both sides of the tree. The Meeting agreed that this is equivalent to the 7.5 g ai/ha rate listed on the label since each side of the tree would have received one half of the 15 g ai/ha treatment. The Meeting noted, however, that at harvest, olives would be taken from both treated and untreated sides of the tree, and since olives are composited within a treated orchard, the Meeting concluded that the use pattern used in the field reflects a 2× application rate in terms of residues on a treated area basis.

In trials approximating the critical GAP but with application rates ranging from 1.87× to 2.13×, residues of cyantraniliprole were (n=9): 0.15, 0.27, 0.37, 0.53, 0.53, 0.66, 0.95, 0.97, and 1.2 mg/kg. After scaling to the critical GAP based on total application rate, residues were (n=9): 0.075, 0.14, 0.17, 0.26, 0.27, 0.35, 0.47, 0.48, and 0.59 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg for table olives and olives for oil production.

Residues in olive flesh from those same trials were (n=9): 0.28, 0.43, 0.48, 0.64, 0.64, 0.92, 1.5, 1.6, and 1.8 mg/kg. After scaling to the critical GAP based on total application rate, residues were (n=9): 0.14, 0.22, 0.22, 0.32, 0.33, 0.49, 0.73, 0.80, and 0.88 mg/kg.

The Meeting estimated an STMR of 0.33 mg/kg for cyantraniliprole in table olives and olives for oil production.

Avocado

The critical GAP for avocado is from Mexico and consists of two applications, each at 80 g ai/ha on a 14-day retreatment interval, with a 1-day PHI.

In trials approximating the critical GAP, residues of cyantraniliprole in whole avocado were (n=7): 0.048, 0.059, 0.088, 0.1, 0.15, 0.15, and 0.16 mg/kg.

Residues of cyantraniliprole in avocado pulp from those trials were (n=7): 0.01, 0.022, 0.022, 0.03, 0.033, 0.042, and 0.077 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.03 mg/kg for cyantraniliprole in avocado.

Tomato

A Codex MRL is established for residues of cyantraniliprole in tomato at 0.5 mg/kg, based on recommendations made by the 2013 Meeting. The current Meeting was asked to evaluate the results of residue trials in tomato conducted in glasshouses. The critical GAP is the same as that evaluated by the 2013 JMPR: 3 applications, each at 150 g ai/ha on a 5-day retreatment interval, with a 1-day PHI. Residue results used by the 2013 JMPR for tomato ranged from 0.04 to 0.26 mg/kg. The maximum residue level recommended by the 2013 JMPR was 0.5 mg/kg (STMR = 0.08 mg/kg) and was based on pooled data from tomatoes, sweet peppers and chilli peppers (values ranging from 0.03 to 0.42 mg/kg).

For data submitted to the current Meeting, residues of cyantraniliprole in tomatoes from glasshouse trials approximating the critical GAP were (n=4): 0.081, 0.11, 0.12, and 0.35 mg/kg.

The Meeting noted that the current STMR (0.08 mg/kg) is similar to the median residue from the new trials (0.115 mg/kg). Although the new trials seem to indicate residues from glasshouse-grown tomatoes may be systematically greater than those arising from field-grown tomatoes, the Meeting agreed that four trials are not sufficient to make a determination on that matter. Noting that the existing Codex MRL is sufficient to cover residues of cyantraniliprole in glasshouse-grown tomatoes and that the name of the crop group has changed since its previous recommendation, the Meeting agreed to estimate a maximum residue level of 0.5 mg/kg and STMR of 0.08 mg/kg for fruiting vegetables, other than cucurbits and to withdraw its previous maximum residue level recommendation for residues of cyantraniliprole in fruiting vegetables, other than cucurbits (excluding sweet corn and mushrooms).

Subgroup of dry beans and subgroup of dry peas

The labels and data submitted to the current Meeting are the same as those evaluated by the 2015 JMPR.

The critical GAP is from the United States for the US legume vegetable group, which includes the commodities in the Subgroup of dry beans and Subgroup of dry peas. The critical GAP consists of four foliar applications, each at 150 g ai/ha on a 5-day interval, with a PHI of 7 days.

In trials matching the critical GAP, residues of cyantraniliprole in beans, dry were (n=10): <0.01 (4), 0.015, 0.021, 0.048, 0.049, 0.088, and 0.22 mg/kg.

In independent trials matching the critical GAP, residues of cyantraniliprole in peas, dry were (n=3): 0.019, 0.086, and 0.51 mg/kg.

In trials matching the critical GAP, residues of cyantraniliprole in soya bean seed were (n=21): <0.01, 0.011, 0.012, 0.017, 0.022, 0.023, 0.027, 0.027, 0.031, 0.031, 0.033, 0.044, 0.056, 0.061, 0.083, 0.10, 0.12, 0.13, 0.15, 0.16, and 0.25 mg/kg.

The Meeting noted that three trials are insufficient to make a recommendation for peas, dry. However, since the median residues from beans, dry; peas, dry; and soya bean seed, dry are within a factor of five and it appears that the residue populations are similar, the Meeting agreed to combine the data for mutual support.

The combined data, in rank order were (n=28): <0.01 (5), 0.011, 0.012, 0.015, 0.017, 0.019, 0.021, 0.022, 0.023, 0.027, 0.027, 0.031, 0.031, 0.033, 0.044, 0.048, 0.049, 0.056, 0.061, 0.083, 0.086, 0.088, 0.1, 0.12, 0.13, 0.15, 0.16, 0.22, 0.25, and 0.51 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.032 mg/kg for the Subgroup of dry beans and the Subgroup of dry peas. The Meeting withdrew its previous recommendations for bean (dry) of 0.3 mg/kg and soya bean (dry) of 0.4 mg/kg.

Potato

The GAP for potato in the United States is seed treatment at 9.79 g ai/100 kg seed pieces followed by three foliar applications, each at 149 g ai/ha on a 5-day retreatment interval, with a PHI of 7 days. The label specifies that field loading from seed treatment must not exceed 197 g ai/ha and that the combined seed treatment and foliar applications must not exceed 448 g ai/ha.

Trials (reviewed by the 2013 Meeting) were provided with use patterns of either seed treatment (or equivalent in-furrow application) at 13.5 g ai/100 kg seed pieces plus a single foliar application of 150 g ai/ha or three foliar applications, each at 150 g ai/ha on a 5-day retreatment interval. Based on planting density, the seed treatments resulted in a field loading of 297 g ai/ha; therefore, both use patterns had a total application rate of ca. 450 g ai/ha; harvest occurred 7 DALA for both.

A comparison of residues from the two use patterns shows that the seed treatment + foliar application consistently results in higher residues than the foliar applications, and that the residues in tubers from the foliar application are most frequently <0.01 mg/kg, thus demonstrating that the seed treatment use is primarily responsible for the residues at harvest.

The seed treatment rates used in the study are exaggerated and, due to the confounding factor of the foliar applications, cannot be adjusted for proportionality; therefore, the Meeting agreed to confirm its previous recommendations for potato: maximum residue level of 0.05 mg/kg, STMR of 0.02 mg/kg, and highest residue for animal dietary burden calculations of 0.044 mg/kg.

Tea

The critical GAP for tea is from Japan and consists of a single foliar application of a 2000-fold dilution of the formulated product (resulting in a spray concentration of 5 g ai/hL) applied at a 4000 L/ha spray rate. The label PHI is 7 days.

In trials approximating the critical GAP, residues of cyantraniliprole in dried tea leaves were (n=10): 0.34, 0.44, 1.5, 2.1, 3.9, 4.2, 8.9, 9.4, 21, and 24 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 4.05 mg/kg for cyantraniliprole in tea, green, black (black, fermented and dried).

Residues in processed commodities

The Meeting received data from processing studies conducted in grapes, olives, and tea. For grapes and olives, analysis included the residues in the residue definition for risk assessment of plant processed commodities (cyantraniliprole and IN-J9Z38); the residue data for tea infusion included only cyantraniliprole. For processed commodities, residues of IN-J9Z38 reported as <LOQ were assumed to be at the LOQ for estimating total residues (cyantraniliprole + IN-J9Z38, expressed as cyantraniliprole). Residues of IN-J9Z38 were converted to cyantraniliprole equivalents using a molecular weight factor of 1.04 (473.717 g/mol ÷ 455.702 g/mol).

Summary of processing factors and residue estimates for cyantraniliprole

Crop	Commodity	Cyantraniliprole		Cyantraniliprole + IN-J9Z38	
		Processing factors [best estimate]	Maximum residue level(mg/kg)	Processing factors [best estimate]	STMR-P (mg/kg)
Grape	Berries	Maximum residue level = 2 mg/kg		STMR = 0.56 mg/kg	
	Must	0.86, 2.7, 2.8 [2.7]	--	0.88, 2.5, 2.6 [2.5]	1.4
	Wet pomace	1.6, 4.8, 6.7 [4.8]	--	1.6, 4.6, 6.3 [4.6]	2.6
	Dry pomace	1.6, 6.1, 8.8 [6.1]	15	1.5, 6.0, 8.8 [6.0]	3.4
	Alcoholic fermentation wine	0.63, 1.9, 2.0 [1.9]	--	0.66, 1.8, 1.9 [1.8]	1.1
	Malolactic fermentation wine	0.62, 1.8, 1.9 [1.8]	--	0.65, 1.7, 1.8 [1.7]	0.95
	Bottled wine	0.61, 1.7, 2.0 [1.7]	--	0.64, 1.6, 1.9 [1.6]	0.90
	Juice	0.81, 0.83, 1.6 [0.83]	--	0.82, 0.88, 1.6 [0.88]	0.49
	Raisins	0.80, 1.4, 1.6 [1.4]	3	0.82, 1.3, 19 [1.3]	0.73
Olive	Whole fruit	Maximum residue level = 1 mg/kg		STMR = 0.33 mg/kg	
	Processed olive	0.14, 0.38, 0.40 [0.38]	--	0.20, 0.57, 0.61 [0.57]	0.19
	Raw oil	0.55, 1.2, 1.7 [1.2]	--	0.60, 1.2, 1.7 [1.2]	0.40
	Refined oil	0.19, 0.65, 1.3 [0.65]	--	0.37, 0.78, 1.2 [0.78]	0.26
Tea	Dried leaves	Maximum residue level = 50 mg/kg		STMR = 4.05 mg/kg	
	Infusion	Not applicable		0.0080, 0.0085, 0.0086, 0.0087, 0.0088, 0.010, 0.010, 0.011, 0.011, 0.011, 0.012, 0.012, 0.012, 0.013, 0.013, 0.013, 0.014, 0.014, 0.014, 0.014, <0.015, 0.015, 0.015, 0.015, 0.015, 0.015, 0.016, 0.016, 0.016, 0.017, 0.017, 0.017 [0.0135]	0.055

Residues of cyantraniliprole or total cyantraniliprole (cyantraniliprole + IN-J9Z38) concentrated in grape must, wet pomace, dry pomace, wine, and raisins. The Meeting estimated maximum residue levels for cyantraniliprole in grape pomace, dry of 15 mg/kg and grape, dried (= Currants, Raisins, and Sultanas) of 3 mg/kg.

Residues do not concentrate in processed commodities from processed products derived from olive or tea. STMR-Ps for processed commodities of grapes, olive, and tea are provided in the table above.

Residues in animal commodities

The current Meeting made recommendations for grape pomace; beans, dry; and peas, dry; all of which are animal feeds. Inclusion of the new recommendations for these feed commodities in the dietary burden calculations resulted in changes to the previous estimates (2015 JMPR) shown below:

Animal	Maximum dietary burden (ppm)	% change from 2015 JMPR	Mean dietary burden (ppm)	% change from 2015 JMPR
Beef cattle	46.8	0	15.94	0
Dairy cattle	35.95	0	13.58	0
Poultry [a)]	5.14	9	1.77	14

a) From layer poultry, which was higher than broiler poultry

The Meeting confirmed its previous maximum residue level recommendations for mammalian commodities: meat (from mammals other than marine mammals) = 0.2 mg/kg (STMR = 0.041 mg/kg), edible offal (mammalian) = 1.5 mg/kg (STMR = 0.38 mg/kg), mammalian fat = 0.5 mg/kg (STMR = 0.1 mg/kg), and milks = 0.6 mg/kg (STMR = 0.21 mg/kg).

For poultry, the Meeting recalculated the anticipated residues for eggs and tissues.

	Feed level (ppm) for egg residues	**Residues (mg/kg) in egg**	**Feed level (ppm) for tissue residues**	**Residues (mg/kg)**		
				Muscle	**Liver**	**Fat**
MRL broiler or layer poultry						
Feeding study	3 10	0.151 0.32	3 10	0.009 0.028	0.098 0.225	0.014 0.084
Dietary burden and high residue	5.14	0.203	5.14	0.015	0.137	0.035
STMR broiler or layer poultry (residues = sum of cyantraniliprole IN-N7B69, IN-J9Z38, IN-MLA84, and IN-MYX98, expressed as cyantraniliprole)						
Feeding study	0 3	0 0.082	0 3	0 0.0075	0 0.0617	0 0.0159
Dietary burden and residue estimate	1.77	0.048	1.77	0.004	0.036	0.009

The Meeting confirmed its previous recommendations for poultry meat (0.02 mg/kg), poultry offal (0.15 mg/kg), and poultry fat (0.04 mg/kg). The Meeting estimated a new maximum residue level of 0.3 mg/kg for eggs to replace its previous recommendation (0.15 mg/kg).

The Meeting estimated STMRs, based on the sum of cyantraniliprole IN-N7B69, IN-J9Z38, IN-MLA84, and IN-MYX98, expressed as cyantraniliprole, for poultry commodities as follows: meat = 0.004 mg/kg, offal = 0.036 mg/kg, fat = 0.009 mg/kg, and eggs = 0.048 mg/kg.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDIs assessments.

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

Definition of residue for estimation of dietary intake for unprocessed plant commodities: *cyantraniliprole*.

Definition of residue for estimation of dietary intake for processed plant commodities: *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole*.

Definition of residue for estimation of dietary intake for animal commodities: *sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide [IN-MYX98], expressed a cyantraniliprole*.

The residue is not fat-soluble.

Note: metabolites IN-K5A78, IN-F6L99, and IN-N5M09 are assessed using Cramer Class III threshold of 1.5 µg/kg per day.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for cyantraniliprole is 0–0.03 mg/kg bw. The IEDIs for cyantraniliprole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 4 to 40 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of cyantraniliprole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2013 JMPR decided that an ARfD for cyantraniliprole was unnecessary. The current Meeting therefore concluded that the acute dietary exposure to residues of cyantraniliprole from the uses considered is unlikely to present a public health concern.

TTC Assessments (Cramer Class III)

The Meeting used the factors described in the residue definition section to make residue estimates for TTC assessments of IN-K5A78, IN-F6L99, and IN-N5M09 using the Cramer Class III threshold of 1.5 µg/kg bw per day.

IN-K5A78

The Meeting estimated STMRs for IN-K5A78 in in rice (husked and polished) of 0.00034 mg/kg (0.01 mg/kg × 0.034), and in maize of 0 mg/kg (STMR for maize is 0), milk of 0.0036

mg/kg (0.21 mg/kg × 0.017), and in mammalian edible offal of 0.038 mg/kg (0.38 mg/kg × 0.1). The maximum exposure estimate across the diet clusters was 0.035 µg/kg bw per day. The Meeting concluded that exposure to IN-K5A78 is unlikely to pose a public health concern.

IN-F6L99 and **IN-N5M09**

The Meeting noted that these metabolites appear to be specific to conditions reflecting baking, brewing, and boiling; however, the food forms available for the IEDI inputs do not allow restriction to those conditions. The Meeting further noted that the maximum IEDI for cyantraniliprole is 11.75 µg/kg bw per day and that the maximum factor to account for these two metabolites is 0.1. Applying that factor to all foods (unprocessed and processed) in the cyantraniliprole IEDI gives an estimate of 1.2 µg/kg bw per day for each of IN-F6L99 and IN-N5M09. The Meeting concluded that exposure to IN-F6L99 and IN-N5M09 is unlikely to pose a public health concern.

5.9 Cyflumetofen (273) (R)

RESIDUE AND ANALYTICAL ASPECTS

Cyflumetofen is a bridged diphenyl acaricide (miticide) and interferes with energy production (inhibition of complex II in mitochondria) on contact with spider mites. It was evaluated by the JMPR in 2014 for toxicology and residues.

Cyflumetofen is a racemic mixture. An ADI of 0–0.1 mg/kg bw was established and an ARfD was considered unnecessary by the 2014 JMPR. The 2014 JMPR Meeting recommended the following residue definitions for plant and animal commodities:

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

Definition of the residue for plant commodities (for estimation of dietary intake): *sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen.*

Definition of the residue for animal commodities (for compliance with the MRL and estimation of dietary intake): *sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen.*

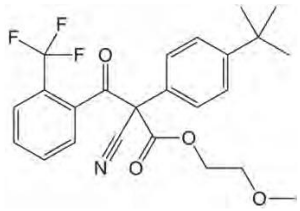
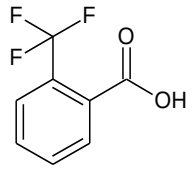
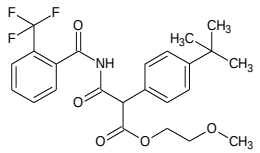
Residue is not fat-soluble.

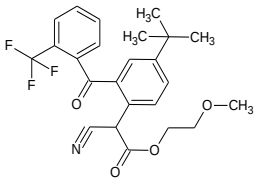
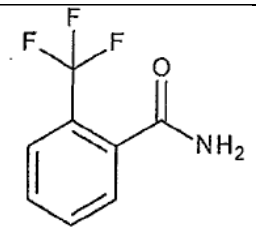
Cyflumetofen was scheduled at the Fifty-fourth Session of the CCPR for evaluation of additional uses by the 2023 JMPR. The Meeting received additional information from the manufacturer on method of residue analysis, use patterns, supervised residue trials (stone fruits, cucurbits, fruiting vegetables other than cucurbits, coffee beans, tea and hops) and processing studies on plums, peaches, coffee beans, tea and hops.

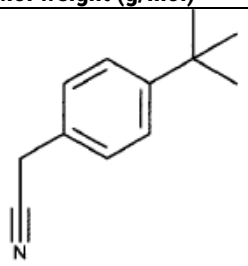
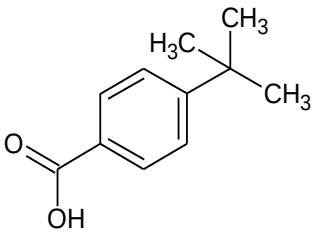
The Meeting noted that coffee beans, tea and hops were not covered by the metabolism studies used to establish the current residue definition and decided to revisit the residue definition.

Chemical names

Compounds referred to in this appraisal

Name	Structural formula Molecular formula Mol weight (g/mol)	Metabolism [JMPR 2014]	Residue trials processing studies
Cyflumetofen 2-methoxyethyl 2-(4-tert-butylphenyl-2-cyano-3-oxo-3-[2-(trifluoromethyl) phenyl]propanoate CAS no 400882-07-7 JMPR 2014 included in ResDef ENF ResDef DRA	 C24H24F3NO4 MW 447.45	Found in, mandarin, apple, eggplant, mandarin leaf goat	Peach/nectarine 0.016-0.59 mg/kg Peach/nectarine wet pomace 0.31-0.80 mg/kg Peach/nectarine juice 0.12-0.28 mg/kg Peach/nectarine dried 0.97-3.5 mg/kg Peach/nectarine jam 0.018-0.031 mg/kg Apricot <0.01-0.35 mg/kg Tomato - field 0.014-0.093 mg/kg Tomato – glasshouse 0.013-0.27 mg/kg dried hops 1.1-24 mg/kg hops beer <0.01 mg/kg hops extract 12-55 mg/kg
Metabolite B-1 2-(trifluoromethyl) benzoic acid CAS no 433-97-6 JMPR 2014 included in ResDef DRA	 C8H5F3O2 MW 190.12	Found in mandarin, apple, eggplant, mandarin leaf apple leaf rat, goat, soil	Peach/Nectarine <0.01-0.019 mg/kg Peach/nectarine wet pomace <0.01-0.025 mg/kg Peach/nectarine juice 0.011-0.019 mg/kg Peach/nectarine dried 0.12-0.46 mg/kg Peach/nectarine jam <0.01-0.014 mg/kg Apricot <0.01 mg/kg Tomato -field <0.01 mg/kg Tomato – glasshouse <0.01-0.019 mg/kg dried hops 0.020-1.1 mg/kg hops beer <0.01-0.018 mg/kg hops extract 7.8-11 mg/kg
Metabolite AB-6 2-methoxyethyl 2-(RS-4-tert-butylphenyl-3-oxo-3-({[2-(trifluoromethyl) phenyl]carbonyl} amino)propanoate	 C24H26F3NO5	Found in mandarin, apple eggplant mandarin leaf apple leaf	Peach/Nectarine <0.01-0.030 mg/kg Peach/Nect wet pomace 0.022-0.061 mg/kg Peach/Nectarine juice <0.01-0.01 mg/kg Peach/nectarine dried 0.068-0.17 mg/kg

Name	Structural formula Molecular formula Mol weight (g/mol)	Metabolism [JMPR 2014]	Residue trials processing studies
CAS no 620170-82-3	MW 465.45		Peach/nectarine jam <0.01-0.018 mg/kg Apricot <0.01-0.014 mg/kg Tomato -field <0.01 mg/kg Tomato glasshouse <0.01 mg/kg dried hops <0.1-0.46 mg/kg Hops beer <0.01 mg/kg Hops extract 0.26-1.7 mg/kg
Metabolite AB-7 2-methoxyethyl 2-(RS-4-tert-butylphenyl-3-oxo-3-({[2-(trifluoromethyl) phenyl]carbonyl} phenyl(cyano)acetate CAS no: not available	 $C_{24}H_{24}F_3NO_4$ MW 447.45	Found in mandarin, apple eggplant mandarin leaf apple leaf	Peach/Nectarine <0.01-0.037 mg/kg Peach/nect wet pomace 0.028-0.10 mg/kg Peach/nectarine juice <0.01 mg/kg Peach/nectarine dried 0.064-0.16 mg/kg Peach/nectarine jam <0.01 mg/kg Apricot <0.01 mg/kg Tomato field <0.01 mg/kg Tomato glasshouse <0.01 mg/kg Dried hops <0.1-0.17 mg/kg Hops beer <0.01 mg/kg Hops extract <0.1-0.65 mg/kg
Metabolite B-3 2-(trifluoromethyl) benzamide CAS no 360-64-5 JMPR 2014 tox monograph applicant position not genotoxic in vivo ADI = 0.01 mg/kg report conclusion not identified as food residue	 $C^8H^6F^3NO$ MW 189.13	Found in soil	Peach/Nectarine <0.001-0.009 mg/kg Peach/Nect wet pomace 0.003-0.012 mg/kg Peach/Nect juice 0.002-0.005 mg/kg Peach/nectarine dried 0.018-0.055 mg/kg Peach/nectarine jam 0.003-0.006 mg/kg Apricot <0.001-0.0026 mg/kg Tomato — field <0.001-0.0011 mg/kg Tomato glasshouse <0.001 mg/kg 0.0078-0.010 mg/kg dried hops <0.01 mg/kg hops beer not analysed hops extract not analyses

Name	Structural formula Molecular formula Mol weight (g/mol)	Metabolism [JMPR 2014]	Residue trials processing studies
Metabolite A-2 4-tert-butylphenyl-acetonitrile SYN M9210I001 CAS no 3288-99-1	 $C^{12}H1^{5}N$ MW 173.26	Found in goat, soil	Peach/Nectarine <0.01 mg/kg Peach/nect wet pomace <0.01-0.012 mg/kg Peach/nect juice <0.01 mg/kg Peach/nectarine dried <0.01-0.036 mg/kg Peach/nectarine jam <0.01 mg/kg Apricot not analysed Tomato -field not analysed Tomato – glasshouse not analysed dried hops not analysed hops beer not analysed hops extract not analysed
Metabolite A-12 4-tert-butylbenzoic acid SYN M9210I002	 MW 178.23	Found in mandarin leaf, goat, soil	not analysed

Methods of analysis

The Meeting received information on HPLC-UV, HPLC-MS, LC-MS/MS and GC-MS/MS methods for the determination of cyflumetofen and its metabolites B-1, AB-6, AB-7, B-3 and A-2 in stone fruits, fruiting vegetables, coffee beans, tea, hops and their processed commodities. Residues were extracted with acidified acetone (tea), acetone/water (90:10, v/v, tea), acetonitrile (coffee beans), acidified acetonitrile (coffee beans), water/acetonitrile (70:30, v/v, coffee beans), acetonitrile/water (90:10, v/v, stone fruits, fruiting vegetables, tea) or acetonitrile/water (75:25, v/v, stone fruits, fruiting vegetables, hops). Extracts from Japanese trials (stone fruits, fruiting vegetables, tea) were hydrolysed by refluxing in hydrochloric acid to release metabolite B-1 from conjugates.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to quantify cyflumetofen and its metabolites in their free forms in plant commodities.

Radio-validation studies on hydrolysis efficiency for metabolite B-1 conjugates were not available. The hydrolysis of B-1 conjugates has been investigated in a plant metabolism study using eggplant and summarized by the 2014 JMPR. This study showed that some but not all B-1 conjugates were hydrolysed with 0.5 mol/L HCl at room temperature. Most of the B-1 conjugates

were hydrolysed by refluxing with a 1 mol/L HCl solution for 1 hour. The methods used in the supervised trials used 0.48-0.66 mol/L HCl reflux for 1 hour. The Meeting concluded that the methods used in the Japanese trials are considered valid for the analysis of metabolite B-1 conjugates.

Stability of pesticide residues in stored analytical samples

The 2014 JMPR concluded that cyflumetofen was stable when stored frozen for 25 months, the longest storage time tested, in almond, apple fruit, apple juice, orange fruit (24 months), orange juice, orange oil and wheat grain. However, it was stable only up to 9 months in kidney bean and lettuce, and up to 3 months in radish root.

The 2014 JMPR further concluded that metabolite B-1 was stable when stored frozen for 30 months, the longest storage time tested, in almond, kidney bean, lettuce, orange fruit, orange juice and wheat grain. It was stable up to 22 months in apple fruit, apple juice and radish root, and up to 6 months in orange oil.

The Meeting received additional studies demonstrating frozen storage stability of cyflumetofen and metabolite B-1 for at least 8 months in cherries, at least 13 months in plums, nectarines, ume and cucumber, at least 7 months in sweet peppers, and at least 11 months in dried green tea.

The Meeting agreed that the demonstrated storage stability on various plant commodities evaluated by the current and the 2014 JMPR covered the residue sample storage intervals used in the field trials and processing studies considered by the current Meeting.

Exceptions are some trials on peach, apricot, cucumber, tomatoes and sweet peppers, where the storage period of 22–24 months for peach, 22–25 months for apricot, 20–21 months for cucumber, 18–26 months for tomatoes and 15–19 months in sweet peppers exceeds the demonstrated storage stability period for high water crops: up to 9 months in lettuce (parent) and up to 22 months in apple fruit (metabolite B-1). Such trials were not taken into account.

Another exception are some trials on dried hops, where the storage period of 27 months exceeds the demonstrated storage stability period of at least 25 months for parent in high-oil crops (almond). This is considered acceptable.

Additional metabolite information

The residues defined by the 2014 JMPR were based on plant metabolism studies in fruits (mandarin, apple) and fruiting vegetables (eggplant). The current Meeting received supervised residue trials on dried tea, coffee beans and dried hops. In the OECD guideline on metabolism, tea is not classified, coffee beans are classified as pulses/oilseeds and hops are classified as leafy crops. These crops are therefore not represented by metabolism studies in fruits and fruiting vegetables.

The relevant PHI for tea Is 7 or 14 days and the relevant PHI for coffee beans and dried hops is 14 days. At these longer PHIs metabolite formation is relevant and metabolite to parent

levels increase. Furthermore, the Meeting noted that metabolite formation was significant in processed commodities. The Meeting therefore decided to revisit the residue definitions for plant commodities.

Information on metabolite formation relevant for tea leaves, coffee beans, dried hops and processed commodities is presented below.

In the plant metabolism studies in mandarin, apples and eggplant submitted to the 2014 JMPR also leaf samples of mandarin trees, apple trees and eggplants were investigated. The Meeting considered metabolism in mandarin and apple tree leaves to be representative for tea leaves as these are both permanent woody crops. The Meeting considered metabolism from all three metabolism studies on leaves representative for dried hops. Since the coffee berries, where the beans are derived from, can be considered fruits, the Meeting concluded that the metabolism studies on fruits and fruiting vegetables are sufficient to cover the metabolism in coffee beans.

A greenhouse-grown mandarin tree received a single foliar spray of 0.6 kg ai/ha using either butylphenyl- or benzoyl- radiolabelled cyflumetofen. Leaf samples were harvested 1, 7 and 14 days after treatment (DAT). Total radioactive residues in leaves were 35–36 mg/kg eq at 1 DAT, 32-34 mg/kg eq at 7 DAT and 30–43 mg/kg eq at 14 DAT. The majority of the radioactivity was found in an acetone surface rinse: 95–97 percent TRR at 1 DAT, 91–93 percent at 7 DAT and 87–94 percent TRR at 14 DAT. Most of the remaining radioactivity could be extracted with acetonitrile/water (8:2, v/v); only 0.––0.5 percent TRR was left as post-extracted solids. Cyflumetofen was the predominant compound identified in the leaf extracts: 89–90 percent TRR at 1 DAT and 73–81 percent TRR at 14 DAT. Identified metabolites in mandarin leaves were < 4.8 percent TRR at 1 DAT and increased to 9.1 percent TRR (B-1), 4.2 percent TRR (AB-6), 1.5 percent TRR (AB-7) and 3.6 percent TRR (A-12) at 14 DAT. The ratio of metabolites to total residues (i.e. sum of parent and metabolite B-1) at 14 DAT is 0.051-0.052 (AB-6), 0.018-0.019 (AB-7), and 0.044 (A-12) respectively.

A greenhouse-grown apple tree received a single foliar spray of 0.6 kg ai/ha either using butylphenyl- or benzoyl- radiolabelled cyflumetofen. Leaf samples were harvested 1, 7 and 30 DAT. Total radioactive residues in leaves were 6.1–7.3 mg/kg eq at 7 DAT and 4.9–9.5 mg/kg eq at 30 DAT. The majority of the radioactivity was found in an acetonitrile surface rinse: 87–91 percent at 7 DAT and 72–82 percent TRR at 30 DAT. Most of the remaining radioactivity could be extracted with acetonitrile/water (1:1, v/v); 1.4–1.6 percent TRR at DAT 7 and 4.9–6.7 percent TRR at DAT 30 were left as post-extracted solids. Cyflumetofen was the predominant compound identified in the extracts: 75–85 percent TRR at 7 DAT and 44–60 percent TRR at 30 DAT. Identified metabolites were B-1 (3.6 and 4.8 percent TRR), AB-6 (2.7–4.7 and 6.8–8.7 percent TRR), AB-7 (3.6–4.2 and 4.9–5.5 percent TRR) at 7 and 30 DAT, respectively. The ratio of metabolites to total residues is 0.032–0.058 (AB-6) and 0.042–0.052 (AB-7) at 7 DAT and 0.11-0.18 (AB-6) and 0.082–0.11 (AB-7) at 14 DAT, respectively.

Greenhouse-grown eggplants received a single foliar spray of 0.6 kg ai/ha either using butylphenyl- or benzoyl- radiolabelled cyflumetofen. Leaf samples were harvested 14 DAT. Total

radioactive residues in leaves were 17–23 mg/kg eq. The majority of the radioactivity was found in an acetonitrile surface rinse: 69–83 percent. Most of the remaining radioactivity could be extracted with acetonitrile/water (1:1, v/v); 2.6–4.7 percent TRR was left as post-extracted solids. Extracts were treated with 1 M HCl at 80 °C to release metabolites from soluble conjugates. Cyflumetofen was the predominant compound identified in the extracts: 47–58 percent TRR 14 DAT. Identified metabolites were B-1 free form (14.8 percent TRR), B-1 conjugates (17.4 percent TRR), AB-6 (3.4 percent TRR), AB-7 (3.6 percent TRR) at 14 DAT, respectively. The ratio of metabolites to total residues (i.e. parent + B-1 free form) is 0.11 (B-1 conjugates), 0.16–0.18 (AB-6) and 0.11–0.12 (AB-7) at 14 DAT, respectively.

Metabolite AB-7 was analysed and found in a single supervised trial in tea dosed at 3x 0.020 kg ai/hL, with an RTI of 3–4 days. At a PHI of 7 days, parent levels were 10 mg/kg and the ratio of parent equivalent metabolite to parent was 0.47 (B-1) or 0.050 (AB-7). The ratio of the parent equivalent AB-7 level to total residues was 0.032.

Metabolites B-1, AB-6, AB-7 and B-3 were analysed and found in supervised trials on dried hops dosed at 2x 0.20 kg ai/ha or 2x 0.65 kg ai/ha, each with an RTI of 10 days. At a PHI of 14 days, parent levels ranged between 2.3–15 mg/kg (n=8) and the ratios of parent equivalent metabolite to parent ranged between 0.042–0.19 (B-1, n=8), 0.011–0.031 (AB-6, n=5), 0.0071–0.016 (AB-7, n=2) and 0.008–0.022 (B-3), n=2) in samples where metabolites were found above the LOQ. The ratios of parent equivalent metabolite levels to total residues were 0.010–0.029 (AB-6), 0.0065–0.015 (AB-7) and 0.0071–0.018 (B-3).

Processed commodities

High temperature hydrolysis studies evaluated by the 2014 JMPR showed that cyflumetofen was susceptible to hydrolysis with formation of metabolite B-1 (44–75 percent AR) and AB-1 (32–49 percent AR) under boiling/brewing conditions (100 °C, pH 5, for 60 minutes) and sterilization conditions (120 °C, pH 6, for 20 minutes). AB-1 was not analysed for in processed commodities of hops beer or tea infusion.

The Meeting further noted that significant metabolite formation is seen in processed commodities. Citrus peel oil, apple sauce, dried fruit, tomato paste and hop extracts are particularly high in metabolites. The ratios of parent equivalent metabolite levels to parent ranged between 0.013–0.75 (AB-6), 0.0083–1.9 (AB-7), 0.033–0.072 (B-3) and 0.032–0.052 (A-2) at a PHI of 7–14 days in samples where metabolites were found above the LOQ. The ratios of parent equivalent metabolite levels to total residues (i.e. parent plus metabolite B-1 free form) ranged between 0.0083–0.11 (AB-6), 0.0033–0.27 (AB-7), 0.035–0.046 (B-3) and 0.026–0.033 (A-2).

B1- conjugates

The Meeting further noted that samples in Japanese trials were analysed for metabolite B1 including its conjugates. The information from the Japanese trials did not allow assessment of the contribution of the conjugates, as only the total B-1 residues were reported. The metabolism studies on eggplants evaluated by the JMPR 2014 indicate that significant amounts of metabolite B-1 could be released from soluble conjugates using 1 M HCl at 80 °C. The ratio B-1 conjugate to B-1 free form is 0.76 at 7 DAT and 1.5 at 14 DAT in eggplant fruits and 1.2 at 14

DAT in eggplant leaves. The ratio of B-1 conjugates to total residues (i.e. parent + B-1 free form) is 0.10 at 7 DAT and 0.39 at 14 DAT in eggplant fruits and 0.11 at 14 DAT in eggplant leaves.

Residue definition

The Meeting noted that coffee beans, tea and hops were not covered by the metabolism studies used to establish the current residue definition and decided to revisit the residue definition.

Based on studies submitted to the current and previous Meetings, the Meeting concluded that parent is the major residue in fruits, fruiting vegetables, tea (tree leaves), dried hops, coffee beans and processed commodities thereof and thus a suitable marker for these commodities.

Metabolites AB-6, AB-7, B-3, A-2 and A-12 were generally found at lower parent equivalent quantities than metabolite B-1 (free form) at DAT 7-14 and contribution of individual metabolites to total residues (i.e. sum of parent and B-1 free form) is generally below 5 percent each. Exceptions are tree leaves, eggplant leaves, dried fruits and tomato paste, where the contribution of metabolite AB-6 or AB-7 to total residues is higher than 5 percent (up to 18 percent AB-6 in apple tree leaves or up to 27 percent AB-7 in tomato paste). Levels of AB-6 and AB-7 relative to parent tend to increase further at longer PHIs, e.g. in apple tree leaves at 30 DAT. Contribution of B-1 conjugates to total residues is significant: 10–39 percent increase of residue in fruiting vegetables (DAT 7-14) and 11 percent in fruiting vegetable leaves at DAT 14.

In the hypothetical situation, where metabolite B-1 conjugates, metabolite AB-6 and AB-7 were included in the residue definition for dietary risk assessment, dietary exposure for the uses considered by this and previous Meetings would increase by 10–27 percent, respectively, depending on the cluster diet. As the overall chronic dietary exposure for cyflumetofen is low (IEDIs ranged from 0.061 to 0.81 percent of the maximum ADI), the inclusion of these additional metabolites would not impact on the dietary exposure.

The Meeting confirmed its previous residue definitions for plant commodities:

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

Definition of the residue for plant commodities (for estimation of dietary intake): *sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen*.

Should uses be extended to commodities other than fruits, fruiting vegetables, tea, tree nuts, coffee and hops, additional metabolism studies for other crop groups are desirable.

Results of supervised residue trials on crops

Supervised trials were available for the use of cyflumetofen on cherries, plums, peach, nectarine, apricot, Japanese apricot, cucumbers, tomatoes (including cherry tomatoes), sweet pepper, chilli pepper, coffee beans, dried green tea and dried hops. The Meeting received pesticide product labels from Australia, Brazil, Canada, the Republic of Croatia, Greece, India, the Islamic Republic of Iran, Italy, Japan, the Lebanese Republic, the Kingdom of the Netherlands, the Portuguese Republic, Republic of Korea, Spain, the Syrian Arab Republic, Taiwan Province of China and the United States.

In trials, where the total amount of metabolite B-1 (free and conjugated) was analysed, the B-1 conjugates are considered to be present in equal amounts as metabolite B-1 in its free form based on metabolism study information from eggplant fruit and leaves. The metabolite B-

1 conjugates are considered not to be present in fruits and tea leaves based on metabolism study information from mandarins and apples.

Subgroup of cherries

The Meeting received supervised residue trials on cherries conducted in Canada, Japan and the United States.

The critical GAP is the cGAP from Japan for a foliar spray on cherry with an application rate of 2x 0.020 kg ai/hL, a retreatment interval (RTI) of 7 days according to usual Japanese practice (not stated on the label) and a PHI of 1 day.

Two supervised residue trials from Japan on greenhouse-grown cherries performed at 2x 0.020 kg ai/hL, RTI 7 days and PHI 1 day matched with the Japanese cGAP.

Residues of cyflumetofen in greenhouse-grown cherries (without stones) were: 1.1, 2.1 mg/kg

The sum of cyflumetofen and B-1 (free form) in greenhouse-grown cherries (without stones) were: 1.2, 2.3 mg/kg eq.

B-1 residues in Japanese trials include metabolite B-1 conjugates. Since metabolism studies indicate that B-1 conjugates are not formed, the Meeting decided to use the B-1 data from the Japanese trials as such.

Two supervised residue trials from the United States on field-grown cherries performed at 2x 0.020-0.021 kg ai/hL, RTI 6 days and PHI 1 day approximated the Japanese cGAP.

Residues of cyflumetofen in field-grown cherries (wo stones) were: 0.30, 0.48 mg/kg.

The sum of cyflumetofen and B-1 (free form) in field-grown cherries (without stones) were: 0.33, 0.51 mg/kg eq.

When residues at longer PHIs were higher, these were taken instead.

As the residue levels in the greenhouse-grown cherries from Japan are higher than those in the field-grown cherries from the United States and Canada, the Meeting decided not to combine the residues from the greenhouse-grown and field-grown trials. Two trials on greenhouse-grown cherries or field-grown cherries are insufficient to derive a maximum residue level for the subgroup of cherries and the Meeting decided to explore other GAPs.

The next critical GAP is the cGAP from the United States for a foliar spray on stone fruits with an application rate of 2x 0.20 kg ai/ha, a retreatment interval (RTI) of 14 days and a PHI of 7 days. None of the trials could be matched to this GAP.

The next critical GAP is the cGAP from the Republic of Korea for a foliar spray on cherries with an application rate of 2x 0.010 kg ai/hL, unstated RTI and a PHI of 7 days.

Ten independent trials from the United States and Canada on field-grown cherries performed at 2x 0.018-0.033 kg ai/hL, RTI 6–7 days and PHI 7 days could be matched to the Korean GAP using the proportionality approach.

Residues of cyflumetofen in field-grown cherries (without stones) were: 0.11, 0.11, 0.12, 0.16, 0.22, 0.27, 0.37, 0.42, 0.44, 0.44 mg/kg (n=10) without scaling and 0.044, 0.056, 0.059, 0.061, 0.084, 0.11, 0.13, 0.17, 0.21, 0.22 mg/kg (n=10) using scaling factors of 0.30-0.53.

The sum of cyflumetofen and B-1 (free form) in field-grown cherries (without stones) were: 0.13, 0.13, 0.14, 0.19, 0.25, 0.29, 0.39, 0.44, 0.46, 0.46 mg/kg eq (n=10) without scaling

and 0.053, 0.067, 0.068, 0.073, 0.092, 0.12, 0.14, 0.18, 0.22, 0.23 mg/kg eq (n=10) using scaling factors of 0.30-0.53.

Furthermore, the 2017 JMPR concluded that for stone fruit, based on the weight of the stone relative to the whole fruit, residues measured in fruit without stones would overestimate whole fruit residues by about 10 percent and that correcting for this factor would lead to the same maximum residue level estimation. Therefore, the Meeting agreed to use the data from the trials to estimate a maximum residue level.

The Meeting estimated a maximum residue level of 0.4 mg/kg for cyflumetofen for the subgroup of cherries and an STMR of 0.106 mg/kg eq for total residues for the subgroup of cherries based on the Korean cGAP.

Subgroup of plums

The Meeting received supervised residue trials on plums conducted in Japan and the United States.

The critical GAP is the cGAP from Japan for a foliar spray on cherry with an application rate of 2x 0.020 kg ai/hL, a retreatment interval (RTI) of 7 days according to usual Japanese practice (not stated on the label) and a PHI of 1 day.

Three supervised residue trials from Japan and the United States on plums performed at 2x 0.018-0.020 kg ai/hL, RTI 7–8 days and PHI 1 day approximated the Japanese cGAP.

Residues of cyflumetofen in plums (without stones) were: <0.05, 0.053, 0.36 mg/kg

The sum of cyflumetofen and B-1 (free form) in plums (without stones) were: 0.077, <0.17 (JP), 0.48 (JP) mg/kg.

B-1 residues in Japanese trials include metabolite B-1 conjugates. Since metabolism studies indicate that B-1 conjugates are not formed, the Meeting decided to use the B-1 data from the Japanese trials as such.

Three trials on plums are insufficient to derive a maximum residue level for the subgroup of plums and the Meeting decided to explore other GAPs.

The next critical GAP is the cGAP from the United States for a foliar spray on stone fruits with an application rate of 2x 0.20 kg ai/ha, a retreatment interval (RTI) of 14 days and a PHI of 7 days. None of the trials could be matched to this GAP.

The next critical GAP is the cGAP from the Republic of Korea for a foliar spray on plums with an application rate of 2x 0.010 kg ai/hL, unstated RTI and a PHI of 14 days.

Three trials from Japan and the United States on plums performed at 2x 0.020 kg ai/hL, RTI 7 days and PHI 14 days could be matched to the Korean GAP using the proportionality approach.

Residues of cyflumetofen in plums (without stones) were: 0.018, <0.05, <0.05 mg/kg without scaling and 0.009, <0.025, <0.025 mg/kg using a scaling factor of 0.50.

The sum of cyflumetofen and B-1 (free form) in plums (without stones) were: 0.041, <0.17 (JP), 0.26 (JP) mg/kg eq without scaling and 0.021, <0.084 (JP), 0.13 (JP) mg/kg eq using a scaling factor of 0.50.

Metabolite B-1 residues in Japanese trials (indicated by JP) include metabolite B-1 conjugates. Since metabolism studies indicate that B-1 conjugates are not formed, the Meeting decided to use the B-1 data from the Japanese trials as such.

Three trials on plums are insufficient to derive an MRL based on the Korean cGAP.

No other GAPs could be matched to the trials and the Meeting concluded that the data were insufficient for estimating a maximum residue level for the subgroup of plums.

Subgroup of peaches

The Meeting received supervised residue trials on peach, nectarine, apricot and Japanese apricot conducted in Germany, France, Italy, Japan, the Kingdom of the Netherlands, Spain, and the United States.

The critical GAP is the cGAP from Japan for a foliar spray on peach, nectarine or small stone fruits with an application rate of 2x 0.020 kg ai/hL, a retreatment interval (RTI) of 7 days according to usual Japanese practice (not stated on the label) and a PHI of 1 day.

One supervised residue trial from the United States on peach performed at 2x 0.019-0.020 kg ai/hL, RTI 6 days and PHI 1 day approximated the Japanese cGAP.

Residues of cyflumetofen in peach were: 0.11 mg/kg

The sum of cyflumetofen and B-1 (free form) in peach (without stones) was: 0.13 mg/kg eq.

Two supervised residue trials from Japan on nectarine performed at 2x 0.020 kg ai/hL, RTI 7 days and PHI 1 day approximated the Japanese cGAP.

Residues of cyflumetofen in nectarine (without stones) were: 0.77, 0.90 mg/kg

The sum of cyflumetofen and B-1 (free form) in nectarine (without stones) were: 0.89, 1.0 mg/kg eq.

B-1 residues in Japanese trials include metabolite B-1 conjugates. Since metabolism studies indicate that B-1 conjugates are not formed, the Meeting decided to use the B-1 data from the Japanese trials as such.

Two supervised residue trials from Japan on Japanese apricot performed at 2x 0.020 kg ai/hL, RTI 7 days and PHI 1 day matched with the Japanese cGAP.

Residues of cyflumetofen in Japanese apricot (without stones) were: 2.1, 3.8 mg/kg

The sum of cyflumetofen and B-1 (free form) in Japanese apricot (without stones) were: 2.2, 3.9 mg/kg eq.

B-1 residues in Japanese trials include metabolite B-1 conjugates. Since metabolism studies indicate that B-1 conjugates are not formed, the Meeting decided to use the B-1 data from the Japanese trials as such.

The Meeting concluded that the data were insufficient for estimating a maximum residue level for individual commodities or for the subgroup of peaches based on the Japanese cGAP. The Meeting decided to explore cGAPs for other countries.

The next critical GAP is the cGAP from the United States for a foliar spray on stone fruits with an application rate of 2x 0.20 kg ai/ha, a retreatment interval (RTI) of 14 days and a PHI of 7 days.

Ten independent trials from France, Germany, Greece, the United States and Canada on peach performed at 2x 0.20-0.21 kg ai/ha, and PHI 6–8 days were available, but with a shorter RTI of six–11 days. These trials could be matched to the cGAP in the United States as two out of four decline trials on peach showed that a shorter RTI of 6–11 days increased the residues by 25-10 percent, which is within 25 percent of the GAP. Another three trials from Germany, Greece and Spain approximating the cGAP in the United States could not be used because the storage period of the samples exceeded the maximum demonstrated period of stability.

Residues of cyflumetofen in peach (with or without stones) from France, Germany, Greece, the United States and Canada were 0.024, 0.036, 0.052, 0.094, 0.097, 0.12, 0.13, 0.14, 0.15, 0.20 mg/kg (n=10).

The sum of cyflumetofen and B-1 (free form) in peach (with or without stones) France, Germany, Greece, the United States and Canada were 0.047, 0.060, 0.076, 0.12, 0.12, 0.14, 0.15, 0.17, 0.17, 0.22 mg/kg eq (n=10).

Two independent trials from the Kingdom of the Netherlands and Spain on apricot performed at 2x 0.18-0.20 kg ai/ha, and PHI 6–8 days were available, but with a shorter RTI of 9–10 days. These trials could be matched to the cGAP in the United States as two out of four decline trials on apricot showed that a shorter RTI of 9–10 days increased the residues by 13–10 percent, which is within 25 percent. Another three trials from France, Italy and the Kingdom of the Netherlands, approximating the cGAP in the United States could not be used because the storage period of the samples exceeded the maximum demonstrated period of stability.

Residues of cyflumetofen in apricot (with stones) were 0.082, 0.11 mg/kg (n=2).

The sum of cyflumetofen and B-1 (free form) in apricot (with stones) were 0.11, 0.13 mg/kg eq (n=2).

Noting that residues in apricot and peach were similar, the Meeting decided to combine the two datasets:

Residues of cyflumetofen in peach and apricots (with or without stones) were 0.024, 0.036, 0.052, 0.082 (ap), 0.094, 0.097, 0.11 (ap) 0.12, 0.13, 0.14, 0.15, 0.20 mg/kg (n=12), where ap indicates apricots.

The sum of cyflumetofen and B-1 (free form) in peach and apricots (with or without stones) were 0.047, 0.060, 0.076, 0.11 (ap), 0.12, 0.12, 0.13 (ap), 0.14, 0.15, 0.17, 0.17, 0.22 mg/kg eq (n=12).

Furthermore, the 2017 JMPR concluded that for stone fruit, based on the weight of the stone relative to the whole fruit, residues measured in fruit without stones would overestimate whole fruit residues by about 10 percent and that correcting for this factor would lead to the same maximum residue level estimation. Therefore, the Meeting agreed to use the data from the trials to estimate a maximum residue level.

The Meeting estimated a maximum residue level of 0.3 mg/kg for cyflumetofen for the subgroup of peaches and an STMR of 0.125 mg/kg eq for total residues for the subgroup of peaches based on the cGAP in the United States.

Cucumbers

The Meeting received supervised residue trials on greenhouse-grown cucumbers conducted in France, Germany, Japan, Italy, the Kingdom of the Netherlands, Spain and the United States.

The critical GAP is the cGAP from the Kingdom of the Netherlands for a foliar spray on greenhouse-grown cucumber with an application rate of 2x 0.020 kg ai/hL per cultivation cycle, a retreatment interval (RTI) of 7 days and a PHI of 1 day.

Two Japanese trials on greenhouse-grown cucumbers performed at 2x 0.020 kg ai/hL, RTI 7–8 days and PHI 1 day approximated the cGAP in the Kingdom of the the Kingdom of the Netherlands. A further eight supervised residue trials from France, Germany, Italy, the Netherlands and Spain on greenhouse-grown cucumbers performed at 2x 0.026-0.042 kg ai/hL, RTI 7 days and PHI 1 day could be matched to cGAP in the Kingdom of the Netherlands using proportionality. Another two trials from the United States could not be used because the storage period of the samples exceeded the maximum demonstrated period of stability.

Residues of cyflumetofen in greenhouse-grown cucumbers were: 0.06, 0.07, 0.09, 0.10, 0.10, 0.15, 0.16, 0.18, 0.24, 0.30 mg/kg (n=10) without scaling and 0.029, 0.043, 0.048, 0.048, 0.050, 0.071, 0.076, 0.17, 0.18, 0.30 mg/kg (n=10) using scaling factors of 0.48-1.0. When residues were higher at higher PHIs these were chosen instead.

The sum of cyflumetofen and B-1 (free form) in greenhouse-grown cucumbers were: 0.084, 0.11, 0.12, 0.16, 0.17, 0.17, 0.18, 0.26, 0.49 (JP), 0.63 (JP) mg/kg (n=12) without scaling and 0.040, 0.054, 0.059, 0.081, 0.083, 0.087, 0.11, 0.19, 0.49 (JP), 0.63 (JP) mg/kg (n=12) using scaling factors of 0.48-1.0.

B-1 residues were analysed in the free form, except in the Japanese trials (indicated by JP) where B-1 conjugates were included. B-1 residues in the Japanese trials were corrected, assuming equal amounts of B-1 free form and B-1 conjugate.

The Meeting estimated a maximum residue level of 0.5 mg/kg for cyflumetofen and an STMR of 0.085 mg/kg eq for total residues in cucumbers based on the cGAP in the Kingdom of the Netherlands.

Melons and watermelons

The Meeting received supervised residue trials on melons and watermelons conducted in Japan.

The critical GAP is the cGAP from Japan for a foliar spray on melon or watermelon with an application rate of 2x 0.020 kg ai/hL, a retreatment interval (RTI) of 7 days according to usual Japanese practice (not stated on the label) and a PHI of one day.

The Meeting concluded that the trials on melons or watermelons could not be used for estimating a maximum residue level because residue data were only available for the flesh and no residue data on the corresponding whole fruit (RAC) were available.

Tomatoes

The 2014 JMPR estimated a maximum residue level of 0.3 mg/kg for cyflumetofen and an STMR of 0.07 mg/kg eq for the sum of cyflumetofen and B-1 (free form) in tomato, based on the cGAP for field-grown tomatoes subgroup from the United States at 2x 0.20 kg ai/ha, a 14-day retreatment interval and a PHI of 3 days and based on 16 supervised residue trials from the United States on field-grown tomatoes.

The Meeting received additional GAPs and additional supervised residue trials on field-grown and greenhouse-grown tomatoes from Australia, France, Germany, Greece, Italy, the Kingdom of the Netherlands, Spain, the Republic of Türkiye, the United Kingdom of Great Britain and Northern Ireland and the United States.

The critical GAP is the cGAP from the Kingdom of the Netherlands for a foliar spray on greenhouse-grown tomatoes at an application rate of 2x 0.20 kg ai/ha, a 10-day retreatment interval (RTI) and a PHI of 1 day.

Four supervised residue trials from Germany, Italy, the Kingdom of the Netherlands and Spain on greenhouse-grown tomatoes performed at 2x 0.19-0.22 kg ai/ha, RTI 8–11 days and PHI 1 day approximated the cGAP in the Kingdom of the Netherlands. A further seven trials from France, Germany, Greece, Italy, the Kingdom of the Netherlands, Spain and the United Kingdom of Great Britain and Northern Ireland on tomatoes and one trial from Germany on cherry tomatoes could be matched to this cGAP but could not be used because the storage period of the samples exceeded the demonstrated period of stability.

Residues of cyflumetofen in greenhouse-grown tomatoes were: 0.050, 0.13, 0.16, 0.16 (n=4) mg/kg. When residues at longer PHIs were higher, these were taken instead.

The sum of cyflumetofen and B-1 (free form) in greenhouse-grown tomatoes were: 0.074, 0.15, 0.18, 0.18 (n=4) mg/kg eq.

B-1 residues were analysed in the free form.

Four trials on tomatoes are insufficient to derive an MRL based on the cGAP in the Kingdom of the Netherlands.

Other GAPs were not further explored as the number of trials would not increase because storage stability was not demonstrated for the sample storage periods used in the field-grown and greenhouse-grown tomatoes from Australia, the United States and European countries. The Meeting confirmed its previous recommendation of 0.3 mg/kg for cyflumetofen and an STMR of 0.07 mg/kg eq for the sum of cyflumetofen and B-1 (free form) in tomato.

Sweet peppers

The Meeting received supervised residue trials on field-grown and greenhouse-grown sweet and chilli peppers from Australia, Japan and the United States.

The critical GAP is the cGAP from Japan for a foliar spray on sweet peppers with an application rate of 2x 0.020 kg ai/hL, a retreatment interval (RTI) of 7 days according to usual Japanese practice (not stated on the label) and a PHI of 1 day.

Two supervised residue trials from Japan on greenhouse-grown sweet peppers performed at 2x 0.020 kg ai/hL, RTI 7 days and PHI 1 day matched the Japanese cGAP. A further two supervised residue trials from the United States on greenhouse-grown sweet peppers could be matched to the Japanese cGAP using the proportionality approach, but could not be used because the storage stability period exceeded the maximum demonstrated period of stability.

Residues of cyflumetofen in greenhouse-grown sweet peppers were: 0.48, 2.6 mg/kg (n=2).

The sum of cyflumetofen and B-1 (free form) in greenhouse-grown sweet peppers were: 0.53, 2.8 mg/kg eq (n=2).

Metabolite B-1 residues in Japanese trials include metabolite B-1 conjugates. B-1 residues in the Japanese trials were corrected, assuming equal amounts of B-1 free form and B-1 conjugate.

Other GAPs were not further explored as the number of trials would not increase because storage stability was not demonstrated for the sample storage periods used in the field-grown and greenhouse-grown sweet and chilli peppers from Australia and the United States. The Meeting concluded that the data were insufficient for estimating a maximum residue level for peppers.

Eggplants

The 2014 JMPR received two supervised residue trials on eggplants from Japan and concluded that the data were insufficient for estimating a maximum residue level for eggplants. The current Meeting received a new study report on eggplants from Japan, but the reported data appeared to be the same as the ones submitted to the 2014 JMPR. The Meeting confirmed its previous conclusion that data were insufficient for estimating maximum residue levels for eggplants.

Green coffee beans

The Meeting received supervised residue trials on coffee conducted in Brazil.

The critical GAP is the cGAP from Brazil for a foliar spray on coffee plants with an application rate of 2x 0.16 kg ai/ha, a retreatment interval (RTI) of 15 days and a PHI of 14 days.

Eight supervised residue trials from Brazil on coffee plants performed at 2x 0.20 kg ai/ha, RTI 15 days and PHI 14 days approximated the Brazilian cGAP. Coffee berries were allowed to dry indoors at room temperature for 38–58 days. Once dry, the beans and coffee husks were separated mechanically to obtain the green coffee beans.

Residues of cyflumetofen in green coffee beans were: <0.01, <0.01, <0.01, <0.01, 0.019, 0.031, 0.040, 0.045 mg/kg (n=8).

The sum of cyflumetofen and B-1 (free form) in green coffee beans were: <0.034, <0.034, <0.034, <0.034, 0.052, 0.065, 0.069, 0.082 mg/kg eq (n=8).

B-1 residues were analysed in the free form.

The Meeting estimated a maximum residue level of 0.08 mg/kg for cyflumetofen and an STMR of 0.043 mg/kg eq for total residues in green coffee beans based on the Brazilian cGAP.

Dried green tea

The Meeting received supervised residue trials on tea plants conducted in Japan and the Republic of Korea.

The critical GAP is the cGAP from Japan for a foliar spray on tea plants with an application rate of 2x 0.020 kg ai/hL, a retreatment interval (RTI) of 7 days according to usual Japanese practice (not stated on the label) and a PHI of 7 days.

Three supervised residue trials from Japan on tea plants performed at 2x 0.020 kg ai/hL, RTI 7 days and PHI 7 days matched the Japanese cGAP. The fresh tea leaves were processed into dried green tea using a tea processing machine or by steaming followed by drying in an oven at 80 °C.

Residues of cyflumetofen in dried green tea were: 1.6, 1.9, 33 mg/kg (n=3).

The sum of cyflumetofen and B-1 (free form) in dried green tea were: 3.5, 5.2, 36 mg/kg eq (n=3).

B-1 residues in the Japanese trials included B-1 conjugates and were corrected, assuming equal amounts of B-1 free form and B-1 conjugate.

The Meeting concluded that the data were insufficient for estimating a maximum residue level for dried green tea based on the Japanese cGAP.

The next critical GAP is the cGAP in the Republic of Korea for a foliar spray on tea plants with an application rate of 2x0.010 kg ai/hL, an unstated retreatment interval and a PHI of 14 days.

One supervised trial from the Republic of Korea on tea plants performed at 2x 0.010 kg ai/hL, RTI 7 days and PHI of 14 days matched with this GAP. Three supervised residue trials from Japan on tea plants performed at 2x 0.020 kg ai/hL, RTI 7–8 days and PHI 14 days could be matched to the cGAP in the Republic of Korea using the proportionality approach. The fresh tea leaves were processed into dried green tea using a tea processing machine or by steaming followed by drying in an oven at 80 °C.

Residues of cyflumetofen in dried green tea were: 0.32, <0.5, <0.8, 5.4 mg/kg (n=4) without scaling and 0.16, <0.25, <0.8, 2.7 mg/kg using scaling factors of 0.5.

The sum of cyflumetofen and B-1 (free form) in dried green tea were: 0.93 (JP), 1.2 (JP), <2.7, 6.3 (JP) mg/kg eq (n=4) without scaling and 0.47 (JP), 0.60 (JP), <2.7, 3.2 (JP) mg/kg eq using scaling factors of 0.5–1.0.

B-1 residues were analysed in the free form, except in the Japanese trials (indicated by JP) where B-1 conjugates were included. B-1 residues in the Japanese trials were corrected, assuming equal amounts of B-1 free form and B-1 conjugate.

The Meeting concluded that the data were insufficient for estimating a maximum residue level for dried green tea.

Dried hop cones

The Meeting received supervised residue trials on hop plants conducted in Germany and the United States.

The critical GAP from the United States is for a foliar spray on hops with an application rate of 2x0.20 kg ai/ha, a retreatment interval of 14 days and a PHI of 14 days.

Five supervised trials from the United States on hop plants performed at 2x 0.20-0.21 kg ai/ha, RTI 13-14 days and PHI of 13-14 days approximated the GAP in the United States. Green hop cones were dried for 7–8 hours at 58-63 °C until a moisture content of 7–12 percent.

Residues of cyflumetofen in dried hop cones were: 2.0, 2.4, 3.0, 3.4, 7.2 mg/kg (n=5).

The sum of cyflumetofen and B-1 (free form) in dried hop cones were: 2.2, 2.9, 3.6, 3.6, 8.0 mg/kg eq (n=5).

B-1 residues were analysed in the free form.

The Meeting estimated a maximum residue level of 15 mg/kg for cyflumetofen and an STMR of 3.6 mg/kg eq for total residues in dried hops based on the US cGAP.

Fate of residues during processing

The Meeting considered new information on the fate of cyflumetofen residues during processing in peach/nectarine, coffee beans and hops.

Parent compound concentrated in dried peach/nectarine (see table below). One trial for dried peach/nectarine led to a processing factor of 21 both for parent and total residues and since this value is implausible, the Meeting decided to discard this processing factor and to use the two remaining processing factors. The Meeting estimated a maximum residue level of 2 mg/kg in dried peach or dried nectarine.

Estimation of processing factors for commodities considered at this and previous Meetings based on parent only for the purpose of maximum residue level estimation

Raw commodity MRL	Processed commodity	Parent Individual processing factors	Parent Mean or best estimate processing factor	MRL x PF (mg/kg)
Peach Nectarine [0.3 mg/kg]	Dried peach Dried nectarine	6.6, 7.9	7.2 (n=2)	2.16 Rounded 2

Processing factors for total residues for the purpose of dietary burden calculations and dietary risk assessment are listed in the table below.

Processing data were also provided for peach/nectarine juice and wet pomace. The processing factors for wet pomace were above 1, indicating concentration of residues in the peel/pulp fraction. This is as expected from metabolism studies where most of the residues are in the surface wash. The processing factors calculated for pasteurized juice for parent are 0.44, 1.4 and 1.7 and for total residues they are 0.54, 1.4 and 1.6, suggesting concentration in the juice. As it is implausible to have concentration of residues both in the pomace and the juice, these processing factors are likely to reflect inhomogeneous sampling and/or variability in the analysis and do not reflect concentration of residues. The Meeting decided not to use the processing factors for juice.

Estimation of processing factors based on the sum of cyflumetofen and B-1 (free form) for the purpose of dietary burden calculations and dietary risk assessment

Raw commodity [STMR]	Processed commodity	Total residue Individual processing factors	Total residue Mean or best estimate processing factor	STMR-P = STMR-RAC × PF (mg/kg)
Peach or nectarine [0.125 mg/kg]	Peach canned Nectarine canned	<0.1, <0.2, <0.2	<0.1	0.012
	Peach dried Nectarine dried	8.5, 9.5	9.0	1.1

Raw commodity [STMR]	Processed commodity	Total residue Individual processing factors	Total residue Mean or best estimate processing factor	STMR-P = STMR-RAC × PF (mg/kg)
	Peach jam Nectarine jam	0.21, 0.22, 0.43	0.22	0.028
Green coffee beans [0.043 mg/kg]	Roasted coffee beans	0.63	0.63 (n=1)	0.027
	Instant coffee powder	0.24	0.24 (n=1)	0.010
Dried hop cones [3.6 mg/kg]	Hops beer	<0.005, 0.022	0.0135 (n=2)	0.049
	Hops extract	3.4, 4.3	3.85 (n=2)	13.9

Residues in animal commodities

None of the commodities evaluated by the present Meeting are fed to livestock. The Meeting therefore confirmed its previous recommendations for maximum residue levels in animal products.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for dietary exposure assessments.

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

Definition of the residue for plant commodities (for estimation of dietary intake): *sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen.*

Definition of the residue for animal commodities (for compliance with the MRL and estimation of dietary intake): *sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen.*

Residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for cyflumetofen is 0–0.1 mg/kg bw. The IEDIs for cyflumetofen were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the 2023 and previous JMPRs. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 0 to 1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of cyflumetofen from uses considered by the 2023 and previous JMPRs is unlikely to present a public health concern.

Acute dietary exposure

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

5.10 Deltamethrin (135) (R)

RESIDUE AND ANALYTICAL ASPECTS

Deltamethrin is a non-systemic synthetic pyrethroid insecticide used in agriculture and public and animal health as a broad-spectrum insecticide in a wide range of fruit, vegetable and field crops. It is also recommended for use against locusts, indoor insects and pests of stored grain and timber and for the control of ticks, mites and insect pests of livestock.

Deltamethrin was first reviewed by JMPR in 1980 with subsequent residue reviews between 1984 and 1992. Full periodic reviews were conducted for toxicology in 2000 and for residues in 2002. Residues resulting from the veterinary uses of deltamethrin were evaluated by JECFA in 1999 and in 2003. The 2016 JMPR reviewed a new use for deltamethrin.

The 2000 JMPR established an ADI of 0–0.01 mg/kg bw and an ARfD of 0.05 mg/kg bw for deltamethrin. The established residue definitions for plant and animal commodities, for both compliance with MRLs and for dietary intake assessment, is the sum of the deltamethrin and its *trans*-, and α-R- isomers. The 2002 JMPR also concluded that the residue is fat-soluble and that residues in milk should be measured on the whole milk.

Deltamethrin was scheduled at the fifty-second Session (2021) of the CCPR for the evaluation of additional uses by the 2022 JMPR and rescheduled for the 2023 JMPR. The current Meeting received GAP information and supporting residue information for mango and papaya.

Methods of analysis

The Meeting received method validation and concurrent recovery data for method 00855/M004. Briefly, the method consists of extraction using acetone + n-hexane + dichloromethane (1+1+1, v/v/v), filtration, evaporation of an aliquot and resuspension in acetonitrile+10 mmol/L ammonium acetate (9+1, v/v), and analysis by LC-MS/MS. This method was determined to be suitable for analysis of deltamethrin and its *trans*-, and α-R- isomers in a variety of plant matrices, with an LOQ of 0.01 mg/kg in all cases.

Stability of residues in stored samples

Mango and papaya have pH levels of 5.8—6.0 and 5.2—6.0, respectively[5]. The Meeting agreed that these fruits should be classified as high-water-content foods. Samples of mango and papaya were stored for no more than 6 months and 5 months, respectively, which is covered by the conclusion of the 2002 JMPR that residues of deltamethrin in high-water-content commodities are stable during frozen storage for at least 16 months in lettuce, 24 months in cabbage, and 24 months in tomato.

The Meeting noted that previously storage stability data did not cover high-acid commodities. For the storage stability data on oranges submitted to the current Meeting, the Meeting concluded that residues of deltamethrin and its *trans*-, and α-(R)- isomers are stable in high-acid commodities during frozen storage for at least 25 months.

[5] https://www.clemson.edu/extension/food/food2market/documents/ph_of_common_foods.pdf; [cited 5 July 2023]

Residues in supervised trials on crops

The Meeting received supervised trial data for residues of deltamethrin in mango and papaya.

Residues reported as <LOQ were assumed to be at the LOQ for calculation purposes, with the exception of papaya flesh, for which each analyte was reported as <LOQ and the total residue was assumed to be at the single-analyte LOQ (e.g. <0.01 mg/kg + <0.01 mg/kg + <0.01 mg/kg = 0.01 mg/kg, not 0.03 mg/kg).

Mango

The critical GAP for mango is from Brazil and consists of 3 applications, each at 12.5 g ai/ha on a 14-day retreatment interval, with a 1-day PHI.

In trials approximating the critical GAP, residues of total deltamethrin (sum of deltamethrin, *trans*-deltamethrin, and *α-(R)*-deltamethrin) in whole fruit (with stone) were (n=4): <0.03, 0.032, 0.038, and 0.039 mg/kg.

In those same trials, residues of total deltamethrin in mango flesh were (n=4): <0.03 (4) mg/kg.

Mango is classified as Minor Crop Category 3, for which at least 5 trials are required. The Meeting agreed that the data are not sufficient to make recommendations for residues of deltamethrin in mango.

Papaya

The critical GAP for papaya is from Brazil and consists of 3 applications, each at 12.5 g ai/ha on a 14-day retreatment interval, with a 1-day PHI.

In trials approximating the critical GAP, residues of total deltamethrin (sum of deltamethrin, *trans*-deltamethrin, and *α-(R)*-deltamethrin) in whole fruit (reconstituted from pulp and peel results) were (n=5): 0.048 (3), 0.056, and 0.066 mg/kg.

In those same trials, residues of total deltamethrin in papaya flesh were (n=5): <0.01 (5) mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, an HR of 0.01 mg/kg and an STMR of 0.01 mg/kg for residues of deltamethrin in papaya.

Residues in processed commodities

No information about residues in processed mango or papaya commodities was provided to the Meeting.

Residues in animal commodities

There are no animal feeds associated with mango or papaya. The Meeting confirmed its previous recommendations.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDIs assessments.

Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *sum of the deltamethrin and its trans- and α-R- isomers.*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for deltamethrin is 0-0.01 mg/kg bw. The IEDIs for deltamethrin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 30 to 100 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of deltamethrin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for deltamethrin is 0.05 mg/kg bw. The IESTIs for deltamethrin were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs varied from 0 to 1 percent of the ARfD for children and 0 to 1 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of deltamethrin from uses considered by the present Meeting is unlikely to present a public health concern.

5.11 Difenoconazole (224) (R)

RESIDUE AND ANALYTICAL ASPECTS

Difenoconazole was evaluated by the JMPR for the first time in 2007 when an ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. In 2007, 2010, 2013, 2015, 2017, 2021 and 2022 the JMPR evaluated for residues and recommended numerous maximum residue levels.

The definition of the residue for compliance with MRL and for dietary intake for plant commodities is parent difenoconazole, while for animal commodities it is defined as sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol (CGA205375), expressed as difenoconazole. The residue is fat-soluble.

Difenoconazole was scheduled at the fifty-third Session of the CCPR for the evaluation of additional MRLs in 2023 JMPR. The current Meeting received additional information on use pattern, residue data of supervised trials and processed commodities on stone fruit, cane berries, brassica leafy vegetables, green onions and chives, radish, sweet potato and maize.

Methods of analysis

The Meeting received additional information on the analytical method REM 147.08 for determination of difenoconazole in plant commodities for data gathering.

The method was previously evaluated by the 2007, 2010, 2015, 2017 and 2020 JMPR and has been fully validated in high oil, high water, high starch, and high acid content commodities, with an LOQ of 0.01 mg/kg. The current Meeting received validation data for the method REM 147.08 in blackberries, mustard greens, radish roots, radish leaves, maize including several processed maize matrices and potato tubers.

Recoveries and percent RSDs were within the acceptable range. The LOQ was 0.01 mg/kg for all commodities tested.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure difenoconazole in plant commodities.

Stability of residues in stored analytical samples

The Meeting did not receive additional information on the storage stability of residues. The under investigated crops belong to the groups of high-water content matrices (mustard greens, cherries, peaches, plums, chives, radish), high acid content commodities (cane berries) and high starch content (sweet potato, maize cereals).

Information provided for the 2007 JMPR indicated that difenoconazole residues were stable at approximately -20 °C for two years in matrices with high oil content, high water content matrices, high starch content and wheat forage and straw.

Results of supervised residue trials on crops

Stone fruits, group

The use of difenoconazole on stone fruits is registered in the United States for ground or air application. The Meeting determined that the critical GAP consists of four applications at 128 g a.i. /ha with a spray interval of 7 d and a PHI of 0 days.

Five[6] supervised trials on cherries conducted in the United States matching the cGAP were provided. In cherry fruits (without stone), residues for difenoconazole were (n=5): 0.29, 0.58, 0.69, 0.77, 0.95 mg/kg. Based on the available dataset, a median of 0.69 mg/kg was estimated.

Nine supervised trials on peaches conducted in the United States matching the cGAP were provided. In peach fruits (without stone), residues for difenoconazole were (n=9): 0.076, 0.13, 0.16, 0.29, 0.33, 0.53, 0.54, 0.77, 0.95 mg/kg. Based on the available dataset, a median of 0.33 mg/kg was estimated.

Six supervised trials on plums conducted in the United States matching the cGAP were provided. In plum fruits (without stone), residues for difenoconazole were (n=6): 0.10, 0.11, 0.30, 0.32, 0.40, 0.54 mg/kg. Based on the available dataset, a median of 0.31 mg/kg was estimated.

As cherries, peaches and plums covered by the registered use correspond to the CODEX group for stone fruits (FS 0012), the Meeting recommends extrapolating the estimates to the whole group.

The Meeting noted that median residues on cherries, peaches and plums are within a five-fold difference and Kruskal-Wallis H-test indicates that these three populations are not significantly different. The Meeting decided to combine these datasets.

The combined dataset for fruits (without stone) is (n= 20) 0.076, 0.10, 0.11, 0.13, 0.16, 2x 0.29, 0.30, 0.32, 0.33, 0.40, 0.53, 2x 0.54, 0.58, 0.69, 2x 0.77, 0.95, 0.95 (highest individual value 1.02 mg/kg) mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.365 mg/kg and an HR of 1.02 mg/kg for stone fruits (FS 0012) based on the combined dataset of cherries, peaches and plums.

[6] Six trials were available but five were considered independent.

Cane berries, subgroup

The use of difenoconazole on cane berries is registered in the United States for ground or air application. The Meeting determined that the critical GAP consists of four applications at 126 g a.i. /ha with a spray interval of 14 days and a PHI of 0 days.

Four supervised trials on blackberries conducted in the United States matching the cGAP were provided. In berries, residues for difenoconazole were (n=8): 0.32, 0.56, 0.81, 1.43 mg/kg. Based on the available dataset, a median of 0.69 mg/kg was estimated.

Four supervised trials on raspberries conducted in the United States matching the cGAP were provided. In berries, residues for difenoconazole were (n=8): 0.53, 0.54, 0.81, 0.83 mg/kg. Based on the available dataset, a median of 0.68 mg/kg was estimated.

The Meeting noted that median residues on blackberries and raspberries are within a five-fold difference and the Mann-Whitney U-test also determined that the datasets are not statistically different, therefore the Meeting decided to combine these datasets for subgroup recommendation.

The combined dataset for blackberries and raspberries is (n=8): 0.32, 0.53, 0.54, 0.56, 2x 0.81, 0.83, 1.4 (highest individual value 1.7) mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.69 mg/kg and a HR of 1.7 mg/kg for subgroup of cane berries (FB 2005).

Brassica leafy vegetable (subgroup 13B)

The use of difenoconazole on brassica leafy vegetables, is registered in the United States for ground or air application or chemigation. The Meeting determined that the critical GAP (cGAP) consists of four applications at 128 g a.i. /ha with a spray interval of 7 days and a PHI of 7 days.

Eight supervised trials on mustard greens conducted in the United States matching the cGAP were provided. In leaves, residues for difenoconazole were (n=8): 0.69, 0.81, 1.00, 1.45, 1.60, 1.65, 2.95, 5.70 mg/kg.

In addition, five supervised trials on radish conducted in the United States. matching the cGAP were provided. In leaves, residues for difenoconazole were (n=5): 0.24, 0.64, 1.62, 1.73, 3.83 mg/kg.

The Meeting noted that median residues on mustard greens and radish leaves are within a five-fold difference and the Mann-Whitney U-test also determined that the datasets are not statistically different, therefore the Meeting decided to combine these datasets. The combined dataset for mustard greens and radish leaves is (n=13): 0.24, 0.64, 0.69, 0.81, 1.00, 1.45, 1.60, 1.62, 1.65, 1.73, 2.95, 3.83, 5.70 (highest individual value 6.1) mg/kg.

The registration covers the subgroup of brassica leafy vegetable and since mustard greens and radish leaves are representative commodities the extrapolation of the estimates to the subgroup is possible. However, the Meeting noted that, the international estimate of short-term intake calculation for Chinese cabbage (VL 0466) resulted in a maximum of 120 percent of ARfD for children, therefore decided to estimate maximum residue level and STRM for the individual commodities of mustard greens and radish leaves only.

The Meeting estimated a maximum residue level of 8 mg/kg, an STMR of 1.6 mg/kg and an HR of 6.1 mg/kg for mustard greens (VL 0485) and radish leaves (VL 0494) based on the combined dataset of mustard greens and radish leaves.

Cauliflower

The use of difenoconazole on cauliflower is registered in the United States for ground or air application or chemigation. The Meeting determined that the critical GAP consists of four applications at 128 g a.i./ha with a spray interval of 7 days and a PHI of 7 days.

The Meeting could not estimate a maximum residue level for cauliflower since no data were available.

Brussels sprouts

The use of difenoconazole on brussels sprouts, is registered in the United States for ground or air application or chemigation. The Meeting determined that the critical GAP consists of four applications at 128 g a.i./ha with a spray interval of 7 days and a PHI of 7 days.

The Meeting could not estimate a maximum residue level for brussels sprouts since no data were available.

Green onions and chives

The use of difenoconazole on green onions and chives is registered in the United States for ground or air application or chemigation. The Meeting determined that the critical GAP consists of three applications at 128 g a.i./ha with a spray interval of 7 days and a PHI of 7 days.

Three supervised trials on spring onions conducted in the United States matching the cGAP were provided. In the whole plant, residues for difenoconazole were (n=3): 2.25, 2.80, 3.75 (highest individual value 4.9) mg/kg.

The trials for spring onion in the United States were insufficient to estimate a maximum residue level, since a minimum of four trials are needed for green onions and chives. The Meeting could not estimate a maximum residue level for green onions (VA 2032) and chives (VA 2605).

Radish roots

The use of difenoconazole on radish is registered in the United States for ground or air application or chemigation. The Meeting determined that the critical GAP consists of four applications at 128 g a.i./ha with a spray interval of 7 days and a PHI of 7 days.

Five supervised trials on radish conducted in the United States matching the cGAP were provided. In the roots, residues for difenoconazole were (n=5): 0.025, 0.038, 0.17, 0.230, 0.29 (highest individual value 0.31) mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg, an STMR of 0.17 mg/kg and a HR of 0.31 mg/kg for radish roots (VR 0494).

Potato and sweet potato

The use of difenoconazole on potatoes and sweet potato is registered in the United States as post-harvest spray. The Meeting determined that the critical GAP consists of one application at 3.3 g a.i./tonne of tuber and a PHI of 0 days.

Five supervised trials on potatoes conducted in the United States matching the cGAP were provided. In tubers, residues for difenoconazole were (n=5): 0.61, 0.87, 1.2, 1.3, 1.9 (highest individual value 1.9) mg/kg.

The above residue data were already assessed in the 2013 JMPR and set an MRL of 4 mg/kg in potatoes. The Meeting confirmed its previous recommendations on potatoes and recommends extrapolating the estimates to sweet potatoes.

The Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 1.2 mg/kg and a HR of 1.9 mg/kg for sweet potato (VR 0508).

Maize cereals, subgroup

The use of difenoconazole on maize, popcorn and teosinte is registered in the United States for foliar application. The Meeting determined that the critical GAP consists of three applications at 126 g a.i. /ha with a spray interval of 7 days and a PHI of 30 days.

Twenty-four supervised trials on maize conducted in the United States matching the cGAP were provided. In the grain residues for difenoconazole were (n=24): 22 x <0.01, 0.011, 0.014 mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg and an STMR of 0.01 mg/kg for maize grain (GC 064). The Meeting recommends extrapolating the estimates to the subgroup of maize cereals (GC 2091).

Animal feed

Maize forage

The use of difenoconazole on maize is registered in the United States for foliar application. The Meeting determined that the critical GAP consists of three applications at 126 g a.i. /ha with a spray interval of 7 days and a PHI of 7 days.

Twenty-four supervised trials on maize conducted in the United States matching the cGAP were provided. In the maize forage residues for difenoconazole were (n=20): 0.29, 0.40, 0.41, 0.46, 0.50, 0.55, 0.57, 0.57, 0.57, 0.67, 0.68, 0.95, 0.97, 1.04, 1.1, 1.2, 1.2, 1.3, 1.4, 2.6 mg/kg.

The Meeting estimated a median residue of 0.68 mg/kg and a highest residue of 2.6 mg/kg for maize forage (AF 0645).

Maize, hay and/or straw (83 percent dry matter)

The use of difenoconazole on maize is registered in the United States for foliar application. The Meeting determined that the critical GAP consists of three applications at 126 g a.i. /ha with a spray interval of 7 days and a PHI of 30 days.

Twenty-four supervised trials on maize conducted in the United States matching the cGAP were provided. In maize fodder residues for difenoconazole were (n=24): 0.6, 0.97, 1.26, 1.38, 1.5, 2x 1.6, 1.9, 2.1, 2.2, 2.3, 2.3, 2.5, 2.5, 2.7, 3.0, 3.2, 3.5, 3.7, 3.7, 3.9, 6.2, 7.5, 8.5 mg/kg (as received).

The Meeting estimated a maximum residue level of 15 mg/kg (dw, based on 83 percent DM content), a median (as received) of 2.4 mg/kg and a highest (as received) of 8.5 mg/kg for maize, hay and/or straw (AS 0645).

Fate of residues during processing

The Meeting received new processing studies on plums, maize and potatoes. Processed commodities from plums (prunes), maize (aspirated grain fractions, milled by-products, dry-milled meal, dry-milled flour, dry-milled grits, dry-milled bran (hulls), dry-milled germ, dry-milled refined oil, wet-milled starch (dried), wet-milled gluten (wet), wet-milled gluten meal (dried), wet-milled germ, wet-milled refined oil, and wet-milled flour (masa dried).) and potatoes (washed, scrubbed tubers, French fries) were derived using simulated commercial practices. Processing factors and residue estimates are summarized below.

Processing factors, STMR-Ps and HR-Ps for difenoconazole used for dietary risk assessment and livestock dietary burden calculation

Raw commodity	Processed commodity	Code	Individual	Median or best estimate processing factor	STMR RAC (mg/kg)	STMR-P (mg/kg)	HR RAC (mg/kg)	HR-P (mg/kg)	MRL
Plums	Prunes	FS 0014	1.9, 2.7, 2.9, 2.7	2.55	0.37	0.94	1.02	2.6	4
Maize	Aspirated grain fraction (AGF)	CF 3516	22.02, 77.18	49.6	<0.01	<0.50	-	-	-
	Dry-milled refined oil	OC 0645	0.88, 0.57	0.73	<0.01	0.007	-	-	-
	Maize, bran	AS 3569	2.70, 3.6	3.2	<0.01	0.032	-	-	0.05
	Maize, flour	CF 1255	0.68, 0.85	0.77	<0.01	0.008	-	-	0.015
	Maize, meal (dry)	CF 0645	0.63, 0.57	0.60	<0.01	0.006	-	-	-
	Wet-milled flour (masa dried)		0.49, 0.57	0.53	<0.01	0.005	-	-	-
	Wet-milled gluten meal (dried)	CF 3517	3.39, 2.82	3.1	<0.01	0.031	-	-	0.05
	Wet-milled refined oil		1.00, 1.37	1.2	<0.01	0.012	-	-	0.02
Potato (extrapolate to sweet potatoes)	Washed, scrubbed tubers	-	0.67	0.67	1.2	0.80	1.9	1.27	-
	French fries	-	0.3	0.3	1.2	0.36	1.9	0.57	-

Residues in animal commodities

Farm animal feeding studies

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

Of the uses considered by the Meeting, only maize fodder, maize forage and radish roots are significant animal feed items.

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the Meeting. The dietary burdens, estimated using the most recent version of the OECD livestock dietary burden calculator, are presented in Annex 6 and summarised below. In the 2016 JMPR the calculations were made according to the animal diets listed in appendix IX of the 2016 edition of the FAO manual.

The Meeting noted a GAP for maize is not registered in Australia and maize forage is not exported from the United States (registered GAP received in the current Meeting) to Australia.

Therefore, refined calculations were preformed excluding maize forage, hay and straw from the Australian dietary burden.

Results of the estimated maximum and mean dietary burdens are summarized in the table below.

Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: parent ppm of dry matter diet							
	US-Canada		**EU**		**Australia**		**Japan**	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	14.5	12.3	18.5 [a]	15.3 [b]	16.2	10.46	6.3	1.5
Dairy cattle	12.5	6.4	15.7	12.3	12.8	10.6	4.5	1.1
Poultry – broiler	0.34	0.34	1.04	0.69	0.8	0.8	0.044	0.044
Poultry –layer	0.4	0.34	1.2 [c,d]	0.74	0.8	0.8	0.17	0.17

[a] Suitable for estimation of maximum residue levels in meat and milk
[b] Suitable for estimation of median residue levels in meat and milk
[c] Suitable for estimation of maximum residue levels in poultry meat
[d] Suitable for estimation of median residue levels in poultry meat and eggs
[e] Suitable for estimation of maximum residue levels in eggs

The difenoconazole dietary burden reached a maximum level of 18.5 ppm of dry matter diet in beef cattle, 15.7 ppm diet in dairy cattle and 1.2 mg/kg diet in poultry. The mean dietary burdens were 15.3 mg/kg in beef cattle, 12.3 mg/kg diet in dairy cattle and 0.8 mg/kg in poultry.

A comparison of the current livestock dietary burden calculations with the previous ones from the 2013 and 2021 JMPR is presented in the table below.

Dietary burden (ppm) comparison from the 2013, 2021 JMPR and the current Meeting

JMPR evaluation	**Beef and dairy cattle**		**Poultry (broiler and layer)**	
	mean	**max**	**mean**	**max**
Current (refined) [a]	15.3	18.5	0.8	1.2
2021	15.0	17.9	0.80	1.11
2013	15.3	17.9	1.11	1.89

[a] without maize commodities for Australian diet

For ruminants and poultry, as the dietary burdens were essentially unchanged compared to those from the previous Meeting, the Meeting confirmed its previous recommendations for residues in animal commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessment.

The definition of the residue for compliance with MRL and for dietary intake for plant commodities is *parent difenoconazole*, while for animal commodities it is defined as *sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol (CGA205375), expressed as difenoconazole*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for difenoconazole is 0–0.01 mg/kg bw. The IEDIs for spiromesifen were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 10 to 100 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of difenoconazole from uses considered by the JMPR is unlikely to present a public health concern.

Short-term dietary exposure

The 2007 JMPR established an ARfD of 0.3 mg/kg bw. The IESTIs for difenoconazole 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 of the 2023 JMPR Report. The IESTIs varied from 0 to 100 percent of the ARfD for children and from 0 to 40 percent for the general population.

The Meeting concluded that the acute dietary exposure to residues of difenoconazole from other uses that have been considered by the present Meeting is unlikely to present a public health concern.

5.12 Diflubenzuron (130) (R)

RESIDUE AND ANALYTICAL ASPECTS

Diflubenzuron is a benzoylurea insect growth regulator (inhibiting chitin synthesis), used in agriculture, horticulture, forestry and public health applications. It was first evaluated by JMPR in 1981 and re-evaluated under the periodic review programme by the 2001 JMPR (toxicology) and the 2002 JMPR (residues), with additional uses evaluated by the 2011 JMPR.

FAO specifications for diflubenzuron (technical material and related formulations) were published in 2020.

The 2001 JMPR established an ADI of 0–0.02 mg/kg bw and agreed that an ARfD was unnecessary and the 2002 JMPR established the following residue definition:

> For compliance with the MRL and for estimation of dietary intake for plant and animal commodities: *diflubenzuron*.
>
> The residue is fat-soluble.

Diflubenzuron was scheduled at the fifty-second Session of the CCPR for new uses by the 2023 JMPR. The Meeting received information on residue analytical methods, residue stability in stored analytical samples, GAP information and supervised residue trials on tea.

Methods of analysis

The Meeting received a description and validation data for method HP-2001-CLFF, an LC-MS/MS method for measuring residues of diflubenzuron in fresh and dried tea leaves and in tea infusions.

In this method, residues of diflubenzuron were extracted from tea samples with acidified (1 percent formic acid) acetonitrile and distilled water. After the addition of sodium chloride and magnesium sulfate and centrifugation, an aliquot of upper layer was transferred to a centrifuge tube containing C18, graphetized carbon black (GCB) and anhydrous MgSO4. After dispersive solid-phase extraction, the purified extracts were filtered and residues of diflubenzuron were determined by LC-MS/MS.

Conclusions

The Meeting concluded that the analytical method (HP-2001-CLFF) used in the supervised trials and processing studies submitted to this Meeting were suitable for measuring residues of diflubenzuron, with LOQs of 0.01 mg/kg for green and black tea, 0.004 mg/kg for fresh leaves and 0.0002 mg/L for tea infusions.

Stability of residues in frozen stored analytical samples

The Meeting received the results of a study on the stability of diflubenzuron residues in frozen analytical samples of fresh tea leaves, green and black tea and their infusions.

Diflubenzuron residues were stable for at least 9 months in stored frozen samples of fresh tea leaves, green tea and black tea. The longest sample storage interval in the supervised field trials was 4.4 months.

Results of supervised residue trials on crops

Supervised trials were available for the use of diflubenzuron on tea and GAP information was available from China.

Teas

Subgroup of tea, black, green, dried and fermented

The critical GAP for diflubenzuron on tea in China is for a single foliar application of 13 g ai/hL with a PHI of 5 days.

In eight independent field trials conducted on tea in China and matching this GAP, diflubenzuron residues in green tea (dried) were: 2.7, 6.0, 6.7, 8.4, 9.3, 14, 15 and 17 mg/kg (n=8).

In these same trials, diflubenzuron residues in black tea (dried and fermented), were: 2.7, 6.8, 7.2, 8.6, 9.5, 13, 14 and 23.5 mg/kg (n=8).

The Meeting noted that these datasets were from the same trial sites, and agreed to use the highest values from each trial to estimate a maximum residue level for green and black tea.

The selected dataset of diflubenzuron residues in green tea (dried) and black tea (dried, fermented) is: 2.7, 7.2, 8.6, 9.3, 9.5, 14, 15 and 23.5 mg/kg (n=8).

The Meeting estimated a diflubenzuron maximum residue level of 40 mg/kg and an STMR of 9.4 mg/kg for the subgroup of tea, black, green, dried and fermented (DT 1114).

Fate of residues during processing

Residues in processed commodities

The current Meeting received information on the transfer of residues from green and black tea into tea infusions.

Tea infusions were prepared according to the Methodology for Sensory Evaluation of Tea (GB/T 23776-2018). Boiling water (100 mL) was added to 2 g green or black tea in a tasting cup and the brew was allowed to stand for four minutes before filtering and sampling (first infusions). A further 100 mL boiling water were added to the drained leaves and after standing for four minutes the second infusions were filtered and sampled. This procedure was repeated once more to obtain the third infusions.

Residues did not concentrate in tea infusions and therefore no maximum residue level was estimated for tea infusions. The Meeting agreed to use the residue results from the first infusions to estimate processing factors for tea infusions.

For risk assessment, an STMR-P was calculated using the STMR for the raw commodites (green tea and black tea) and applying the calculated mean processing factors for tea infusions.

Calculated diflubenzuron STMR-Ps for tea infusions

RAC	Processing factors		Diflubenzuron residue (mg/kg)	
	Calculated Processing factors(1)	Best Estimate	STMR-P (mg/kg)	HR-P (mg/kg)
Tea, Black, Green			STMR=9.4	-
Green tea infusions	0.0024, 0.0032, 0.0035	0.004	0.038	-
Black tea infusions	0.0044, 0.0046, 0.0047			

(1) The mean ratios of the residue in the tea infusions divided by the residue in the Raw Agricultural Commodity (dried leaves). A correction factor of 0.02 was used to convert reported residues (expressed on a dry leaf basis) to concentrations in the infusions.

Residues in animal commodities

Since tea is not a livestock commodity, the Meeting agreed that the MRLs and STMRs for cattle and poultry commodities need not be re-estimated.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for International Estimated Daily Intakes (IEDIs) assessments.

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

Definition of the residue for dietary risk assessment for plant and animal commodities: *diflubenzuron.*

The residue is fat-soluble.ch

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for diflubenzuron is 0–0.02 mg/kg bw. The IEDIs for diflubenzuron were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 3 to 20 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of diflubenzuron from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

An ARfD for diflubenzuron is not considered necessary and no International Estimate of Short Term Intake (IESTI) was calculated.

5.13 Dinotefuran (255) (R)

RESIDUE AND ANALYTICAL ASPECTS

Dinotefuran was first evaluated by the JMPR in 2012 when an ADI of 0–0.2 mg/kg bw and an ARfD of 1 mg/kg bw were established.

The definition of the residue for plants for compliance with the MRL is *dinotefuran* and for dietary intake is *the sum of dinotefuran, 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF), and 1-methyl-3-(tetrahydro-3-furylmethyl) guanidiumdihydrogen (DN), expressed as dinotefuran.* The definition of the residue for animals for compliance with the MRL and dietary intake is *the sum of dinotefuran and UF, expressed as dinotefuran.*

The residue is not fat-soluble.

Dinotefuran was scheduled at the fifty-second Session of the CCPR for the evaluation of additional MRLs at the 2023 JMPR. The current Meeting received additional information on analytical methods, storage stability, GAP, and magnitude of the residues to support the use on goji berries.

Methods of analysis

The Meeting received additional information on analytical methods for dinotefuran in fresh and dried goji berry.

Dried goji berries were allowed to soak in water. Residues were then extracted with formic acid/acetonitrile (5/95; v/v) and QuEChERS extraction salts (4 g of anhydrous magnesium sulphate (MgSO4), 1 g of sodium chloride (NaCl), 1 g of sodium citrate (C6H9Na3O9), and 0.5 g sodium citrate dibasic sesquihydrate). Extracts were purified by dispersive solid-phase extraction. Dinotefuran, UF, and DN were quantified from the purified extract by UPLC-MS/MS.

Recoveries and percent RSDs were within the acceptable range. The LOQ was 0.01 mg/kg for dinotefuran, UF, and DN in fresh and dried goji berry.

The Meeting concluded that the presented method was sufficiently validated and is suitable to measure dinotefuran in fresh and dried goji berry.

Stability of pesticides in stored analytical samples

The current Meeting received additional information on freezer storage stability of dinotefuran in fresh and dried goji berry.

Residues of dinotefuran, UF, and DN were stable for at least 91 days in fresh goji berry and at least 84 days in dried goji berry when stored frozen at ≤-18 °C.

The Meeting concluded that the storage stability data were sufficiently validated and are adequate to support the storage durations in the studies submitted to the current Meeting.

Results of supervised residue trials on crops

Goji berry

The 2012 Meeting established a maximum residue level of 0.5 mg/kg for dinotefuran in fruiting vegetables other than cucurbits except sweet corn and mushrooms, which includes goji berry. This maximum residue level is based on tomato and pepper residue data following two foliar-directed applications at 0.20 kg ai/ha and a 1-day pre-harvest interval (PHI).

The 2023 Meeting received data for a foliar-directed use of dinotefuran on goji berry in China. The Meeting determined that the cGAP consists of one treatment at a target application concentration of 0.0050 kg ai/hL with a PHI of 5 days.

In independent trials in China matching the cGAP, residues of dinotefuran in goji berries were (n=5): 0.018, 0.028, 0.099, 0.12, and 0.28 mg/kg.

In independent trials in China matching the cGAP, residues of the sum of dinotefuran, UF, and DN (expressed as dinotefuran) in goji berries were (n=5): 0.038, 0.055, 0.12, 0.14, and 0.32 mg eq/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg for dinotefuran in goji berry.

The Meeting estimated an STMR of 0.12 mg eq/kg and a HR of 0.34 mg eq/kg (from a single sample) for dinotefuran in goji berry.

Meeting withdrew its previous recommendation of 0.5 mg/kg for dinotefuran in fruiting vegetables other than cucurbits except sweet corn and mushrooms and recommended a new maximum residue level of 0.5 mg/kg for dinotefuran in fruiting vegetables other than cucurbits except goji berry.

Goji berry, dried

Samples from all goji berry trials were sun dried and hot air dried. The higher of the two values from each trial was chosen for the summary below.

In independent trials in China matching the cGAP, residues of dinotefuran in dried goji berries were (n=5): 0.038, 0.14, 0.20, 0.78, and 0.90 mg/kg.

In independent trials in China matching the cGAP, residues of the sum of dinotefuran, UF, and DN (expressed as dinotefuran) in dried goji berries were (n=5): 0.061, 0.22, 0.26, 0.80, and 1.1 mg eq/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for dinotefuran in goji berry, dried.

The Meeting estimated an STMR of 0.26 mg eq/kg and an HR of 1.1 mg eq/kg (from a

single sample) for the sum of dinotefuran, UF, and DN in goji berry, dried.

Fate of residues during processing

The Meeting calculated processing factors for goji berry, dried. These factors were not used for maximum residue level, STMR, or HR determination as there are sufficient data for dried goji berry at the cGAP to derive a maximum residue level, STMR, and HR directly from the submitted data.

Estimated processing factors for dried goji berry

Analyte (mg eq/kg)	Processed Commodity	Processing Factor	Median Processing Factor
Dinotefuran	Dried goji berry	1.6, 2.1, 2.2, 2.8, 2.9, 3.0, 3.2, 5.0, 7.9, 11.7,	3.0
Dinotefuran, UF, and DN (expressed as dinotefuran)	Dried goji berry	1.2, 1.6, 2.5 (2), 3.1, 3.4, 3.6, 4.7, >4.7, 6.7	3.3

Residues in animal commodities

No animal feeds are associated with the uses considered by the current Meeting. The Meeting confirmed its previous recommendations.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

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

Definition of the residue for dietary risk assessment for plant commodities: *sum of dinotefuran, UF, and DN, expressed as dinotefuran.*

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of dinotefuran and UF, expressed as dinotefuran.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for dinotefuran is 0–0.2 mg/kg bw. The IEDIs for dinotefuran were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the previous and present JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 0 to 1 percent of the maximum ADI.

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

Short-term dietary exposure

The ARfD for dinotefuran is 1 mg/kg bw. The IESTIs for dinotefuran were calculated for the food commodities for which STMRs or HRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs were less than 1 percent of the ARfD for children the general population.

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

5.14 - Emamectin benzoate (247) (T)

TOXICOLOGY

Emamectin benzoate is the ISO-approved name for (4''*R*)-4''-deoxy-4''-(methylamino)avermectin B1 benzoate, with the Chemical Abstracts Service number 155569-91-8. It is a macrocyclic lactone insecticide belonging to the avermectin group. It is a mixture of at least 90 percent (4''*R*)-4''-deoxy-4''-(methylamino)avermectin B1a benzoate, and at most 10 percent (4''*R*)-4''-deoxy-4''-(methylamino)avermectin B1b benzoate, both as their salts. Emamectin is structurally similar to abamectin and ivermectin. Emamectin was originally developed as the hydrochloride salt MK 243 (L-656, 748-010V), but the commercial product was subsequently changed to the benzoate salt MK 244 (L-656, 748-038W) and benzoate hydrate (L-656, 748-052S) because of their improved storage and handling characteristics.

Emamectin was previously evaluated by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 2011 when an ADI for emamectin benzoate of 0–0.000 5 mg/kg body weight (bw) and an ARfD of 0.03 mg/kg bw were established. Emamectin benzoate was evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2013. The committee confirmed the health-based guidance values (HBGVs) established by JMPR in 2011. The 2014 JMPR Meeting withdrew the ARfD of 0.03 mg/kg bw and established a new ARfD of 0.02 mg/kg bw. Emamectin was evaluated by the present Meeting within the programme of follow-up evaluations after a spontaneous submission of data on the parent compound and its photodegradation metabolites, due to a request for additional information on analytical methodology, storage stability and MRLs. The present Meeting evaluated all newly provided studies. Detailed evaluation of studies is in the monograph addendum that has been prepared. The results of these studies did not affect the previously established ADI or ARfD for emamectin benzoate.

Studies were performed with emamectin benzoate, unless stated otherwise. All studies were conducted according to internationally recognized guidelines (generally Organisation for Economic Co-operation and Development, OECD), and followed good laboratory practice (GLP) or were otherwise quality audited; if not this is indicated.

Toxicological data on metabolites and/or degradates

A number of photodegradation metabolites of emamectin benzoate had been tested for acute toxicity in CD-1 mice to determine an oral median lethal dose (LD_{50}) in a microbial mutagenesis assay, and in a 15-day dietary study in CF-1 mice or a neurotoxicity study in dogs. The CF-1 mice used in the neurotoxicity studies lack the expression of mdr1a P-glycoprotein and are therefore not an appropriate model for human risk assessment with avermectins.

Summary of toxicological characterization of photodegradation products/metabolites of emamectin benzoate

Compound, codes and structure	**Major rat metabolite** (>10% AD)	**Genotoxicity assessment** (data, QSAR, read-across)	**General toxicity**	**Toxicological reference values**
Emamectin benzoate	Parent	Data Not genotoxic	Full dataset	ADI: 0– 0.000 5 mg/kg bw ARfD: 0.02 mg/kg bw
L-657,831 (4"-*epi*-(*N*-formyl)-amino-4"-deoxy-avermectin B; FAB1a)	No	Ames: negative	LD_{50}: 66 mg/kg bw	Parent ADI and ARfD
L-653,649 (4"-*epi*-amino avermectin; AB1a)	No	Ames: negative	LD_{50}: 100 mg/kg bw 15-day neurotox study comparative (including emamectin) study (dog) LOAEL: 1.5 mg/kg bw per day, (only one dose tested); Displayed effects were similar to emamectin	Parent ADI and ARfD
L-695,638 (8,9-Z-4"-*epi*-methylamino-avermectin B1a benzoate salt; 8,9-Z MAB1a; NOA438376)	No	Ames: negative	LD_{50}: >200 mg/kg bw	Parent ADI and ARfD
L-660,599 (4"-*epi*-(*N*-formyl-*N*-methyl)-amino-4"-deoxy-avermectin B1; MFB1a)	No	Ames: negative	LD_{50}: 31 mg/kg bw	Parent ADI and ARfD

QSAR: Quantitative structure–activity relationship; AD: Administered dose; ADI: Acceptable daily intake; ARfD; Acute reference dose

The Meeting concluded that for the photodegradation metabolites L-657,831, L-695,638, L-660,599 and L-653,649, the ADI and the ARfD of the parent compound should be used as the relevant values. In the case the ADI, this is lower than the Cramer class III threshold of 1.5 µg/kg bw per day. Currently it is unknown whether the photodegradation metabolites occur as residues in commodities.

Toxicological evaluation

In 2011 the Meeting established an ADI of 0–0.000 5 mg/kg bw for emamectin benzoate based on the one-year and two-year rat studies, and an overall NOAEL for 14-week and 53-week toxicity studies in dogs, applying a safety factor of 100 and an additional safety factor of five based on steep dose–response curves and irreversible histopathological effects in neural tissue at the LOAEL. The current Meeting concluded that the parent ADI applies also to metabolites L-657,831, L-695,638, L-660,599 and L-653,649, should they be found in food commodities.

In 2014 the Meeting established an ARfD of 0.02 mg/kg bw, on the basis of the five-week and 14-week dog studies, and applying a safety factor of 100. The current Meeting concluded that the parent ARfD applies also to metabolites L-657,831, L-695,638, L-660,599 and L-653,649, should they be found in food commodities.

An addendum to the toxicological monograph was prepared.

The acceptable daily intake (ADI) for emamectin, established by JMPR in 2011

0–0.000 5 mg/kg bw*

The acute reference dose (ARfD) for emamectin, established by the JMPR in 2014

0.02 mg/kg bw*

* Applies to emamectin benzoate, and if necessary will apply to metabolites L-657,831, L-695,638, L-660,599 and L-653,649

Summary

	Value	Study	Safety factor
ADI	0–0.000 5 mg/kg bw [a]	One-year and 2-year rat studies and 14- and 53-week toxicity studies in dogs	500[b]
ARfD	0.02 mg/kg bw [a]	Five-week and 14-week studies in dogs	100

[a] Applies to emamectin benzoate and will apply to L-657,831, L-695,638, L-660,599 and L-653,649, if necessary

[b] An additional safety factor of five was applied to the standard safety factor of 100 based on the steep dose–response curves and irreversible histopathological effects in neural tissue at the LOAEL

5.15 Florylpicoxamid (332) (T,R)*

TOXICOLOGY

Florylpicoxamid is the ISO-approved common name for (2*S*)-1,1-*bis*(4-fluorophenyl)propan-2-yl-*N*-{[3-(acetyloxy)-4-methoxypyridin-2-yl]carbonyl}-*L*-alaninate, with the Chemical Abstracts Service number 1961312-55-9. Florylpicoxamid is a picolinamid fungicide the mode of action of which is a quinone inside inhibitor (respiration inhibitor at the cytochrome bc1 complex).

Florylpicoxamid has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR).

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified. No additional information from a literature search was identified that complemented the toxicological information submitted for the current assessment.

Biochemical aspects

When radiolabelled florylpicoxamid was administered orally to mice, rats or rabbits, radioactivity was rapidly absorbed. For a single dose of [*pyridinyl-2*-^{14}C]florylpicoxamid at 100 mg/kg bw, the maximum plasma concentration (C_{max}) occurred 2–3 hours after administration in rats and 0.5 hours in rabbits. In mice, the blood C_{max} occurred between 30 minutes and six hours after dosing. Alpha and beta plasma/blood elimination half-lives ($t½$) for radiolabelled florylpicoxamid were 3–12 and 22–44 hours respectively, with no significant differences in $t½$ when positions of radiolabel or different species were compared. Radiolabelled metabolite X12485649, the first metabolite of florylpicoxamid formed by deacetylation, showed a similar toxicokinetic profile to the parent when administered to rats. Florylpicoxamid was highly metabolized and quickly eliminated in all species.

Following oral administration of [*pyridinyl-2*-^{14}C]florylpicoxamid at 100 mg/kg bw, total urinary elimination over 168 hours accounted for 19–22 percent, 18–33 percent and 75 percent of administered dose (AD) in mice, rats and rabbits respectively. Faecal elimination of [*pyridinyl-2*-^{14}C]florylpicoxamid accounted for 61–82 percent, 69 –73 percent and 17 percent of AD in rats, mice and rabbits respectively. Biliary elimination in bile duct-cannulated rats treated with 25 or 250 mg/kg bw of [*pyridinyl-2*-^{14}C]florylpicoxamid or [*phenyl-UL*-^{14}C]florylpicoxamid, was up to 21 percent of AD. Absorption rates in mice, rats and rabbits were approximately 21 percent, 34 percent and 77 percent respectively.

When radiolabelled florylpicoxamid was administered orally to rats, values for C_{max} and the area under the concentration–time curve (AUC) in plasma were approximately 2- to 3-fold (for the C_{max}) and 5-fold to 6-fold (for the AUC) greater at 250 mg/kg bw than at 25 mg/kg bw. The results indicate saturation of absorption with increasing dose from 25 to 250 mg/kg.

Tissue distribution of florylpicoxamid was widespread, but levels in tissues were low.

Tissue:plasma ratios indicated very low potential for accumulation. The highest tissue:plasma ratios were in the gastrointestinal tract and liver. Female rats tended to have lower retained tissue levels than did males.

Up to five metabolites were identified in rat urine. The most abundant identified urinary metabolite in all species was X12485473 after administration of radiolabelled florylpicoxamid or X12485649. The overall metabolism was consistent with hydrolysis, hydroxylation, and glucuronide conjugation reactions.

The in vitro metabolism of radiolabelled florylpicoxamid was compared in human, rat, mouse, dog, and rabbit hepatocytes, and in another study in liver microsomes from mouse, rat, rabbit, dog, and human donors. No unique human metabolites were identified in the hepatocyte samples when compared to the rat, mouse, dog and rabbit preparations. Chiral analysis was carried out to investigate possible interconversion of stereoisomeric florylpicoxamid and the florylpicoxamid metabolite X12485649 (deacetylated) and their isomers; no interconversion of stereoisomers was observed.

The key initial metabolic step in the metabolism of florylpicoxamid involved deacetylation to give X12485649. Subsequent reactions involved, aromatic oxidation, aliphatic and aromatic hydroxylation, ester bridge formation and amide cleavage, O-demethylation, and phase II glucuronide conjugation. Metabolites identified in bile and plasma were generally consistent with those previously identified in faeces and urine, and confirmed the role of first-pass hepatic metabolism contributing to biliary elimination and systemic uptake as key processes in the extensive metabolism and elimination of florylpicoxamid.

Toxicokinetic evaluation of florylpicoxamid associated with continuous daily dietary intake indicated rapid absorption, hydrolysis of parent florylpicaxamid to X12485649 and further metabolism to X12485473 and X12641325. Quantitation of X12485473 and X12641325 in blood, urine, and/or milk confirmed these analytes were the major metabolites in animals exposed to florypicoxamid. Blood analysis as part of reproductive and development toxicity studies indicated no apparent direct transfer of florylpicoxamid or its metabolites (X12485649, X12584261, and X12530093) from dams to fetuses via the blood.

Toxicological data

The acute oral median lethal dose (LD_{50}) for florylpicoxamid in rats was greater than 2000 mg/kg bw and the dermal LD_{50} was greater than 2000 mg/kg bw. The inhalation median lethal concentration (LC_{50}) for florylpicoxamid was greater than 5.48 mg/L. Florylpicoxamid was not irritating to the skin, but produced a slightly irritating effect on rabbit eyes. Florylpicoxamid was shown not to be sensitizing in a local lymph node assay (LLNA) test in mice.

In repeat-dose oral toxicity studies with florylpicoxamid in mice, rats and dogs the main targets of toxicity were decreased food consumption, body weight and body weight gain. Florylpicoxamid showed CAR/PXR activation leading to liver hypertrophy.

In a 13-week dietary toxicity study in which mice were given florylpicoxamid at dietary concentrations of 0, 150, 500 or 1500 ppm (equal to 0, 19.1, 59.7 and 192 mg/kg bw per day for males, 0, 21.9, 68.3 and 201 mg/kg bw per day for females), the NOAEL was 500 ppm (equal to 59.7 mg/kg bw per day) based on slight decreases in body weight, body weight gain and food consumption in females at 1500 ppm (equal to 201 mg/kg bw per day).

In a 28-day dietary toxicity study in which rats were given florylpicoxamid at dietary concentrations of 0, 300, 1000 or 3000 ppm (equal to 0, 24.9, 84.0 and 230 mg/kg bw per day for males, 0, 26.1, 85.2 and 243 mg/kg per day for females), the NOAEL was 1000 ppm (equal to 84.0 mg/kg bw per day) based on decreases in food consumption, suppressed body weight gains and effects on haematological parameters in males at 3000 ppm (equal to 230 mg/kg bw per day).

In a separate 28-day dietary toxicity study florylpicoxamid was administered to a different strain of rats from the first study, at dietary concentrations of 0, 1000, 3000, 4000 or 5000 ppm (equal to 0, 69.9, 206, 278 and 345 mg/kg bw per day for males, 0, 75.8, 247, 320 and 355 mg/kg bw per day for females) The NOAEL was 3000 ppm (equal to 206 mg/kg bw per day) based on marginal hepatocellular hypertrophy and thyroid follicular cell hypertrophy in males at 4000 ppm (equal to 278 mg/kg bw per day).

In a 13-week dietary toxicity study rats were given florylpicoxamid at dietary concentrations of 0, 300, 1000 or 3000 ppm (equal to 0, 18.2, 59.4 and 177 mg/kg bw per day for males, 0, 18.8, 63.0 and 185 mg/kg bw per day for females). The NOAEL was 1000 ppm (equal to 59.4 mg/kg bw per day) based on slight decreases in body weight and suppressed body weight gain, and lowered haematological parameters in males at 3000 ppm (equal to 177 mg/kg bw per day). Florylpicoxamid induced metabolic enzymes in the liver in both sexes via CAR/PXR.

In a 90-day oral toxicity study dogs were administered florylpicoxamid in capsules at doses of 0, 60, 150 or 400 mg/kg bw per day. The NOAEL was 60 mg/kg bw per day based on lower body weights, decreased body weight gains and decreased food consumption in males at 150 mg/kg bw per day.

In an 18-month carcinogenicity study in mice, florylpicoxamid was given to mice at dietary concentrations of 0, 150, 500 or 1500 ppm (equal to 0, 16.4, 55.3 and 172 mg/kg per day for males, 0, 20.4, 72.2 and 230 mg/kg bw per day, but only 45 weeks at this highest dose for females). All female mice receiving 1500 ppm were euthanized at 46 weeks due to high mortality. No further investigation was conducted with this group. The NOAEL for chronic toxicity in mice was 500 ppm (equal to 55.3 mg/kg bw per day) based on lower body weight in males at 1500 ppm (equal to 172 mg/kg bw per day). The NOAEL for carcinogenicity in male mice was 1500 ppm (equal to 172 mg/kg bw per day), the highest dose tested. In females, the high dose of 1500 ppm caused excess mortality that prevented proper evaluation of carcinogenicity. No increased cancer incidence was found at 500 ppm (equal to 72.2 mg/kg bw per day).

In a 2-year combined toxicity and carcinogenicity study in rats, florylpicoxamid was administered at dietary concentrations for males of 0, 300, 1000 or 3000 ppm (equal to 0, 11.9, 39.7 and 123 mg/kg bw per day), and for females of 0, 300, 1000 or 4000 ppm (equal to 0, 14.0, 46.9 and 200 mg/kg bw per day). The NOAEL for chronic toxicity was 1000 ppm (equal to 46.9 mg/kg bw per day) based on low body weight in females at 4000 ppm (equal to 200 mg/kg bw per day). The NOAEL for carcinogenicity was 3000 ppm (equal to 123 mg/kg bw per day), the highest dose tested.

The meeting concluded that florylpicoxamid is not carcinogenic in male mice or rats.

Florylpicoxamid was tested for genotoxicity in an adequate range of studies. No evidence of genotoxicity was found.

The Meeting concluded that florylpicoxamid is unlikely to be genotoxic.

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

In a two-generation reproductive toxicity study, rats were administrated florylpicoxamid at dietary concentrations of 0, 300, 1000 and 3000 ppm (males only) or a top dose of 4000 ppm in the case of females. Corresponding time-weighted average doses of florylpicoxamid were 0, 17.5, 58.4 or 179 mg/kg bw per day for males of the first-generation parents (F0), and 0, 19.3, 65.3 and 255 mg/kg bw per day during gestation. The NOAEL for parental toxicity was 1000 ppm (equal to 58.4 mg/kg bw per day) based on lowered body weight in males at 3000 ppm (equal to 179 mg/kg bw per day) in the F0 and F1 adult males. The NOAEL for reproductive toxicity (based on males only) was 3000 ppm (equal to 179 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 1000 ppm (equal to 58.4 mg/kg bw per day) based on decreased body weight and decreases in red blood cell parameters in male and female F2 weanlings at 3000 ppm (equal to 179 mg/kg bw per day).

In a rat developmental study, florylpicoxamid was given to rats at dietary levels of 0, 300, 1000, or 4000 ppm (equal to 0, 21.3, 73.1 and 271 mg/kg bw per day), from gestation day (GD) 6 to GD 21. The NOAEL for maternal toxicity was 1000 ppm (equal to 73.1 mg/kg bw per day), based on decreases in body weight and food consumption at 4000 ppm (equal to 271 mg/kg bw per day). The NOAEL for embryo/fetal toxicity was 4000 ppm (equal to 271 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study, female rabbits were given florylpicoxamid at dietary concentrations of 0, 125, 250 or 750 ppm (equal to 0, 4.73, 9.58 and 25.9 mg/kg bw per day) from GD 7 to GD 28. The Meeting considered the incidence of crooked hyoid which occurred at a frequency slightly above the historical control data not to be adverse because it is known that eventually the bones ossify and the angulation resolves after the birth. The NOAEL for maternal toxicity was 250 ppm (equal to 9.58 mg/kg bw per day) based on abortions. The NOAEL for embryo/fetal toxicity was 750 ppm (equal to 25.9 mg/kg bw per day), the highest dose tested.

The Meeting concluded that florylpicoxamid is not teratogenic.

In a 13-week dietary toxicity study in rats that included specific investigations of neurotoxicity and immunotoxicity, no evidence of neurotoxicity or immunotoxicity was observed up to 3000 ppm (equal to 177 mg/kg bw per day), the highest dose tested.

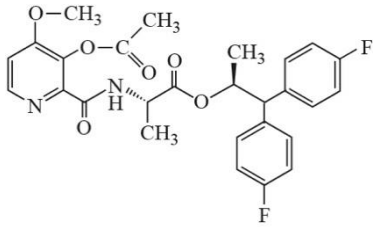
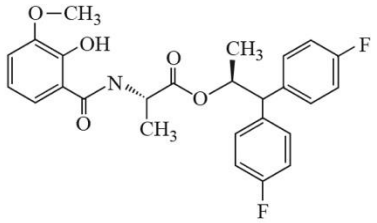
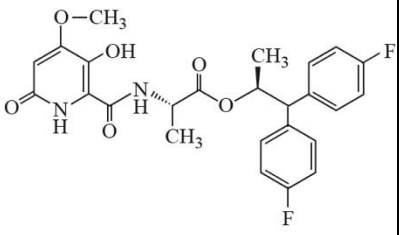
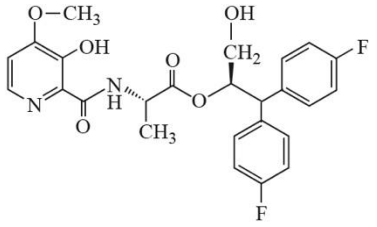
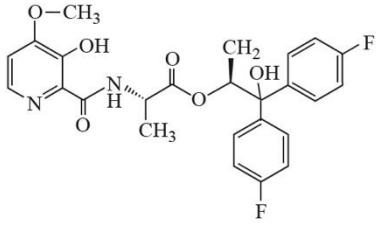
The Meeting concluded that florylpicoxamid is not neurotoxic.

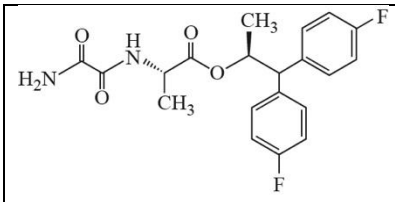
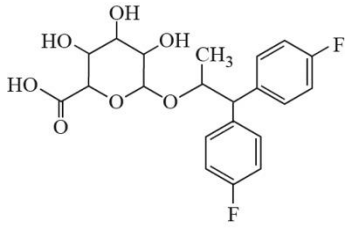
The Meeting concluded that florylpicoxamid is not immunotoxic.

Florylpicoxamid did not show any estrogenic agonist or antagonist activity in vitro.

Toxicological data on metabolites and/or degradates

Summary of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	**Major rat metabolite** (>10% AD)	**Genotoxicity assessment** (data, QSAR, read-across)	**General toxicity**	**Toxicological reference values**
Florylpicoxamid (X12485659; XDE-659;) 	Parent	Not genotoxic (data)	Full dataset	ADI: 0–0.1 mg/kg bw per day ARfD: Unnecessary
X12485649 	The first metabolite of the parent; X12485649-glucuronide was observed at >10% of AD in rat bile.	Not genotoxic in QSAR analysis	Covered by parent	Parent ADI
X12629973 	No	Not genotoxic in QSAR analysis	No information	TTC Cramer class III value: 1.5 µg/kg bw/day
X12641685 	No	Not genotoxic in QSAR analysis	No information	TTC Cramer class III value: 1.5 µg/kg bw/day
X12584261 	No	Not genotoxic in QSAR analysis	No information	TTC Cramer class III value: 1.5 µg/kg bw/day
X12563767	No	Not genotoxic (data)	No information	TTC Cramer class III value: 1.5 µg/kg bw/day

				
X12641325 	>10% of AD in rat urine and bile	Not genotoxic as covered by parent	Covered by parent	Parent ADI

QSAR: Quantitative structure–activity relationship; AD: Administered dose; ARfD: Acute reference dose;
TTC: Threshold of toxicological significance; ADI: Acceptable daily intake

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of florylpicoxamid residues on the human intestinal microbiome.

Human data

A compilation of all the medical assessment program data revealed no reports or findings of adverse health effects deemed attributable to exposure to the product. Additionally, no reports of any adverse health effects deemed attributable to exposure to the product were found in searches of the personal medical records of the employees involved.

No clinical cases of poisoning incidents have been detected from the open literature, based on the data collected by the sponsor.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.1 mg/kg bw for florylpicoxamid based on the NOAEL of 9.58 mg/kg bw per day in the developmental toxicity study in rabbits, and applying a safety factor of 100. This ADI also applies to metabolites X12485649 and X12641325.

The Meeting concluded that it was not necessary to establish an ARfD for florylpicoxamid in view of its low acute oral toxicity and the absence of developmental toxicity likely to be elicited by a single dose or any other toxicological effects likely to be elicited by a single dose. The early suppression of body weight gain, observed in the rabbit developmental toxicity study, was considered not to be a suitable basis for an ARfD because the effect was likely caused by lower palatability. A toxicological monograph was prepared.

Levels relevant to risk assessment of florylpicoxamid

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity[a]	Toxicity	500 ppm, equal to 55.3 mg/kg bw per day	1500 ppm, equal to 172 mg/kg bw per day
		Carcinogenicity	1500 ppm, equal to 172 mg/kg bw per day[g]	-
	13-week toxicity study [a]	Toxicity	500 ppm, equal to 68.3 mg/kg bw per day	1500 ppm, equal to 201 mg/kg bw per day
Rat	13-week toxicity study [a]	Toxicity	1000 ppm, equal to 59.4 mg/kg bw per day	3000 ppm, equal to 177 mg/kg bw per day
		Neurotoxicity	3000 ppm, equal to 177 mg/kg bw per day[c]	-
		Immunotoxicity	3000 ppm, equal to 177 mg/kg bw per day[c]	-
	Two-year studies of toxicity and carcinogenicity[a,d]	Toxicity	1000 ppm, equal to 46.9 mg/kg bw per day	4000 ppm, equal to 200 mg/kg bw per day
		Carcinogenicity	3000 ppm, equal to 123 mg/kg bw per day[c]	-
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	3000 ppm, equal to 179 mg/kg bw per day[c]	-
		Parental toxicity	1000 ppm, equal to 58.4 mg/kg bw per day	3000 ppm, equal to 179 mg/kg bw per day
		Offspring toxicity	1000 ppm, equal to 58.4 mg/kg bw per day	3000 ppm, equal to 179 mg/kg bw per day
	Developmental toxicity study [a]	Maternal toxicity	1000 ppm, equal to 73.1 mg/kg bw per day	4000 ppm, equal to 271 mg/kg bw per day
		Embryo/fetal toxicity	4000 ppm, equal to 271 mg/kg bw per day [c]	-
Rabbit	Developmental toxicity study [a]	Maternal toxicity	250 ppm, equal to 9.58 mg/kg bw per day	750 ppm, equal to 25.9 mg/kg bw per day
		Embryo/fetal toxicity	750 ppm, equal to 25.9 mg/kg bw per day[c]	-
Dog	13-week studies of toxicity [b]	Toxicity	60 mg/kg bw per day	150 mg/kg bw per day

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

[d] Two or more studies combined; [e] Lowest dose tested; [f] Capsule administration

[g] The value was obtained from males; no available information on toxicity or carcinogenicity in females at 1500 ppm due to early termination. The NOAEL for carcinogenicity in males was 172 mg/kg bw per day, the highest dose tested.

Acceptable daily intake (ADI) applies to florylpicoxamid, metabolites X12485649 and X12641325 expressed as florylpicoxamid

0–0.1 mg/kg bw

Acute reference dose (ARfD)

Unnecessary

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 florylpicoxamid

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid: 21% (mice), 34% (rats), 77% (rabbits)
Dermal absorption	No data
Distribution	Widespread
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid elimination via faeces, urine or bile
Metabolism in animals	Deacetylation, aromatic oxidation, aliphatic and aromatic hydroxylation, ester bridge formation or amide cleavages, O-demethylation, and phase II glucuronide conjugation
Toxicologically significant compounds in animals and plants	Florylpicoxamid, X12485649, X12641325, X12641685, M12563767, X12584261 and X12629973
Acute toxicity	
Rat, LD_{50}, oral	>2000 mg/kg bw
Rat, LD_{50}, dermal	>2000 mg/kg bw
Rat, LC_{50}, inhalation	5.48 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Slightly irritating
Mouse, dermal sensitization	Not sensitizing (LLNA)
Short-term studies of toxicity	
Target/critical effect	Body weight, body wt gain, food consumption (rat, dog)

Lowest relevant oral NOAEL	59.4 mg/kg bw per day (rat) 60 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Body weight
Lowest relevant NOAEL	46.9 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic[a]
Genotoxicity	Unlikely to be genotoxic[a]
Reproductive toxicity	
Target/critical effect	Body weight/red blood cells
Lowest relevant parental NOAEL	58.4 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	58.4 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	179 mg/kg bw per day, highest dose tested (rat)
Developmental toxicity	
Target/critical effect	Abortion
Lowest relevant maternal NOAEL	9.58 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	25.9 mg/kg bw per day, highest dose tested (rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	No evidence from routine studies
Subchronic neurotoxicity NOAEL	177 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	177 mg/kg bw per day, highest dose tested (rat)
Studies on metabolites	

X12485649	Acute oral LD_{50}: 1000 mg/kg bw (rat) Acute dermal LD_{50}: >2000 mg/kg bw Acute inhalation LC_{50}: 0.125 mg/L air Mildly irritating
X696476	Not irritating (EpiDerm reconsituted human epidermis) Not clastogenic (micronucleus in vitro)
X12563767	Not mutagenic (in vitro bacterial reverse mutation test) Not clastogenic (in vitro mammalian micronucleus test)
Microbiological aspects	No data submitted
Human data	No reports of any adverse health effects

[a] Unlikely to pose a carcinogenic risk to humans via exposure from the diet

Summary

	Value	Study	Safety factor
ADI	0–0.1 mg/kg bw [a]	Developmental toxicity study in rabbits	100
ARfD	Unnecessary		

[a] Applies to florylpicoxamid, X12485649 and X12641325, expressed as florylpicoxamid

Florylpicoxamid (XDE-659) is used as a broad-spectrum fungicide belonging to the picolinamide group of chemicals. It is a fully synthetic neo-picolinamide fungicide and the mode of action is a quinone inside inhibitor (respiration inhibitor at the cytochrome bc1 complex). Florylpicoxamid is a highly potent inhibitor of mitochondrial electron transport complex III (MET III) at Qi site.

Florylpicoxamid has not previously been evaluated by JMPR and was scheduled at the fifty-third Session of the CCPR (2023), for toxicology and residue evaluation as a new compound by the 2023 JMPR.

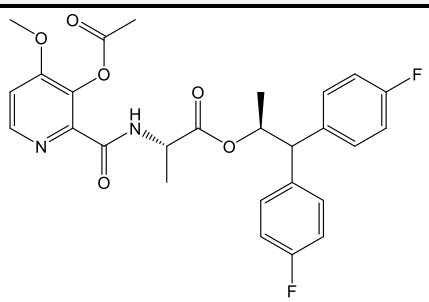
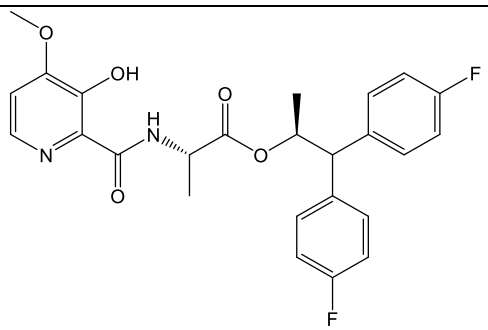
The Meeting received information on identity, physical-chemical properties, plant and animal metabolism, analytical methods, storage stability, use patterns, residues resulting from supervised trials, fate of residues in succeeding crops, fate of residues during processing and livestock feeding studies.

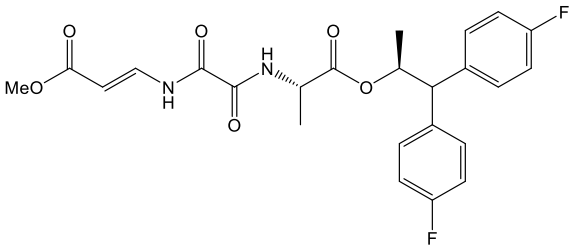
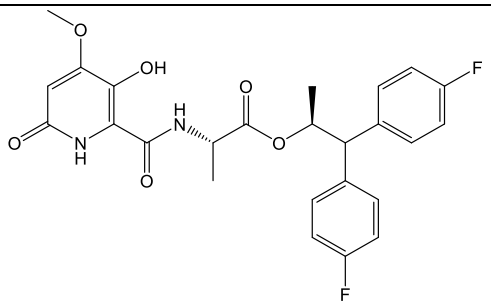
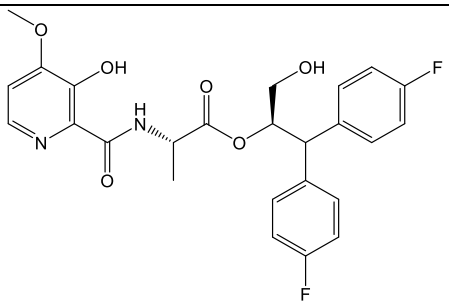
All critical studies contained statements of compliance with GLP and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified.

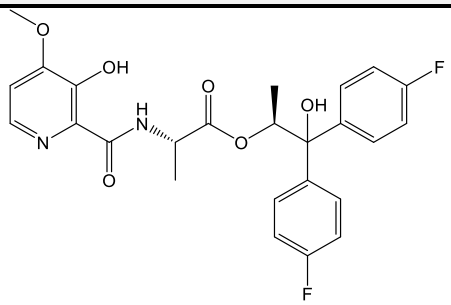
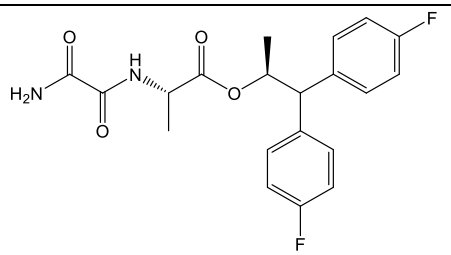
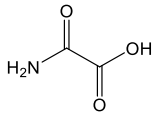
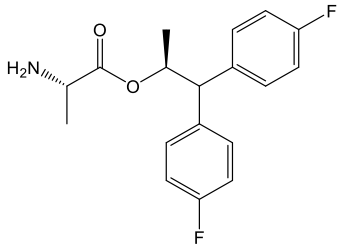
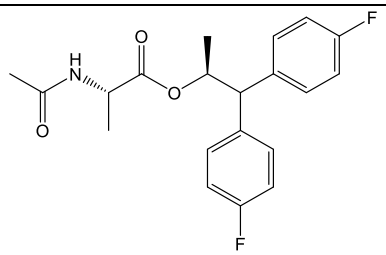
Florylpicoxamid is the ISO-approved common name for (1S)-2,2-bis(4-fluorophenyl)-1-methylethyl N-[(3-acetoxy-4-methoxy-2-pyridyl)carbonyl]-L-alaninate.

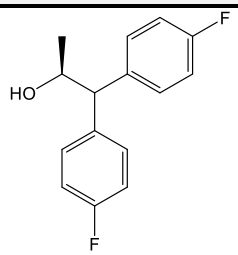
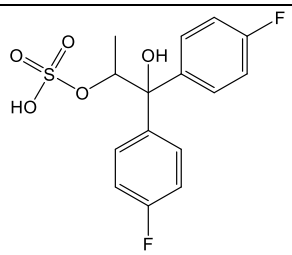
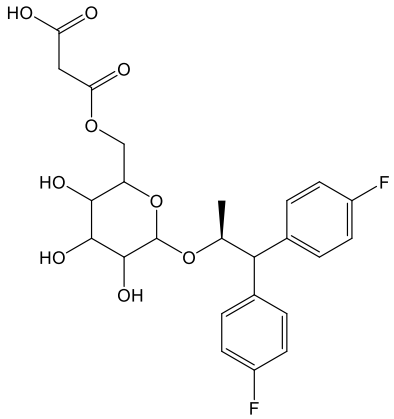
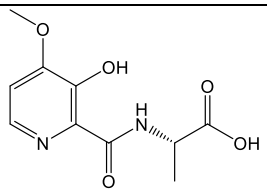
The abbreviations, chemical names, and structures of the parent and of metabolites discussed in the appraisal are summarized in **Error! Reference source not found.**.

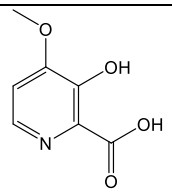
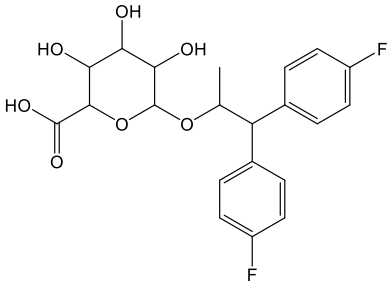
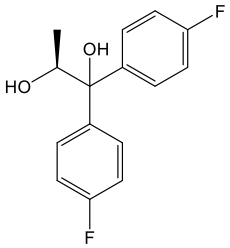
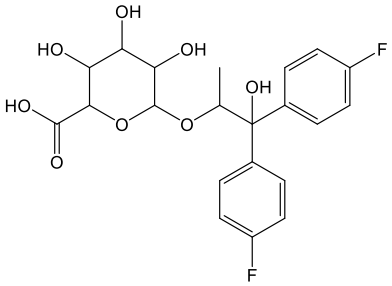
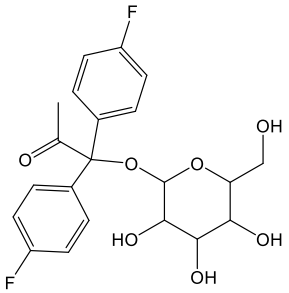
Table 1. Abbreviations for the relevant compounds referred to in this document

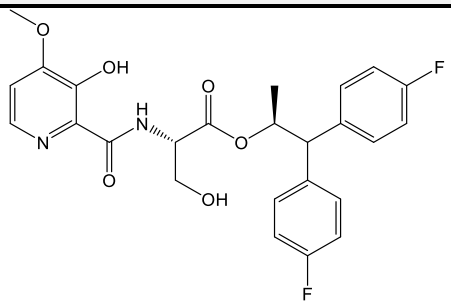
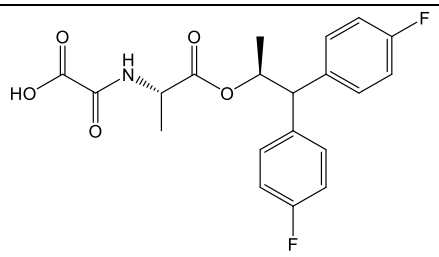
Name and compound code (other names)	**Matrix**	**Structure**
Florylpicoxamid (XDE-659, X12485659)	Wheat forage, Wheat hay Wheat straw, Tomato fruit (PHI 1, 7, 14 d), Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Hen skin with fat	
X12485649	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Rotated wheat forage (PBI 30, 60, 120 d) Rotated wheat hay (PBI 30, 60, 120, 270 d)	

Name and compound code (other names)	Matrix	Structure
	Rotated wheat straw (PBI 30, 60, 90 d) Rotated wheat grain (PBI 30 d) Rotated immature lettuce (PBI 30, 60 d) Rotated mature lettuce (PBI 30, 60 d) Rotated radish foliage (PBI 30, 60, 120 d) Rotated radish root (PBI 30 d) Eggs Hen liver Hen fat Hen skin with fat Hen breast and leg muscle Milk Goat liver Goat kidney Goat muscle Goat fat (om, sub, ren)	
X12568155	Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Rotated mature lettuce (PBI 30 d) Rotated radish foliage (PBI 30 d)	
X12629973	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (1DAT5) Hen liver Hen skin with fat Hen breast and leg muscle	
X12641685	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Rotated wheat forage (PBI 120 d) Rotated wheat straw (PBI 60 d) Rotated radish foliage (PBI 30, 120 d)	

Name and compound code (other names)	Matrix	Structure
X12584261	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Milk Goat fat (om, sub, ren)	
X12563767	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Rotated wheat forage (PBI 120 d) Rotated wheat hay (PBI 120 d) Eggs Hen liver Hen skin with fat Hen breast and leg muscle Goat liver, muscle, fat, milk (when fed with X12563767)	
Oxamic Acid	Wheat forage Wheat hay Wheat straw Wheat grain Lettuce (7DAT3, 1DAT5, 8DAT5)	
X12485647	Wheat forage Wheat hay Wheat straw	
X12516991	Wheat forage Wheat hay Wheat straw Lettuce (7DAT3, 1DAT5, 8DAT5) Rotated wheat straw (PBI 60 d) Hen fat	

Name and compound code (other names)	Matrix	Structure
X12485631	Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Rotated wheat forage (PBI 120 d) Rotated wheat straw (PBI 90 d) Rotated mature lettuce (PBI 30, 60 d) Rotated radish foliage (PBI 30 d) Rotated radish root (PBI 30 d) Eggs Hen liver Hen fat Hen skin with fat Hen breast muscle Goat liver Goat kidney Goat liver, muscle, fat (when fed X12563767)	
Sulphate conjugate of X12485631	Goat kidney, muscle, milk (when fed X12563767)	
X12675171 & X12675167 (Anomers of glucose-malonyl conjugate of X12485631, combined alpha and beta anomers referred to as X12717067)	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5) Rotated wheat forage (PBI 30, 60, 90, 120 d) Rotated wheat hay (PBI 30, 60, 90, 120 d) Rotated wheat straw (PBI 30, 60, 90, 120, 270 d) Rotated immature lettuce (PBI 30, 60 d) Rotated mature lettuce (PBI 30, 60 d) Rotated radish foliage (PBI 30, 60, 120 d) Rotated OSR forage (PBI 90 d)	
X12485473	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5)	

Name and compound code (other names)	Matrix	Structure
	Rotated wheat straw (PBI 30 d)	
X696476	Wheat forage Wheat hay Wheat straw Tomato fruit (PHI 1, 7, 14 d) Tomato vines Lettuce (7DAT3, 1DAT5, 8DAT5)	
X12641325	Hen liver Hen skin with fat Hen leg muscle Goat liver Goat kidney Goat liver, kidney, muscle, fat (when fed X12563767)	
X12493055	Rotated wheat forage (PBI 30, 120 d) Rotated wheat hay (PBI 120 d) Hen liver Hen fat Goat liver, muscle, fat, milk (when fed with X12563767)	
X12714411	Goat liver Goat kidney	
Glucose conjugate of X12764243 (Metabolite B)	Rotated wheat forage (PBI 30, 60, 90, 120 d) Rotated wheat hay (PBI 30, 60, 90, 120, 270 d) Rotated wheat straw (PBI 30, 60, 90, 120, 270 d) Rotated wheat grain (PBI 30 d) Rotated immature lettuce (PBI 30, 60 d) Rotated mature lettuce (PBI 30, 60 d) Rotated radish foliage (PBI 30, 60, 120 d) Rotated radish root (PBI 30 d) Rotated OSR forage (PBI 90 d)	

Name and compound code (other names)	Matrix	Structure
X12530089	Eggs Hen liver Hen skin with fat Hen leg muscle	
X12562911	Goat liver, kidney, muscle, milk (when fed X12563767)	

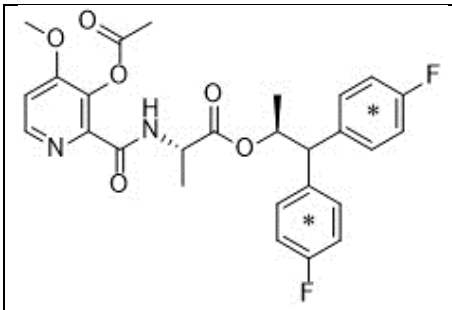
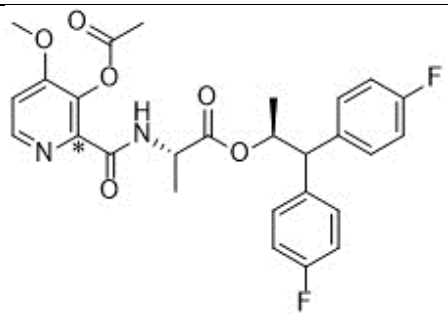
Physical-chemical properties

Florylpicoxamid is not soluble in water (0.004 g/L at 20oC), but is soluble in organic solvents (>250 g/L in methanol, acetone and ethyl acetate). Hydrolytically is not stable at pH 4, 7 and 9 forming the degradation products X12485649, X12485631 and X12485473. Photolysis is not a significant route of degradation. The octanol/water partition coefficient log Pow of 4.2 suggests potential to partition into fat.

Plant metabolism

The Meeting received plant metabolism studies for florylpicoxamid in wheat (cereal/grass crops), tomatoes (fruit crops) and lettuce (leafy crops). Florylpicoxamid was applied using either florylpicoxamid -bis-Ph-UL-^{14}C (phenyl-label) or florylpicoxamid -Py-2-^{14}C (pyrazol-label). In metabolism studies, total radioactive residues (TRR) are expressed in mg flopylpicoxamid equivalents/kg. The active substance of florylpicoxamid used was S,S stereoisomer. From all studies, chiral analysis of florylpicoxamid and X12485649 metabolite showed no significant interconversion to other stereoisomers.

Table 2. Overview of the different labels used in the plant metabolism studies

	
[phenyl-UL-^{14}C]- florylpicoxamid (PH label) used in all primary metabolism studies.	[pyrazolyl-2-^{14}C]- florylpicoxamid (PY label) used in all primary metabolism studies.

The use patterns received include foliar application (tomatoes, lettuce and wheat).

Tomatoes (fruit crops)

The metabolic fate of PH label and PY label florylpicoxamid was investigated in tomatoes following five foliar applications with approximately 7-day intervals before harvest (BBCH 12—89) at a rate of 150 g ai/ha each.

Samples of immature plants (BBCH 64) were collected 7 days after the third application and fruit samples were collected one, seven and 14 days after the last (fifth) application. On the fourteenth day vine samples were also collected. Homogenized samples were extracted with acidified acetonitrile/water. The post-extraction solids (PES) were further submitted to acidic (HCl) or alkaline (pH 9 buffer) hydrolysis.

TRR radioactivity was up to 2 mg eq./kg in in immature plants. In tomatoes, residues declined from 0.11 to 0.19 mg eq./kg, (1 day after the last application) to 0.061—0.092 mg eq./kg (14 days after the last application).

The extractability of residues using organic solvents was 89.4—115.8 percent TRR depending on the matrix. Using further acidic/alkaline hydrolysis an additional 1—3 percent TRR was released. TRR levels were up to 115.8 percent TRR (up to 0.185 mg eq/kg) in fruit and up to 101.8 percent (up to 1.58 mg eq/kg) in vines. Unextracted residues in fruits after hydrolysis accounted for up to 6.6 percent TRR (up to 0.005 mg eq/kg) and were not further characterized.

Parent **florylpicoxamid** accounted for up to 38.9 percent TRR (up to 0.067 mg eq/kg) in fruits.

The **X12485649** metabolite accounted for up to 40.9 percent TRR (up to 0.073 mg eq/kg) in fruits. Residues declined from 0.046 mg eq/kg (40.9 percent TRR) at 1d PHI to 0.017 mg eq/kg (18.6 percent TRR) at 14d PHI.

The **X12675171, X12485649, X12563767, X12516991, X12568155, X12485631, X12584261, X12629973, X696476, X12568155, X12485473, X12641685, X696476,** oxamic

acid and a non-polar uncharacterized PY metabolites accounted for below 10 percent TRR (<0.05 mg eq/kg) in fruits at all PHIs.

Lettuce (leafy crops)

The metabolic fate of PH label and PY label florylpicoxamid was investigated in lettuce (Butter crunch, leaf lettuce variety) following five foliar applications with approximately 7-day intervals at a rate of 150 g ai/ha each.

Samples of immature plants (BBCH 37) were collected 7 days after the third application and samples of mature plants (BBCH 49) were collected one and 8 days after the last (fifth) application. Homogenized samples were extracted with acidified acetonitrile/water. Further characterization on PES was not performed.

TRR radioactivity was up to 2.2 mg eq./kg in immature plants and up to 3.2 mg eq./kg in mature plants (1d PHI).

The extractability of residues using organic solvents was 88.4—100.4 percent TRR depending on the matrix. TRR levels accounted up to 97.4 percent TRR (up to 2.1 mg eq/kg) in immature lettuce and up to 100.4 percent TRR (up to 3.07 mg eq/kg) in mature plants.

Parent **florylpicoxamid** accounting for up to 37.2 percent TRR (up to 0.84 mg eq/kg) in immature plants and up to 40 percent TRR (up to 1.3 mg eq/kg) in mature plants.

X12485649 metabolite accounting for up to 38.5 percent TRR (up to 0.86 mg eq/kg) in immature plants and up to 46.4 percent TRR (up to 1.3 mg eq/kg) in mature plants.

X12641685 metabolite accounting for up to 3.07 percent TRR (up to 0.068 mg eq/kg) in immature plants and up to 7.3 percent TRR (up to 0.089/0.14 mg eq/kg) in mature plants.

X12563767 metabolite accounting for up to 2.55 percent TRR (up to 0.044 mg eq/kg) in immature plants and up to 3.15 percent TRR (up to 0.062 mg eq/kg) in mature plants.

The **X12675171, X12516991, X12568155, X12485631, X12584261, X12629973** metabolites accounted for below 10 percent TRR (<0.05 mg eq/kg) in plants at all PHIs.

Wheat (cereals/grass crops)

The metabolic fate of PH label and PY label florylpicoxamid was investigated in wheat following two foliar applications with approximately 35-day intervals (BBCH 32—69; end of flowering) at a rate of 50 g ai/ha each.

Samples of wheat forage (BBCH 47) were collected at 14 days after the first foliar application, wheat hay (BBCH 83) were collected 13 days after the second foliar application[7], wheat straw and grain (BBCH 89) were collected 48 days after the second foliar application. Homogenized samples were extracted with acidified acetonitrile/water. The PES were further submitted to acidic (HCl), alkaline (pH 9 buffer) or enzyme hydrolysis.

[7] The wheat hay samples were cut and dried in the green house for 7 days.

TRR was up to 0.65 mg eq./kg in forage, up to 2.9 mg eq./kg in hay, up to 2.5 mg eq./kg in straw and up to 0.13 mg eq./kg in grain.

The extractability of residues using organic solvents was 50—88.6 percent TRR depending on the matrix. Using further acidic/alkaline/enzymic hydrolysis, TRR levels accounted up to 91 percent TRR (up to 0.59 mg eq/kg) in forage, up to 82.5 percent TRR (up to 2.34 mg eq/kg) in hay, up to 81.8 percent TRR (up to 1.95 mg eq/kg) in straw and 63 percent TRR (0.09 mg eq/kg) in grain (only for the PY label since in the PH label residues were not detected). Unextracted residues after hydrolysis accounted for up to 3.7 percent TRR (up to 0.041 mg eq/kg) and were not further characterized.

Relatively small amounts of radioactive residues were detected in grain. The majority of residue was found in feed commodities (forage, hay and straw).

Parent **florylpicoxamid** was extensively metabolized in wheat accounting for up to 6.4 percent TRR (up to 0.039 mg eq/kg) in forage, up to 1.4 percent (up to 0.042 mg eq/kg) in hay and up to 2.3 percent (up to 0.053 mg eq/kg) in straw. In grain, parent was not detected.

The **X12675171** metabolite (PH label) accounted for 24.1 percent TRR (0.16 mg eq/kg) in forage, 4.79 percent TRR (0.14 mg eq/kg) in hay and 9.39 percent TRR (0.209 mg eq/kg) in straw.

The **X12485649** metabolite (both labels) accounted for up to 14.69 (up to 0.087mg eq/kg) in forage, up to 13.63 percent TRR (up to 0.38 mg eq/kg) in hay, up to 6.03 percent TRR (up to 0.15 mg eq/kg) in straw.

The **X12641685** metabolite (both labels) accounted for up to 6.8 percent TRR (up to 0.044 mg eq/kg) in forage, up to 7.38 percent TRR (up to 0.21 mg eq/kg) in hay, up to 9.23 percent TRR (up to 0.23 mg eq/kg) in straw.

The **X12563767** metabolite (PH label) accounted for up to 5.95 percent TRR (up to 0.033 mg eq/kg) in forage, up to 8.77 percent TRR (up to 0.25 mg eq/kg) in hay, up to 11.56 percent TRR (up to 0.29 mg eq/kg) in straw.

The **X12516991** metabolite (PH label) accounted for 3.3 percent TRR (0.022 mg eq/kg) in forage, 1.97 percent TRR (0.057 mg eq/kg) in hay, 1,5 percent TRR (0.034 mg eq/kg) in straw.

The **X12568155** metabolite (PH label) accounted for 2.23 percent TRR (0.065 mg eq/kg) in hay and 0.8 percent TRR (0.019 mg eq/kg) in straw.

The **X12485647** metabolite (PH label) accounted for 3.96 percent TRR (0.026 mg eq/kg) in forage, 2.61 percent TRR (0.076 mg eq/kg) in hay, 3.39 percent TRR (0.075 mg eq/kg) in straw.

The **X12485631** metabolite (PH label) accounted for 1.26 percent TRR (0.037 mg eq/kg) in hay and 2.55 percent TRR (0.057 mg eq/kg) in straw.

The **XDE-659-M4** metabolite (both labels) accounted for up to 3.9 percent TRR (up to 0.025 mg eq/kg) in forage, up to 2.17 percent TRR (up to 0.063 mg eq/kg) in hay and up to 3.01percent TRR (up to 0.067 mg eq/kg) in straw.

The **XDE-659-M5** metabolite (both labels) accounted for 2.1 percent TRR (0.014 mg eq/kg) in forage, 1.84/0.36 percent TRR (0.053/0.01 mg eq/kg) in hay and up to 2.2 percent TRR (up to 0.049 mg eq/kg) in straw.

The **XDE-659-M2**, **XDE-659-M3**, **X12584261, X12629973, X12485473, X696476**, oxamic acid, a non-polar and polar uncharacterized PY metabolites accounted for below 10 percent TRR (<0.05 mg eq/kg) in forage, hay and straw. In straw, only the non-polar uncharacterized PY metabolite was found at 6 percent TRR (0.15 mg eq/kg).

Summary of plant metabolism

Plant metabolism studies were conducted in wheat (cereal/grass crops), tomatoes (fruit crops) and lettuce (leafy crops) as a foliar application at rates that accommodate the anticipated maximum total seasonal GAP application rates.

Overall, the metabolic pathway is consistent between the three crops, with the primary metabolite being X12485649 following a short PHI. More extensive metabolism is observed at longer PHI, in which parent florylpicoxamid declines significantly leading to higher levels of metabolites X12717067, X12641685 and X12563767 in livestock feed commodities.

Environmental fate

The Meeting received information on aerobic degradation in soil under laboratory conditions, soil photolysis, hydrolysis, aqueous photolysis, confined and field rotational crops.

Hydrolysis

The hydrolytic stability of florylpicoxamid and X12485649 metabolite were investigated in aqueous buffer solutions at three environmentally relevant pH values. Initial tests were performed with the PH label for up to 5 days at 50 °C in the dark using buffer solutions at pH 4, 7 and 9. Follow-up tests at pH 4, 7 and 9 were performed with PH and PY labels at 10 °C, 25 °C and 35 °C and incubated for up to 30 days.

Florylpicoxamid, in the initial test, was not stable, declining rapidly from 97.3 to 13.0 percent AR at pH 4, from 93.2 to 6.3 percent AR at pH 7 and completely degraded from 62.8 percent AR at 0 days at pH 9. In the follow-up studies, parent degraded significancy from 94.7/97.4 to 8.5/7.8 percent AR, at 35°C, and to 43/44.5 percent at 25°C. At 10°C no significant degradation occurred (down to 79.8/83.5 percent AR) indicating the hydrolytic stability is related to temperature levels. The major degradates identified were X12485649 (both labels) accounting for up to 108.8 percent AR, and X12485631 (PH label, only), X12485473 (PY label, only) observed at lower levels.

X12485649 metabolite, in the initial tests was found to be stable under hydrolysis with radioactivity ranging from 96.7 to 102.2 percent AR at different pH levels (4, 7 and 9). In the follow-up studies, X12485649 when incubated at 35°C, degraded rapidly while a proportionally slower rate of degradation was observed at 25°C and 10°C.

Photochemical degradation

The soil photodegradation was investigated on a clay loam soil, either dry or moist, **following** a single application at 750 g/ha, irradiated under continuous irradiation for 15 days equivalent to up to 29 summer sunlight and incubated in the dark the same period.

In all samples, extractible radioactivity was from 95.7 to 109.7 percent AR. The degradation of florylpicoxamid was similar in both dark and irradiated samples. In dry soil, parent degraded significantly down to 45.3 percent AR in dark dry soil and down to 34.5 percent AR in irradiated dry soil. Similar in moist soil, parent completely degraded in dark and irradiated soil. The Meeting concluded that degradation of florylpicoxamid was not due to photolytic processes. Thus, photolysis is not considered a significant route of degradation in soil surface.

Similar to hydrolysis degradation, the main degradation products were X12485649 and X12485631. X12485649 was the major degradation product and accounted for up to 63.4 percent AR in dry irradiated soil, up to 81.6 percent AR in moist irradiated soil and up to 91.6 percent AR in moist dark soil (control). X12485631 was also found at proportions from 5.2 to 17.1 percent AR.

Soil metabolism

The soil metabolism of florylpicoxamid was investigated under aerobic conditions for 120 days in four different soils following a single application at 3.0 mg a.i./kg soil. As to differentiate between biotic and abiotic degradation, one soil type (sandy loam only) was sterilized and investigated. DT_{50} values for florylpicoxamid ranged from 0.21 to 0.57 days with a geomean DT_{50} of 0.37 days, indicating low persistence in soil.

Under laboratory conditions, in aerobic soil the major transformation product was X12485649 observed at 87.5 percent AR by the end of the study. In sterilized soil, X12485649 and X12485631 were the two major products observed at 71.8 and 16.5 percent AR by the end of the study respectively.

The Meeting received an additional soil metabolism study in which X12485631, was investigated under aerobic conditions for 120 days in four different soils following a single application at 1.05 mg a.i./kg soil. DT_{50} values for X12485631 ranged from 2.6 to 7.2 days with a geomean DT_{50} of 4.4 days, indicating low persistence in soil.

Residues in succeeding or rotational crop

The Meeting received information on the metabolism of florylpicoxamid in lettuce (leafy crop), radish (root crops) and wheat (cereal crop) grown as confined rotational crops.

Confined rotational crop studies

In two confined rotational crop studies in the United Kingdom of Great Britain and Northern Ireland, bare soil was treated either with PH or PY label florylpicoxamid at 750 g ai/ha and planted with lettuce (leafy crop), radish (root crops) and wheat (cereal crop) at plant-back

intervals (PBI) of 30, 60, 120 and 270 days. In a second study, bare soil was treated either with PH or PY label florylpicoxamid at 100 g ai/ha and planted with at PBI of 90 days with lettuce (leafy crop), radish (root crops), wheat (cereal crop) and rape seed (oil seed crops). After ageing for 375 days wheat and rape seed were planted.

Lettuce (immature and mature), radish foliage and roots, wheat commodities (forage, hay, straw and grain) and rapeseed commodities (forage, straw and seed; sampled 90-d and 375-d only) were harvested from the plots at each of the PBI. Homogenized samples were extracted with acidified acetonitrile/water or hexane/ acetonitrile/water. The PES were further submitted to acidic (HCl), alkaline (pH 9 buffer) or enzyme hydrolysis.

Analysis of soil (collected at 30d PBI) demonstrated complete degradation of florylpicoxamid, to primarily metabolite X12485649. Therefore, florylpicoxamid would not be available for uptake into the crops, at any PBI.

TRR levels in the different matrices were higher in the PH label declining at later PBIs (PBI 30d to 270d). Residues accounted for up to 0.12 mg eq/kg in wheat forage, up to 0.45 mg eq/kg in wheat hay, up to 0.19 mg eq/kg in wheat straw, up to 0.11 mg eq/kg in wheat grain, up to 0.056 mg eq/kg in immature lettuce, up to 0.045 mg eq/kg in mature lettuce, up to 0.047 mg eq/kg in radish foliage, up to 0.046 mg eq/kg in radish roots, up to 0.024 mg eq/kg in rapeseed forage, up to 0.096 mg eq/kg in rapeseed straw and up to 0.12 mg eq/kg in rapeseed.

Extractability of residues using organic solvents was 57.1 – 77.7 percent TRR in wheat forage, 40.6 – 87.2 percent TRR in wheat hay, 34.4 – 84 percent TRR in wheat straw, 15.4 – 26.5 percent TRR in wheat grain, 62.4 – 74.3 percent TRR in immature/mature lettuce, 50.4 – 64.8 percent TRR in radish foliage, 54.5 – 68.6 percent TRR in radish roots, 27.1 – 30.3 percent TRR in rapeseed forage, up to 16.6 percent TRR in rapeseed straw and 51.8 – 52.5 percent TRR in rapeseed. In samples (wheat forage, lettuce, radish leaves, radish roots) where residues in PES were >10 percent TRR but <0.05 mg eq/kg) no further characterization was done. In wheat hay, wheat straw, rapeseed straw and rapeseed samples, PES were further characterized using acidic/alkaline/enzyme hydrolysis and the radioactivity remaining was ≤ 15.1 percent TRR (< 0.031 mg eq/kg) except in wheat straw at 90d. (45.6 percent TRR; 0.0399 mg eq/kg), wheat grain at 60d (30.3 percent TRR; 0.031 mg eq/kg), rapeseed straw (59.9 percent TRR; 0.058 mg eq/kg) and rapeseed (19.9 percent TRR; 0.023 mg eq/kg). Further characterization was not performed.

The identified residues were common in all crops, but the magnitude varied depending on the individual crop, matrix and PBI.

Metabolite A (PH label only) accounted for up to 7.5 percent TRR (up to 0.009 mg eq/kg) in wheat forage, up to 6.3 percent TRR (up to 0.024 mg eq/kg) in wheat hay, up to 9.8 percent TRR (up to 0.015 mg eq/kg) in wheat straw, up to 4.5 percent TRR (up to 0.002 mg eq/kg) in lettuce, up to 2.1 percent TRR (up to 0.001 mg eq/kg) in radish foliage and 1.1 percent TRR (<0.001 mg eq/kg) in rapeseed forage.

Metabolite B (glucose conjugate of X12764243) accounted for up to 22.9 percent TRR (up to 0.028 mg eq/kg) in wheat forage, up to 13.7 percent TRR (up to 0.062 mg eq/kg) in wheat hay, up to 15.3 percent TRR (up to 0.028 mg eq/kg) in wheat straw, up to 35.7 percent TRR (up

to 0.02 mg eq/kg) in lettuce, up to 9.9 percent TRR (up to 0.005 mg eq/kg) in radish foliage, up to 6,1 percent TRR (up to 0.003 mg eq/kg) in radish roots, and 4.3 percent TRR (0.001 mg eq/kg) in rape forage.

X12675171 accounted for up to 6.3 percent TRR (up to 0.004 mg eq/kg) in wheat forage, up to 8.3 percent TRR (up to 0.021 mg eq/kg) in wheat hay, up to 12.6 percent TRR (up to 0.017 mg eq/kg) in wheat straw, up to 6.5 percent TRR (up to 0.004 mg eq/kg) in lettuce, up to 12.3 percent TRR (up to 0.003 mg eq/kg) in radish foliage, and 5.4 percent TRR (0.002 mg eq/kg) in rapeseed forage.

Field rotational crop studies

Field rotation crop studies were not submitted to the Meeting.

Summary of environmental fate

Florylpicoxamid is not stable under hydrolysis with X12485649 being the predominant product in all conditions. X12485649 was found to be stable under hydrolysis conditions, degrading only at 35°C. X12485631 and X12485473 as degradation products of either florylpicoxamid or X1248564 were also identified at lower levels.

Photolysis is not considered a significant route of degradation of florylpicoxamid in soil surface.

Florylpicoxamid indicates low persistence in soil (geomean DT_{50} of 0.37 days), degrading rapidly with X12485649 and X12485631 found in significant proportions. X12485649 seems to persistence in soil however the Meeting did not receive any studies investigating the soil dissipation of this degradation product.

Confined rotational crop studies indicate that florylpicoxamid was extensively metabolized into a large number of metabolites, but the residues of each metabolite were < 0.01 mg eq/kg in all rotated crop matrices at all PBI, except metabolite A (accounted up to 0.024 mg eq/kg in wheat forage, wheat hay, wheat straw, lettuce, radish foliage and rapeseed foliage), metabolite B (up to 0.062 mg eq/kg in wheat forage, wheat hay, wheat straw, lettuce, radish foliage, radish roots and rapeseed foliage).

In conclusion, no residues of florylpicoxamid are expected in rotated crops under the conditions investigated in the studies provided to the Meeting, however trace levels for Metabolite B, may be expected in leafy crops and some feed commodities. Should a more cGAP or additional uses received in the future, the expectation of residues of florylpicoxamid in rotational crops may need to be re-evaluated.

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hens, where animals were dosed with florylpicoxamid radiolabelled in the (phenyl ring) or the (pyrazole ring).

From all studies, chiral analysis of florylpicoxamid and X12485649 metabolite showed no significant interconversion to other stereoisomers.

Laboratory animals

The metabolism of florylpicoxamid in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2023 JMPR.

Lactating goats

Two lactating goats were orally dosed by capsule once daily for 7 consecutive days either with PH or PY label florylpicoxamid at 13.1 or 12.8 ppm feed, corresponding to 0.44 or 0.36 mg/kg bw/day, respectively. Milk was collected twice daily (morning and evening) and excreta were collected once daily. The goats were sacrificed approximately 6–8 hours after the last dose. Samples of liver, kidney, muscle (flank and loin, maintained separately) and fat (subcutaneous, omental, renal) were collected.

Homogenized samples were extracted with acidified acetonitrile/water. Further characterization on PES was not performed.

The majority of the applied radioactivity (AR) was recovered in the excreta (up to 82 percent AR), with lower levels in the gastrointestinal tract (up to 19 percent AR). Plateau level in milk was reached within 5 days of the first dose (0.01 percent AR; 0.09 mg eq/kg). The radioactivity recovered in tissues accounted up to 0.03 percent AR (up to 0.055 mg eq/kg) in fat, 0.01 percent AR (up to 0.03 mg eq/kg) in kidney, 0.13 percent AR (up to 0.18 mg eq/kg) in liver and 0.02 percent AR (up to 0.016 mg eq/kg) in muscle.

The extractability of residues using organic solvents was 84.7 – 104.6 percent TRR depending on the matrix. Extracted radioactivity was up to 94.6 percent TRR (up to 0.17 mg eq/kg) in liver, 96.2 percent TRR (up to 0.029 mg eq/kg) in kidney, up to 104.6 percent TRR (up to 0.052 mg eq/kg) in fat, 96 percent TRR (0.016 mg eq/kg) in muscle, up to 75.1 percent TRR (up to 0.01 mg eq/kg) in cream and up to 25.6 percent TRR (up to 0.002 mg eq/kg in skimmed milk.

The PES from all matrices was found to contain < 10 percent TRR or a low residue level in all matrices except liver (20.2 percent TRR; 0.031 mg eq/kg) therefore, no further characterization of unextracted residue was conducted.

Parent **florylpicoxamid** was extensively metabolized and not detected in milk or tissues.

X12485649 metabolite is the predominant metabolite, accounting up to 36.1 percent TRR (up to 0.004 mg eq/kg) in cream, 81.7 percent TRR (0.013 mg eq/kg) in muscle, up to 82 percent TRR (up to 0.042 mg eq/kg) in fat, up to 32.9 percent TRR (up to 0.059 mg eq/kg) in liver and up to 45.7 percent TRR (up to 0.009 mg eq/kg) in kidney.

X12641325 metabolite (PH label), was observed in significant levels in liver (up to 6.34 percent TRR; 0.011 mg eq/kg) and kidney (27.3 percent TRR; 0.008 mg eq/kg).

X12584261 metabolite (both labels) was observed in significant levels in fat (up to 10.35 percent TRR; up to 0.047 mg eq/kg) and identified in cream (up to 15.8 percent TRR; up to 0.006 mg eq/kg)

The **X12714411, X12485631** metabolites accounted for below 10 percent TRR (<0.05 mg eq/kg) in milk cream and animal tissues.

Laying hens

A group of laying hens was orally dosed by capsule once daily for 10 consecutive days either with PH or PY label- florylpicoxamid at 13.2 or 12.7 ppm feed, corresponding to 0.66 or 0.59 mg/kg bw/day, respectively.

Eggs (whites and yolks) and excreta were collected twice daily (morning and evening). Hens were sacrificed approximately 6–8 hours after the last dose. Samples of liver, kidney, muscle (breast and leg, maintained separately), fat and skin with fat were collected. Homogenized samples were extracted with acidified acetonitrile:water. Further characterization on PES was not preformed.

The majority of the applied radioactivity was recovered in the excreta (up to 92.4 percent AR). Plateau level in eggs was reached within the seventh (PY label) or the ninth (PH label) day of the first dose (up to 0.02 percent AR; up to 0.048 mg eq/kg). Radioactivity was higher in egg yolk (up to 0.01 percent AR; up to 0.13 mg eq/kg) compared to egg whites (up to 0.01 percent AR; up to 0.028 mg eq/kg). The radioactivity recovered in tissues accounted for up to 0.12 percent AR (0.38 mg eq/kg in liver, up to 0.09 percent AR (up to 0.067 mg eq/kg) in muscle and up to 0.02 percent AR (up to 0.062 mg eq/kg) in fat.

The 201xtractabilityy of residues using organic solvents was 70.1[8]—106.5 percent TRR depending on the matrix. Extracted radioactivity was up to 90.3 percent TRR (up to 0.35 mg eq/kg) in liver, up to 97 percent TRR (up to 0.058 mg eq/kg) in fat, up to 101.6 percent TRR (up to 0.066 mg eq/kg) in muscle, up to 89.5 percent TRR (up to 0.033 mg eq/kg) in eggs.

The PES from all matrices was found to contain < 10 percent TRR or a low residue level in all matrices except liver and eggs therefore, no further characterization of unextracted residue was conducted. In eggs and liver, PES accounted for up to 43.7 percent TRR (up to 0.021 mg eq/kg) and up to 10.9 percent TRR (up to 0.048mg eq/kg) respectively, however were not further analysed.

Parent **florylpicoxamid** was extensively metabolized and was only detected in skin with fat (1.87 percent TRR, 0.003 mg eq/kg).

X12485649 metabolite accounted for 15.4 percent TRR (0.002 mg eq/kg. PH label only) in eggs, up to 16.6 percent TRR (up to 0.007 mg eq/kg) in breast muscle, up to 19.1 percent TRR (up to 0.011 mg eq/kg) in leg muscle, up to 14.4 percent TRR (up to 0.022 mg eq/kg) in skin with fat, up to 40.26 percent TRR (up to 0.012 mg eq/kg) in fat and up to 1.34 percent TRR (up to 0.005 mg eq/kg) in liver.

X12629973 metabolite accounted for up to 50.3 percent TRR (up to 0.022 mg eq/kg) in breast muscle, up to 25.7 percent TRR (up to 0.015 mg eq/kg) in leg muscle, up to 22.5 percent TRR (up to 0.034 mg eq/kg) in skin with fat and up to 5.9 percent TRR (up to 0.023 mg eq/kg) in liver.

[8] refers to the extractability in eggs on day nine (PY label). Extractability in eggs on days 7 and 9. 59.4 and 57.3 percent AR respectively, but further extraction with acidic/alkaline conditions was not preformed.

The **X12493055, X12641325, X12516991, X12563767 and X12530089** metabolites accounted for below 10 percent TRR (<0.05 mg eq/kg) in eggs and animal tissues.

Summary of animal metabolism

The metabolism of florylpicoxamid in poultry and ruminants demonstrates a comparable metabolite profile and was found similar with rats. The majority of the administered dose was rapidly excreted and parent was extensively metabolized via ester hydrolysis to form X12485649 which is further hydrolysed to form X12485631. In addition, in poultry, X12485649 is also oxidized to form X12629973.

Methods of analysis

Several analytical methods with minor modifications were available for the determination of florylpicoxamid and its metabolites (X12485649, X12563767, X12641685, X12717067, X12629973, X12485473) in plant (carrots, dry navy bean, oranges, soya bean, spinach, wheat grain, wheat forage, wheat hay, wheat straw, oilseed rape, cherries) commodities.

Several analytical methods with minor modifications were available for the determination of florylpicoxamid, X12485649 and X12629973 in animal (milk, skimmed milk, cream, bovine muscle, poultry muscle, bovine liver, poultry liver, bovine kidney, bovine fat, poultry fat, eggs) commodities.

For data gathering, the methods involve extraction with acetonitrile/water acidified with H_3PO_4 and purified with SPE. In all methods, residues were determined by LC-MS/MS with LOQ of 0.01 mg/kg for each analyte and in all matrices.

For enforcement, the methods involve extraction with acetonitrile/water acidified with acetic acid and purified with SPE. In all methods, residues were determined by LC-MS/MS with LOQ of 0.01 mg/kg for each analyte and in all matrices.

The solvent system used in the methods for enforcement/data gathering (acidified acetonitrile/water) was similar as that used in the metabolisms studies. The methods were compared to the QuEChERS extraction method analysing plant (barley grain, canola seed and peach) and animal (cream, bovine fat, bovine kidney, bovine liver, and bovine muscle) samples with incurred residues of florylpicoxamid and X12485649. The methods showed similar results with recoveries of florylpicoxamid and X12485649 ranging from 86 to 120 percent in plant and 91—124 percent in animal commodities.

In conclusion, the provided analytical methods are suitable for the analysis of florylpicoxamid and metabolites in plants and/or animal commodities. Mean recoveries were within the range of 70–120 percent and relative standard deviations (RSD) were less than 20 percent for all analytes tested.

Stability of residues in stored analytical samples

The Meeting received freezer storage stability data for florylpicoxamid and its metabolites, (X12485649, X12563767, X12641685, and X12717067) in various plant commodities covering six crop groupings, high-water (spinach), high oil (dry soybean), high

protein (dry navy bean), high starch (carrot, wheat grain), high acid (orange). Samples were fortified with each analyte at 0.1 mg/kg.

Residues of florylpicoxamid and metabolite X12485649 were stable at frozen storage conditions (≤-18 °C) for at least 774 days in all commodities, except spinach for florylpicoxamid. In spinach, florylpicoxamid was stable for up to 268 days.

Metabolites X12563767, X12641685 and X12717067 were stable at frozen storage conditions (≤-18 °C) for at least 970 days in all commodities, except spinach for X12717067. In spinach, X12717067 was stable for up to 61 days.

Storage stability of florylpicoxamid, X12485649 and X12629973 were investigated within the feeding studies in ruminants and lying hens.

Florylpicoxamid, was found to be stable up to 57 days in milk, up to 71 days in cream, up to 70 days in skim milk, up to 22 days in poultry liver (but not stable in ruminant liver), up to 69 days in muscle, up to 56 days in fat, and up to 62 days in kidney. Florylpicoxamid, was not stable in eggs.

Metabolite X12629973 was found to be stable up to 57 days in milk, up to 13 days in cream, up to 70 days in skim milk, up to 68 days in liver, up to 20 days in muscle, up to 21 days in poultry fat (but not stable in ruminant fat), up to 21 days in kidney,

Metabolite X12485649 was found to be stable up to 57 days in milk, up to 71 days in cream, up to 70 days in skim milk, up to 68 days in liver, up to 62 days in kidney, up to 69 days in muscle, up to 56 days in fat), up to 21 days in eggs.

Residue definition

Plant commodities

The metabolism of florylpicoxamid was assessed in wheat, tomatoes, lettuce and found to be similar in all crops. The metabolism in rotational crops was similar to the metabolism observed in primary crops. The processing of florylpicoxamid is expected to modify the nature of residues due to extensive degradation in high temperature hydrolysis conditions.

Florylpicoxamid was extensively metabolized in primary crops. In the wheat metabolism study, parent is not detected in grains, in the tomato metabolism study, accounted for up to 38.9 percent TRR (up to 0.067 mg eq/kg) in fruits, and in the lettuce metabolism study, accounted for up to 40 percent TRR (up to 1.3 mg eq/kg) in plants (immature and mature). In feed commodities, florylpicoxamid accounting for up to 6.43 percent TRR (up to 0.039 mg eq/kg) in forage, up to 1.44 percent (up to 0.042 mg eq/kg) in hay and up to 2.32 percent TRR (up to 0.053 mg eq/kg) in straw. Due to extensive soil degradation, parent was not up taken by the plants, thus not detect in rotation crop commodities.

X12485649 metabolite is found in the tomato metabolism study in fruits up to 40.9 percent TRR (up to 0.073 mg eq/kg) and in the lettuce metabolism up to 46.4 percent TRR (up to 1.3 mg eq/kg) in plants (immature and mature). This metabolite is also formed under hydrolysis

conditions. In feed commodities, X12485649 accounted for up to 14.69 (up to 0.087mg eq/kg) in forage, up to 13.63 percent TRR (up to 0.38mg eq/kg) in hay, up to 6.03 percent TRR (up to 0.15 mg eq/kg) in straw.

In deciding which compounds should be included in the residue definition for enforcement the Meeting noted that in fruit and leafy crops, parent represents a significant part of the residue, however in cereal commodities parent often remained unquantified. The residue levels of metabolite X12485649 from the field trials are significantly higher than those of the parent (approximately up to four times in forage, up to nine times in hay and up to 19 times in straw) which often remained unquantified, especially in grain (approximately 1.5 times higher). In addition, in other crops X12485649 also contributes at significant amount to the total residue. The Meeting concluded that parent florylpicoxamid and X12485649 were the major compounds and found to be suitable markers in all crops investigated.

Suitable analytical methods for enforcement are available for florylpicoxamid and X12485649 in plant matrices. The Meeting concluded that *sum of* florylpicoxamid and X12485649 expressed as florylpicoxamid should be considered as a suitable marker compound for enforcement purposes.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates X12485649, X12641685, X12563767.

The toxicity of X12485649 is covered by the toxicological properties of the parent. X12485649 represents a significant part of the total residue in food as well as in process products subject to sterilization. The Meeting decided to include the metabolite in the residue definition for dietary risk assessment.

X12641685 metabolite is found in the lettuce metabolism study up to 7.3 percent TRR (up to 0.14 mg eq/kg) in mature plants. In the field trials residues were <LOQ in all commodities. For the general toxicity of X12641685 no information are available, the metabolite is not genotoxic and the TTC Cramer class III value: 0.0015 mg/kg bw/day can be applied.

X12563767 metabolite is found in the lettuce metabolism up to 3,15 percent TRR (up to 0.062 mg eq/kg) in mature leaves. In the field trials residues were <LOQ in all commodities. For the general toxicity of X12563767 no information are available, the metabolite is not genotoxic and the TTC Cramer class III value: 0.0015 mg/kg bw/day can be applied.

In summary, the Meeting agreed that the residue definition for dietary risk assessment should be *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid*.

Animal commodities

The metabolism of florylpicoxamid was assessed in lactating goats and laying hens and found to be similar.

Florylpicoxamid was extensively metabolized and not detected in milk, eggs or animal tissues except skin with fat found <10 percent TRR; (<0.01 mg eq/kg).

X12485649 metabolite was observed at major proportions in ruminant tissues (muscle, fat, liver and kidney) and poultry tissues (leg muscle, skin with fat and fat). In the feeding studies, X12485649 was present in all matrices/tissues, up to 0.028 mg/kg in whole milk, 0.18 mg/kg in liver, 0.049 mg/kg in kidney, 0.021 mg/kg in muscle and 0.24 mg/kg in fat. In the poultry studies, X12485649 was not detected in any matrix/tissue.

X12641325 metabolite was observed in ruminant liver (6.3 percent TRR; 0.011 mg eq/kg) and ruminant kidney (27.3 percent TRR; 0.008 mg eq/kg). The toxicity of X12641325 is covered by the toxicological properties of the parent. The Meeting noted that although the proportions of X12641325 compared X12485649 are approximately 20 percent in liver and 130 percent in kidney, the contribution of these commodities to the overall dietary exposure was considered as insignificant and decided not to include this metabolite in the residue definition for enforcement or dietary risk assessment.

X12584261 metabolite was observed at major proportions (up to 10.35 percent TRR; up to 0.047 mg eq/kg) in ruminant fat only. For the general toxicity of X12584261 no information are available, the metabolite is not genotoxic and the TTC Cramer class III value: 0.0015 mg/kg bw/day can be applied.

X12629973 metabolite was observed at major proportions (up to 50.3 percent TRR; up to 0.034 mg eq/kg) in poultry tissues (breast muscle, leg muscle, skin with fat and liver). In the feeding studies, X12629973 was not detected in any matrix/tissue. For the general toxicity of X12584261 no information are available, the metabolite is not genotoxic and the TTC Cramer class III value: 0.0015 mg/kg bw/day can be applied.

In conclusion, X12485649 was the major residue in most animal matrices and the predominant residue found in the livestock feeding studies (goat only). Suitable analytical methods for enforcement are available for florylpicoxamid and X12485649 in animal matrices.

Storage stability data demonstrated that parent may degrade in stored animal commodities and its residues might be underrepresented in animal metabolism and feeding studies. The Meeting decided that florylpicoxamid and X12485649 expressed as florylpicoxamid represents a suitable marker for enforcement purposes and in animal matrices.

Florylpicoxamid residues are not found in fat or other animal tissue in the metabolism nor in feeding studies. X12485649 is observed in the goat metabolism study at levels up to 0.053 mg eq/kg in fat which are approximately four times higher compared to flank muscle (up to 0.013 mg eq/kg) and at levels up to 0.007 mg eq/kg in cream which are approximately 3 – 7 times higher compared to skim milk (up to 0.002 mg eq/kg). In the cow feeding study, levels of X12485649 in fat are approximately 11 times higher compared to muscle. In the poultry study, levels in fat (up to 0.012 mg eq/kg) are 1.7 times higher compare to breast muscle (up to 0.007 mg eq/kg) similar compared to leg muscle (up to 0.011 mg eq/kg).

The Meeting decided that the residue is fat-soluble.

In summary, the Meeting agreed that the residue definition for compliance with the MRL and dietary risk assessment for animal commodities should be: *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid.*

The residue is fat-soluble.

Based on the above, the Meeting recommended the following residue definitions:

- residue definition for compliance with the MRL and dietary exposure for plant and animal commodities: *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid*
- residues to be included in the livestock dietary burden calculations: *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid*.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data for foliar applications of florylpicoxamid on grapes, strawberries, banana, mango, fruiting vegetables (cucurbits and other), sugar beet, wheat, and rapeseed.

The Meeting received data on barley, dry peas and dry beans but no registered uses were provided for these crops.

In this appraisal, the following residue summaries are given:

- Florylpicoxamid (total): *sum florylpicoxamid and X12485649 expressed as florylpicoxamid*: For maximum residue level estimation in plant commodities, dietary exposure calculations and dietary burden calculations.
- Results of X1245649 are adjusted by the conversion factor 1.089 prior to summing with the result of florylpicoxamid. Any results that are ND or <LOQ are given 0.021 mg/kg for these calculations. Residues are rounded to two significant figures, unless addition of LOQs.

Grape

The use of florylpicoxamid on grapes is registered in Australia for foliar application. The Meeting determined that the critical GAP consists of three applications at corresponding to 15 g ai /hL with a spray interval of 10 d and a PHI of 10d.

Fourteen supervised trials on table and wine grapes conducted in Australia (8), the United States of America (4) and Argentina (2) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n= 14): 0.074, 0.090, 0.15, 0.28, 0.31, 0.34, 0.37, 0.38, 0.45, 0.50, 0.67, 0.97, 1.0, 1.5 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR of 0.375 mg/kg for grapes (FB 0269).

Strawberries

The use of florylpicoxamid on strawberries is registered in Australia for foliar application under outdoor or protected conditions. The Meeting determined that the critical GAP consists of three applications at 150 g ai /ha, with a spray interval of 7d and a PHI of 1d.

Nineteen supervised trials on outdoor strawberries conducted in Australia (4), Brazil (6), the United States (8), Canada (1) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=19): 0.084, 0.085, 0.17, 0.22, 0.22, 0.22, 0.22, 0.24, 0.26, 0.27, 0.29, 0.44, 0.46, 0.51, 0.61, 0.66, 0.68, 0.68, 0.99 mg/kg.

Seven supervised trials on protected strawberries conducted in Australia (2), the United States (3), Canada (2) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=7): 0.11, 0.17, 0.17, 0.26, 0.31, 0.37, 0.44 mg/kg.

The Meeting noted that median residues on outdoor and protected trials are within a 5-fold difference and the Mann-Whitney U-test also determined that the datasets are not statistically different, therefore the Meeting decided to combine these datasets for a recommendation. The combined data set for fruits is (n= 26): 0.084, 0.085, 0.11, 0.17, 0.17, 0.17, 0.22, 0.22, 0.22, 0.22, 0.24, 0.26, 0.26, 0.27, 0.29, 0.31, 0.37, 0.44, 0.44, 0.46, 0.51, 0.61, 0.66, 0.68, 0.68, 0.99 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.26 mg/kg for strawberries (FB 0275) based on the combined dataset.

Banana

The use of florylpicoxamid on bananas is registered in Panama for foliar application. The Meeting determined that the critical GAP consists of three applications at 50 g ai /ha, with a spray interval of 7d and a PHI of 0d.

Twenty-three supervised trials conducted in Australia (7), Colombia (3), Costa Rica (4), Ecuador (3), Brazil (6) matching the cGAP were provided. In 17 trials (all except from the Brazilian trials), banana pulp was analysed separately. In all trials bananas were treated bagged and unbagged thus for the calculations, the highest residue derived from either treatment was selected.

In bananas (whole fruit) residues for florylpicoxamid in ranked order were (n=23) [9]: <0.021 (6), 0.027, 0.027, 0.03, 0.031, 0.032, 0.04 (b), 0.04, 0.041, 0.042, 0.043, 0.044, 0.058 (b), 0.064 (b), 0.1, 0.11, 0.22, 0.3 mg/kg.

Residues in the edible portion (banana pulp) for dietary risk assessment in ranked order were (n = 17): <0.021 (11), 0.021, 0.026, 0.03, 0.031, x0.032 (2) mg/kg.

[9] For residues derived from bagged treatments the symbol (b) is added, next to the value.

The Meeting estimated a maximum residue level of 0.4 mg/kg (whole fruit) and an STMR of 0.021 mg/kg (banana pulp) for bananas (FI 0327).

Mango

The use of florylpicoxamid on mangos is registered in Nicaragua for foliar application. The Meeting determined that the critical GAP consists of three applications at 150 g ai /ha, with a spray interval of 7 d and a PHI of 7d.

Eight supervised trials conducted in Brazil matching the cGAP were provided. In mangos (whole fruit without stone) residues for florylpicoxamid in ranked order were (n=8): 0.043, 0.075, 0.086, 3x 0.13, 0.20, 0.37 mg/kg. Residues in the edible portion (mango pulp) for dietary risk assessment in ranked order were (n = 8): <0.021 (7), 0.023 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg (assuming the pit constitutes 15 percent of the whole fruit weight), and an STMR of 0.021 mg/kg (mango pulp) for mango (FI 0345).

Fruiting vegetables, cucurbits–cucumbers and summer squashes, subgroup

The use of florylpicoxamid on the subgroup of cucurbits–Cucumbers and summer squashes, is registered in Australia for foliar application under protected and outdoor conditions with different GAP for each condition. For outdoor conditions, the cGAP consists of three applications at 150 g ai /ha, BBCH not specified[10], with a spray interval of 7d and a PHI of 1d. For the protected conditions, the cGAP consists of three applications at 15 gr ai /hL[11], BBCH not specified[4], with a spray interval of 7d and a PHI of 1d.

Summer squash and cucumber (outdoor)

Ten supervised trials on outdoor summer squash conducted in the United States (8) and Australia (2) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=10): 0.045, 0.049, 0.063, 0.068, 0.070, 0.089, 0.10, 0.12, 0.12, 0.19 mg/kg. Two additional supervised trials on outdoor summer squash conducted in Australia with a GAP of five applications (instead of 3) at 150 g/ha and a PHI of 1d. were provided. In fruits, residues for florylpicoxamid (total) were (n=2): <0.021, 0.057 mg/kg.

The Meeting concluded that due to the high growth rate of summer squash, the two earlier treatments do not contribute significantly in the final residues and decided to combine the two datasets. The combined residues based on summer squash were (n=12): <0.021, 0.045, 0.049, 0.057, 0.063, 0.068, 0.070, 0.089, 0.10, 0.12, 0.12, 0.19 mg/kg.

[10] Use as a protectant spray. Apply prior to disease infection or when conditions favour disease development (wet and cloudy conditions).

[11] The chosen spray volume, amount of product per 100 L of water, and the sprayer set up and operation may need to be changed as the crop grow

Cucumber (outdoor)

Three supervised trials on outdoor cucumbers conducted in China matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=3): 0.063, 0.092, 0.17 mg/kg. Thirteen supervised trials on outdoor cucumbers conducted in Australia (4), Europe (4), the United States (5) with a GAP of five applications (instead of 3) at 150 g/ha and a PHI of 1d. were provided. In fruits, residues for florylpicoxamid (total) were (n=13): 0.029, 2x 0.031, 0.038, 0.042, 0.046, 0.054, 0.055, 0.067, 0.086, 0.10, 0.11, 0.14 mg/kg.

The Meeting concluded that due to the high growth rate of cucumbers, the two earlier treatments do not contribute significantly in the final residues and decided to combine the two datasets. The combined residues based on summer squash were (n=16): 0.017, 0.029, 2x 0.031, 0.038, 0.042, 0.046, 0.054, 0.055, 0.063, 0.067, 0.086, 0.092, 0.10, 0.11, 0.14, 0.17 mg/kg.

Cucumbers (indoor)

Eight supervised trials on indoor cucumbers conducted in the United States (5) and China (3) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=8): <0.021, 0.022, 0.025, 0.049, 0.054, 0.11, 0.13, 0.14 mg/kg.

Four supervised trials on indoor cucumbers conducted in Europe with a GAP of five applications (instead of 3) at 150 g/ha and a PHI of 1d. were provided. In fruits, residues for florylpicoxamid (total) were (n=4): 0.043, 0.051, 0.12, 0.16 mg/kg.

The Meeting concluded that due to the high growth rate of cucumbers, the two earlier treatments do not contribute significantly in the final residues and decided to combine the two datasets. The combined residues based on cucumber were (n=12): <0.021, 0.022, 0.025, 0.043, 0.049, 0.051, 0.054, 0.11, 0.12, 0.13, 0.14, 0.16 mg/kg. Based on the combined dataset, a median of 0.053 mg/kg is estimated.

The registration covers the subgroup of fruiting vegetables, cucurbits - cucumber and summer squashes and since cucumber and summer squashes are representative commodities the Meeting recommends the estimates for the subgroup. The Meeting noted that the outdoor dataset gives higher residues compared to the protected dataset and decided to derive a maximum residue level and STMR based on the outdoor dataset. The Meeting noted that median residues on summer squash and cucumbers from the outdoor uses are within a 5-fold difference and the Mann-Whitney U-test also determined that the datasets are not statistically different, therefore the Meeting decided to combine these datasets for a recommendation. The combined dataset for fruits is (n= 29): 0.017, <0.021, 0.029, 0.031 (2), 0.038, 0.042, 0.045, 0.046, 0.049, 0.054, 0.055, 0.057, 0.063, 0.063, 0.067, 0.068, 0.070, 0.086, 0.089, 0.092, 0.10, 0.10, 0.11, 0.12, 0.12, 0.14, 0.17 0.19 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR of 0.063 mg/kg for the subgroup of fruiting vegetables, cucurbits–cucumbers and summer squashes (VC 2039) based on the outdoor dataset.

Fruiting vegetables, cucurbits–melons, pumpkins and winter squashes, subgroup

The Meeting determined that the critical GAP for outdoor conditions, consists of three applications at 150 g ai /ha, BBCH not specified[12], with a spray interval of 7d and a PHI of 1d.

Sixteen supervised trials on outdoor melons conducted in the United States (8), Brazil (6), Australia (2) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=16): 0.027, 0.031, 0.037, 0.046, 0.052, 0.056, 0.062, 0.076, 0.083, 0.084, 0.09, 0.092, 0.094 (2), 0.14, 0.31 mg/kg. The registration covers the subgroup of fruiting vegetable, cucurbits - melons, pumpkins and winter squashes and since melon is the representative commodity the Meeting recommends the estimates for the subgroup.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.0795 mg/kg for the subgroup of fruiting vegetable, cucurbits - melons, pumpkins and winter squashes (VC 2040).

Fruiting vegetables, other than cucurbits

The use of florylpicoxamid on fruiting vegetables, other than cucurbits[13] is registered in Australia for foliar application under outdoor and protected conditions under protected and outdoor conditions with different GAP for each condition. For outdoor conditions, the cGAP consists of three applications at 150 g ai /ha, BBCH not specified[14], with a spray interval of 7d and a PHI of 1d. For the protected conditions, the cGAP consists of three applications at 15 gr ai /hL[15], BBCH not specified[4], with a spray interval of 7d and a PHI of 1d.

Tomatoes (outdoor)

Thirty-five supervised trials on outdoor tomatoes conducted in Australia (6), Brazil (6), Argentina (6) and the United States (17) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=35): 0.025, 0.028, 0.045, 0.052, 0.050, 0.054, 0.057, 0.060, 0.067, 0.075, 0.081, 0.091, 0.095, 0.097, 0.098, 0.11, 0.11, 0.12 (2), 0.13 (3), 0.14 (2), 0.15 (3), 0.16, 0.17 (2), 0.19 (2), 0.27 0.41, 0.85 mg/kg.

[12] Use as a protectant spray. Apply prior to disease infection or when conditions favour disease development (wet and cloudy conditions).

[13] Fruiting vegetables, other than cucurbits.

[14] Use as a protectant spray. Apply prior to disease infection or when conditions favour disease development (wet and cloudy conditions).

[15] The chosen spray volume, amount of product per 100 L of water, and the sprayer set up and operation may need to be changed as the crop grow

Tomatoes (indoor)

Five supervised trials on indoor tomatoes conducted in the United States (3) and Canada (2) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=5): 0.062, 0.11, 0.15, 0.16, 0.70 mg/kg.

The Meeting estimated a maximum residue level of 0.9 mg/kg and an STMR of 0.12 mg/kg for the subgroup of tomatoes (VO 2045) based on the more critical outdoor dataset. The Meeting recommends extrapolating the estimates to eggplants (VO 2046).

Peppers

For peppers, the Meeting received supervised trials for the outdoor uses only, for the protected uses data are not available.

Thirty supervised trials on outdoor peppers conducted in Australia (6), the United States (18) and Argentina (6) matching the cGAP were provided. In fruits, residues for florylpicoxamid (total) were (n=30): 0.027, 0.032, 0.034, 0.038, 0.049, 0.050, 0.053, 0.068, 0.078, 0.096, 0.10 (3), 0.14, 0.15 (2), 0.18 (2), 0.21, 2x0.26, 0.30 (2), 0.31 (2), 0.32, 0.37, 0.39, 0.47, 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg and an STMR of 0.15 mg/kg for peppers, chilli (VO 0444) and peppers, sweet (VO 0445).

Peppers, chilli, dried

On the basis of the maximum residue level and the STMR for peppers, chilli and default dehydration factor of 10, the Meeting estimated a maximum residue level of 8 mg/kg and an STMR value of 1.5 mg/kg for

Lentils

The use of florylpicoxamid on lentils is registered in Canada for foliar application. The Meeting determined that the critical GAP consists of one application at 50 g ai/ha, up to BBCH 72 and a PHI of 30d.

For lentils, supervised residue data were not provided. Residue trials on dry beans and peas were available. The Meeting agreed that since beans and peas are the representative commodities for the group that includes lentils to consider the trials from beans and peas.

Ten supervised trials on dry beans (5) and peas (5) conducted in the United States (8) and Canada (2) at a more critical use pattern of two applications, at exaggerated rates of 100–260 g ai/ha and a PHI of 21- 36 d, were available. In seeds, residues for florylpicoxamid (total) were (n=10): 10x <0.021 mg/kg.

Noting the residues from all trials with exaggerated rates, were < 0.021 mg/kg, the Meeting agreed to estimate a maximum residue level of 0.02 and an STMR of zero in lentil (VD 0533).

Sugar beet roots

The use of florylpicoxamid on sugar beet is registered in Canada for foliar application. The Meeting determined that the critical GAP consists of two applications at 150 g ai/ha with a spray interval of 10 d and a PHI of 21d.

Eighteen supervised trials on sugar beets conducted in the United States (12) and Canada (6) matching the cGAP were provided. In roots, residues for florylpicoxamid (total) were (n=18): 14x <0.021, 2x 0.021, 0.026, 0.050 mg/kg.

The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR of 0.021 mg/kg for sugar beet roots (VR 0596).

Wheat

The use of florylpicoxamid on wheat is registered in Canada and Australia for foliar application. The Meeting determined that the critical GAP consists of two applications at 50 g ai/ha, up to BBCH 69, with a spray interval of 14 d with a PHI not required.

Sixty-nine supervised trials on wheat conducted in Australia (10), Europe (27), the United States (15) and Canada (17) matching the cGAP were provided. In grain, residues for florylpicoxamid (total) were (n=69): 68x <0.021, 0.023 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.021 mg/kg for wheat (GC 0654).

Rape seed

The use of florylpicoxamid on rape seed is registered in Canada for foliar application. The Meeting determined that the critical GAP consists of two applications at 150 g ai/ha with a spray interval of 7 d and a PHI of 21d.

Twenty supervised trials on rape seed conducted in Australia (8), the United States (5) and Canada (7) matching the cGAP were provided. In seed residues for florylpicoxamid (total) were (n=20): 10<0.021, 0.021, 0.022, 0.024, 0.028, 0.029, 0.061, 0.068, 0.081, 0.083, 0.10 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg, an STMR of 0.021 mg/kg for rape seed (SO 0495).

Feed commodities

Wheat forage

The use of florylpicoxamid on wheat is registered in in Canada and Australia for foliar application. The Meeting determined that the critical GAP consists of two applications at 50 g ai/ha, up to BBCH 69, with a spray interval of 14 d and a PHI of 14 days for feed commodities.

Fifty-four supervised trials on wheat conducted in Australia (10), Europe (12), the United States (16) and Canada (16) matching the cGAP were provided. In forage, residues for florylpicoxamid (total) were (n=54): <0.021, 0.021, 0.027, 0.047, 0.058, 0.059, 0.062, 0.070, 0.070, 0.075, 0.084, 3x 0.093, 2x 0.13, 0.15, 4x 0.16, 2x 0.17, 2x 0.19, 0.20, 0.21, 0.22, 3x 0.23, 0.29, 0.34, 0.35, 0.42, 0.43, 0.45, 0.47, 0.73, 0.53, 0.81, 0.90, 0.91, 0.94, 1.1, 1.2, 1.2, 1.3, 1.3, 1.4, 1.5, 2.7, 4.1, 6.0 mg/kg.

The Meeting estimated a median residue of 0.22 mg/kg and a highest residue of 6 mg/kg for wheat forage (AS 3552).

Wheat, hay and/or straw

The use of florylpicoxamid on wheat is registered in Canada and Australia for foliar application. For feed, the Meeting determined that the critical GAP consists of two applications at 50 g/ha, up to BBCH 69, with a spray interval of 14 d with a PHI of 14d for feed commodities.

Wheat hay (88 percent dry matter)

Six supervised trials on wheat conducted in the United States matching the cGAP were provided. In hay, residues for florylpicoxamid (total) were (n=6): 0.03, 0.03, 0.036, 0.073, 0.57, 0.74 mg/kg (as received).

Wheat straw (89 percent dry matter)

Sixty-five supervised trials on wheat conducted in Australia (10), Europe (23), the United States (16) and Canada (16) matching the cGAP were provided. In straw, residues for florylpicoxamid (total) were (n=65): <0.021 (2), 0.021, 0.028, 0.029 (2), 0.030 (3), 0.032 (2), 0.033 (3), 0.035, 0.039 (2), 0.040, 0.043 (2), 0.045, 0.048, 0.051, 0.057 (2), 0.058, 0.062, 0.067, 0.079, 0.084, 0.085 (2), 0.086, 0.092, 0.10 (2), 0.11 (3), 0.12 (4), 0.13, 0.14, 0.17, 0.18, 0.19, 0.20, 0.21 (3), 0.22, 0.27 (2), 0.28, 0.30, 0.38, 0.59, 0.98 (2), 1.1, 1.4, 1.5, 1.6 mg/kg (as received).

The Meeting estimated a maximum residue level of 2 mg/kg mg/kg (based on a dry matter content of 89 percent), a median of 0.086 mg/kg (as received), and a highest of 1.6 mg/kg (as received) for wheat, hay and/or straw (AS 0654) based on the more critical dataset of wheat straw.

Rape seed, forage

The use of florylpicoxamid on rape seed is registered in Canada for foliar application. The Meeting determined that the critical GAP consists of two applications at 150 g ai/ha with a spray interval of 7 d and a PHI of 21d.

Five supervised trials on rape seed conducted in Australia matching the cGAP were provided. In four, forage was collected and analysed. In forage, residues for florylpicoxamid (total) were (n=4): 2x 0.057, 0.083, 0.12 mg/kg.

The Meeting estimated a median of 0.07 mg/kg and a highest residue of 0.12 mg/kg for rape seed, forage (AM 0495).

Sugar beet tops

The use of florylpicoxamid on sugar beet is registered in Canada for foliar application. The Meeting determined that the critical GAP consists of two applications at 150 g ai/ha with a spray interval of 10 d and a PHI of 21d.

Eighteen supervised trials on sugar beets conducted in the United States and Canada matching the cGAP were provided. In leaves, residues for florylpicoxamid (total) were (n=18): <0.021 (3), 0.021 (2), 0.024, 0.025, 0.026, 0.032, 0.033, 0.043, 0.056, 0.069, 0.076, 0.093, 0.12, 2x 0.20 mg/kg.

The Meeting estimated a median of 0.0325 mg/kg and a highest residue of 0.2 mg/kg for sugar beet tops (AM 0596).

Fates of residues during processing

High temperature hydrolysis

The Meeting received information on the hydrolysis of phenyl (PH) and pyrazole (PY)-labelled florylpicoxamid, simulating typical processing conditions (90 °C, pH 4, 20 minutes to simulate pasteurization, 100 °C, pH 5, 60 minutes to simulate boiling, baking and brewing and 120 °C, pH 6, 20 minutes to simulate sterilization). Significant hydrolysis was observed in all conditions studies.

Florylpicoxamid was stable under pasteurization and baking/brewing/boiling conditions, (accounting for 90.1, 83.6 percent AR) and significantly degraded under sterilization, (accounting for 43.9 percent AR). Parent is degraded into X12485649 (9.9, 16.4 and 48.6 percent AR, respectively) and X12485631 (6.9 percent AR only at sterilization).

The Meeting received an additional study on the hydrolysis of metabolites X12485649, X12563767, X12717067 and X12641685 simulating pasteurization, baking/brewing/boiling, and sterilization conditions.

X12485649 was hydrolytically stable in all conditions tested.

X12563767 was stable under the conditions representing pasteurization and baking/brewing/boiling. Under the conditions representing sterilization, X12563767 degraded (56 percent AR) with the major degradation product being X12485631 (27.1 percent AR).

X12717067 (PH label only) was stable under conditions representing pasteurization (87.3 percent AR) and unstable under baking/brewing/boiling and sterilization conditions, accounting for 60 and 5.4 percent AR respectively.

X12641685 was unstable in all conditions (51, 38 and seven percent AR under pasteurization, baking/brewing/boiling, and sterilization, respectively). The major degradation products were X12728951 (48, 58 and 11 percent AR respectively), X12485473 (67.9 percent AR

during pasteurization) and X12512159 (5.1 and 94.8 percent AR during baking/brewing/boiling and pasteurization respectively).

Stereoisomer analysis demonstrated that no significant conversion of florylpicoxamid and X12485649 is observed.

Residues in processed commodities

The fate of florylpicoxamid residues after processing has been examined in grape, tomato, sugar beet and wheat. Additional study on barley and soya bean were available however a use pattern was not submitted. The results are shown in Table 3.

Table 3. Processing factors for florylpicoxamid used for estimation of maximum residue levels, median and highest residue

Commodity	Processed commodity or fraction	Code	Raw commodity [$STMR_{RAC}$/MRL_{RAC}] (mg/kg)	Individual processing factors	Median or best estimate processing factor	STMR-P (mg/kg)	MRL (mg/kg)
Grape	Grape, dried	DF 0269	0.38/3	1.5, 2.1, 7.5	2.1	0.8	7
	Juice	JF 0269		0.14, 0.25, 0.25	0.25	0.1	-
	Jelly	-		0.050, 0.061, 0.088	0.061	0.023	-
	Grape, wine (red)	-		0.063, 0.064	0.064	0.02	-
	Grape, wine (white)	-		0.023	0.023	0.01	-
Tomato	Tomato, dried (Sun-Dried)	DV 0448	0.12/0.9	4.1, 6.0, 11	6.0	0.72	6
	Tomato, Paste	DM 0448		0.29, 0.63, 1.2	0.63	0.076	
	Tomato, Puree	DM 0448		<0.030, 0.19, 0.24	0.19	0.023	
	Tomato, Juice	JF 0448		<0.064, 0.11, 0.64	0.11	0.01	
	Pomace, Wet	DM 3525		7.7, 12, 13	12	1.4	
	Tomato, Canned Fruit			<0.015, <0.030, <0.064	<0.03	<0.004	
Sugar beet	Refined Sugar	DM 3523	0.02/0.05	<0.17, <0.20, <0.87	<0.2	<0.004	
	Pulp, Wet	AM 1201		0.96, 0.97, 1.6	0.97	0.019	
	Pulp, Dried	AM 3599		4.8, 6.4, 8.3	6.4	0.13	
	Molasses	DM 0596		<0.17, <0.20, <0.87	<0.2	<0.004	
	Ensiled Pulp	Yes		0.91, 1.0, 1.3	<1	<0.02	
Wheat	aspirated grain fractions	CF 3521	0.021/0.03	8.6	8.6	0.18	0.3
	Middlings	CF 3514		0.95	0.95		

Commodity	Processed commodity or fraction	Code	Raw commodity [$STMR_{RAC}/MRL_{RAC}$] (mg/kg)	Individual processing factors	Median or best estimate processing factor	STMR-P (mg/kg)	MRL (mg/kg)
	Shorts (cereal grain milling by-product)	CF 3515		1.2	1.2	0.025	
	Wheat Bran (unprocessed)	CM 0654		2.2	2.2	0.046	0.07
	Wheat White flour (550)	CF 1211		<0.91	<0.91	<0.019	
	Wheat Wholemeal flour	CF 1212		1.2	1.2	0.025	
	Wheat Wholemeal bread	-		1.0	1.0	0.021	
	Wheat Germ	CF 1210		<0.91	<0.91	<0.019	
	Gluten feed meal	CF 3522		0.95	0.95	0.02	
	Wheat Starch	-		<0.91	<0.91	<0.019	
	Wheat Gluten	CF 3522		1.3	1.3	0.027	0.04

$STMR\text{-}P = STMR_{RAC} \times PF$

Residues in animal commodities

In a feeding study in lactating goats, florylpicoxamid was fed via the diet to three cows per dose group for 29 consecutive days. The animals received equivalents of 3.15, 6.20, 18.96 or 63.7 ppm in the diet (DM). Residues of florylpicoxamid and metabolites X12485649 and X12629973 were determined. Due to stability issues of parent and metabolites in several animal commodities, samples were analysed between ten and19 days, thus the observed degradation during storage has limited impact in the results.

In the lower level (3 ppm) residues of florylpicoxamid, X12485649, and X12629973 were not detected (<LOD) in any whole milk, skim milk or cream samples or aminal tissues (kidney, muscle, liver and fat). At the highest level (63.7 ppm) florylpicoxamid was not detected (<LOD) in milk or animal tissues. X12485649 was found in all matrices/tissues except skim milk, up to 0.028 mg/kg in whole milk, 0.039 mg/kg in cream, 0.18 mg/kg in liver, 0.049 mg/kg in kidney, 0.021 mg/kg in muscle and 0.24 mg/kg in fat (mesenterial, perirenal and subcutaneous).

In a feeding study in laying hens, 12 hens/treatment group were dosed with florylpicoxamid for 28 days, at feeding levels equivalent to 0.63, 1.25, 6.35 and 17.44 ppm in the diet. Depuration in egg was performed on the group dosed. Residues of florylpicoxamid and metabolites X12485649 and X12629973 were determined. The storage period of the samples (20–22 days) is covered by te storage stability study.

In all matrices (eggs and animal), residues of of florylpicoxamid and metabolites X12485649 and X12629973 were not detectable (<LOD). In one sample at the intermediate level of 1.25 ppm, residues of florylpicoxamid in fat were found at 0.045 mg/kg while samples obtained from higher dose levels did no contain detactable residues. In the poultry metabolisms study, conducted with 13.2 or 12.7 ppm feed, florylpicoxamid was detect in skin with fat only (1.87 percent TRR, 0.003 mg eq/kg), therefore and based on the overall residue behaviour results of florylpicoxamid in the feeding study the Meeting concluded that values should not be included in the calculations.

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR by the current Meeting, including processed and forage commodities. Those commodities are included in Table 5. The input was based on the intake of parent florylpicoxamid and X12485649 expressed as florylpicoxamid.

The dietary burdens, estimated using the 2018 OECD Feed diets listed in appendix XIV Electronic attachments to the 2016 edition of the FAO manual[16], are presented in Annex 6 and summarized in Table 5.

Table 4. Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: parent ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.64	0.38	5,3	0.51	**24,0**[a]	**1,7**[b]	0.48	0.48
Dairy cattle	5,12	0.48	5,34	0.51	22,4	1,65	0.44	0.44
Poultry – broiler	**0.43**[d]	**0.43**[c]	0.18	0.18	0.18	0.18	0.04	0.04
Poultry – layer	0.43	0.43	2,65	0.29	0.25	0.18	0.25	0.25

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

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk

[c] Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and poultry eggs

[d] Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and poultry eggs

The Meeting used the calculated beef and dairy cattle maximum and mean dry weight dietary burdens of 24 ppm and 1.7 ppm for estimating residue levels in milk and ruminant tissues.

The Meeting used the calculated poulty – layer maximum and mean dry weight dietary burdens of 0.43 ppm and 0.43 ppm for estimating residue levels in eggs and poultry tissues.

Animal commodity maximum residue levels

Ruminants

The calculations used to estimate maximum residue levels and STMR values for ruminant matrices are shown in Table 6 below.

[16] http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/

Table 5. Anticipated residues of sum of florylpicoxamid and X12485649 expressed as florylpicoxamid in ruminant commodities

Anticipated residues of florylpicoxamid in cattle commodities							
	Feed Level (ppm) for milk residues	Total residues (mg eq/kg) in milk	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle) - Parent							
Feeding Study	18.96	<0.021	18.96	<0.021	0.074	0.034	0.11
	63.66	0.040	63.7	0.033	0.20	0.063	0.27
Dietary burden and estimate of highest residue	24.00	0.023	24.00	0.024	0.086	0.036	0.12
STMR Determination (beef or dairy cattle)							
Feeding Study	0	<0.021	0	<0.021	<0.021	<0.021	<0.021
	3.15	<0.021	3.15	<0.021	<0.021	<0.021	0.023
Dietary burden and estimate of highest residue	1.70	0.013	1.70	0.018	0.023	0.022	0.043
MRL Determination (beef or dairy cattle)							
Feeding Study	18.96	<0.021	18.96	0.021	0.074	0.034	0.113
	63.66	0.040	63.66	0.033	0.202	0.063	0.270
Dietary burden and estimate of highest residue	24.00	0.03	24.00	0.03	0.09	0.02	0.15

The Meeting estimated maximum residue levels of 0.03 mg/kg in milk, of 0.15 mg/kg in mammalian fats and meat (mammalian except marine mammals) and of 0.09 mg/kg in mammalian edible offal's.

The Meeting also estimated an STMR of 0.013 mg/kg in milk, of 0.043 mg/kg in mammalian fats, of 0.024 in mammalian muscle, of 0.023 mg/kg in mammalian liver and of 0.022 mg/kg in mammalian kidney.

Poultry

The calculations used to estimate maximum residue levels, and STMR values for poultry matrices are shown in Table 7 below.

Table 6. Anticipated residues of sum of florylpicoxamid and X12485649 expressed as florylpicoxamid in poultry commodities

	Feed Level (ppm) for eggs residues	Total residues (mg eq/kg) in eggs	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (broiler or layer poultry)							
Feeding Study	1.25	<0.021	1.25	<0.021	<0.021	<0.021	<0.021
	3.53	<0.021	3.53	<0.021	<0.021	<0.021	<0.021
Dietary burden and estimate of highest residue	3.47	0.02	3.47	<0.021	<0.021	<0.021	<0.021
STMR Determination (broiler or layer poultry)							
Feeding Study	0.63	<0.021	0.63	<0.021	<0.021	<0.021	<0.021
	1.25	<0.021	1.25	<0.021	<0.021	<0.021	<0.021
Dietary burden and estimate of highest residue	0.89	0.02	0.89	<0.021	<0.021	<0.021	<0.021
MRL Determination (broiler or layer poultry)							
Feeding Study	1.25	<0.021	1.25	<0.021	<0.021	<0.021	<0.021
	3.53	<0.021	3.53	<0.021	<0.021	<0.021	<0.021
Dietary burden and estimate of highest residue	3.47	0.02	3.47	0.02	0.02	0.02	0.02

The Meeting estimated a maximum residue level of 0.02 mg/kg in eggs, poultry muscle, fat and edible offal's.

The Meeting also estimated an STMR of zero in eggs, poultry muscle and edible offal's.

RECOMMENDATIONS

On the basis of the data from supervised trials, processing studies, storage stability studies and feeding studies the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

The residue definition for compliance with the MRL and dietary exposure for plant commodities is *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid*.

The residue definition for compliance with the MRL and dietary exposure for animal commodities is *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid*.

The residue is fat-soluble.

Table 8. Residue levels suitable for establishing maximum residue limits and for IEDI assessment

CCN	Commodity name	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg
		New	Previous	
FI 0327	Banana	0.4		0.021
MO 0105	Edible offal (mammalian)	0.09		0.023 (liver) 0.022 (kidney)
PE 0269	Eggs	0.02		0
DF 0269	Grape, dried	7		0.8
	Grape, jelly	-		0.023
JF 0269	Grape, juice	-		0.1
	Grape, wine (red)	-		0.02
	Grape, wine (white)	-		0.01
FB 0269	Grapes	3		0.375
VD 0533	Lentil (dry)	0.02		0
MF 0100	Mammalian fats (except milk fats)	0.15		0.043
FI 0345	Mango	0.5		0.021
MM 0095	Meat (from mammals other than marine mammals)	0.15		0.024 (muscle) 0.043 (fat)
ML 0095	Milks	0.03		0.013
VO 0444	Peppers, chilli	0.8		0.15
HS 0444	Peppers, chilli, dried	8		1.5
VO 0445	Peppers, sweet	0.8		0.15
PF 0111	Poultry fats	0.02		0
PM 0111	Poultry meat	0.02		0
PO 0111	Poultry, edible offal of	0.02		0
SO 0495	Rape seed	0.15		0.021
DM 3523	Refined sSugar	-		<0.004
FB 0275	Strawberry	1.5		0.26
VO 2046	Subgroup of eggplants	0.9		0.12
VC 2039	Subgroup of fruiting vegetables, cucurbits - cucumbers and summer squashes	0.3		0.063
VC 2040	Subgroup of fruiting vegetables, cucurbits – melons, pumpkins and winter squashes	0.4		0.0795
VO 2045	Subgroup of tomatoes	0.9		0.12
VR 0596	Sugar beet	0.05		0.021
	Tomato, canned fruit	-		<0.004
DV 0448	Tomato, dried	6		0.72
JF 0448	Tomato, juice	-		0.01
DM 0448	Tomato, paste/ puree	-		0.076
GC 0654	Wheat	0.03		0.021
CM 0654	Wheat bran (unprocessed)	0.07		0.046
CF 1210	Wheat germ	-		<0.019
CF 3522	Wheat gluten	0.04		0.027
	Wheat starch	-		<0.019
	Wheat white flour (550)	-		<0.019
	Wheat wholemeal bread	-		0.021

CCN	Commodity name	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg
		New	Previous	
	Wheat wholemeal flour	-		0.025
AS 0654	Wheat, hay and/or straw	2 (dw)		0.086 (as received)

Table 9. Additional values used in estimating livestock dietary burdens

CCN	Commodity name	Median residue (-P) mg/kg	highest residue (-P) mg/kg
AM 0495	Rape seed, forage	0.07	0.12
AM 0495	Rapeseed, forage	0.07	0.12
	Sugar beet pulp, dry	0.13	-
	Sugar beet, ensiled pulp	0.02	-
AM 0596	Sugar beet, leaves or tops	0.0325	0.2
	Sugar beet, molasses	0.004	-
DM 3525	Tomato pPomace, wWet	1.4	-
CF 3521	Wheat aspirated grain fractions	0.18	-
CF 3522	Wheat gGluten feed meal	0.02	-
CF 3515	Wheat milled bypdts (Shorts)	0.025	-
AS 3552	Wheat, forage	0.22	6
AS 0654	Wheat, hay and/or straw	0.086	1.6

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for florylpicoxamid is 0–0.1 mg/kg bw. The IEDIs for florylpicoxamid were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 0 to 1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of florylpicoxamid from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The Meeting decided that an ARfD for florylpicoxamid was unnecessary. Therefore, the Meeting concluded that the acute dietary exposure to residues of florylpicoxamid from the uses considered is unlikely to present a public health concern.

5.16 Fluazinam (333) (T,R)*

TOXICOLOGY

Fluazinam was evaluated by the present Joint FAO/WHO Meeting on Pesticide Residues (JMPR) at the request of the Codex Committee on Pesticide Residues (CCPR). A toxicity data package on fluazinam was received by the Meeting and a draft toxicological monograph was prepared. However, the Meeting concluded that there were outstanding issues regarding metabolites, impurities and carcinogenicity.

The Meeting received information on metabolites and impurities too late for evaluation and the assessment was postponed. The Meeting re-emphasized the importance of a timely and complete submission of all relevant data to enable JMPR to perform a state-of-knowledge risk assessment.

(See also general consideration: 2.5 On the rolling submission of data.)

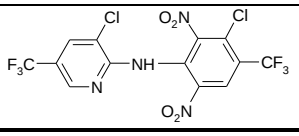
RESIDUE AND ANALYTICAL ASPECTS

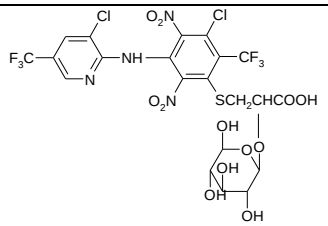
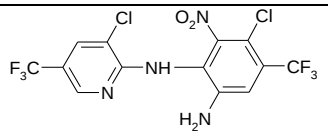
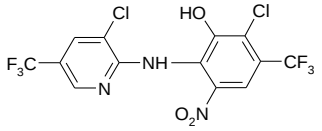
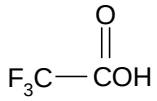
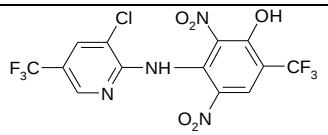
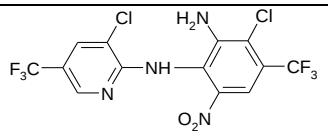
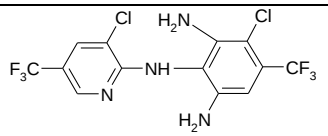
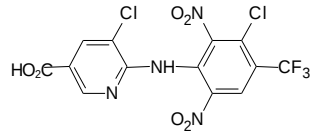
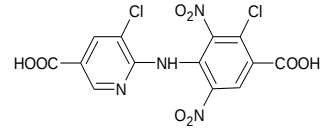
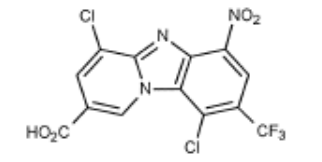
Fluazinam acts as a fungicide with activity against fungus from the class of Oomycetes, especially against *Phytophthora infestans*. It works protectively and needs to be applied before the disease attacks.

Fluazinam was considered by the 2018 JMPR. The definition of the residue for compliance with MRLs for plant commodities was agreed as fluazinam. For dietary risk assessment for plant commodities, it was not possible to conclude on a residue definition. In addition, the JMPR noted that the rotational crop metabolism studies were underdosed by a factor of 2.3, compared to the use patterns considered in the Meeting, and a conclusion on the residue levels of TFAA (trifluoroacetic acid) in crops could not be reached. For livestock, the 2018 JMPR decided that owing to the instabilities observed in samples and poor recoveries of the analytical methods that the livestock metabolism and feeding studies were not suitable to recommend residue definitions and estimate residue levels in livestock. In addition, the 2018 Meeting was unable to complete the toxicological evaluation of fluazinam.

At the Forty-eighth Session of the CCPR (2016), it was scheduled for the evaluation as a new compound by the 2018 JMPR. The 2023 Meeting received new information from the manufacturer on methods of residues analysis, storage stability, use patterns and supervised residue trials for tea.

In this document, the common names, chemical structures and chemical names of the compounds are as follows:

Chemical name (IUPAC)	**Compound Name/Code**	**Structure**
3-Chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-*α,α,α*-trifluoro-2,6-dinitro-*p*-toluidine	**Fluazinam, IKF-1216**	

Chemical name (IUPAC)	Compound Name/Code	Structure
3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridyl]amino]- *α,α,α*-trifluoro-6-nitro-*o*-tolyl]thio]-2-(β-D-glucopyranosyloxy) propionic acid	**AMGT**	
2-(6-amino-3-chloro-*α,α,α*-trifluoro-2-nitro-*p*-toluidino)-3-chloro-5-(trifluoromethyl) pyridine	**AMPA** **AMPA-fluazinam**	
2-chloro-6-[(3-chloro-5-(trifluoromethyl)-2-pyridyl)amino]- *α,α,α*-trifluoro-5-nitro-*m*-cresol	**SDS-67230**	
Trifluoroacetic acid	**TFAA**	
5-[(3-chloro-5-(trifluoromethyl)-2-pyridyl)amino]- *α,α,α*-trifluoro-4,6-dinitro-*o*-cresol	**HYPA**	
2-(2-amino-3-chloro-*α,α,α*-trifluoro-6-nitro-*p*-toluidino)-3-chloro-5-(trifluoromethyl) pyridine	**MAPA**	
3-chloro-2-(2,6-diamino-3-chloro-*α,α,α*-trifluoromethyl-*p*-toluidino)-3-chloro-5-(trifluoromethyl) pyridine	**DAPA**	
5-Chloro-6-(3-chloro-2,6-dinitro-4-trifluoromethylanilino) nicotinic acid	**CAPA**	
6-(4-Carboxy-3-chloro-2,6-dinitroanilino)-5-chloronicotinic acid	**DCPA**	
4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-α]benzimidazole-2-carboxylic acid	**G-504**	

The 2018 JMPR considered the physical and chemical properties of fluazinam. With respect to how these properties may impact the residues in crops, fluazinam is not regarded as

volatile, it has a higher solubility in organic solvents compared to its solubility in water, the partition coefficient indicates its potential to sequester in fat, and aqueous photolysis and hydrolysis may play an important role in its degradation.

Plant metabolism

The 2018 JMPR considered the metabolism of fluazinam in primary crops of grapes, apples, potatoes and peanuts. The 2018 Meeting noted that TFAA was identified in the plant metabolism studies (primary and rotational) formed as a result of ring cleavage and fragmentation. The plant metabolism studies were conducted with phenyl or pyridyl labelled fluazinam. The Meeting noted that it would not be possible to identify and quantify residues of TFAA that may have arisen from the pyridyl radiolabelled studies.

In summary, the metabolism of fluazinam in primary crops of grapes, apples, potatoes and peanuts has been investigated. The metabolism of fluazinam proceeds through the reduction of the nitro group to form AMPA-fluazinam and then replacement of the phenyl chlorine with a sulphur-containing side chain, followed by attachment of glucose to form AMGT. The metabolite SDS-67230 was also identified in apples and grapes.

Fluazinam is the main residue on plant parts such as foliage or fruit that are exposed to the spray application. However, fluazinam was not found in peanut nutmeats and only at low levels in potato tubers.

The appearance of radiolabelled natural products provides evidence that fluazinam is extensively metabolized. The presence of TFAA also supports the extensive metabolism of fluazinam and the incorporation into natural products. In potatoes, the fact that radioactivity from both phenyl ring- and pyridyl ring-labelled fluazinam appeared in starch indicated that both rings were broken down into fragments that could enter the carbon pool.

For the plant metabolites identified, only AMPA-fluazinam was observed in the rat metabolism studies.

Environmental fate

The 2018 JMPR Meeting received information on the environmental fate and behaviour of fluazinam, including aerobic soil degradation, soil photolysis, aqueous photolysis and aqueous hydrolysis. Studies were also received on the behaviour of [^{14}C]-fluazinam in rotational crops. The 2018 Meeting considered that fluazinam was moderately – medium persistent in soil under aerobic conditions, was stable in soil when exposed to light and that photolysis and hydrolysis may play an important role in the degradation of fluazinam.

Rotational crop studies

No new data on confined or field rotational crop studies were received by the current Meeting.

The current Meeting noted that for the crops that can be rotated the maximum application rate for the uses being considered by the Meeting is 5.26 kg ai/ha and therefore the rotational crop study is underdosed by a factor of 2.3. The Meeting therefore confirmed its previous conclusion that based on the study being underdosed and the uncertainties on how TFAA was quantified

within the rotational crop metabolism study, the study was unsuitable to estimate TFAA concentrations under field conditions.

Methods of analysis

Plant commodities

No new methods for enforcement in plants were submitted to the current Meeting. The 2018 JMPR concluded that the LC-MS/MS enforcement method was validated (primary and ILV) for the determination of fluazinam in crops of high starch, high acid, high water, high protein and high oil content.

The 2018 JMPR concluded that sufficient methods were available for the determination of fluazinam and its metabolites in crops using several different analytical methods. New methods were received by the current Meeting for tea. The Meeting concluded that the methods were suitable for the determination of fluazinam and MAPA, CAPA, HYPA, AMPA-fluazinam, G-504, DCPA and TFAA in tea. The LOQ validated for fluazinam and its metabolites, except TFAA, was 0.01 mg/kg. The LOQ validated for TFAA in tea is 2 mg/kg.

Stability of residues in stored analytical samples

Plant commodities

The current Meeting considered the storage stability of fluazinam and its metabolites based on the data considered by the 2018 JMPR and the new data submitted for the 2023 JMPR. The Meeting agreed that the storage stability data generated in the residue trials considered by the 2018 JMPR for broccoli, mustard greens, snap beans, lima beans and ginseng were not relevant to the uses being considered by the current Meeting.

The freezer storage stability of fluazinam in homogenized plant samples fortified with fluazinam was considered by the 2018 JMPR for a number of matrices. Fluazinam was found to be stable on storage in crops of a high water content for at least 30 months, crops of a high acid content for at least 38 months and crops of a high oil content for at least 26 months. Data generated specifically on soya bean, alongside the residue trial samples, demonstrated that fluazinam was stable in soya bean under the storage conditions employed in the residue trial (≤ -10°C for 153 days). Data considered by the current Meeting confirms the stability of fluazinam in crops of a high acid, high water and high oil content. Specifically in peanut meal it was noted fluazinam was only stable for 21 days. The current Meeting concluded that fluazinam is stable in crops of a high protein content for at least 12 months.

Data considered by the 2018 JMPR for fluazinam in crops of a high starch content (potatoes) demonstrated stability for at least 36 months. Data considered by the current Meeting for potatoes showed a decline in fluazinam to 55 percent of the time zero level at the first time point of 30 days. The Meeting agreed that the evidence presented on the impact of the fortification procedure on the freezer storage stability was inconclusive. The Meeting noted that a decline in residues of fluazinam was also observed in various potato fractions considered by the 2018 JMPR. The Meeting decided fluazinam was not stable in crops of a high starch content.

The Meeting agreed that AMPA-fluazinam was stable for at least 12 months in crops of a high starch content, high acid content, high protein content and a high oil content. For crops of a high water content, the Meeting agreed AMPA-fluazinam was stable for up to 3 months. The Meeting agreed AMGT was stable for at least 39 months and at least 36 months for crops of a high acid content and high water content respectively. For crops of a high starch content, high protein content and high oil content AMGT was stable for at least 12 months.

Specifically for dried tea leaves, the Meeting agreed fluazinam, MAPA and HYPA were stable on storage for at least 5 months. AMPA-fluazinam, AMGT, DCPA, G-504 and CAPA were all stable in dried tea leaves for at least 2 months of storage.

The Meeting agreed that TFAA was stable for at least 12 months in crops of a high starch, high water, high acid, high protein and high oil content. In dried tea leaves, TFAA was stable for at least 5 months.

The Meeting decided that the residue trials for the uses being considered by the current Meeting were supported by the freezer storage stability data, except for potatoes. As fluazinam was found to be unstable in crops of a high starch content, the Meeting decided that the residue trials for potatoes were not suitable for making residue recommendations.

Definition of the residue

Plants

The 2018 JMPR recommended that fluazinam was a suitable marker for the enforcement of MRLs for all crops. Suitable analytical methods are available to determine fluazinam.

From a dietary risk perspective, as the WHO core assessment group could not conclude on Health Based Guidance values for fluazinam, the Meeting was unable to consider a residue definition for risk assessment.

In summary, based on the above, the Meeting recommended the following residue definition for compliance with MRLs:

definition of the residue for plant commodities for enforcement of MRLs: *fluazinam*

The Meeting was unable to conclude on a residue definition for risk assessment.

Results of supervised trials on crops

The 2018 JMPR and the current Meeting received residue trials for blueberries, lettuce, cucumber, peppers, potato, soya beans, peanuts and tea. The Meeting decided that STMRs and HRs could not be estimated for blueberries, potatoes, lettuce, cucumbers, peppers, soya beans and peanuts as insufficient information was available to estimate the TFAA residue levels in primary and rotational crops. The Meeting confirmed the maximum residue levels estimated for these crops by the 2018 JMPR. In addition, the Meeting did not estimate STMRs and HRs for tea as the Meeting was unable to conclude on the residue definition for risk assessment.

Tea, green, black (black, fermented and dried)

The critical GAP is for Japan which is one foliar application at a rate of 0.025 kg ai/hL with a PHI of 14.

In 2018, seven independent trials matching the GAP were assessed by the JMPR. The residues of fluazinam were reported as (n=7): 0.40, 0.64, 0.68, 2.39, 2.59, 3.05, 8.97 mg/kg with the highest analytical result reported as 10 mg/kg.

The current Meeting received eight additional independent trials that match the GAP for Japan. Residues of fluazinam were (n=8): 0.69, 0.72, 1.81, 2.30, 2.38, 2.88, 4.52 and 5.49 mg/kg. Based on all the trials, residues of fluazinam in dried tea were (n=15): 0.40, 0.64, 0.68, 0.69, 0.72, 1.81, 2.30, 2.38, 2.39, 2.59, 2.88, 3.05, 4.52, 5.49 and 8.97 mg/kg with the highest analytical result reported as 10 mg/kg.

The Meeting re-estimated a maximum residue of 15 mg/kg for *tea*, green, black (black, fermented and dried).

Animal feeds

Soya bean forage and hay, and Peanut hay and threshings

For soya bean and peanut the authorized label from the United States of America does not permit the feeding of animal feed items to livestock. In addition, the residue trials did not include the analysis for TFAA. Therefore, the animal feed items from soya bean and peanut were not considered further.

Fate of residues during processing

High temperature hydrolysis

In the high temperature hydrolysis study considered by the 2018 JMPR, fluazinam was found to be stable under conditions representative of pasteurization (pH 4, 90°C, 20 minutes). However, under conditions representative of baking/brewing/boiling (pH 5, 100°C, 60 minutes) and sterilization (pH 6, 120°C and 20 minutes) fluazinam was degraded to CAPA (maximum 56 percent AR), G-504 (maximum 11 percent AR) and DCPA (maximum 37 percent AR).

Processing

The 2018 Meeting received information on the effects of processing on the magnitude of fluazinam residue levels for apple, grape, soybeans, potato and peanuts. The major degradates identified on hydrolysis (CAPA, G-504 and DCPA) were not investigated.

The current Meeting received data showing the residue levels of fluazinam and its metabolites in tea infusions. Fluazinam and its metabolites were determined in tea infusions prepared from dried tea leaves taken from the residue trials submitted to the 2023 JMPR. Tea infusions were prepared from samples taken from the trials 3–21 DALA. Processing factors and residue estimates relevant to the GAP considered by the current Meeting are summarized below.

Processing factors and residue estimates for fluazinam residues in tea infusions

	Residue in RAC, mg/kg				Processing Factors		Residue in processed commodity (mg/kg)		
Raw commodity	Max	STMR	HR	Processed commodity	Individual	Best estimate	Max-P	STMR-P	HR-P
Tea	15	2.38	10	Tea infusion	<0.0003 (2), 0.007, 0.009 (2), 0.011, 0.013 (2)	0.009	-	0.02	-

RECOMMENDATIONS

Definition of the residue for plant commodities for enforcement of MRLs: *fluazinam*

Definition of the residue for plants for dietary risk assessment:
the Meeting was unable to conclude on a residue definition for risk assessment.

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

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

- Information on TFAA levels in primary crops
- Field rotational crop residue trials, including the levels of TFAA.

5.17 Fluopyram (243) (R)

RESIDUE AND ANALYTICAL ASPECTS

Fluopyram, whose IUPAC name is *N*-(2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl)-2-(trifluoromethyl)benzamide, is a broad-spectrum fungicide. Fluopyram was first evaluated for residues and toxicological aspects by the 2010 JMPR and subsequently in 2012, 2014, 2015, 2017 and 2021 (extra) for residues. The 2010 JMPR established an ADI of 0–0.01 mg/kg bw and an ARfD of 0.5 mg/kg bw.

The 2010 JMPR recommended the following residue definitions:

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

Definition of the residue for compliance with the MRL for animal commodities: *sum of fluopyram and 2-(trifluoromethyl)benzamide, expressed as fluopyram.*

Definition of the residue for dietary risk assessment for animal commodities: sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues of N-(E)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide and N-(Z)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide, all expressed as fluopyram.

The residue is not fat-soluble.

At the fifty-second CCPR (2021), fluopyram was listed for consideration of further additional maximum residue levels by the 2022 JMPR, and the evaluation was carried over to the 2023 JMPR.

The current Meeting received new information on method of analysis, use patterns and supervised residue trials on wheat, barley and sorghum.

Methods of analysis

The Meeting received information on a new analytical method (GM-006-P18-01). Fluopyram was extracted by acetonitrile-water (4:1, v/v) and analysed using LC-MS/MS. The Meeting confirmed that Method GM-006-P18-01 is validated for the analysis of wheat (grain, hay, straw and forage) and sorghum (grain, fodder and forage) with an LOQ of 0.01 mg/kg.

The Meeting also received recovery data of fluopyram in barley for Method GM-001-P07-01, evaluated by the 2017 JMPR. The Meeting confirmed that Method GM-001-P07-01 is validated for barley (grain, hay and straw) with an LOQ of 0.01 mg/kg.

Results of supervised residue trials on crops

Wheat, similar grains, and pseudocereals without husks

Wheat

The 2017 JMPR estimated a maximum residue level for wheat, rye and triticale of 0.9 mg/kg based on the critical GAP in the United States (two foliar applications at 0.25 kg ai/ha, minimum

interval of 14 days and PHI of 14 days). An identical GAP existed in Canada. The use corresponding to the critical GAP evaluated by the 2017 Meeting is no longer registered.

The current critical GAP for cereals except rice in the United States (separate instructions for corn and sorghum) is two foliar applications at 0.125 kg ai/ha with a minimum interval of 14 days and PHI of 30 days.

In independent trials matching the US GAP, residues of fluopyram in wheat were (n=18): <0.010 (3), 0.012, 0.015, 0.021, 0.024, 0.027, 0.034, 0.036, 0.040, 0.042, 0.046, 0.053, 0.079, 0.088, 0.098 and 0.14 mg/kg.

The Meeting estimated a maximum residue level and an STMR value of fluopyram in wheat of 0.2 and 0.035 mg/kg, respectively, to replace its previous recommendation on wheat.

Since the US GAP covered rye and triticale, both of which belong to the same subgroup in the Codex classification (wheat, similar grains, and pseudocereals without husks), the Meeting decided to extrapolate the maximum residue level and STMR of fluopyram in wheat to rye and triticale to replace its previous recommendations on rye and triticale.

Barley, similar grains, and pseudocereals with husks

Barley

The 2017 JMPR estimated a maximum residue level for barley and oat of 0.2 mg/kg based on the critical GAP in Estonia (a foliar application at 0.078 kg ai/ha at the timing of BBCH 61 or earlier).

The new critical GAP for cereals except rice in the United States (separate instructions for corn and sorghum) is two foliar applications at 0.125 kg ai/ha with a minimum interval of 14 days and PHI of 30 days.

In trials matching the US GAP, residues of fluopyram in barley were (n=16): 0.013, 0.014, 0.019, 0.023, 0.029, 0.031, 0.034, 0.040, 0.042 (2), 0.058, 0.081, 0.097, 0.16, 0.23, and 0.29 mg/kg.

The Meeting estimated a maximum residue level and an STMR value of fluopyram in barley of 0.4 and 0.041 mg/kg, respectively, to replace its previous recommendation on barley.

Since the US GAP covered oats and buckwheat, both of which belong to the same subgroup in the Codex classification (barley, similar grains, and pseudocereals with husks), the Meeting decided to extrapolate the maximum residue level and the STMR of fluopyram in barley to oats and buckwheat, to replace its previous recommendations on oats.

Sorghum

The critical GAP for sorghum in the United States is one foliar application at 0.200 kg ai/ha with PHI of 30 days.

In independent trials matching the US GAP, residues of fluopyram in sorghum were (n=11): 0.054, 0.093, 0.11, 0.12, 0.17, 0.18, 0.19, 0.22, 0.23, 0.27 and 0.30 mg/kg.

The Meeting estimated a maximum residue level and an STMR value of fluopyram in sorghum of 0.6 and 0.18 mg/kg, respectively.

Animal feed commodities

Wheat forage

The new critical GAP for cereals except rice in the United States (separate instructions for corn and sorghum) is two foliar applications at 0.125 kg ai/ha with a minimum interval of 14 days and PHI of 14 days for forage.

In independent trials matching the US GAP, residues of fluopyram in wheat forage as received were (n=18): <0.010, 0.049, 0.086, 0.13 (2), 0.14, 0.15, 0.16, 0.17, 0.22, 0.26, 0.33, 0.41, 0.49, 0.70, 0.82 (2) and 1.1 mg/kg.

The Meeting estimated median and highest values of fluopyram in wheat forage of 0.195 and 1.1 mg/kg, respectively (as received). The Meeting decided to extrapolate the median and highest values in wheat to rye and triticale.

Subgroup of cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay and/or straw)

The 2017 JMPR estimated a maximum residue level for hay and/or straw of wheat, rye and triticale of 23 mg/kg based on the US GAP (two foliar applications at 0.25 kg ai/ha, minimum interval of 14 days and PHI of 14 days). An identical GAP existed in Canada. The use corresponding to the critical GAP evaluated by the 2017 Meeting is no longer registered.

The 2017 JMPR also estimated a maximum residue level for hay and/or straw of barley and oat of 2 mg/kg based the Estonian GAP (a foliar application at 0.078 kg ai/ha at the timing of BBCH 61 or earlier).

The new critical GAP for cereals except rice in the United States (separate instructions for corn and sorghum) is two foliar applications at 0.125 kg ai/ha with a minimum interval of 14 days and PHI of 30 days for straw or 14 days for hay.

Straw

In barley straw, residues of fluopyram in independent trials matching the US GAP as received were (n=15): 0.22, 0.24, 0.30, 0.34, 0.50, 0.54 (2), 0.62, 0.67 (3), 0.88, 0.91, 1.1 and 1.9 mg/kg.

In wheat straw, residues of fluopyram in independent trials matching the US GAP as received were (n=18): 0.13 (2), 0.46 (2), 0.50, 0.56, 0.57, 0.90, 0.98, 1.0, 1.1 (4), 1.2, 1.5 and 1.7 (2) mg/kg.

Since the US GAP covered wheat, barley, oat, rye and triticale, and The Mann-Whitney U Test indicated that the residue data in straw of barley and wheat were not significantly different, the Meeting decided to combine the datasets of straw of wheat and barley to extrapolate to straw of oat, rye and triticale, all of which belong to the same subgroup in the Codex classification (cereal grains (including pseudocereals) feed products with low water (<20 percent) content (hay and/or straw)).

The residues of fluopyram in wheat and barley, straw as received were (n=33): 0.13 (2), 0.22, 0.24, 0.30, 0.34, 0.46 (2), 0.50 (2), 0.54 (2), 0.56, 0.57, 0.62, 0.67 (3), 0.88, 0.90, 0.91, 0.98, 1.0, 1.1 (5), 1.2, 1.5, 1.7 (2) and 1.9 mg/kg. The Meeting estimated median and highest values of fluopyram in straw of cereal grains (including pseudocereals) feed products with low water (<20

percent) content (except rice, maize and sorghum) of 0.67 and 1.9 mg/kg, respectively (as received).

Hay

In barley hay, residues of fluopyram in independent trials matching the US GAP as received were (n=15): 0.42, 0.53, 0.70, 0.77, 1.0 (2), 1.1, 1.2 (2), 1.3, 1.6, 1.7 (2), 2.6 and 4.1 mg/kg.

In wheat hay, residues of fluopyram in independent trials matching the US GAP as received were (n=20): 0.18, 0.27, 0.60, 0.71, 0.74, 0.78, 0.83, 1.0, 1.2 (2), 1.4, 1.5 (2), 1.6 (2), 1.7, 2.3, 2.4, 3.1 and 3.6 mg/kg.

Since the US GAP covered wheat, barley, oat, rye and triticale, and The Mann-Whitney U test indicated that the residue data in barley and wheat were not significantly different, the Meeting decided to combine the datasets of hay of wheat and barley to extrapolate to hay of oat, rye and triticale, all of which belong to the same subgroup in the Codex classification (cereal grains (including pseudocereals) feed products with low water (<20 percent) content).

The residues of fluopyram in wheat and barley, hay as received were (n=35): 0.18, 0.27, 0.42, 0.53, 0.60, 0.70, 0.71, 0.74, 0.77, 0.78, 0.83, 1.0(3), 1.1, 1.2 (4), 1.3, 1.4, 1.5 (2), 1.6 (3), 1.7 (3), 2.3, 2.4, 2.6, 3.1, 3.6 and 4.1 mg/kg. The Meeting estimated median and highest values of fluopyram in hay of wheat, barley, oat, rye and triticale of 1.2 and 4.1 mg/kg, respectively (as received).

Since the residues in hay were greater than those in straw, the Meeting estimated a maximum residue level of fluopyram in wheat, barley, oat, rye and triticale, hay and/or straw of 6 mg/kg (dw) (based on the dry matter content of 89 percent in barley hay and 88 percent in wheat) based on the combined residue data of hay of barley and wheat. The Meeting withdrew its previous recommendations of maximum residue level at 23 mg/kg for fluopyram in straw and fodder, dry of wheat, rye, triticale. The Meeting also withdrew its previous recommendations of maximum residue level at 2 mg/kg for fluopyram in straw and fodder, dry of barley and oat.

The Meeting estimated median and highest values of fluopyram in wheat, barley, oat, rye and triticale; hay and/or straw of 1.2 and 4.1 mg/kg, respectively (as received) based on the combined residue data of barley and wheat, hay.

Sorghum forage

The critical GAP for sorghum forage in the United States is one foliar application at 0.200 kg ai/ha with PHI of 14 days.

In independent trials matching the US GAP, residues of fluopyram in sorghum forage as received were (n=11): 0.13, 0.14, 0.26, 0.32, 0.36, 0.43, 0.44, 0.51, 0.73, 1.3 and 3.2 mg/kg.

The Meeting estimated median and highest values of fluopyram in sorghum forage of 0.43 and 3.2 mg/kg, respectively (as received).

Sorghum, stover

The critical GAP for sorghum (stover) in the United States is one foliar application at 0.200 kg ai/ha with PHI of 30 days.

In independent trials matching the US GAP, residues of fluopyram in sorghum stover as received were (n=11): 0.059, 0.18, 0.25, 0.33, 0.37, 0.45, 0.48, 0.55, 1.2 and 1.5 (2) mg/kg.

The Meeting estimated median and highest values of fluopyram in sorghum stover of 0.45 and 1.5 mg/kg, respectively (as received). The Meeting also estimated a maximum residue level of 3 mg/kg (dw) (based on dry matter content of 88 percent).

Fates of residues during processing

Processing

The Meeting estimated STMR-P and maximum levels for processed commodities based on the processing factors estimated by the 2010 JMPR as follows:

RAC	**Processed commodity**	**Processing factor**	**RAC STMR (mg/kg)**	**STMR-P or median (mg/kg)**	**Maximum residue level for RAC (mg/kg)**	**Maximum residue level for processed commodity (mg/kg)**
Wheat	Wheat bran	2.7	0.035	0.0945	0.2	0.6
	Wheat flour	0.12		0.0042		
	Wheat germ	2.4		0.084		0.5
	Aspirated grain fraction	70		2.45		

Residues in animal commodities

Farm animal dietary burden

The OECD diets include several commodities evaluated by the Meeting. Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the Meeting. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarized below.

	Animal dietary burden of fluopyram, ppm of dry matter diet							
	US-Canada		**EU**		**Australia**		**Japan**	
	Max	**Mean**	**max**	**mean**	**max**	**mean**	**Max**	**Mean**
Beef cattle	4.8	2.7	28	9.3	65/a	32/b	4.3	1.8
Dairy cattle	14	5.8	36	13	55/c	31/d	5.0	2.7
Poultry – broiler	0.37	0.37	0.41	0.32	0.56	0.56	0.18	0.18
Poultry – layer	0.37	0.37	9.1/e	3.1/f	0.56	0.56	0.30	0.30

a/ Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian tissues

b/ Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian tissues

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 tissues and eggs

f/ Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues and eggs

Animal commodity maximum residue levels

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

Cattle	Feed Level (ppm) for milk residues	Residues (mg /kg) in milk	Feed Level (ppm) for tissue residues	Residues (mg /kg)			
				Muscle	Liver	Kidney	Fat
Maximum residue level Determination (beef or dairy cattle) – residues of fluopyram + BZM							
Feeding Study	44 133	0.62 1.42	44 133	0.83 1.53	6.0 11	0.93 1.68	0.78 1.81
Dietary burden and estimate of maximum residue	55	0.72	65	1.0	7.2	1.1	1.0
HR Determination (beef or dairy cattle) – residues of fluopyram + BZM + olefins							
Feeding Study			44 133	0.86 1.57	6.13 11.6	0.97 1.83	1.1 2.75
Dietary burden and estimate of highest residue			65	1.0	7.4	1.2	1.5
STMR determination (beef or dairy cattle) – residues of fluopyram + BZM + olefins							
Feeding Study	14.4 44	0.27 0.65	14.4 44	0.32 0.64	1.96 4.99	0.41 0.79	0.31 0.91
Dietary burden and estimate of highest residue	31	0.48	32	0.51	3.8	0.64	0.67

BZM: 2-(trifluoromethyl)benzamide, expressed as fluopyram

Olefins: sum of N-(E)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide and N-(Z)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide, all expressed as fluopyram

The Meeting confirmed its previous decision of maximum residue levels of 1.5 mg/kg for meat (from mammals other than marine mammals), 1.5 mg/kg for mammalian fats (except milk fats), 8 mg/kg for edible offal (mammalian), and 0.8 mg/kg for milk.

The Meeting estimated HRs for muscle, mammalian fats and edible offal (mammalian) of 1.0, 1.5 and 7.4 mg/kg, respectively. The Meeting also estimated medians for milk, muscle, mammalian fats and edible offal of, of 0.48, 0.51, 0.67 and 3.8 mg/kg, respectively.

Poultry	**Feed Level (ppm) for egg residues**	**Residues (mg /kg) in egg**	**Feed Level (ppm) for tissue residues**	**Residues (mg /kg)**		
				Muscle	**Liver**	**Fat**
Maximum residue level Determination (poultry and eggs) – residues of fluopyram + BZM						

Feeding Study	4.8 26	0.72 3.47	4.8 26	0.33 3.23	1.6 8.74	0.64 1.17
Dietary burden and estimate of maximum residue	9.1	1.3	9.1	0.92	3.0	0.75
HR Determination (poultry and eggs) – residues of fluopyram + BZM + olefins						
Feeding Study	4.8 26	0.95 3.47	4.8 26	0.39 3.25	1.6 8.78	0.72 1.63
Dietary burden and estimate of highest residue	9.1	1.5	9.1	0.97	3.1	0.90
STMR determination (poultry and eggs) – residues of fluopyram + BZM + olefins						
Feeding Study	1.6 4.8	0.22 0.74	1.6 4.8	0.09 0.31	0.41 1.42	0.12 0.46
Dietary burden and estimate of median residue	3.1	0.46	3.1	0.19	0.88	0.28

The Meeting estimated a maximum residue level of 4 mg/kg for poultry, edible offal of, to replace previous recommendation. The Meeting confirmed its previous decision of maximum residue levels of 2 mg/kg for eggs, 1.5 mg/kg for poultry meat and 1 mg/kg for poultry fat.

The Meeting estimated HRs for eggs, poultry muscle, edible offal of poultry and poultry fats of 1.5, 0.97, 3.1 and 0.90 mg/kg, respectively. The Meeting also estimated medians for eggs, poultry muscle, edible offal of poultry, and poultry fats of 0.46, 0.19, 0.88 and 0.28 mg/kg, respectively.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for International Estimated Daily Intakes (IEDIs) and International Estimated Short-Term Intake (IESTI) assessment.

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

Definition of the residue for compliance with the MRL for animal commodities: *sum of fluopyram and 2-(trifluoromethyl)benzamide, expressed as fluopyram.*

Definition of the residue for dietary risk assessment for animal commodities: *sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues of N-(E)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide and N-(Z)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide, all expressed as fluopyram.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for fluopyram is 0–0.01 mg/kg bw. The IEDIs for fluopyram were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the current and earlier JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 10 to 80 percent of the maximum ADI for fluopyram. The Meeting concluded that long-term dietary exposure to residues of fluopyram from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The IESTI for fluopyram was calculated. The results are shown in Annex 4 to the Report.

The IESTIs for fluopyram from the intake of the residue evaluated by the Meeting were 0–10 percent for general population and children of the ARfD (0.5 mg/kg bw). The Meeting concluded that acute dietary exposure from the residues of fluopyram, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

5.18 Imazapyr (267) (R)

RESIDUE AND ANALYTICAL ASPECTS

Imazapyr, 2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazoline-2-yl]nicotinic acid (IUPAC name), is a broad-spectrum systemic herbicide in the imidazolinone family and is used for the control of grasses and broadleaf weeds in a variety of crops.

Imazapyr was evaluated by JMPR in 2013 as a new compound and subsequently in 2015 and 2017. The 2013 JMPR decided the following residue definition and health-based guidance values:

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

Residue is not fat-soluble.

The ADI is 0–3 mg/kg bw and an ARfD is unnecessary.

Imazapyr was listed by the fifty-second Session of CCPR (2021) for the evaluation of new MRL for rice grain by the 2022 Meeting, which was postponed to the 2023 JMPR. The current JMPR received information on anaerobic soil and sediment/water degradation, analytical method, use pattern, supervised trials, and processing to support estimation of maximum residue levels for wheat and rice.

Environmental fate

Anaerobic degradation in soils

Degradation of imazapyr in sandy loam soil flooded with water and flow of nitrogen was studied at 25 or 35°C for 60 days in the dark following aerobic ageing with air flow and without water for 30 days. After 60 days of anaerobic incubation, 86 percent of imazapyr remained. During the anaerobic incubation, no degradates were identified.

Anaerobic sediment/water degradation

Degradation of imazapyr in a sediment/water mixture was studied in the dark with nitrogen flow at 19–22°C. During 3 months of incubation, imazapyr was stable.

In summary, imazapyr is stable in the anaerobic soils flooded with water. No degradates were identified.

Residue analytical methods

Analytical methods

The Meeting received description and validation data of an analytical method for residues of imazapyr in wheat matrices (forage, grain and straw) using HPLC-MS/MS. This method is

based on a QuEChERS technique. Imazapyr was extracted with acidified acetonitrile from homogenized, hydrated and acidified samples. Magnesium sulphate and sodium acetate were added, shaken and centrifuged. An aliquot of supernatant was cleaned up with dispersive solid phase extraction, evaporated and reconstituted for analysis by HPLC-MS/MS. The method was validated at fortification levels of 0.01 and 0.10 mg/kg in these matrices, resulting in mean recoveries ranging from 76 to 96 percent with RSD ≤9.2 percent. The LOQ was 0.01 mg/kg for imazapyr in these three matrices.

Results of supervised residue trials on crops

The Meeting received supervised trial data for imazapyr residues on wheat and rice using ground spray of imazapyr.

Wheat

New critical GAP in Australia for wheat allows one ground spray application of imazapyr at the maximum rate of 0.011 kg ai/kg up to first node stage (Z31).

The Meeting received eight supervised trials conducted on wheat in Australia during the 2021 growing season. In two of these trials, grain or straw samples were not collected or analysed.

Each trial used ground spray application at BBCH 31 at a target rate of 0.011 or 0.022 kg ai/ha. Residues from trials approximating cGAP in Australia were, in rank order (n=6): 0.049, 0.067, 0.085, 0.124, 0.124 and 0.224 mg/kg.

There were three additional trials conducted in the United States using ca. 4N rate application at BBCH 30 or 31 for the purpose of estimating processing factors. Since the proportionality concept can be used when the difference of application rate is in a range of 0.3–4N compared to cGAP rate, the Meeting decided to use these trials after applying the proportionality.

The residues after adjustment to the cGAP rate were (n=3): 0.310 (1.233 x 0.011/0.0437), 0.025 (0.098 x 0.011/0.0438) and 0.062 (0.247 x 0.011/0.0439) mg/kg.

The Meeting applied the proportionality concept to residue levels from the residue trials and processing trials after adjusting to the cGAP rate (n=9): 0.025, 0.054 (0.049 x 0.011/0.010) 0.062, 0.069 (0.067 x 0.011/0.0107), 0.079 (0.085 x 0.011/0.0118), 0.114 (0.124 x 0.011/0.012), 0.126 (0.124 x 0.011/0.0108), 0.265 (0.224 x 0.011/0.0093), and 0.310 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg to replace the previous recommendation of 0.05 * mg/kg for wheat. It also estimated an STMR of 0.079 mg/kg.

Rice

Critical GAP in Malaysia for paddy rice allows one ground spray application of imazapyr at the maximum rate of 0.11 kg ai/kg made 7–14 days after sowing.

The Meeting received six supervised trials conducted on rice in Viet Nam during the 2017

and 2018 growing seasons and three trials in the Republic of the Philippines during the 2021 growing season. Two of the three trials in the Philippines were conducted in nearby areas but applications were made more than 30 days apart and therefore these trials were considered independent from each other.

Residues in rice grain from supervised trials in Viet Nam and the Philippines approximating cGAP in Malaysia were, in rank order (n=9): <0.01 (7), 0.031 and 0.031 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.06 mg/kg and 0.01 mg/kg, respectively, for rice.

Residues in husked rice from supervised trials approximating cGAP in Malaysia were, in rank order (n=9): <0.01 (6), 0.014, 0.036 and 0.036 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.07 mg/kg and 0.01 mg/kg, respectively, for husked rice.

Residues in polished rice from supervised trials approximating cGAP in Malaysia were, in rank order (n=9): <0.01 (7), 0.026 and 0.029 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.05 mg/kg and 0.01 mg/kg, respectively, for polished rice.

Wheat forage, hay and/or straw

The label in Australia specifies the following restrictions, "Do not graze or cut for stock food for 4 weeks after application." The FAO Manual (2016) defines "wheat forage" to be "cut to stem elongation (jointing) stage" (BBCH macro-stage 3) while "wheat hay" to be "cut at early flower (boot) to soft dough stage" (BBCH macro-stage 4 to BBCH 85) and should be field-dried". In the eight trials on wheat, green plants (reported as "forage") were collected 28 days (in one trial, 27 days) after application but at BBCH 43–55 (except in the Tummaville trial, BBCH 37–41). Therefore, the collected samples are more consistent with the commodity "hay", although the samples were not dried in the field. The residue concentrations were reported on a dry weight basis using the analytical results of fresh green plants and their moisture contents. Since in the trial in Tummaville, green plants were collected at only slightly earlier BBCH growth stage or during the growth stage for "hay", the Meeting decided to consider the residue level in this trial as well as other trials.

The residues of imazapyr in the green plant collected during and later than BBCH macro-stage 4 on a dry weight basis from trials matching the GAP were (n=8): 0.153, 0.175, 0.192, 0.281, 0,359, 0.396, 0.425 and 0.532 mg/kg. The Meeting estimated a maximum residue level of 1 mg/kg (dry weight basis), median residue of 0.32 mg/kg (dw) and highest residue of 0.532 mg/kg (dw) for wheat hay.

Residues of imazapyr, on a dry weight basis, in straw from trials approximating cGAP were (n=6): <0.005 (4), 0.011 and 0.012 mg/kg. Even with the application of double rate, the maximum residue concentration was 0.022 mg/kg, much lower than the residues in the hay and covered by the maximum residue level for hay. The Meeting estimated a median residue of 0.005 mg/kg (dw) and highest residue of 0.012 mg/kg (dw) for wheat straw.

The Meeting estimated a maximum residue level of 1 mg/kg (dw) for wheat, hay and/or straw, based on the residue data on hay. The Meeting withdrew its previous recommendation on wheat straw and fodder, dry.

Rice hay and/or straw

Residues of imazapyr in rice straw from trials approximating cGAP were (n=9): <0.01 (7), 0.012 and 0.013 mg/kg. The Meeting estimated a maximum residue level of 0.015 mg/kg, median residue of 0.01 mg/kg (as received), and highest residue of 0.012 mg/kg (as received) for rice hay and/or straw on a basis of residue data in straw.

Fate of residues during processing

Processing

The Meeting received information on processing of wheat to various kinds of processed commodities.

Wheat

Processing factors of imazapyr for wheat to its processed commodities as well as STMR-P values for the processed commodities of wheat are shown below.

Commodity	**N**	**Processing factor for imazapyr**		**Maximum residue level (mg/kg)**	**STMR/ STMR-P (mg/kg)**
		Individual	Best estimate		
Wheat grain (RAC)		-		0.6	0.079
Bran	3	1.19, 1.42, 1.79	1.47	1 (0.882) [a/]	0.116
White flour	3	0.54, 0.54, 0.80	0.63	-	0.050
Germ	3	1.36, 1.38, 1.44	1.39	1 (0.834) [a/]	0.110
Middlings	3	0.65, 0.66, 0.86	0.72	-	0.057
Shorts	3	0.70, 0.76, 0.93	0.80	-	0.063
Gluten	3	0.14, 0.31, 0.76	0.40	-	0.032
Gluten feed meal	2	0.16, 0.72,	0.44	-	0.035
Milled by-products	3	0.92, 0.93,	0.99	-	0.078

Commodity	N	Processing factor for imazapyr		Maximum residue level (mg/kg)	STMR/ STMR-P (mg/kg)
		Individual	Best estimate		
		1.13			
Starch	3	0.02,<0.04, <0.10	0.05	-	0.004
Wholemeal flour	3	0.92, 0.94, 1.10	0.99	-	0.078
Whole-grain bread	3	0.63, 0.81, 0.94	0.79	-	0.062

[a/] Value in a pair of parentheses is the product of the (STMR for RAC) X processing factor, i.e., before rounding.

As the processing factors for bran and germ were >1, maximum residue levels were estimated for these processed commodities using the maximum residue level for wheat and their processing factors as shown in the above table.

Rice

Rice grain and its processed commodities, husked rice, polished rice and bran, were prepared and analysed in the supervised residue trials. Since seven out of nine trials, imazapyr in rice grain (RAC) was below the LOQ of 0.01 mg/kg, the Meeting decided to use the residue data from residue trials to estimate the maximum residue levels and STMR values for husked rice and polished rice (described in the residue trial section) and bran (below).

The residue values in bran from supervised trials matching or approximating cGAP were (n=9): <0.01 (3), 0.013, 0.015, 0.015, 0.022, 0.074 and 0.12 mg/kg.

The Meeting estimated a maximum residue level and STMR-P at 0.2 mg/kg and 0.015 mg/kg, respectively for rice bran (unprocessed).

The processing factors for husked rice, polished rice and bran were calculated and shown below.

Commodity	N	Processing factor for imazapyr	
		Individual	Best estimate
Rice grain (RAC)		-	-
Husked rice	2	1.16, 1.16	1.16
Polished rice	2	0.94, 0.84	0.89
Bran	2	2.39, 3.87	3.13

Residues in animal commodities

The highest maximum and mean animal dietary burden calculated for beef and dairy cattle, using STMRs, STMR-Ps, median residues, highest residues recommended by the 2013, 2015, 2017 and the current JMPR, were the same as calculated by the 2015 JMPR when the maximum residue levels for milk and tissues were estimated (18 ppm and 9.6 ppm, respectively, in dry feed for

dairy cattle in the US/CA ration). When calculating, forage of grass was included only in the US/CA ration as decided by the 2015 JMPR, since "use on grass was only registered in the United States". The situation remains the same at present. Therefore, no revision was necessary for maximum residue levels or STMRs for milk and tissues of cattle.

The highest maximum and mean animal dietary burden calculated for poultry broiler and layer, using STMRs, STMR-Ps, median residues, highest residues recommended by the 2013, 2015, 2017 and the current JMPR, were slightly higher than what were calculated in 2015. However, while the calculated highest maximum dietary burden was 0.63 ppm, in a poultry metabolism study evaluated by the 2013 JMPR, a dose of 9.7 ppm imazapyr in feed resulted in all imazapyr residues in eggs and tissues less than 0.01 mg/kg. Therefore, no revision was necessary for maximum residue levels or STMRs for eggs and tissues of poultry.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDIs assessment.

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

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI of 0–3 mg/kg bw was established for imazapyr. The IEDIs for imazapyr were calculated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the 2013, 2015, 2017 and current JMPR. The results are shown in Annex 3 to the 2023 JMPR Report.

The IEDIs were < 1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of imazapyr from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2013 Meeting decided that an ARfD for was unnecessary for imazapyr. The Meeting therefore concluded that the acute dietary exposure of imazapyr is unlikely to present a public health concern.

5.19 Iprodione (111) (T,R)**

TOXICOLOGY

Iprodione is the ISO-approved common name for3-(3,5-dichlorophenyl)-2,4-dioxo-*N*-(propan-2-yl)imidazolidine-1-carboxamide (IUPAC), Chemical Abstracts Service number 3674-19-7. It belongs to the class of organic compounds known as phenylhydantoins. It is a broad-spectrum foliage contact fungicide which inhibits DNA and RNA synthesis in the germinating fungal spore as well as inhibiting the enzyme NADH cytochrome c reductase, thereby preventing lipid and membrane synthesis and ultimately mycelial growth.

Iprodione was previously evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1977, 1992 and 1995. In 1977 an (ADI of 0–0.3 mg/kg body weight (bw) was established. In 1992, the ADI was reduced to 0–0.2 mg/kg bw. The Meeting in 1995 withdrew the previous value and established a new ADI of 0–0.06 mg/kg bw. Iprodione was reviewed by the present Meeting under the periodic review programme of the Codex Committee on Pesticide Residues (CCPR).

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with relevant national or international test guidelines, unless otherwise specified. Several studies previously reviewed by the JMPR were not submitted for the present evaluation. These studies were not critical to the risk assessment or for setting guidance values. Although studies on metabolites submitted to other regulatory bodies were not made available to the Meeting, the Meeting was able to conclude the evaluation. A search of the open literature did not reveal any relevant publications that would have an impact on the evaluation.

Biochemical aspects

After oral administration to CD rats of a single radiolabelled dose of iprodione by gavage at 50 or 900 mg/kg bw and repeated administration of 50 mg/kg bw of unlabelled iprodione for 14 days followed by one radiolabelled dose, [^{14}C]iprodione was rapidly and nearly completely absorbed. More than 70 percent of the label was excreted within 48 hours. Urinary excretion of iprodione was 53 percent, 43 percent and 46 percent of the administered dose (AD) at 50, 900 mg/kg bw and after repeated exposure, respectively. Faecal excretion of iprodione was 39 percent, 56 percent and 52 percent of AD at 50, 900 mg/kg bw and after repeated exposure, respectively. At 168 hours after oral administration of [^{14}C]iprodione, tissue concentrations (including carcass) of radioactivity were about 0.2 percent of AD.

Concentrations greater than 0.1 µg eq/g were found in liver, stomach, small and large intestine, pancreas, kidney, uterus, salivary gland, adrenals, lymph nodes, ovary, fat, and blood. The peak concentration of radioactivity in blood was observed four hours (males) and two hours (females) after administration of 50 mg/kg bw, and about six hours (males and females) after administration of 900 mg/kg bw. Blood levels did not increase proportionately with dose. The half-life of elimination of radiolabelled iprodione from blood was 8.9 ± 1.5 hours for males and 6.9 ± 1.7 hours for females, both given a single oral dose at 50 mg/kg bw. At the higher dose (900 mg/kg bw), the half-life of elimination from blood was 19.8 ± 3.8 hours for males and 12.5 ± 3.0 hours for females.

About 1.5 percent to 4.5 percent unmetabolized iprodione was excreted in the urine. The excretion of intact iprodione was dose-dependent, ranging from 34 percent to 80 percent of the

radioactivity found in faeces in 24 hours in males, and 31 percent to 85 percent in females during the same period. The major metabolites in the urine were found to be compounds RP32490 and RP36114 in males, and RP32490 and parent compound in females. The main routes of metabolism were hydroxylation of the aromatic ring, degradation of the isopropylcarbamoyl chain and rearrangement followed by cleavage of the hydantoin moiety. No significant difference in absorption or metabolism were seen according to sex.

Toxicological data

The acute oral median lethal dose (LD_{50}) of iprodione was greater than 2000 mg/kg bw and the dermal LD_{50} was greater than 2000 mg/kg bw. The inhalation median lethal concentration (LC_{50}) was greater than 3.29 mg/L. Iprodione was not irritating to skin but mildly irritating to the eyes in rabbits, and was not skin sensitizing in the Guinea pig Buehler protocol.

In repeat-dose toxicity studies on mice, rats and dogs, the main effects were on body weight, adrenal glands, erythrocytes, spleen, ovaries, uterus and testes.

In a 1-year dietary toxicity study in dogs, iprodione was administered at concentrations of 0, 100, 600 or 3600 ppm (equal to 0, 4.1, 24.9 and 145 mg/kg bw per day for males, 0, 4.3, 28.3 and 153 mg/kg bw per day for females). The on-observed-adverse-effect level (NOAEL) was 600 ppm (equal to 24.9 mg/kg bw per day) based on increased incidence of Heinz bodies, and histopathological changes in adrenals and kidneys at 3600 ppm (equal to 145 mg/kg bw per day).

In a second 1-year dog study, iprodione was administered in the diet for 52 weeks to dogs at concentrations of 0, 200, 300, 400 or 600 ppm (equal to 0, 7.8, 12.4, 17.5 and 24.6 mg/kg bw per day for males, 0, 9.1, 13.1, 18.4 and 26.4 mg/kg bw per day for females). The NOAEL was 600 ppm, (equal to 24.6 mg/kg bw per day), the highest dose tested.

The overall NOAEL for 1-year dog studies was 600 ppm (equal to 24.9 mg/kg bw per day) based on effects at 3600 ppm (equal to 145 mg/kg bw per day).

In an 18-month combined chronic toxicity and carcinogenicity study in mice, iprodione was administered in the diet at concentrations of 0, 200, 500 or 1250 ppm (equal to 0, 27.5, 67.6 and 171 mg/kg bw per day for males, 0, 31.2, 78.2 and 193 mg/kg bw day for females). The NOAEL for toxicity and carcinogenicity was 1250 ppm (equal to 171 mg/kg bw per day), the highest dose tested.

In a 99-week combined chronic toxicity and carcinogenicity study in mice, iprodione was administered in the diet at concentrations of 0, 160, 800 or 4000 ppm (equal to 0, 23, 115 and 604 mg/kg bw per day for males, 0, 27, 138 and 793 mg/kg bw per day for females). The NOAEL for toxicity was 160 ppm (equal to 23 mg/kg bw per day), based on microscopic changes in the testes (generalized vacuolation and hypertrophy of the testicular interstitial cells, Leydig cells) and ovaries (interstitial cell hyperplasia with luteinization) at 800 ppm (equal to 115 mg/kg bw per day). The NOAEL for carcinogenicity was 800 ppm (equal to 115 mg/kg bw per day) based on an increased incidence of hepatocellular carcinomas and adenomas in both sexes at 4000 ppm (equal to 604 mg/kg bw per day).

In a combined chronic toxicity and carcinogenicity study in rats, iprodione was administered for 104 weeks in the diet at concentrations of 0, 150, 300 or 1600 ppm (equal to 0, 6.1, 12.4 and 69 mg/kg bw per day for males, 0, 8.4, 16.5 and 95 mg/kg bw per day for females). The NOAEL for toxicity was 150 ppm (equal to 6.1 mg/kg bw per day), based upon histopathological changes in the adrenal cortex, testicular interstitial cell hyperplasia and

reduced secretion and absent/empty secretory colloid of the seminal vesicles in males, and increased haemosiderosis in the spleen in females, all at 300 ppm (equal to 12.4 mg/kg bw per day). The NOAEL for carcinogenicity was 300 ppm (equal to 12.4 mg/kg bw per day) based upon an increased incidence of Leydig cell adenomas in males at 1600 ppm (equal to 69.0 mg/kg bw per day).

The Meeting concluded that iprodione is carcinogenic in mice and male rats, but not in female rats.

A series of in vitro and in vivo studies was undertaken to investigate the mode of action (MOA) for induction of Leydig cell tumours in the rat. These studies supported the hypothesis that iprodione interferes with testosterone biosynthesis, resulting in decreased testosterone levels and increased luteinizing hormone (LH) secretion, a known MOA for induction of Leydig cell tumours in rats. However, histopathological changes were also observed in mouse Leydig cells, so it was not possible to reach a conclusion on the human relevance of the effects on Leydig cells.

In a study investigating the MOA for induction of hepatocellular adenomas and carcinomas in mice, induction of CYP2B and CYP3A enzymes and hepatocellular proliferation were observed. The profile of liver changes observed after iprodione treatment was similar to that observed following treatment with phenobarbital, suggesting possible activation of the CAR/PXR receptor. The data suggest that iprodione may induce liver tumours by a phenobarbital-like MOA, but this was not reliably established.

Iprodione was tested for genotoxicity in an adequate range of in vitro and in vivo assays and gave negative results in all relevant studies.

The Meeting concluded that iprodione is unlikely to be genotoxic.

As iprodione is unlikely to be genotoxic and there is a clear threshold for liver tumours in mice and Leydig cell tumours in male rats, the Meeting concluded that iprodione is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation reproductive toxicity study in rats, iprodione was administered at dietary concentrations of 0, 300, 1000 or 3000 ppm. The high dose for F1 animals was reduced to 2000 ppm at the time of first mating of F1a rats because of excessive toxicity in the F1 generation. The mean administered doses, calculated during premating phases, were equal to 0, 17, 55 and 159 mg/kg bw per day for F0 males, and for F0 females 0, 21, 71 or 214 mg/kg bw per day. The NOAEL for parental toxicity was 300 ppm (equal to 17 mg/kg bw per day) based on reduced body weight and body weight gain, and reduced food consumption at 1000 ppm (equal to 55 mg/kg bw per day). The NOAEL for reproductive toxicity was 3000 ppm (equal to 159 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 1000 ppm (equal to 55 mg/kg bw per day) based on clinical signs, reduced offspring viability and reduced pup weight at 3000 ppm (equal to 159 mg/kg bw per day).

In a second two-generation reproductive toxicity study in rats, iprodione was administered in the diet at concentrations of 0, 300, 750 or 1500 ppm (equal to 0, 27, 67 and 136 mg/kg bw per day for males, 0, 24, 59 and 116 mg/kg bw per day for females). The NOAEL for parental toxicity was 750 ppm (equal to 59 mg/kg bw per day) based on decreased body weight and food consumption, increased absolute and relative adrenal weights and an increased incidence of adrenal vacuolation at 1500 ppm (equal to 116 mg/kg bw per day). The NOAEL for reproductive toxicity was 1500 ppm (equal to 116 mg/kg bw per day), the highest

dose tested. The NOAEL for offspring toxicity was 300 ppm (equal to 24 mg/kg bw per day), based on the delayed onset of male puberty at 750 ppm (equal to 59 mg/kg bw per day).

In a developmental toxicity study in rats, iprodione was administered by gavage from gestation day (GD) 5 to GD 15 at doses of 0, 40, 90 or 200 mg/kg bw per day. The NOAELs for maternal toxicity and embryo/fetal toxicity were 200 mg/kg bw per day, the highest dose tested.

In a study aiming to determine effects of iprodione on pregnancy and sex differentiation, it was administered to rats from GD 6 to GD 19 by gavage at doses of 0, 20, 120 or 250 mg/kg bw per day. The NOAEL for maternal toxicity was 20 mg/kg bw per day based on decreased body weight gain, food intake, food efficiency and enlarged adrenals, at 120 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 120 mg/kg bw per day, based on reduced fetal body weight at 250 mg/kg bw per day.

In a developmental toxicity study in rabbits, iprodione was administered by gavage from GD 6 to GD 18 at doses of 0, 20, 60 or 200 mg/kg bw per day. The NOAEL for maternal toxicity was 20 mg/kg bw per day based on decreased body weight gain at 60 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 60 mg/kg bw per day based on increased abortions and post-implantation losses at 200 mg/kg bw per day. Animals in the high-dose group experienced body weight loss and reduced food consumption during the first six days of treatment and this persisted throughout the study, which may be indicative of an acute adverse effect. A NOAEL for acute maternal toxicity of 60 mg mg/kg bw was identified, based on body weight loss between GD 6 and GD 12 at 200 mg/kg bw per day.

The Meeting concluded that iprodione is not teratogenic.

No specific data were submitted regarding neurotoxicity, but no evidence of neurotoxicity was reported in routine toxicological studies with iprodione.

The Meeting concluded that iprodione is unlikely to be neurotoxic.

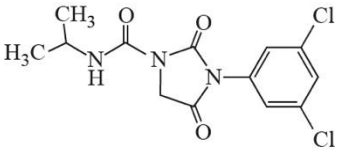
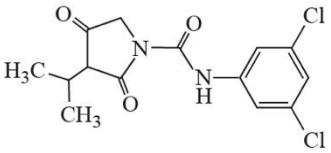
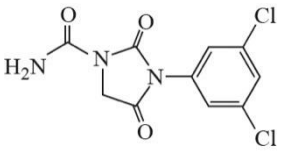
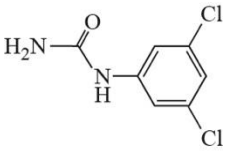
In an immunotoxicity study in female rats, iprodione was administered at dietary concentrations of 0, 500, 1200 or 3000 ppm (equal to 0, 39, 95 and 225 mg/kg bw per day). The NOAEL for systemic toxicity was 1200 ppm (equal to 95 mg/kg bw per day), based on reduced body weight and body weight gain at 3000 ppm (equal to 225 mg/kg bw per day). The NOAEL for functional immunotoxicity (T-helper cell-mediated antibody production after immunization with sheep red blood cells) was 3000 ppm (equal to 225 mg/kg bw per day), the highest dose tested.

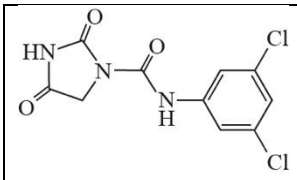
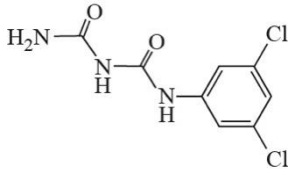
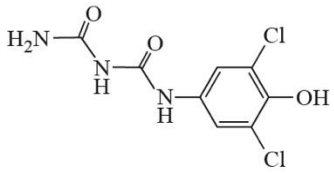
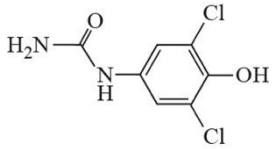
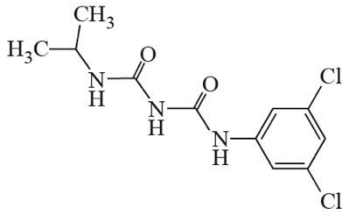
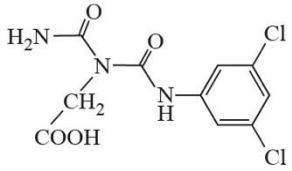
The Meeting concluded that iprodione is not immunotoxic.

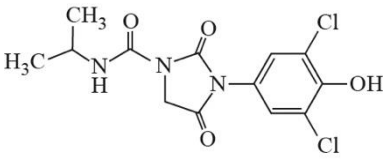
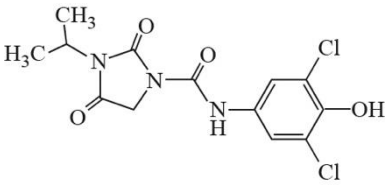
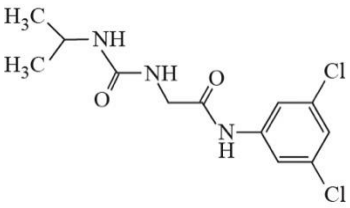
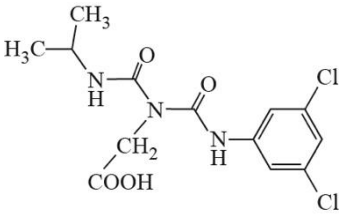
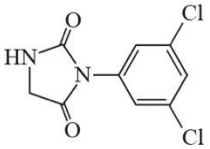
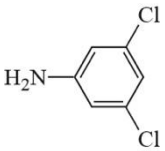
Toxicological data on metabolites and/or degradates

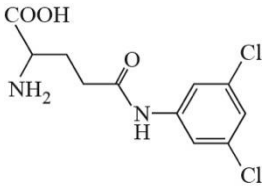
A toxicological evaluation was performed on metabolites and the table below shows an overall summary of the toxicological characterization of those metabolites requested for consideration in the residue definition.

Summary of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	**Major rat metabolite** (>10% AD)	**Genotoxicity assessment** (data, QSAR, read-across)	**General toxicity**	**Toxicological reference values**
Iprodione RP26019 	Parent	Not genotoxic (data)	Full dataset	ADI: 0–0.06 mg/kg bw ARfD: 0.6 mg/kg bw
RP30228 *N*-(3,5-Dichlorophenyl)-3-isopropyl-2,4-dioxoimidazolidine-1-carboxamide 	No	Not genotoxic (QSAR; RA)	LD_{50}: >2000 mg/kg bw	TTC Cramer class III value: 1.5 µg/kg bw per day
RP32490 3-(3,5-Dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide 	Yes (15% in urine)	Not genotoxic as covered by parent	Covered by parent	Parent ADI and ARfD
RP44247 Amino-*N*-(3,5-dichlorophenyl)amide 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP36112 *N*-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day

				
RP36115 Amino-*N*-[*N*-(3,5-dichlorophenyl) carbamoyl]amide 	Yes (>15% in urine)	Not genotoxic as covered by parent	Covered by parent	Parent ADI and ARfD
RP336114 *N*-(3,5-Dichloro-4-hydroxyphenyl)-2-carbamoylacetamide 	Yes| (>15% in urine)	Not genotoxic as covered by parent	Covered by parent	Parent ADI and ARfD
DCHPU Amino-*N*-(3,5-dichloro-4-hydroxyphenyl)amide 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP36221 1-(3,5-Dichlorophenyl)-5-isopropyl biuret 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP44160 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day

RP37677 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP36119 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP37176 *N*-(3,5-Dichlorophenyl)-2-[(isopropylcarbamoyl)amino] acetamide 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP35606 *N*-(3,5-Dichlorophenylcarbamoyl) -*N*-isopropylcarbamoyl-glycine 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP25040 3-(3,5-Dichlorophenyl)-imidazolidine-2,4-dione 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
RP32596 3,5-Dichloroaniline 	No	Not genotoxic (Ames test; QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day

***N*-(3,5-Dichlorophenyl)-*L*-glutamine** 	No	Not genotoxic (QSAR; RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day

RA: Read-across; TTC: Threshold of toxicological concern;QSAR: Quantitative structure–activity relationship analysis;

ADI: Acceptable daily intake; ARfD: Acute reference dose

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of iprodione residues on the human intestinal microbiome.

Human data

No information was provided on the health of workers involved in the manufacture or use of iprodione. No information on accidental or incidental poisoning in humans was available.

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

Toxicological evaluation

The Meeting re-affirmed the ADI for iprodione of 0–0.06 mg/kg bw on the basis of a NOAEL of 150 ppm (equal to 6.1 mg/kg bw per day) in the two-year chronic toxicity and carcinogenicity study in rats, and using a safety factor of 100. This gives a margin of 10 000 to the lowest dose causing tumours in mice and 1150 for the corresponding margin in rats.

This ADI also applies to metabolites RP32490, RP36114 and RP36115.

The Meeting established an ARfD for the general population of 0.6 mg/kg bw for iprodione, on the basis of a NOAEL of 60 mg/kg bw, based upon body weight loss and reduced food consumption between GD 6 and GD 12, at 200 mg/kg bw per day in the developmental toxicity study in rabbits, and using a safety factor of 100.

This ARfD also applies to metabolites RP32490, RP36114 and RP36115.

A toxicological monograph was prepared.

Levels relevant to risk assessment of iprodione

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity [a]	Toxicity	1250 ppm, equal to 171 mg/kg bw per day [c]	-
		Carcinogenicity	1250 ppm, equal to 171 mg/kg bw per day [c]	-
	99-week study of toxicity and carcinogenicity [a]	Toxicity	160 ppm, equal to 23 mg/kg bw per day	800 ppm, equal to 115 mg/kg bw per day
		Carcinogenicity	800 ppm, equal to 115 mg/kg bw per day	4000 ppm, equal to 604 mg/kg bw per day
Rat	Two-year studies of toxicity and carcinogenicity [a, d]	Toxicity	150 ppm, equal to 6.1 mg/kg bw per day	300 ppm, equal to 12.4 mg/kg bw per day
		Carcinogenicity	300 ppm, equal to 12.4 mg/kg bw per day	1600 ppm, equal to 69.0 mg/kg bw per day
	Two-generation study of reproductive toxicity [a]	Reproductive toxicity	3000 ppm, equal to 159 mg/kg bw per day [c]	-
		Parental toxicity	300 ppm, equal to 17 mg/kg bw per day	1000 ppm, equal to 55 mg/kg bw per day
		Offspring toxicity	1000 ppm, equal to 55 mg/kg bw per day	3000 ppm, equal to 159 mg/kg bw per day
	Two-generation study of reproductive toxicity [a]	Reproductive toxicity	1500 ppm, equal to 116 mg/kg bw per day [c]	-

Species	Study	Effect	NOAEL	LOAEL
		Parental toxicity	750 ppm, equal to 59 mg/kg bw per day	1500 ppm, equal to 116 mg/kg bw per day
		Offspring toxicity	300 ppm, equal to 24 mg/kg bw per day	750 ppm, equal to 59 mg/kg bw per day
	Developmental toxicity study [b]	Maternal toxicity	20 mg/kg bw per day	120 mg/kg bw per day
		Embryo/fetal toxicity	120 mg/kg bw per day	250 mg/kg bw per day
Rabbit	Developmental toxicity study [b]	Maternal toxicity	20 mg/kg bw per day	60 mg/kg bw per day
	Developmental toxicity study [b]	Acute maternal toxicity	60 mg/kg bw per day	200 mg/kg bw per day
	One-year studies of toxicity [a, d]	Embryo/fetal toxicity	60 mg/kg bw per day	200 mg/kg bw per day
		Toxicity	600 ppm, equal to 24.9 mg/kg bw per day	3600 ppm, equal to 145 mg/kg bw per day
Dog	One-year studies of toxicity [a, d]	Toxicity	600 ppm, equal to 24.9 mg/kg bw per day	3600 ppm, equal to 145 mg/kg bw per day

[a] Dietary administration

[b] Gavage administration

[c] Highest dose tested

[d] Two or more studies combined

[e] Lowest dose tested

Acceptable daily intake (ADI) applies to iprodione, RP32490, RP36114 and RP36115, expressed as iprodione.

0–0.06 mg/kg bw

Acute reference dose (ARfD) applies to iprodione, RP32490, RP36114 and RP36115, expressed as iprodione.

0.6 mg/kg bw

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

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapidly and almost completely absorbed
Dermal absorption	No data
Distribution	Distributed rapidly and eliminated quickly from the tissues Highest levels were found in liver, stomach, small and large intestine, pancreas and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid and nearly complete; 82% in urine and faeces within 48 hours
Metabolism in animals	Extensive metabolism in rats, primary route of metabolism was hydroxylation of the aromatic ring, degradation of the isopropylcarbamoyl chain and rearrangement followed by cleavage of the hydantoin moiety
Toxicologically significant compounds in animals and plants	Iprodione (parent), RP32490, RP36114 and RP36115
Acute toxicity	
Rat, LD_{50}, oral	>2000 mg/kg bw
Rat, LD_{50}, dermal	>2000 mg/kg bw
Rat, LC_{50}, inhalation	>3.29 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Mildly irritating

Mouse, dermal sensitization	No data
Guinea pig, dermal sensitization	Not sensitizing (Buehler)
Short-term studies of toxicity	
Target/critical effect	Increased incidence of Heinz bodies; histopathological changes in adrenals and kidneys (dog)
Lowest relevant oral NOAEL	24.9 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day, highest dose tested (rabbit)
Lowest relevant inhalation NOAEC	0.217 mg/L (rat)
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Histopathological changes in adrenal cortex, testes, seminal vesicles and spleen (rat)
Lowest relevant NOAEL	6.1 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in mice and male rats[a]
Genotoxicity	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Reduced body weight, body weight gain and food consumption (parental); delayed onset of male puberty
Lowest relevant parental NOAEL	17 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	24 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	116 mg/kg bw per day, highest dose tested (rat)
Developmental toxicity	
Target/critical effect	Decreased body weight gain (rat and rabbit maternal); Enlarged adrenals (rat maternal) Decreased fetal weight (rat offspring)
Lowest relevant maternal NOAEL	20 mg/kg bw per day (rat, rabbit)
Lowest relevant embryo/fetal NOAEL	60 mg/kg bw per day (rabbit)
Neurotoxicity	

Acute neurotoxicity NOAEL	No evidence from routine studies
Subchronic neurotoxicity NOAEL	No evidence from routine studies
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity NOAEL	225 mg/kg bw per day, highest dose tested (rat)
Studies on toxicologically relevant metabolites	No data submitted
Microbiological data	No data submitted
Human data	No data submitted

[a] Unlikely to pose a carcinogenic risk to humans via exposure from the diet

Summary

	Value	**Study**	**Safety factor**
ADI	0– 0.06 mg/kg bw [a]	Two-year study of toxicity and carcinogenicity (rat)	100
ARfD	0.6 mg/kg bw [a]	Developmental toxicity study (rabbit)	100

[a] Applies to iprodione, *RP32490*, *RP36114* and *RP36115*, expressed as iprodione

Iprodione is a contact fungicide. The mode of action of iprodione involves blocking the growth of the fungal mycelium and inhibiting the germination of fungal spores. The IUPAC name for iprodione is 3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxoimidazolidine-1-carboxamide. Iprodione belongs to the non-systemic dichlorophenyl-dicarboxamide fungicides and imidazole fungicides and is also a member of the ureas and benzenes.

Iprodione was first evaluated for residues in 1977 and again in 1980, and in 1994 under the CCPR Periodic Review Programme, and for toxicology in 1992 and 1995, followed by a re-evaluation of tomato data in 2001.

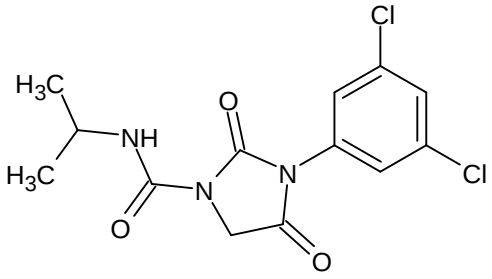
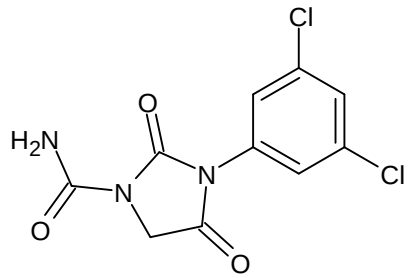
Iprodione was scheduled at the fifty-fourth Session of the CCPR (2022) for periodic review by the 2023 JMPR for toxicology and residues.

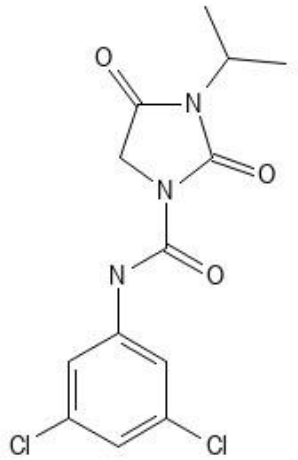
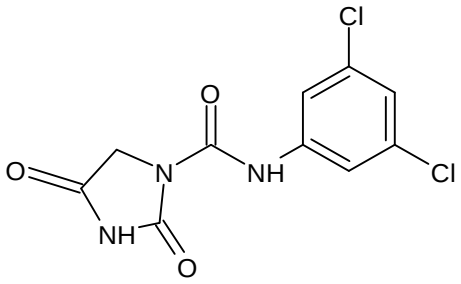
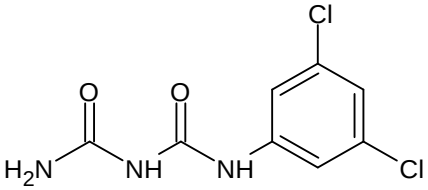
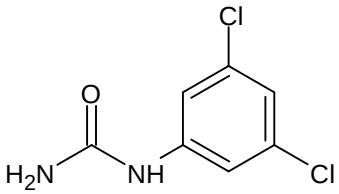
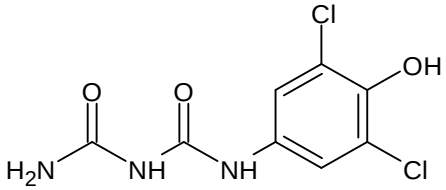
Iprodione has been evaluated by JMPS in 2019 and FAO specifications for technical and formulated iprodione have been published.

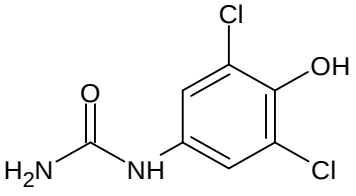
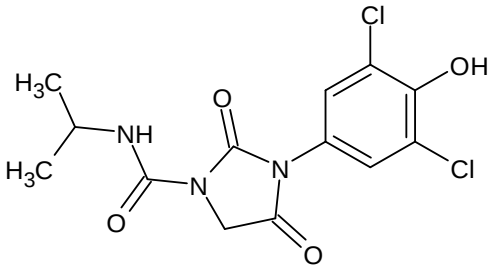
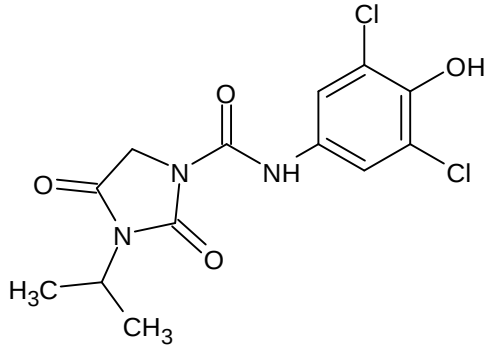
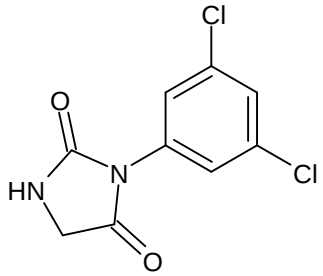
The Meeting received information on identity, physical-chemical properties, plant and animal metabolism, aerobic soil degradation, residue analysis, storage stability, use patterns, residues resulting from supervised trials on apples, stone fruits (cherries and peaches), blackberries, raspberries, grapes, broccoli, leafy greens (leaf lettuce, endives and escarole), succulent beans with pods, dry beans, carrots, potatoes, and almonds, as well as fate of residue studies during processing, and livestock feeding studies.

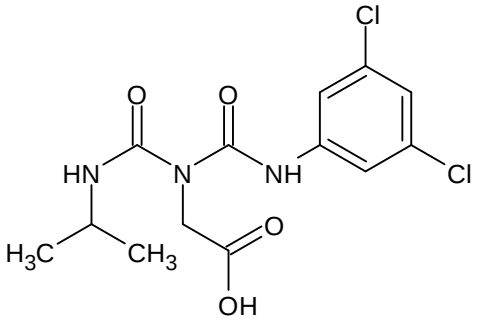
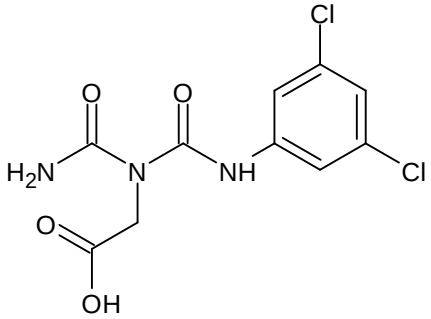
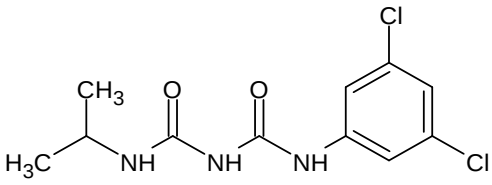
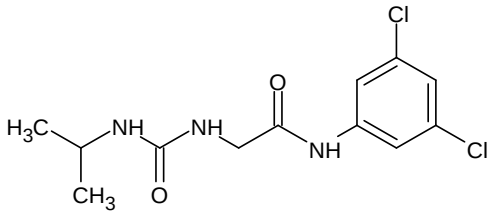
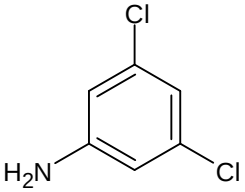
The structure of iprodione and of the major metabolites discussed in this appraisal are shown in the table below.

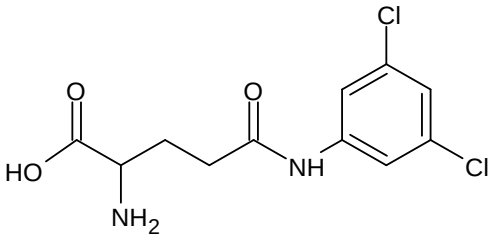
Table 7: Abbreviations used for relevant compounds referred to in the appraisal

Name/ abbreviation or Code	Chemical structure and SMILES CODE	Chemical name, molecular formula and molecular weight	Found in/comments
Parent compound			
Iprodione RP26019 Code: 101169	 SMILES CODE: O=C2N(c1cc(Cl)cc(Cl)c1)C(=O)CN2C(=O)NC(C)C	3-(3,5-dichlorophenyl)-N-isopropyl-2,4-dioxoimidazolidine-1-carboxamide Molecular formula: $C_{13}H_{13}Cl_2N_3O_3$ Molecular weight: 330.17 g/mol	Primary & rotational crops, Poultry, & ruminant tissues
Metabolites			
RP32490 Code: 5079628		3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide Molecular formula: $C_{10}H_7Cl_2N_3O_3$ Molecular weight: 288.09 g/mol	Primary crops, major in all poultry & ruminant tissues.

Name/ abbreviation or Code	Chemical structure and SMILES CODE	Chemical name, molecular formula and molecular weight	Found in/comments
	SMILES CODE: O=C2CN(C(=O)N)C(=O)N2c1cc(Cl)cc(Cl)c1		
RP30228 M610F001 Code: 5079647 Iprodione isomer	 SMILES CODE: O=C2CN(C(=O)Nc1cc(Cl)cc(Cl)c1)C(=O)N2C(C)C	*N*-(3,5-dichlorophenyl)-3-isopropyl-2,4-dioxoimidazolidine-1-carboxamide Molecular formula: $C_{13}H_{13}Cl_2N_3O_3$ Molecular weight: 330.17 g/mol	Primary & rotational crops, minor in several poultry & ruminant tissues.
RP36112 Code: 5079623	 SMILES CODE: O=C2NC(=O)CN2C(=O)Nc1cc(Cl)cc(Cl)c1	*N*-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide Molecular formula: $C_{10}H_7Cl_2N_3O_3$ Molecular weight: 288.09 g/mol	Found in hen eggs, goat & hen liver and kidney.
RP36115 Code: 5079624	 SMILES CODE: NC(=O)NC(=O)Nc1cc(Cl)cc(Cl)c1	amino-N-[N-(3,5-dichlorophenyl)carbamoyl]amide Molecular formula: $C_8H_7Cl_2N_3O_2$ Molecular weight: 248.07 g/mol	Found in hen eggs, goat & hen liver and kidney
RP44247 Unknown Y Code: 89517	 SMILES CODE: NC(=O)Nc1cc(Cl)cc(Cl)c1	amino-N-(3,5-dichlorophenyl)amide Molecular formula: $C_7H_6Cl_2N_2O$ Molecular weight: 205.04 g/mol	Rotational crops, and in hen liver, kidney and eggs
RP36114 Code: 5079627		N-(3,5-dichloro-4-hydroxyphenyl)-2-carbamoylacetamide Molecular formula: $C_8H_7Cl_2N_3O_3$	Found in cow milk and in goat and hen kidney and liver

Name/ abbreviation or Code	Chemical structure and SMILES CODE	Chemical name, molecular formula and molecular weight	Found in/comments
	SMILES CODE: NC(=O)NC(=O)Nc1cc(Cl)c(O)c(Cl)c1	Molecular weight: 264.07 g/mol	
DCHPU Unknown X Code: 5932706	 SMILES CODE: NC(=O)Nc1cc(Cl)c(O)c(Cl)c1	amino-N-(3,5-dichloro-4-hydroxyphenyl)amide Molecular formula: $C_7H_6Cl_2N_2O_2$ Molecular weight: 221.04 g/mol	Found in goat kidney
RP37677 Code: -	 SMILES CODE: CC(C)NC(=O)N1CC(=O)N(C1=O)c2cc(Cl)c(O)c(Cl)c2	3-(3,5-dichloro-4-hydroxy-phenyl)-N-isopropyl-2,4-dioxo-imidazolidine-1-carboxamide Molecular formula: $C_{13}H_{13}Cl_2N_3O_4$ Molecular weight: 346.17 g/mol	Found in goat and hen liver and kidney
RP36119 Code: 5079629	 SMILES CODE: CC(C)N1C(=O)CN(C(=O)Nc2cc(Cl)c(O)c(Cl)c2)C1=O	N-(3,5-dichloro-4-hydroxy-phenyl)-3-isopropyl-2,4-dioxo-imidazolidine-1-carboxamide Molecular formula: $C_{13}H_{13}Cl_2N_3O_4$ Molecular weight: 346.17 g/mol	Found in goat liver and kidney
RP25040 M610F004 Code: 207099	 SMILES CODE: Clc1cc(Cl)cc(c1)N2C(=O)CNC2=O	3-(3,5-dichlorophenyl)-imidazolidine-2,4-dione Molecular formula: $C_9H_6Cl_2N_2O_2$ Molecular weight: 245.1 g/mol	Rotational crops and photolytic (soil) degradation

Name/ abbreviation or Code	Chemical structure and SMILES CODE	Chemical name, molecular formula and molecular weight	Found in/comments
RP35606 Code: 5079626	 SMILES CODE: -	N-(3,5-dichlorophenylcarbamoyl)-N-isopropylcarbamoyl-glycine Molecular formula: $C_{13}H_{15}Cl_2N_3O_4$ Molecular weight: 348.2 g/mol	Found after hydrolysis as a function of pH. Found in soil. Intermediate product (ring opening) in the formation of RP30228.
RP44160 Code: -	 SMILES CODE: NC(=O)N(CC(=O)O)C(=O)Nc1cc(Cl)cc(Cl)c1	2-[carbamoyl-[(3,5-dichlorophenyl)carbamoyl]-amino]acetic acid Molecular formula: $C_{10}H_9Cl_2N_3O_4$ Molecular weight: 306.1 g/mol	Found goat liver and kidney
RP36221 M610F002 Code: 5079618	 SMILES CODE: Clc1cc(NC(=O)NC(=O)NC(C)C)cc(Cl)c1	1-(3,5-dichlorophenyl)-5-isopropyl biuret Molecular formula: $C_{11}H_{13}Cl_2N_3O_2$ Molecular weight: 290.15 g/mol	Found in goat and hen liver and kidney
RP37176 Code: 5079612	 SMILES CODE: CC(C)NC(=O)NCC(=O)Nc1cc(Cl)cc(Cl)c1	*N*-(3,5-dichlorophenyl)-2-[(isopropylcarbamoyl)amino]acetamide Molecular formula: $C_{12}H_{15}Cl_2N_3O_2$ Molecular weight: 304.18 g/mol	Found in processed commodities (hydrolysis and in soil.
RP32596 3,5-DCA M610F012 Code: 85831	 SMILES CODE: Nc1cc(Cl)cc(Cl)c1	3,5-dichloroaniline Molecular formula: $C_6H_5Cl_2N$ Molecular weight: 162.02 g/mol	Not observed in unbound form in plants. Found after processing (hydrolysis) and in photolysis studies. Found in goat liver and kidney.

Name/ abbreviation or Code	Chemical structure and SMILES CODE	Chemical name, molecular formula and molecular weight	Found in/comments
M610F007 Code: 5916256 (L-Form)	 SMILES CODE: -	N-(3,5-dichlorophenyl)-L-glutamine Molecular formula: $C_{11}H_{12}Cl_2N_2O_3$ Molecular weight: 291.13 g/mol	L-glutamine complex with 3,5-DCA, found in carrot metabolism study, but this study was not submitted.

Physical-chemical properties

Iprodione has a vapour pressure of <2.49 × 10^{-5} Pa at ambient temperature (indicating a moderate probability for volatilization from water to air). It's solubility in water is low (15 mg/L), but higher in organic solvents (0.63 g/L in n-heptane to 467 g/L in dichloromethane). The n-octanol/water partition coefficient of 3.5 suggests that iprodione may have a tendency to partition in fat. Iprodione is slowly hydrolysed at pH5 and more rapidly at higher pH and thus considered not to be stable in neutral and alkaline media.

Plant metabolism

The meeting received plant metabolism studies for iprodione after different types of application on crops in five different crop groups: fruits (strawberries & peaches), leafy vegetables (lettuce), cereals (wheat & rice), pulses and oilseeds (peanuts). In all metabolism studies [phenyl-^{14}C]-labelled iprodione was used. Though a metabolism study in carrot roots is available, the applicant was not able to retrieve it. The summary of the study is included in the evaluation and the conclusions are included in this appraisal for supportive information only.

Strawberries - foliar (and soil) - indoor

^{14}C-phenyl labelled iprodione was applied to greenhouse grown strawberry plants (variety Revada), either as single foliar spray (spraying leaves at 1 or 2 kg ai/ha) at flowering stage or as a single soil application (4 or 10 kg ai/ha) before planting (soil type: clay loam). Strawberries treated by foliar spray were harvested at various days after application. Strawberries grown on treated soil were harvested 35–125 days after application, depending on use rate and growth stage.

When applied by foliar spray, iprodione and its metabolites undergo little translocation within the plant. Stems+leaves contained up to 100 mg eq/kg, with only up to 1.7 mg eq/kg in roots and 0.8 mg eq/kg in fruits at the 1 kg ai/ha foliar application rate. When applied to soil of strawberries at the rate of 4 and 10 kg ai/ha a small portion (1-5 percent TAR) of iprodione is taken up by plants, with 25.6–64 percent of the radioactive residue in roots and 41–75 percent of the residue in stems+leaves, depending on DAT. Absolute levels reached up to 4.2 mg eq/kg in stems+leaves and up to 16.2 mg eq/kg in roots.

After division into relevant plant parts (leaves, fruits) and washing with water, the samples were extracted in acidified acetone. Samples from plants treated at the higher rates received an additional extraction with acidified methanol. After foliar application >95 percent of the radio activity was extracted in both stem + leaves and roots, whereas extraction of the radioactivity ranged from 43 to 62 percent TRR in the samples taken after soil application. No

further attempts were undertaken to identify the relatively high proportion of unextracted residues (38–55 percent TRR).

After foliar application iprodione was the major compound observed in strawberry fruit at 29.2–76.6 percent TRR (0.68–3.2 mg/kg) in stem + leaves at 78–87 percent TRR (19–30 mg/kg). The isomer RP30228 was found at 0.64–3.28 percent TRR in strawberry fruits and 0.34–5.1 percent TRR (0.34–1.97 mg eq/kg) in leaves. Metabolite RP32490 accounted for <0.01–1.64 percent TRR (<0.01–0.02 mg eq/kg) in strawberry fruits and 2.53-3.14 percent TRR (0.61–1.06 mg eq/kg) in stem+leaves.

After soil application iprodione was the major compound observed in stem and leaves 0.36 to 16 percent TRR and 0.01–0.39 mg /kg (43 percent TRR or 11.2 mg eq/kg at high dose rate) and in roots at 15–29 percent TRR (1.3–3.0 mg/kg), with 47.3 percent TRR (19.2 mg/kg at the high dose rate). The isomer RP30228 was found at approximately 6 percent TRR (0.23–0.25 mg eq/kg) in stems+leaves and 5.1–10 percent TRR (0.37–1.1 mg eq/kg) in roots with 22.2 percent TRR (9.0 mg/kg at the high dose rate). Metabolite RP32490 accounted for 2.3–2.9 percent TRR (<0.01–0.06 mg eq/kg) in stems+ leaves and 4.1–6.2 percent TRR (0.27–0.81 mg eq/kg) in leaves.

Roots in samples from foliar applications contained only traces of radioactivity and were not further analysed. The same applies for strawberry fruits after soil applications.

The residue appears to be rather extensively degraded over time in strawberry plant matrices. With decreasing levels of parent increasing levels of RP30228 and RP32490 were observed (never higher than 10 percent TRR, 0.78 mg eq/kg).

Peaches – foliar – outdoor

^{14}C-phenyl labelled iprodione was applied three times to two outdoor grown peach trees at a rate of 1.1 kg ai/ha, each. Applications were made at pink bud, petal fall and maturing fruit stages (-93 DAT, -72 DAT, and -8 DAT, respectively). Fruits were collected at 70–80 percent maturity, either after two treatments (64 DAT) or after three treatments (8 DAT).

A high extractability (94–99 percent TRR) was established by using acetone, followed by methanol extraction, leaving 6 percent TRR (0.0025 mg eq/kg) and 0.5 percent TRR (0.007 mg eq/kg) unextracted in the samples taken respectively after two and three treatments.

Of the total radioactive residue in fruit 61.5 percent TRR (0.025 mg/eq kg) was identified as unchanged parent compound in samples taken after two treatments and 94 percent TRR (1.77 mg/kg) in samples taken after three treatments. Other compounds were characterized, but not identified: 33 percent TRR (0.008 mg eq/kg) after 2 treatments and 4.8 percent TRR (0.1 mg eq/kg) after 3 treatments. RP30228 and RP32490 were found only at low levels in the samples taken after 3 treatments: 0.8 and 0.5 percent TRR (0.015 and 0.01 mg eq/kg), respectively.

Lettuce – foliar – outdoor

^{14}C-phenyl labelled iprodione was applied once to indoor grown lettuce (variety Trocadero a graine noire) at a dose equivalent to 0.75 kg ai/ha two weeks after transplanting (46 days after sowing). At this time the plants had about 15 leaves. Plants were harvested zero and 38 days after treatment.

Total radioacitve residues ranged from 64.2 to 6.14 mg eq/kg on day 0 DAT to 38 DAT. The plants were extracted with acetone and subsequently with methanol. A high extraction efficiency (>95 percent TRR) was reached.

In lettuce, 38 days after treatment, parent iprodione was found at 81 percent TRR or 4.94 mg/kg (98 percent TRR and 63 mg/kg at PHI zero days), and metabolite RP30228 accounted for 9.5 percent TRR and 0.58 mg eq/kg (0.25 percent TRR and 0.16 mg eq/kg at PHI zero days). The non-identified and bound parts of TRR amounted to a maximum of 4.5 percent TRR (0.28 mg eq/kg) each.

Carrot

In the absence of the original study report, the following information is based on the summary derived from the European Renewal Assessment Report (EU-RAR) and will only be used for supportive information.

^{14}C-phenyl labelled iprodione was applied four times to indoor grown carrots (variety Daucus carrota) at a dose equivalent to 0.75 kg ai/ha. The foliar sprays ware applied with RTI of ten days and plants were harvested at 28 DALA. Mature plants were harvested 28 and 58 DALA and separated into leaves and roots.

Total radioactive residues were 0.48 mg eq/kg in roots and 60 mg eq/kg in leaves. The extractability with methanol (3×) and water (2×) was 64.4 percent TRR for carrot root and 98.0 percent TRR for carrot leaf. For both matrices the major part of the radioactivity was extracted with methanol (root: 62.6 percent TRR and leaf: 96.8 percent TRR) and only minor amounts were subsequently released with water (root: 1.7 percent TRR and leaf: 1.1 percent TRR). Post extraction solids were 35.7 percent (0.172 mg/kg) in roots and 2.1 percent TRR (1.228 mg/kg) in leaves and were solubilized with ammonia, macerocyme, hesperidinase, amylase, pepsin (only root) and pancreatin (only root). This released another 3.9 percent TRR in carrot root and 1.0 percent TRR in carrot leaf.

In carrot root iprodione accounted for 7.6 percent TRR (0.037 mg/kg). The isomer RP30228 represented 14 percent TRR (0.067 mg eq/kg). Another major component was the glutamic acid conjugate of 3,5-dichloroaniline (M610F007) with 16.4 percent TRR (0.79 mg eq/kg). The remaining identified components (carbohydrates (not specified), M610F009/others, RP44247, RP36115, M610F011, RP36112 and RP36221) ranged from 1.2 to 6.1 percent TRR (0.006-0.029 mg eq/kg).

In carrot leaf, the sum of iprodione accounted for 80.6 percent TRR and RP30228 for 14.5 percent TRR. In addition, only small portions of carbohydrates, RP44247, M610F011, RP36112 and RP36221 were identified (≤1.1 percent TRR).

Wheat – foliar (and soil) – indoor

The metabolic fate of ^{14}C-phenyl labelled iprodione was investigated in wheat after either one application to soil before sowing at 1 or 10 kg ai/ha or by spraying once at 1 kg ai/ha at a plant height of 15-20 cm, i.e. 15 days after sowing. Wheat plants treated by foliar spray were harvested 0, 7, 15, 33, 70 and 96 days after application. Wheat plants grown on treated soil were harvested 30, 58 and 77 days after application (1 kg ai/ha) and 16, 44 and 89 days after application (10 kg ai/ha). Wheat plants were sampled into stems+leaves and roots, heads (77 and 98 DAT, only) and grains (89 DAT only). Growth stages were not reported, but plants sampled at 77 days or after were assumed to be mature.

Following soil application, the TRR in stem plus leaves and roots was 14.7 mg eq/kg and 1.35 mg eq/kg, respectively at 30 DAT, and 0.1 mg eq/kg, 4.7 mg eq/kg and 0.7 mg eq/kg at 77 DAT in heads, stem+leaves and roots, respectively. The results indicate that, when applied to soil, only a small portion (1—5 percent TAR) of iprodione is taken up by plants.

Extraction with acidified acetone released 32 to 73 percent TRR in stem+leaves after 1 kg ai/ha application, 89 to 99 percent TRR in steam+leaves after 10 kg ai/ha soil application and 8.4 to 29.5 percent TRR and 21 tp 84 percent TRR in roots at the 1 and 10 kg ai/ha soil application, respectively. Post-extracted solids were 1.7-68 percent TRR in stems+leaves and 17–91 percent TRR in roots. Except for the head samples taken at 89 DAT (10 kg ai/ha soil application), absolute residue levels were too low for identification of metabolites in heads and grain.

Parent compound was the major component identified in stems+leaves: 66 percent TRR at 16DAT and 26 percent TRR at 89DAT and in roots: 49 percent TRR at 16DAT and 2.9 percent TRR at 89DAT. In stem+leaves isomer RP30228 and metabolite RP32490 were identified: 6.4 percent TRR at 16DAT and 17 percent TRR at 89DAT and 4.4 percent TRR at 16DAT to 14 percent TRR at 89DAT, respectively. In roots RP30228 was identified at varying concetrations, generally decerasing over time (14 to 1 percent TRR). Metabolite RP32490 was not found except at 89DAT in roots.

When applied by foliar spray, the TRR was 6.6 mg eq/kg in roots and 145 mg eq/kg in stems+leaves on 0DAT. Radioactiviy in heads was only observed at 96DAT and was 1.4 mg eq/kg.

After foliar application the majoritiy of the radioactivity could be extracted with acidified acetone (72–100 percent TRR in stem and leaves and 40–98 percent TRR in roots); 0.10–28 percent TRR in stem and leaves and 1.8–60 percent TRR was left as post-extracted solids. The radioactivity could not be identified in heads (total 1.35 mg eq/kg, with 0.54 mg eq/kg non-identified extract and 0.81 mg eq/kg PES).

Parent compound was the major residue in stem plus leaves, ranging from 94 percent TRR at 0 DAT to 25 percent TRR at 96 DAT). The isomer RP30228 was identified: 1.21 percent TRR at 0 DAT to 33 percent TRR at 96DAT). Metabolite RP32490 was observed at lower concentrations: 1.5 percent TRR at 0 DAT to 4.1 percent TRR at 7 DAT). Unidentified extracted metabolites accounted for a maximum of 16 percent TRR (4.6 mg eq/kg). In roots, absolute residue levels were much lower, but a similar distribution pattern could be observed, with an increasing percentage of unextracted residue in time (1.8 to 61 percent TRR).

Rice – foliar – outdoor

Rice plots were treated twice with ^{14}C-phenyl ring labelled iprodione at a rate equivalent to 1.1 kg ai/ha, each, once at the "booting stage" and once again at the “heading” stage (RTI = 16 days). Various samples were taken: immature plants were sampled at different time points; -16DAT (before and after first application), -8DAT (seven days after first application), -0DAT (prior to second application), and 0, 7, and 21DAT. Heads plus stalks, straw, chaff, mill feed, bran plus polish, brown rice and polished rice were sampled at 40DAT (harvest).

Total residues were 0.78 mg/eq kg in brown rice, 0.26 mg eq/kg in polished rice, 9.92 mg eq/kg in heads+stalks, 36.14 mg eq/kg in straw, 6.17 mg eq/kg in chaff, 8.30 mg eq/kg in mill feed, and 4.54 mg eq/kg in bran+polish.

Rice samples were extracted with acetone, followed by refluxing with a mixture of acetone and water (1:1) and subsequent aqueous hydrolysis under acidified conditions (mature plant samples only). In immature plants at -16DAT to 21DAT the total extracted residue was 73.4–95.6 percent TRR, with 4.4–26.6 percent unextracted residues. In mature plant samples, the acetone extract released 42 to 71 percent identifiable TRR, followed by 4.5–32 percent TRR

released by acetone reflux and another 1.79—10 percent TRR following aqueous hydrolysis. The unextracted residue in mature plant samples ranged from 4. percent TRR to 26 percent TRR, with the highest levels in brown and polished rice. Radioactive residues were only identified in samples harvested at 40DAT.

Iprodione was the major component and accounted for 37 percent TRR (0.19 mg/kg) in brown rice, 36 percent TRR (0.07 mg/kg) in polished rice, and 32—60 percent TRR (no absolute values reported) in head/stalks, straw, chaff, mill feed and bran/polish. Metabolite RP30228 was found at levels of 21 percent TRR (0.04—0.10 mg eq/kg) in brown and polished rice, and at 11—28 percent TRR (no absolute values reported) in the other matrices. Metabolites RP32490, RP36122 and RP36221 could poorly be resolved from each other in brown rice and polished rice and accounted for approximately 5 percent TRR. RP36221 could be distinguished from RP32490/RP36112 in other matrices ranging from 0.33 to 4.12 percent TRR, with levels of RP32490/RP36112 ranging from 0.94 to 4.38 percent TRR in the other rice matrices. Metabolite RP25040 was found at levels of 3.7—5 percent TRR in brown rice and polished rice and up to 9 percent TRR in other rice matrices.

Peanut – foliar – outdoor

Peanut plants were treated three times with ^{14}C-phenyl ring labelled iprodione at a rate equivalent to 1.1 kg ai/ha, each. The foliar applications were done 2 months after planting (66 days prior to harvest); 3 months after planting (35 days prior to harvest) and once ten days before harvest, with intervals of 31 and 15 days.

Peanut plants were sampled just prior to the second and third application (-35 DAT and -0DAT) and at 0 DAT and 10 DAT. The mature plants (10 DAT) were harvested, the aerial portions were air-dried to obtain hay, and the mature peanuts were separated into hulls and nutmeat. A portion of the nutmeat was extracted to obtain peanut oil and peanut meal.

The reported total residues in samples taken ten days after the last treatment were 0.047 mg eq/kg in peanut nutmeat, 0.037 mg eq/kg in peanut oil, 43 mg eq/kg in peanut hay, 0.13 mg eq/kg in peanut hulls, 1.68 mg eq/kg in peanut roots. Total residues in the immature whole plant samples taken immediately after the last treatment were 123 mg eq/kg.

Peanut hay samples were extracted with acetone followed by refluxing in a mixture of water and acetonitrile. The total extracted residue was 95 percent TRR (40.5 mg eq/kg) in hay, with 5.2 percent TRR identified in the reflux fraction. Peanut hulls samples were only extracted with acetone releasing 88.3 percent TRR (0.115 mg eq/kg).

In peanut hulls and hay, the most significant residue was unchanged iprodione, accounting for about 43 percent and 54 percent TRR (0.055 and 23.3 mg/kg), respectively. In hulls, no individual metabolite was present at a level greater than 5.9 percent TRR and 0.008 mg eq/kg. In hay, RP30228 and RP32490 accounted for up to 15 percent TRR (6.3 mg eq/kg) and 9 percent TRR (3.8 mg eq/kg), respectively. In addition, metabolites RP36112 and RP25040 could be identified occurring up to 7 percent TRR (one exception: immature plant, day 31, RP36112 was 27 percent TRR). A large portion of the residues remained unidentified or could not be extracted

(ca. 14 percent TRR in hay and 45 percent TRR in hulls). In hulls, the radioactivity was too low for further characterization (<0.05 mg eq/kg).

Summary of plant metabolism

Several indoor and field studies indicate that iprodione is taken up in plants after foliar application, but uptake is limited after soil treatments (strawberry and wheat studies), being 1—5 percent TAR).

The plant metabolism studies performed in strawberry, peach, lettuce, and wheat show essential similarities: In all cases unchanged parent iprodione was reported to be the major compound (43—94 percent TRR), followed by its rearranged isomer RP30228, though in much lower levels (levels ranging from 0 to 15 percent TRR in food matrices). Metabolite RP32490 was found in the majority of studies and matrices, though in varying amounts up to 9 percent TRR, except peanut whole plant (14 percent TRR), with highest levels in feed matrices. In the rice and peanut studies additional metabolites, RP36112 and RP25040, were found, mostly below 6 percent TRR (1.2—2.3 mg eq/kg in peanut hay, no absolute levels in rice grain were reported). In all studies, the amount of unextracted residues increased in time.

The metabolism in the different crops showed qualitative similarities but quantitative differences.
Metabolism reactions observed in all crops:

- transformation of parent iprodione by ring-opening of the heterocyclic ring and rearrangement, to form its isomer RP30228;
- a second step is the removal of the isopropyl group resulting in metabolites RP32490 (dealkylation of parent) and RP36112 (dealkylation of isomer RP30228);
- removal of the amide group of RP32490 leads to the formation of RP25040 (observed in rice and peanut feed matrices);
- decarboxylation (removal of COOH) of an open chain intermediate between parent and RP30228 (RP35606, which was not observed) leads to the formation of RP36221 (observed in rice matrices).

In carrots some additional metabolites were observed:

- additional open chain intermediates RP36115 and RP44247, suggesting that these may also occur in other crops, but were probably not detected in the old studies due to very small amounts;
- conjugates of 3,5-dichloroaniline (M610F007) or urea-derivative RP44247 (M610F011);
- degradation products of iprodione are eventually incorporated into high molecular structures which explains the high amount of unextracted residues found in all crops investigated.

Environmental fate

The Meeting received studies on hydrolysis, photochemical degradation, aerobic soil degradation, and on the behaviour of iprodione in confined and field rotational crops.

Hydrolysis

The hydrolysis of ^{14}C-iprodione was investigated in aqueous solutions at pH 5, 6, 7, 8 and 9 at 25 ± 1°C in two studies. The rate of hydrolysis of iprodione as well as the formation of

hydrolysis products were investigated over a duration of 30—32 days. The results show that the DT_{50} of iprodione depends on the pH. Where iprodione slowly degrades at pH 5 (DT_{50} of 103—146 days), the DT_{50} decreases with higher pH to 25, 3—6.4, 0.2 and 0.019 days at pH 6, 7, 8, and 9 respectively. An intermediate reaction product, RP35606 (pH-dependent ring opening of parent), was detected at higher pH, and was the precursor of the formation of the RP30228 (ring closure), the isomer of iprodione. RP35606 increased from 0.4 to 11 percent in 30 days at pH 5 (no RP 30228), At pH 7 RP35606 reached a maximum of 10 percent by 40 minutes and RP30228 was formed up to a maximum of 46 percent by 125 hours. At pH 9 RP30228 was formed up to a maximum of 92 percent by 114 minutes.

Three additional hydrolysis studies using metabolites RP35606 and/or RP30228 confirm pH dependency of the formation of iprodione and RP30228. A hydrolysis study with the ring-opened metabolite RP35606 shows that it converts to a pH-dependent mixture of iprodione and RP30228 consisting primarily of iprodione at pH 4 and primarily of RP30228 at pH 9. Commencing with the RP30228 shows that this metabolite is stable at all pH levels, indicating that iprodione is not formed back from RP30228.

The Meeting concluded that hydrolysis is likely to be a minor route of degradation for iprodone under environmental conditions.

Photochemical degradation

The photolysis in sterile water of ^{14}C-phenyl iprodione was studied under simulated sunlight in sterile aqeuous acetate buffer (pH 5, 25 °C) with a DT_{50} of 67 days (SFO) compared to summer sunlight in Florida. None of the photoproducts individually exceeded 5 percent AR. Iprodione was stable under dark conditions.

The Meeting concluded that aqueous photolysis is a minor route of degradation.

In two soil photodegradation studies, ^{14}C-iprodione was applied to a thin layer of sandy loam soil (at a rate equivalent to about 5 kg ai/ha and 10 kg ai/ha, respectively). Degradation of iprodione was observed after an initial lag period of 1 to 2 weeks. In the dark control experiment iprodione was rapidly degraded (DT_{50} of approximately 1 week and 5.15 days in both studies, respectively).

The major degradate observed in the dark controls was RP32596 (3,5-dichloroaniline or 3,5-DCA); up to 26.5 percent AR in study one after 30 days and up to 37 percent AR after 21 days in study two, as well as up to 29 percent AR in irradiated samples in study 2. RP25040 was observed in the dark control samples up to 14.8 percent AR in the irritated samples in the second study. RP30228 was a minor degradation product in study 1 (up to 2.6 percent AR) and occurred in levels up to 14.35 percent AR and 34 percent AR in dark and irradiated samples, respectively in the second study. 3,5-dichlorophenyl wasobserved in the dark control samples up to 58.6 and 28 percent AR at day 21 and 30, respectively, but was not found in the second study. Other degradates accounted for <5 percent AR.

The Meeting concluded that soil degradation is a significant route of degradation, but photolysis will not be an important factor in its environmental fate.

Aerobic soil metabolism

The biotransformation of ^{14}C-iprodione was investigated in three US, one UK soils under laboratory conditions in two different studies. In the US soils 16.2 mg/kg was applied. In the UK trial the equivalent of 10 kg ai/ha (UK soil) was mixed with soil and incubated under aerobic conditions in the dark at ca. 20-25 °C for 122–276 days.

Several metabolites were detected and identified as RP25040 (1.9—12.2 percent AR in US study and up to 7.79 percent AR in the the United Kingdom of Great Britain and Northern Ireland), 3,5-DCA (1.5—28 percent AR in US soils, found in group with RP36119 in the United Kingdom of Great Britain and Northern Ireland up to 6.38 percent AR), and RP30228 (5.4—30 percent AR in US soils, not in UK soil).

An additional aerobic soil degradation study in German soils was available. The original study report could not be retrieved by the manufacturer. The summary of the study, based on the summary in the EU RAR, is included in the evaluation and the conclusions are included in this appraisal as supportive information. In this study similar values for RP25404, 3,5-DCA, and RP30228 were found in in four German soils. In that study the equivalent of 4 kg ai/ha was mixed with soil and incubated under aerobic conditions in the dark at 20 °C for 120 days. Some additional degradates were found RP35606 (up to 25.5 percent TAR) and RP36221 (up to 6.9 percent TAR.) Minor other metabolites were found, but the sum never accounting for more than 4.2 percent TAR.

The rate of degradation of iprodione in soil under aerobic conditions and the degradation half-life is various soils show that the half-life ranges from 6.3 to 103 days and seems to be dependent on the PH.

The aerobic degradation of ^{14}C-RP30228 was investigated in three different UK soils in the dark (20 °C) and showed limited degradation. Data were insufficient to calculate a DT_{50} and no data under light conditions were generated.

The aerobic degradation of ^{14}C-32596 (3,5-DCA) (application rate of 3,300 g 3,5-DCA/ha with an equivalent application rate of 6,725 g ai/ha) was investigated in two different US soils in the dark (~20 °C). The result show that under aerobic conditions, 3,5-DCA dissipated primarily to bound residues, with some formation of carbon dioxide and low quantities of minor degradates. The DT_{50} of 3,5-DCA in silt loam and sand were 28 days and 72 days, respectively.

The Meeting concluded that, under laboratory conditions, iprodione is not persistent in soil.

Soil degradation (field studies)

No field dissipation studies were submitted.

Rotational crop metabolism

The Meeting received information on the metabolism of iprodione in wheat, turnip and swiss chard grown as confined rotational crops and in a range of representative field crops grown in iprodione treated soil.

Confined rotational crop studies

The Meeting received four confined rotational crop metabolism studies.

In the first study, 0.8 kg ai/ha ^{14}C-labelled iprodione was applied five times at two-week intervals, on a clay loam soil (total rate = 4 kg ai/ha). After plant back intervals of 4 and 12 months, the nature and level of the radioactive residues was investigated in wheat (Kolibri variety), common beans (Beurre variety) and sugar beets (Ceres variety).

Plant samples were extracted with acidified solvents (acetone, methanol). The extracted radioactivity ranged from 5.2 percent TRR (wheat grain) to 67.3 percent TRR (sugar beet tops) at 4 months PBI and from 15.7 percent TRR (sugar beet roots) to 71.9 percent TRR (wheat straw) at 12 months PBI.

Extracted absolute residue levels in food commodities were low; wheat grain 0.06 mg eq/kg, bean seed 0.28 mg eq/kg, and sugar beet roots 0.4 mg eq/kg at PBI 4 months. At PBI 12 months extracted residues accounted for 0.18, 0.11, 0.02 mg eq/kg, respectively. Due to the rather low specific activity of the test substance employed in the study and to poor extractability of residues, metabolite characterization could only be performed in the aerial parts of the plants at PBI 4 months. Iprodione and RP30228 were the major components observed; iprodione at 0.07—0.42 mg/kg; RP30228 0.14—0.74 mg eq/kg. The ratio between parent iprodione and its isomer reversed with increasing PBI, with higher levels of parent in immature plants and higher levels of the isomer in mature plants. Other extracted residues could not be identified and amounted up to 0.16—0.98 mg eq/kg in the leaf commodities.

In a second confined rotational crop study, ^{14}C-labelled iprodione was applied to a US soil at a rate of 4.4 kg ai/ha. After PBIs of one, four and 12 months spinach, radish and oat were planted. Total radioactive residues at PBI 30 days were 0.27 mg eq/kg for radish root, 0.89 mg eq/kg for spinach foliage, 0.24 mg eq/kg for oat grain, and 6.8 mg eq/kg for oat straw. Generally, residue levels decreased over time: 0.19 to 3.4 mg eq/kg at PBI 4 months and 0.17 to 0.59 mg eq/kg at PBI 12 months, with the exception of oat straw at 4.6 mg eq/kg.

Plant samples were extracted with acetone, then by refluxing in a water:acetonitrile mixture. The extracted radioactivity in radish roots ranged from 71 to 76 percent TRR and from 97 to 98 percent TRR in spinach leaves. The extracted radioactivity oat grain was low, ranging from 37 to 41 percent TRR, but high in oat straw (93–96 percent TRR). In spinach, with 30-42 percent TRR 0.19—0.27 mg/kg parent accounted for the majority of the residue in spinach, RP32490 was also a major compound with levels of 32 percent TRR at PBI 1 month to 24 percent TRR at PBI 12 months. RP25040 was found at levels ranging from 8.1–10 percent TRR. RP36112 was observed in spinach leaves only at 7.2–9.6 percent TRR. The other metabolites (RP30228 and RP36221) were either not found or only reached levels up to 4.2 percent TRR.

In radish roots parent compound accounted for 52—53 percent TRR (0.10—0.14 mg/kg). RP30228 was the main metabolite found (7.5—9.7 percent TRR) at all PBIs. All other metabolites accounted for ≤2.2 percent TRR.

With 21-25 percent TRR (0.04—0.06 mg eq/kg) parent represented the major part of the radioactivity in oat grain, directly followed by RP25040 with 12.2—19 percent TRR. RP32490 reached levels up to 9.1 percent TRR and RP30228 remained below 5 percent TRR at all PBIs.

Parent accounted for 20—23 percent TRR (0.76—1.35 mg/kg) in oat straw, followed by RP32490 (13.8—15.7 percent TRR), RP30228 (5.9—7.5 percent TRR) and even lower levels of RP362221 and RP25040 (max 1.6 percent TRR).

In a third confined rotational crop study, ^{14}C-labelled iprodione was applied three times at a rate of 1.1 kg ai/ha each (total rate 3.3 kg ai/ha) and a RTI of 31 and 25 days to outdoor peanut plots (total rate 3.3 kg ai/ha). After PBIs of 4-, 8- and 12-months maize, peanuts, soya beans, turnips and wheat were planted. At PBI 8 months and 12 months total radioactive residues in food commodities ranged from were 0.10 and 0.13 mg eq/kg in peanut nutmeat, 0.13 and 0.15 mg eq/kg in soya bean seeds, 0.04 and 0.01 mg eq/kg in corn grain and 0.08 mg eq/kg (8 months only) in wheat grain. TRRs in feed commodities ranged from 0.05 (turnip whole plant) to 0.63 mg eq/kg (peanut stems+leaves) at PBI 4 months and at PBI 8 months from 0.15 mg eq/kg (peanut hulls) to 1.46 mg eq/kg (corn stems+leaves). At PBI 12 months levels decreased further ranging from 0.02 mg eq/kg in turnip roots to 0.70 mg eq/kg in corn stems+leaves.

Plant samples were extracted twice with acetone and 1 mol/L HCl and then analysed for parent, RP30228, RP25040, RP32490, RP36112, and RP36221. The extracted radioactivity ranged from 67 percent TRR (peanut nutmeat) to 97.5 percent TRR (soya bean seeds). The extractability in corn husks and corn cobs was very low (5.8–10.1 percent TRR) as was the total recovery (17.6—21.9 percent TRR).

In soya bean seed, parent compound accounted for 2.3 and 3.9 percent TRR at PBI 8 and 12 months (<0.01 mg/kg). Metabolite RP32490 was the major component observed at PBI 8 months (13.5 percent TRR), but was only 2.4 percent TRR at PBI 12 months. Other metabolites accounted for ≤5.4 percent TRR, each.

In peanut nutmeat parent compound accounted for 3.3 and 6.1 percent TRR at PBI 8 and 12 months (<0.01 mg/kg). Apart from one finding of RP32490 at 9.6 percent TRR (0.01 mg eq/kg) at PBI 8 months, levels of all metabolites were similar to the levels or parent.

In maize cobs, parent represented 27.5 percent (0.07 mg eq/kg) of the residue at PBI eight months. RP32490 accounted for 14.2 percent TRR (0.03 mg eq/kg) and the other metabolites were also identified but all with levels ≤7.5 percent TRR.

In wheat ears parent accounted for 15.1 percent TRR (0.01 mg/kg) at 8-month PBI. RP25040 and RP32490 could not be separated and together represented 14 percent TRR (0.01 mg eq/kg) of the extracted radioactivity. RP36112, RP36221, and RP30228 represented 9.1, 7.9, and 4.5 percent TRR.

In feed commodities iprodione levels were highest at PBI 4 months declining from 22.7 to 11 percent TRR (0.14-0.02 mg eq/kg) in peanut stems+leaves and from 18.9 to 7.4 percent TRR in soya bean stems+leaves (0.06—0.02 mg eq/kg). A similar decline was observed in turnip, maize and wheat stems+leaves fractions. Other metabolites identified were RP30228, RP32490, RP25040, RP36221, and RP36112. RP30228 slowly increased at increasing PBIs, e.g., from 4.8 percent TRR to 23.5 percent TRR in peanut stems+leaves, but at very low absolute levels (<0.01 to 0.04 mg eq/kg), except for maize stems+leaves, with absolute levels of 0.25 and 0.13 mg eq/kg at PBI 8 and 12 months, respectively (17 and 19.4 percent TRR). RP25040 and/or RP32490 showed a similar profile to parent, with combined levels ranging from 13.1 to 37.9 percent TRR (<0.01—0.08 mg eq/kg) at PBI 4 months in the various stems+leaves fractions and lower levels at PBI eight and 12 months. RP36221 and RP36112 were generally below 10 percent TRR, except for one finding of 14.4 percent TRR (absolute value not reported) in wheat stems+leaves.

In a fourth confined rotational crop study, soil of plots were treated with 4.7 kg ai/ha of ^{14}C-phenyl labelled iprodione once. Radish, mustard and winter or spring wheat were planted at PBI 31, 125 and 364 days.

TRR levels were highest in short-term PBIs and declined from 0.81 mg eq/kg to 0.23 mg eq/kg in mustard greens, from 0.94 to 0.19 mg eq/kg in radish tops, from 2.6 to 0.14 mg eq/kg in radish roots, 0.14 to 0.021 mg eq/kg in wheat grain at PBI 31 days to PBI 364 days. Similar declines were observed in feed commodities, with highest levels in wheat straw (declining from 5.17 to 0.65 mg eq/kg). The PBI 125 days wheat grain sample and the PBI 364 days mustard green sample had TRR levels <0.010 mg/kg and were not further characterized.

Plants were extracted several times with different ratios of acetonitrile and water. The extraction efficiency with acetonitrile/water was low in all radish root samples (22—26 percent TRR), in radish tops (27 percent TRR) at PBI 364 days and in wheat grain and straw at PBI 125

and 364 days (41—55 percent TRR) but ranged from 60 to 85 percent TRR in the other matrices and time points.

All samples were also subjected to Bligh-Dyer extraction, acetone extraction, and acidified water extraction. This resulted in significantly more extracted radioactivity in wheat grain (7.3—26.1 percent TRR) and wheat straw (2.4—6.7 percent TRR) but did not result in significantly more extracted radioactivity in other matrices, e.g., radish matrices (up to 0.6 percent TRR in radish roots, up to 1.2 percent TRR in radish tops).

Attempts to characterize residues in the polar soluble fractions of wheat straw samples by mild and exhaustive acid/base hydrolysis and by enzymatic treatments produced inconclusive results. Small amounts of RP31162, RP44247, RP25040 and possibly RP32490 were released. The results from enzyme treatments suggested that glycosides, protein conjugates, glucuronide conjugates, sulfate conjugates and conjugates that could be hydrolysed with urease or papain were not present in any significant amounts, if at all.

For residues in the PES, mild, moderate, and exhaustive acid/base hydrolysis were also carried out on wheat straw samples. Only under exhaustive hydrolysis conditions (10 mol/L NaOH or six mol/L HCl) ^{14}C-residues were released, primarily RP44247.

A limited percentage of the residue was identified.

In mustard greens parent accounted for 1.4 to 3.8 percent TRR (<0.01-0.02 mg eq/kg) at PBI 31—364 days; RP25040 was the major compound declining from 38.8 percent TRR at PBI 31 to 9.2 percent TRR at PBI 364; RP44247 was observed at levels ranging from 3.4 to 11.7 percent TRR (<0.01-0.07 mg eq/kg). RP30228 was only detected at 364 PBI (1.5 percent TRR, <0.01 mg eq/kg). A similar profile was observed in radish tops.

In radish roots parent was found a level 1.7—3.2 percent TRR (<0.01—0.08 mg eq/kg). RP25040 was the major compound with levels decreasing from 8.3 to 1.9 percent TRR over time. RP44247 and RP30228 did not reach levels above 0.9 percent TRR (0.02 mg/eq/kg).

In wheat grain parent compound accounted for 0.9—1.1 percent TRR (<0.01 mg eq/kg). RP25040 was not observed. RP44247 was observed at levels ranging from 0.9 to 2.6 percent TRR (<0.01 mg eq/kg). RP30228 was low over all PBIs (0.4—1.6 percent TRR, <0.01 mg eq/kg).

In the feed commodities wheat forage and straw, parent represented 0.9 to 5.9 percent TRR (<0.01—0.08 mg/kg). RP44247 and RP30228 did not reach levels above 3.5 percent TRR (<0.01—0.08 mg/eq/kg). RP44247 reached levels op to 14.2 percent TRR (0.23 mg eq/kg) in wheat straw at PBI 125 days. RP44247 was not observed in other rational crop studies and might have been formed by hydrolysis during extraction as it can be formed from RP25040, RP32490, RP36112 and RP30228.

Field rotational crop studies

Four field rotation crop studies were performed, three in the United States and one in Europe in various growing seasons.

In one rotational crop study performed in the United States, where bare soil was treated with 10 × 1.1 kg iprodione/ha (RTI seven days), a total rate 11 kg ai/ha, where succeeding crop were planted at ca. 30 days, no residues were found in cabbage heads, tomato, peppers, cucumber, squash, watermelon, dry soya bean seeds, sugar beet (root and tops), sweet corn ears with husk, maize grain, sorghum grains, wheat grains, peas (succulent seeds and pods).

The only food matrices where residues (expressed in total residues) were observed was in mustard greens (0.17—0.36 mg eq/kg), alfalfa (0.09 and 0.1 mg eq/kg for first and second cut), radish leaves and roots (3.7 and 0.77 mg eq/kg, respectively) and peas (dry seed) with 0.05-0.06 mg eq/kg.

In feed commodities residues (expressed in total residues) were found in sorghum forage (0.11 mg eq/kg), in sweet corn forage (0.05 mg eq/kg), in maize fodder (0.06—0.52 mg/kg), in soya bean trash (0.07 mg eq/kg), wheat straw (0.15 mg eq/kg) and wheat forage (0.05 mg eq/kg), pea straw after (0.05 mg eq/kg) and vines (0.55 mg eq/kg), cabbage wrapper leaves (1 mg eq/kg), clover (0.23—0.29 mg eq/kg).

In a second field rotational crop study performed in the United States, a primary crop, lettuce, was treated with either 2 × 2.2 kg ai/ha, 7 × 2.2 kg ai/ha, or 8 × 2.2 kg ai/ha. Two rotations of lettuce were treated in the trials using 7 and 8 applications. Total application rates were 4.4, 15.4 and 17.6 kg ai/ha, respectively. After harvest of lettuce, rotation crops were planted: radish, maize, carrot (harvest 44 DAT, planting 50, 162 and 50 DAT), wheat (harvest 0 DAT, planting 2), soya beans (harvest 0 DAT and planting 234 DAT), tomatoes (harvest 46 DAT and planting 67 DAT), cauliflower (harvest 51 DAT and planting 59 DAT), celery (harvest 52 DAT and planting 73 DAT), and/or broccoli (harvest 40 DAT and planting 70 DAT).

No residues were found in rotational crops after low treatment rate (2 × 2.2 kg ai/ha). The 7 × 2.2 and 8 × 2.2 kg ai/ha rate showed residues in some rotated crops.

In food commodities, at the rate of 7 × 2.2 kg ai/ha, total iprodione residues were observed in radish roots (1.14 mg/kg, PBI 50 days) and carrot roots (0.23 mg/kg at PBI 162 days) No residues were found in maize grains or winter wheat grain (at rate of 8 × 2.2 kg ai/ha) at a PBI of two days.

Total iprodione residues were also observed in feed commodities; 7.89 mg/kg in maize fodder at PBI 50 days and 2.85 mg/kg in winter wheat straw at PBI of days at the 7 × 2.2 and 8 × 2.2 kg ai/ha rates, respectively.

In a third field rotation crop study in the United States iprodione was sprayed on bare ground at the rate of 1.1 kg ai/ha at weekly intervals for 10 weeks (total application rate 11 kg). About 1 month after the last application, sugar beets, cotton and tomatoes were planted and sampled at commercial harvest. In all samples residue levels were below the LOQ of 0.05 mg/kg.

Finally, a field rotational crop study was also conducted in Europe. Bare soil plots were treated once at a rate of 4.0 kg ai/ha. Carrot, cauliflower, spinach (Germany only) and lettuce (France, Spain, and Belgium) were planted back at 31–38 days after last application. All samples were analysed for parent, its isomer RP30228, and metabolites RP32490, RP32490, 3,5-DCA, ad M610F007 (the conjugate of 3,5-DCA). All residue levels measurements were below the LOQ of 0.01 mg/kg, except for RP30228 in carrot whole plant at two of the four sites (0.015 and 0.065 mg/kg) and in carrot tops at one site (0.017 mg eq/kg) at BBCH 49. No residues were observed in carrot roots.

Conclusion on rotational crops

In the confined rotational crop studies, parent iprodione was generally found to be the major component in all food commodities (20—53 percent TRR). Depending on the rotated crop, metabolite RP32490 contributed significantly to the total residue (highest in spinach with 32 percent TRR), except in radish root. The isomer RP30228 (isomer) did not contribute for more than 10 percent TRR. Metabolite RP25040 was observed at significant levels in oat grain only

(12.2—19 percent TRR). In addition to these, RP36221 and RP36112 were found in lower and varying amounts together with considerable amounts of bound residues. Though quantitively different, similar residues were found in the confined rotational crops as observed in primary crops.

In the field rotational crop studies the magnitude of residues was determined. Considering only the bare soil application studies, the results are still inconclusive. The older study (10 × 1.1 = 11 kg ai/ha) indicates that residues might occur in root crops and leafy food crops, and certainly in feed commodities. This study was overdosed, and a different use pattern was applied. The more recent studies focused on the current uses (1 × 4 kg ai/ha and 10 × 1.1 kg ai/ha) do not result in residues in rotated crops (LOQ of 0.05 mg/kg). The highest application rates based on the labels submitted to the current Meeting is 4 × foliar application of 1.2 kg ai/ha (carrots and potatoes only). Other uses either employ a lower number of applications or lower application rates or are post-harvest applications. The Meeting concluded that there is no concern for carry-over of iprodione residues in rotational crops.

Animal metabolism

The Meeting received animal metabolism studies on rats, a lactating goat, lactating cows and laying hens where animals were dosed with iprodione radiolabelled in the phenyl ring.

Rats

The metabolism of iprodione in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2023 JMPR.

Lactating goats

The metabolic fate of ^{14}C-phenyl-iprodione was studied in a lactating goat, by feeding the goat gelatin capsules for five days at a daily dose of approximately 2 mg/kg of body weight (188 ppm dry feed). The goat was sacrificed 4 hours after last dose after which samples of liver, kidney, fat, muscle and blood were collected.

The majority of the radioactivity was excreted in urine (50.7 percent TAR) and in feces (8.7 percent TAR) with 0.3 percent TAR recovered in milk and 4.1 percent TAR in tissues and blood. The uncovered material may still be in the digestive tract considering the short time frame between last dose and sacrifice.

The highest residue levels were found in the liver (7.04 mg eq/kg, 1.2 percent TAR) and the kidney (6.3 mg eq/kg, 0.2 percent TAR), with lower levels in fat and muscle (0.727 and 0.38 mg eq/kg, respectively, 1.5 and 0.1 percent TAR). The milk samples contained radioactivity up to a maximum of 0.1 percent TAR (1.54 mg eq/kg), but had not reached a plateau 96 hours after the first dose.

The extractability of the residue with HCl/acetone from tissues ranged from 77.3 percent TRR in muscle to 93.4 percent TRR in kidney. The extractability using acetone was 59.9, 63.5, 78.0 and 87.7 percent TRR in liver, kidney, muscle and fat, respectively. The identification of metabolites determined in the HCl/acetone extracts was considered. Residues in milk were not extracted nor identified.

In liver, parent iprodione was a major component (10.9 percent TRR, 0.761 mg/kg), with higher levels of RP32490 (15.8 percent TRR, 1.1 mg eq/kg). DCHPU acounted for 7.1 percent TRR (0.505 mg eq/kg). All other metabolites were <5 percent TRR (≤0.32 mg eq/kg) each.

In kidney parent accounted for only 1.7 percent TRR. DCHPU (21.3 percent TRR, 1.34 mg eq/kg) and RP32490 (11 percent TRR, 0.693 mg eq/kg) were the major metabolites. Followed bij RP36115 (7.0 percent TRR, 0.439 me eq/kg). Other metabolites were ≤ 3.4 percent TRR (≤0.212 mg eq/kg).

In muscle RP32490 (27.6 percent TRR, 0.105 mg eq/kg) was the only major compund observed. Parent and other metabolites were ≤2.4 percent TRR (≤0.009 mg eq/kg).

In fat, the profile was similar to muscle, with RP32490 at 58.7 percent TRR (0.427 mg eq/kg) being te only major contributor to the radioactive residue. Parent accounted for 6.6 percentTRR (0.048 mg eq/kg) and all other metabolites were ≤2.8 percent TRR (≤0.02 mg eq/kg).

Metabolites found in the different animal matrices accounting for <10 percent TRR, but >0.1 mg eq/kg were RP36115 (0.154 mg eq/kg, 2.7 percent TRR and 0.439 mg eq/kg, 7 percent TRR in liver and kidney, resp.) and RP44247 (0.323 mg eq/kg, 5.7 percent TRR in liver). RP36114 and RP36221 were oberved in kidney at 0.212 mg eq/kg, 3.4 percent TRR and 0.109 mg eq/kg (1.7 percent TRR).

Traces (≤2.4 percent TRR and ≤0.088 mg eq/kg) of RP30228, RP36112, RP44160, 3,5-DCA, RP36114, RP36119 and RP37677 were observed in liver and kidney and some in fat and muscle at even lower concentrations.

Lactating cows

The metabolic fate of ^{14}C-phenyl-iprodione was studied in two lactating cows. One cow received a single dose of 1.83 mg/kg bw and the second cow received two doses at a total of 1.67 mg/kg bw over a period of five days (anticipated rates were 2 mg/kg bw based on 60 ppm daily feed intake). The cows were sacrificed seven days after dosing. Liver, kidney, muscle, and fat were collected.

The majority of the radioactivity was excreted in urine (42—47 percent TAR) and in feces (27—46 percent TAR) and minimal transfer to milk (0.3—0.4 percent TAR). Due to the non-consecutive dosing, no plateau could be established.

Residue levels in tissues were low. Total retention in tissues was 0.7 percent TAR and 0.3 percent TAR in single and multi dosed cow, respectively. The highest residue levels were found in the liver (0.131 and 0.447 mg/eq/kg, corresponding with 0.1 and 0.05 percent TRR in single and multidosed cow). It is noted that tissues were sampled seven days after the last application, during which degradaton and decline is to be expected.

The extractability of milk samples with acetone was 89 percent TRR. Residue levels in tissues were too low (<0.05 mg eq/kg) to determine extractability, except for liver. The extractability of liver samples with acetone was low (10 percent TRR) and additional extractions (acidified acetone, acetone after proteolytic enzyme treatment, acidic and basic extractions under reflux, fractionation into naturally occurring components) only resulted in further characterization rather than identification of metabolites.

Identification of metabolites was only possible in milk sampled at 24 hours (single dose cow) and 108 hours (multidose cow). Parent iprodione was present only in minor amounts (3.5 and 2.8- percent TRR, or 0.006 and 0.012 mg/kg in single and multidose cow, respectively). The 4-hydroxylated metabolite RP36114 and the non-hydroxylated metabolite RP32490 were the major compounds in the single dose cow (0.038 mg eq/kg; 22.1 percent TRR and 0.036 mg eq/kg; 20.9 percent TRR respectively). In multidose cow only RP36114 was above 10 percent TRR (0.156 mg eq/kg; 36.1 percent TRR). None of the other identified metabolites (RP30228, RP32596 (3,5-

DCA), RP36119, RP36221, RP37677, RP36112, RP36115, and RP44160) reached levels above 10 percent TRR and/or above 0.1 mg eq/kg.

Laying hens

The metabolism of ^{14}C-iprodione was studied in laying hens. Three groups of the test hens were dosed orally by capsule with the test substance for 15 consecutive days. The daily dose was 0.7 mg/kg body weight, or 10 ppm based dry feed intake. The treated hens were sacrificed at 2 hours, three days or seven days after the last dose. The control group was killed on day seven. Liver, kidney, heart, gizzard, breast muscle, thigh muscle, fat, skin and blood were collected from each carcass. Eggs and excreta were collected throughout the treatment and withdrawal periods.

The majority of the total radioactivity was recovered in excreta after the final dose and ranged from 78.3 to 85.4 percent TAR. Radioactive residues were mostly found in samples with 2 hours withdrawal periods, ranging from 2.81 mg eq/kg in the liver to 0.205 mg eq/kg in breast muscle. After three days of withdrawal, most of the residue was found in the liver with 0.08 mg eq/kg and after seven days, residues in all tissues were less than 0.02 mg eq/kg.

The 2-hour samples of liver, kidney, muscle, fat, and eggs were extracted with acetone acidified with hydrochloric acid (except fat, extracted with acetone only). The extractability ranged from 83 percent TRR in eggs to 99 percent TRR in fat but was 66 percent TRR in muscle.

In liver parent was present only at 1.6 percent TRR. RP44247 was a major contributor in liver (22.9 percent TRR, 0.71 mg eq/kg), followed by RP32490 (19.6 percent TRR, 0.60 mg eq/kg). A unknown metabolite was observed at 22.9 percent TRR (0.70 mg eq/kg). Several other metabolites were identified, but all ≤2.82 percent TRR (0.086 mg q/kg).

In kidney RP32490 accounted for the majority of the residue (28.6 percent TRR, 0.53 mg eq/kg), followed by RP44247 at 13.5 percent TRR (0.25 mg eq/kg), together with an unknown metabolite at 13.5 percent TRR (0.25 mg eq/kg). Parent was present at 3.05 percent TRR (0.057 mg eq/kg). Several other metabolites were identified, but all ≤3.59 percent TRR (0.067 mg eq/kg).

In muscle RP32490 accounted for 48.8 percent TRR (0.12 mg eq/kg), Parent was present at 3.63 percent TRR (0.009 mg eq/kg). Several other metabolites were identified, but all ≤2.02 percent TRR (≤0.005 mg eq/kg).

In fat parent accounted for 29.6 percent TRR (0.6 mg/kg). The major contributor to the residue in fat was RP32490 with 61.9 percent TRR (0.76 mg eq/kg). Several other metabolites were identified, but all ≤1.96 percent TRR (≤0.024 mg eq/kg).

In eggs RP32490 accounted for 30.7 percent TRR (0.18 mg eq/kg), other major contributors to the residue were RP36112 (16.6 percent TRR, 0.098 mg eq/kg), RP36115 (10.6 percent TRR, 0.063 mg eq/kg), and RP44247 (9.63 percent TRR, 0.057 mg eq/kg). Several other metabolites were identified, but all ≤2.70 percent TRR (≤0.016 mg eq/kg).

Other metabolites observed at trace levels (<10 percent TRR and <0.1 mg eq/kg) in various, but not all, matrices were RP30228, RP36221, RP44160, 3,5-DCA, RP36114, RP36119 and RP37677.

Summary of animal metabolism

In general, the routes and products of metabolism were similar across all animals and the available metabolism studies show that the first step in metabolization of iprodione is hydrolyzation to the metabolite RP32490. Subsequent oxidation reactions mainly at the isopropyl group and/or at the phenyl ring led to several hydroxylated and carboxylic metabolites.

Parent iprodione was present only in minor amounts (<10 percent TRR and <0.1 mg/kg) in all matrices, except in hen fat (29.6 percent TRR, 0.6 mg/kg) and goat liver (11 percent TRR, 0.76 mg eq/kg). The most prominent residue (>>10 percent TRR) found in all tissues, eggs and milk is RP32490, ranging from 10 to 74 percent TRR (0.036-1.1 mg eq/kg).

Several metabolites were exclusively found as major metabolites in some matrices, with only low or trace levels in other matrices.

RP36114 was a major metabolite in milk only (21—22 percent TRR, 0.036—0.038 mg eq/kg).

In poultry liver and kidney metabolite RP44247 was a major metabolite (13.5—22.9 percent TRR, 0.25—0.71 mg eq/kg) and in goat liver (5.7 percent TRR, 0.323 mg eq/kg). An unknown major metabolite (Z) was found in hen liver (22.9 percent TRR, 0.70 mg eq/kg) and kidney (13.5 percent TRR, 0.25 mg eq/kg).

In eggs two major components were present, RP36112 (16.6 percent TRR, 0.098 mg eq/kg) and RP36115 (10.6 percent TRR, 0.063 mg eq/kg). RP44247 was also observed in eggs at 9.63 percent TRR (0.057 mg eq/kg).

In goat kidney DCHPU represented a major part of the residue (21.3 percent TRR, 1.34 mg eq/kg), with RP36115 also being present at 7 percent TRR (0.439 mg eq/kg).

None of the other identified metabolites (RP30228, RP32596 (3,5-DCA), RP36119, RP36221, RP37677, and RP44160) reached levels above 10 percent TRR and/or above 0.04 mg eq/kg.

Methods of analysis

The Meeting received information on analytical methods for iprodione in plant and animal matrices.

Plant matrices

Analytical methods for plant matrices included component specific methods, a common moiety method and a QuEchERs method.

Several methods were available involving extraction with acetonitrile (ACN), methanol, acetone, or ethanol either or not in combination with acidified water and subsequent analysis by HPLC-MS, GC-ECD, GC-MSD or HPLC-UV. The methods were sufficiently validated for the determination of iprodione, RP30228 and RP32490 in all crop groups, with LOQs of 0.01 to 0.05 mg/kg.

Common moiety method 97R13413 for all 3,5-dichloroaniline containing metabolites: This method determines iprodione and all its metabolites containing the common 3,5-dichloroaniline core structure. After overnight hydrolysis, the hydrolysis product, 3,5-dichloroaniline, is distilled and partitioned into methylene chloride, and reacted with 2-chloropropionyl chloride (CPC) to yield N-(3,5-dichlorophenyl)-2-chloropropylamide (3,5-DCPA). Further purification is performed by Florisil chromatography. Quantification of 3,5-DCPA in the final extract was performed by GC-ECD. The LOQ of this method was tested against iprodione, RP30228 and RP32490 and is 0.05 mg eq/kg iprodione in various bean matrices, cherries, peaches, raspberries, and strawberries.

LC-MS/MS Method VR-083/13 (QuEChERS) for iprodione: Extraction with acetonitrile and a mixture of extraction salts (8 parts of magnesium sulfate, 2 parts of sodium chloride, 2 parts of trisodium citrate dihydrate and 1 part of disodium hydrogen citrate sesquihydrate). After homogenization

and centrifugation, the supernatant was filtered and analysed by LC-MS/MS. The practical quantification limit of the method is 0.1 mg/kg in apple.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure parent compound, and metabolites RP30228 and RP32490, separately or as 3,5-dichloro-analine containing compounds as total residue (common moiety method) in plant commodities.

Animal matrices

The Meeting received the description and validation for analytical methods for the determination of iprodione residues in animal commodities. In the study reports in animal commodities different common moiety methods (CMMs) were used for the analyses of iprodione and its hydroxylated and non-hydroxylated metabolites in various matrices.

CMM for non-hydroxylated metabolites in bovine tissues and milk (iprodione and RP32490): After an initial extraction with acetone/HCl, followed by extraction with acetone and NaOH and subsequent clean-up all components containing the 3,5-DCA moiety are converted into N-heptafluorobutyryl (HFB) derivative. Analyses was performed by GC-ECD, with an LOQ of 0.05 mg/kg for iprodione and its major hydroxylated metabolite RP32490 in bovine tissues (kidney, muscle, fat) and an LOQ of 0.005 mg eq/kg in milk.

CMM for non-hydroxylated metabolites in poultry tissues and eggs (RP32490, RP 36112 and RP36115, as well as RP 30228, the isomer of iprodione): the extract is heated for 2 hours at hexane reflux after addition of 40 percent sodium hydroxide, granular zinc, titanium trichloride and hexane to release the 3,5-DCA moiety. After partitioning and clean-up residues are quantitated by GC-ECD or GC-NPD Residues are reported in terms of iprodione equivalents. The method has an LOQ of 0.05 mg eq/kg in chicken eggs, muscle and skin/fat and an LOQ of 0.10 mg eq/kg in chicken liver.

CMM for hydroxylated metabolites in milk and poultry tissues and eggs (metabolite RP36114 specifically): A method was developed for metabolites containing the dichloroaminophenol moiety (3,5-DCAP) to account for residues that are not determined by the dichoroaniline moiety.

Milk samples are extracted using acetone. Any conjugated metabolites present are released using a mild acid hydrolysis. Components containing the hydroxylated metabolites are methylated using diazomethane and then converted to a common moiety, 4-methoxy-3,5-dichloro aniline, by means of basic hydrolysis and derivatized using HFBA to form the heptafluorobutyrate.

In poultry tissue and eggs, initial extraction was done with acetone:acidified water. After harher treatment, methylation and subsequent derivatization with 2-chioropropionyl chloride to form N-(4-methoxy-3,5-dichlorophenyl)-2-chloropropylamide.

The final derivatives are cleaned up by Florisil Column Chromatography and determination is made by GC-ECD, with an LOQ of 0.005 mg/kg for RP36114 in milk and 0.05 mg/kg in eggs and poultry tissues.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure the non-hydroxylated compounds iprodione, RP30228 and RP32490, as 3,5-DCA(P) containing compounds as total residue (common moiety method) in animal commodities (0.05 mg/kg, except chicken liver with an LOQ of 0.1 mg/kg) and the hydroxylated metabolite RP36114 in milk (LOQ of 0.005 mg/kg), eggs and poultry tissues (LOQ of 0.05 mg/kg).

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of iprodione, its isomer RP30228, and metabolite RP32490 in raw plant commodities and of iprodione and its (non-)hydroxylated metabolites in animal commodities.

Storage stability studies (spiked samples) showed that iprodione, RP30228 and RP32490 was stable for at least 15 months at -10 °C in crop commodities representative of the high water (at least 35 months), high acid (at least 15 months), high starch (at least 34 months), and high oil (at least 31 months) commodity groups. The Meeting did not receive storage stability data in high protein commodities (dry legume vegetables or pulses).

The Meeting agreed that the demonstrated storage stability on various representative plant commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting, except for dry beans.

Storage stability studies on stored samples (incurred residues) from animal metabolism studies showed that iprodione and its non-hydroxylated metabolites are stable in milk (at least 22 months) and liver (at least 13 months). The hydroxylated metabolite showed a lower recovery in milk (58 percent), which was accompanied by a low concurrent recovery (68 percent).

The storage stability study with spiked residues in hen matrices showed that iprodione, RP32490, RP36112 and RP36115 were stable over a period of 3 months in all poultry matrices. The storage stability of the hydroxylated metabolite RP36114 showed that it was stable after 11 months in eggs and liver. The stability was not demonstrated in muscle but accompanied with a low procedural recovery. The storage stability of RP36114 in skin+fat after 11 months was not sufficiently demonstrated. However, in the animal studies relevant for evaluation of the nature and magnitude of residues, tissues were analysed within a period of 3 months.

The Meeting agreed that the demonstrated storage stability animal commodities covered the residue sample storage intervals used in the animal feeding studies considered by the current Meeting.

Definition of the residue

Plant commodities

Iprodione is found in all raw (25-98 percent TRR) and processed crop commodities and is considered a suitable marker compound. The Meeting noted that suitable analytical methods exist to measure iprodione in plant commodities. The Meeting decided to define the residue for enforcement purposes as iprodione.

In addition to iprodione, its rearranged isomer RP30228 was observed in all primary crops (up to 33 percent TRR), where the ratio of these two components may shift towards the isomer at higher pH and over time. Metabolite RP32490 was also found in all studies, however in varying amounts up to 9 percent TRR (one exception 14 percent TRR in peanut whole plant). In the more recent studies metabolite RP36112 was observed in peanut whole plant and hay and RP25040 found in rice and peanut matrices, but mostly below 6 percent TRR (only quantifiable in peanut hay and hulls to a maximum of 2.3 mg eq/kg). RP36221 was found in rice matrices at low levels (0.17-5.6 percent TRR). The common metabolite 3,5-DCA (other active substances procymidone and vinclozolin) was found in conjugated form in carrot roots (16.4 percent TRR (0.79 mg eq/kg.)

High-temperature hydrolysis studies gave inconclusive results but suggest that 3,5-DCA may also be formed under processing conditions, either at levels up to 42 percent (non-OECD Guideline high-temperature hydrolysis study) or 5.5 percent (according to current guidelines), depending on the study design. In the second study, in addition to 3,5-DCA also RP30228 and RP31767 were formed, up to levels of 30.3 and 20.5 percent of the applied radioactivity, respectively.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compound and its toxicological properties for the metabolites RP30228, RP32490, RP36112, RP36221, RP25040, 3,5-DCA and RP31767 either observed in primary crop and confined rotational crop studies, and/or high-temperature hydrolysis studies.

The 2023 JMPR concluded that RP32490 is covered by the health-based guidance value for iprodione. However, considering that the metabolite does not contribute significantly to the parent in food commodities in metabolism studies and even less in field trials (<<10 of parent), it was not included in the residue definition for dietary risk assessment.

The 2023 JMPR concluded that for metabolites RP30228, RP36112, RP36221, RP25040, 3.5-DCA-(conjugate) and RP31767 no indications of genotoxicity were identified. Therefore, the TTC approach for a Cramer Class III compound was applied.

The Meeting decided to define the residue for dietary risk assessment for plant commodities as iprodione.

Animal commodities

In the animal metabolism studies parent iprodione was only a minor component in all matrices (<10 percent TRR and <0.1 mg/kg), except in hen fat (29.6 percent TRR, 0.6 mg/kg) and goat liver (11 percent TRR, 0.76 mg eq/kg). Metabolite RP34290 is a major compound found in all bovine and poultry tissues, milk and eggs at levels ranging from 10 percent TRR (0.041 mg eq/kg) in milk to 74 percent TRR (0.12 mg eq/kg) in hen muscle and might be a more suitable marker for enforcement than parent. However, only CMM were developed, which measure all the non-hydroxylated or hydroxylated metabolites containing the 3,5-dichloraniline (3,5-DCA) moiety. 3,5-DCA is a common moiety also observed in (metabolites) from vinclozolin and procymidone and therefore not considered a suitable overall marker for enforcement.

The Meeting noted that the sum of iprodione and RP32490 represent suitable markers for enforcement in animal commodities. However, in the absence of a suitable targeted analytical method for enforcement, the Meeting decided that it was not possible to propose a residue definition for enforcement purposes in animal commodities.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compound and its toxicological properties for the metabolites RP32490, RP36114, RP36112, RP36221, and RP36115, RP44247, and DCHPU.

The 2023 JMPR Meeting concluded that, in addition to parent compound, RP32490, RP36115, and RP36114 are covered by the health-based guidance values for iprodione and should be considered for inclusion in the residue definition:

RP32490 is a major metabolite in found in all bovine and poultry tissues, milk and eggs at levels ranging from 10 percent TRR (0.041 mg eq/kg) in milk to 74 percent TRR (0.12 mg eq/kg) in hen muscle and is far more abundant than parent and should be included in the residue definition for dietary risk assessment in tissues, milk and eggs.

RP36115 was found in eggs (10.6 percent TRR, 0.063 mg eq/kg) and was also present in goat liver and kidney (0.154 mg eq/kg, 2.7 percent TRR and 0.439 mg eq/kg, 7 percent TRR, resp.). It contributes up to 30 percent to the toxicological residue only in eggs and less in all other tissues and milk (max 23 percent). The Meeting concluded that this metabolite need not be included in the residue definition for animal tissues, milk and eggs.

RP36114 is a major metabolite in milk (21-22 percent TRR, 0.036-0.038 mg eq/kg), but found only in trace levels in other animal matrices, (maximum of 3.4 percent TRR, 0.21 mg eq/kg in goat kidney). In milk it represents 72 percent of the toxicological relevant residue. The Meeting concluded that this metabolite shoud be included in the residue definition for dietary risk assessment.

The 2023 JMPR Meeting concluded that the TTC Cramer Class III (no indication for genotoxicity) could be applied for the following metabolites; RP36112, RP36221, P44247 and DCHPU.

Based on the results of the animal metabolism studies and the toxicological assessment of the metabolites the Meeting decided to define the residue for dietary risk assessment for animal commodities as iprodione + RP32490 + RP36114, expressed as iprodione.

The Meeting recommended the following residue definitions for iprodione:

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

Definition of the residue for compliance with the MRL for animal commodities: *not concluded*.

Definition of the residue for dietary risk assessment for animal commodities: *iprodione + 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide (RP32490) + N-(3,5-dichloro-4-hydroxyphenyl)-2-carbamoylacetamide (RP36114), expressed as iprodione*.

Results of supervised residue trials on crops

Supervised trials were available for the use of iprodione on pome fruit (apples), stone fruit (cherry, peach plum), berries and other small fruit (cane berries and grapes), bulb vegetables (onions), flowerhead brassicas (broccoli, leafy vegetables (leaf lettuce, endive), legume vegetables (succulent beans), pulses (dry beans), root and tuber vegetables (carrot (root vegetables) and tuberous and corm vegetables (potato)), tree nuts (almonds).

GAP information was available from Brazil (post-harvest treatment of apples, foliar treatment of cherries, grapes, strawberries, onions, lettuce, carrots, potatoes), Chile (foliar treatment of apples, cherries, peaches, grapes, strawberries, onions, lettuce, and tree nuts) and the United States (foliar treatment of cherries, peaches, cane berries, grapes, strawberries, onions, brocolli, lettuce, succulent beans, and dried beans, carrots, potatoes, and tree nuts).

No GAP information was provided for uses on barly, cucumber, kiwifruit, lettuce head, pome fruit (now apples only), rape seed, spices (roots and rhizomes), spices (seeds), sugar beet, sunflower seeds, tomato, witloof chicory (sprouts). The Meeting recommended to withdraw the previous recommendations for these commodities.

For maximum residue estimation in principle only iprodione levels should be used. However, in a number of studies a common moiety method was used, which does not distinguish between the different 3,5-DCA containing components. Since other studies show that total

residues are often similar to total residues and generally do not increase by more than 10 percent , the this slight overestimation of the residue will not significantly influence the height of the MRL. The Meeting concluded that residue data based on the common moiety method could be used for maximum residue evaluation. In this appraisal the term 'total residues' refers to the sum of iprodione, RP30228, and RP32490. Since residues in the evaluation were expressed as parent equivalents, no conversion factor is needed.

Pome fruit

Pome fruit - Apple

The critical GAP for apples in Chile is two foliar applications in the field at 67 g ai/hL up to petal fall followed by a 2-minute post-harvest immersion at 100 g ai/hL with a PHI of 3 days. Since the last foliar application is up to petal fall, insignificant residue is expected in the fruits. The Meeting concluded that only the post-harvest treatment contributed to the residue,

In four trials conducted in apples in Brazil approximating the post-harvest GAP from Chile residues were (n=4): 3.5, 4.0, 4.0 and 4.8 mg/kg.

Noting that apple is a major crop, the Meeting concluded that information from supervised field trials is insufficient to estimate maximum residue levels and withdraws its previous recommendation for pome fruit of 5 mg/kg (Po).

Stone fruit

The critical GAPs for cherries or peaches are the GAPs for post-harvest treatments from Chile. No trials were submitted in support of these GAPs.

The next critical GAP is for stone fruit in the United States and includes apricots, cherries, nectarines, peaches, plums and prunes. The GAP allows for two foliar applications of 1.1 kg ai/ha, with the first application at full bloom and the last application at petal fall (BBCH67-69). Fruits have not been formed at this stage. Trials have been submitted for cherries, peaches, and plums.

Cherries, subgroup of

In eight trials conducted in cherries in the United States matching the US cGAP residues were (n=8): <0.01 (2), 0.025, 0.033, <0.05 (2), 0.13 and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR of 0.042 mg/kg and an HR of 0.14 mg/kg for iprodione in the Subgroup of Cherries withdrawing its previous recommendation of 10 mg/kg, (Po) for cherries.

Plums (including fresh prunes), subgroup of

In four trials conducted in plums in the United States three instead of two applications were given. Noting that the last application is never given after the last petal fall and iprodione residues were all below the LOQ, in both whole fruit and pulp, the residue levels were considered suitable for maximum residue estimation and were (n=4): <0.05 (4) mg/kg.

Noting that plums are a major crop, the Meeting concluded that four trials are insufficient to estimate a maximum residue level.

Peaches (including nectarine and apricots), subgroup of

In seven trials conducted in peaches in the United States, three instead of two applications were given. Noting that the last application is never given after the last petal fall, and iprodione residues were all below the LOQ, in both whole fruit and pulp, the residue levels were considered suitable for maximum residue estimation were (n=7): <0.05 (7) mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg, an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg for iprodione in the Subgroup of Peaches (including nectarine and apricots) and withdraws its previous recommendation for peaches of 10 mg/kg (Po).

Berries and other small fruits

Cane berries – Blackberries and Raspberries

The critical GAP for Cane berries is in the United States and allows for four foliar applications of 1.1 kg ai/ha with an RTI of 14 days and a PHI of 0 days.

In nine trials conducted in raspberries in the United States matching the US cGAP residues were (n=9): 1.2, 2.9, 4.2, 4.3, 4.5, 5.5, 7.5, 12, and 14 mg/kg.

In four trials conducted in blackberries in the United States matching the US cGAP iprodione residues were (n=4): 6.0, 11, 16 and 22.6 mg/kg.

Noting that the STMRs do not differ 5-fold, but that the datasets differ (Mann-Whitney test), the Meeting estimated a maximum residue level of 50 mg/kg, an STMR of 13.5 mg/kg and an HR of 22.6 mg/kg for iprodione in the Subgroup of Cane berries, based on the data set in blackberries and withdraws its previous recommendations of 30 mg/kg for raspberries and for blackberries.

Small fruit vine climbing - grapes

Table grapes

GAPs for tables grapes in the United States (one foliar application at 1.1 kg ai/ha, applied at mid-bloom) and Chile (one x post-harvest immersion in 720 g ai/hL, PHI 1 day) were submitted, but without supporting trial data.

Wine grapes

The critical GAP for wine grapes is in the United States and allows for four foliar applications of 1.1 kg ai/ha applied early to mid-bloom (1); prior to bunch closing (2); at veraison (3); and 7 days pre-harvest (4).

In one trial in wine grapes conducted in the United States matching this GAP, iprodione residues were (n=1): 1.1 mg/kg.

The Meeting concluded that information from supervised field trials is insufficient to estimate maximum residue levels and withdraws its previous recommendation for iprodione in grapes of 10 mg/kg.

Low growing berries - strawberry

The critical GAP for strawberry is in Brazil and allows for four applications at 750 g ai/ha with an RTI specified by growth stage and a PHI of 1 day. No trials in support of this GAP were submitted.

The next critical GAP is the critical GAP in the United States which is a single foliar spray

application no later than the first flower. Only trials were submitted where a combination of a pre-planting dip and a foliar spray application at bud stage were used. The Meeting concluded that the pre-planting application will not contribute significantly to the total residue at harvest and that the trials could be used for maximum residue level estimation.

In the five trials conducted in strawberries in the United States matching the US GAP residues were (n=5): <0.05 (2), 0.076, 0.097 and 0.37 mg/kg.

Noting that strawberry is a major crop, the Meeting concluded that information from supervised field trials is insufficient to estimate maximum residue levels and withdraws its previous recommendation in strawberries of 10 mg/kg.

Bulb vegetables

Bulb onions - onions

The critical GAP for bulb onion is in the United States and allows for four applications of 842 g ai/ha, each, with an RTI of 14 days and a PHI of 7 days.

In four trials conducted in bulb onions in the United States matching the US GAP, residues were (n=4): <0.05 (3) and 0.08 mg/kg (highest individual value 0.11 mg/kg). Two additional trials were included (4 x 1.1 kg ai/ha) since, despite the higher application rate, no residues were observed. Residues observed in the combined trials were (n=6): <0.05 (5) and 0.08 mg/kg (highest individual value of 0.11 mg/kg).

The Meeting estimated a maximum residue level of 0.15 mg/kg (taking into account the highest residue in an individual sample), an STMR of 0.05 mg/kg and an HR of 0.11 mg/kg for iprodione in onion, bulb, replacing its previous recommendation of 0.2 mg/kg for onion, bulb.

Brassica vegetables, except brassica leafy vegetables

Flowerhead brassicas - broccoli

The critical GAP for broccoli is in the United States and allows for two applications of 1.1 kg ai/ha, each, with an RTI specified by growth stage (first application immediately after thinning; 2-4 leaf stage) and a PHI of 0 days.

In eight trials conducted in broccoli in the United States matching the US GAP residues were (n=8): 4.5, 4.5, 6.0, 8.8, 10, 15, 16 and 24 mg/kg.

The Meeting estimated a maximum residue level of 40 mg/kg, an STMR of 9.4 mg/kg and an HR of 24 mg/kg for iprodione in broccoli, replacing its previous recommendation of 25 mg/kg for broccoli.

The Meeting noted that acute dietary exposure assessment showed that residues in broccoli exceeded the ARfD of 0.6 mg/kg bw (190 percent for toddlers in the Netherlands and 160 percent for children <6 years in Canada). No alternative GAP was available.

Leafy vegetables (including Brassica leafy vegetables)

Leafy greens - lettuce

The critical GAP for lettuce is in Brazil and allows for two applications at 1 kg ai/ha, an RTI of 10

days and a PHI of 7 days. No trials in support of this GAP were submitted.

The next critical GAP for lettuce (head and leaf) is in the United States and allows for three applications of 1.1 kg ai/ha, each, with an RTI of 10 days and a PHI of 14 days.

In three trials conducted in lettuce (leaf) in the United States matching the US GAP residues were (n=3): 0.23, 1.1 and 12.3 mg/kg.

The Meeting concluded that information from supervised field trials is insufficient to estimate maximum residue levels and withdrew its previous recommendation for iprodione in lettuce leaf of 25 mg/kg.

Legume vegetables

Succulent beans with pods

The critical GAP for succulent beans with pods is in the United States (beans; snap, dry and lima) and allows for two applications at 1.1 kg ai/ha, each, with an RTI of 5 days and last application up to peak bloom (=full bloom, BBCH 65).

Snap beans

In five independent trials conducted in the United States in succulent beans with pods (snap beans) matched the US GAP residue levels were (n=5): 0.096, 0.11, 0.31, 0.32, and 0.81 mg/kg.

Lima beans

One independent trial in succulent lima beans with pods was conducted in the United States matching the US GAP with a residue level of 0.08 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.31 mg/kg and an HR of 0.81 mg/kg for iprodione in succulent beans with pods based on the dataset for snap beans, also covering for the result in lima beans. The Meeting withdrew its previous recommendation of 2 mg/kg for common bean (pods and/or immature seeds).

Pulses

Beans (dry)

The critical GAP for dry beans is in the United States (beans; snap, dry and lima) and allows for two applications at 1.1 kg ai/ha, each, with an RTI of 5 days and last application up to peak bloom (=full bloom, BBCH65).

In six trials conducted in dry beans in the United States matching the US GAP residues were (n=6): <0.05 (4), 0.11 and 0.24 mg/kg.

Noting that there are no storage stability data on high protein crops, the Meeting the Meeting decided not to estimate a maximum residue level for iprodione in beans (dry), *Phaseolus* spp. and withdrew its previous recommendation of 0.1 mg/kg for beans (dry).

Root and tuber vegetables

Root vegetables - carrot

The critical GAP for carrots is in the United States and allows for four applications at a rate of 1.1 kg ai/ha, each, with an RTI of 7 days and a PHI of 0 days.

In three trials conducted in carrots in the United States matching the US GAP residues were (n=3): <0.05 (2) and 0.12mg/kg.

Noting that carrot is a major crop, the Meeting concluded that information from supervised field trials is insufficient to estimate maximum residue levels and withdrew its previous recommendation for iprodione in carrots of 10 mg/kg.

Tuberous and corm vegetables – potato

The critical GAP for potatoes is in the United States and allows for four applications at a rate of 1.1 kg ai/ha, each, with an RTI of 14 days and a PHI of 0 days.

In 14 trials conducted in potatoes in the United States matching the US GAP residues were (n=14): <0.05 (14) mg/kg.

Residues for dietary burden calculations (parent + RP32490) were (n=14): <0.1 (12), 0.16 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.05* mg/kg, an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg for iprodione in potatoes.

The Meeting also estimated a median residue for potato based processed feed commodities of 0.1 mg/kg.

Tree nuts

Tree nuts - almonds

The critical GAP for almonds is in the United States and allows for four applications at a rate of 560 g ai/ha with an RTI depending on growth stage with the last application up to 5 weeks after petal fall.

In six trials conducted in almonds in the United States matching the US GAP residues were (n=6): 0.012, 0.018, 0.031, 0.048, 0.061 and 0.17 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, an STMR 0.0395 mg/kg and an HR of 0.17 mg/kg for iprodione in almonds and replaced its previous recommendation of 0.2 mg/kg for almonds.

Residues in animal feeds

Bean forage

The critical GAP for beans is in the United States and allows for two applications at 1.1 kg ai/ha, each, with an RTI of 5 days and last application up to peak bloom (=full bloom, BBCH65). The label states “Do not allow foraging for 14 days after last application”.

In four trials conducted in beans for bean forage in the USA matching the US GAP residues for dietary burden calculation (parent + RP32490) were (n=4): 1.25, 3.1, 11.7 and 12.2

mg/kg.

The Meeting estimated a median residue level of 7.4 mg/kg and a highest residue of 12.2 mg/kg for iprodione in bean forage.

Bean hay

The critical GAP for beans is in the United States and allows for two applications at 1.1 kg ai/ha, each, with an RTI of 5 days and last application up to peak bloom (=full bloom, BBCH65). The label states "Do not feed dry snap or succulent bean hay to livestock; Do not feed dry bean hay to livestock until 45 days after last application."

In four trials conducted in beans for dry bean hay in the United States matching the US GAP residues for maximum residue level estimation were (n=4): 0.76, 1.6, 5.5 and 6.9 mg/kg.

Residues for dietary burden calculations (parent + RP32490) were (n=4): 0.96, 1.6, 5.8, 7.7 mg/kg.

The Meeting estimated a maximum residue level of 20 mg/kg (dw) based on a dry weight content of 85 percent, a median residue level of 3.7 mg/kg (a.r.) and a highest residue of 7.72 mg/kg (a.r.) for iprodione in bean, hay and/or straw.

Potato culls

The critical GAP for potatoes is in the United States and allows for four applications at a rate of 1.1 kg ai/ha, each, with an RTI of 14 days and a PHI of 0 days.

In 14 trials conducted in potatoes in the United States matching the US GAP residues for maximum residue level estimation were (n=14): <0.05 (11), 0.08, 0.09 and 0.11 mg/kg.

Residues for dietary burden calculations (parent + RP32490) were (n=14): <0.1 (9), 0.11 (2), 0.13 (2) and 0.16 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg (ar) and a median residue level of 0.1 mg/kg respectively for iprodione in potato culls.

Almond hulls

The critical GAP for almonds is in the United States and allows for four applications at a rate of 560 g ai/ha with RTIs based on growth stage and last application up to 5 weeks after petal fall.

In six trials conducted in almonds in the United States matching the US GAP residues for maximum residue level estimation in almond hulls were (n=6): 7.4, 8.0, 13, 16, 17 and 18 mg/kg.

Residues for dietary burden calculation (parent + RP32490) in almond hulls were (n=6): 7.6, 8.3, 13.3, 16.4, 17.5 and 18.5 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg (dw), based on a dry matter content of 90 percent , and a median residue level of 14.85 mg/kg for iprodione in almonds hulls and withdrew its previous recommendation of 2 mg/kg in almond hulls.

Fate of residues during processing

The Meeting received information on the nature and magnitude of iprodione residues during processing.

Nature of residues in processing

The Meeting received a hydrolysis study where conditions were not typical for baking/brewing/boiling, sterilization and pasteurization. In this study, sterilization for 30 minutes at pH6 and 130 degrees Celsius significant degradation of iprodione was observed. Degradation product 3,5-DCA was observed up to levels of 42 percent of the applied radioactivity. Other degradation products were also observed, with in particular RP37176, RP30228, RP36233 and RP30181.

An additional high-temperature hydrolysis study was available. The original study report could not be retrieved by the manufacturer. The summary of the study, based on the summary of the EU RAR, is included in the evaluation and the conclusions are included in this appraisal as supportive information. This study showed that under standard conditions the degradation profile was significantly different. The original report was not submitted, but the summary of EU RAR indicate that 3,5-DCA was observed but only up to 5.5 (pH 6). RP30228 was found up to 30.3 percent TAR and RP37176 up to 20.5 percent TAR. Considering the apparent inconsistent results, in the absence of the original report, the Meeting concluded that it was not possible to draw a quantitative conclusion on the nature of residues under the conditions simulating baking/brewing/boiling, pasteurization and sterilization.

Magnitude of residues in processing

The Meeting considered a processing study in potatoes iprodione, RP30228 and RP32490. The degradation product 3,5-DCA was not determined.

Table 8: Estimation of processing factors based on parent only residues for commodities considered at this Meeting

Crop	Residue (mg/kg) in RAC [a]			Processed commodity	Individual PF (based on parent only)	Mean, median or best estimate PF	Residue (mg/kg) in processed commodity [a]	
	MRL	STMR	HR				MRL-P	STMR-P
Potatoes	0.05*	0.05	0.05	Chips	0.29, 0.61	0.45	n.a.	0.0225
				Flakes/ granules	0.16, 0.29 0.29, 0.50	0.29	0.05*	0.0145

n.a. = not applicable; n.r.: no recommendation.
[a] Residues in raw commodities consist only of parent iprodione. In processed commodities other metabolites (a.o. 3,5-DCA) may have been formed under high-temperature and ≥pH6 and were not determined in the submitted studies.

Table x Estimation of processing factors based on total residues (parent + RP32490) for feed commodities considered at this Meeting

Crop	Residue (mg/kg) in RAC [a]		Processed commodity	Individual PF (based on parent + RP32490)	Mean or best estimate PF	Residue (mg/kg) in processed commodity [a]
	Median residue	Highest residue				median residue-P
Potato	0.1	n.a.	Peel [b]	0.27, 0.40, 0.45, 1.4, 1.7, 2.0	1.1	0.11

n.a. = not applicable; n.r. = no recommendation.
[a] Residues in raw feed commodities consist of parent iprodione plus RP23490.
[b] Several different peel fractions were sampled (peel from chips, peel from flakes and peel from granules) and results included in the table.

Residues in animal commodities

Farm animal feeding studies

The Meeting receive feeding studies involving iprodione in lactating cows and laying hens.

In the study with lactating cows dairy cattle were treated once daily for 29 days with iprodione at levels anticipated levels of 5, 15, 50 and 200 ppm in the feed (actual levels 4.6, 14.4, 50.5 and 192.2 ppm). Milk samples were collected on treatment day 8, 17 and 28 and tissue samples at slaughter. At the 4.6 ppm feeding level there were no detectable residues of iprodione or its metabolites in milk (<0.01 mg/kg) or tissues (<0.05 mg/kg).

At the 14.4 and 50.5 ppm feeding levels the mean total residues in milk ranged from <0.01 to 0.118 mg/L and at the 192.2 ppm feeding level from 0.273 to 0.337 mg/L.

At the 14.4 ppm feeding level the mean (and highest) total residue levels were <0.05 (<0.05) mg/kg in muscle and fat, 0.11 (0.13) mg/kg in liver and 0.10 (0.16) mg/kg in kidney.

At the 50.5 ppm feeding level the mean (and highest) total residue levels were <0.05 (0.07) mg/kg in muscle, 0.47 (0.62) mg/kg in liver, 0.63 (0.78) mg/kg in kidney and 0.15 (0.20) mg/kg in fat.

At the 192.2 ppm feeding level the mean (and highest) total residue levels were 0.09 (0.10) mg/kg in muscle, 1.47 (1.94) mg/kg in liver, 2.25 (2.52) mg/kg in kidney and 0.46 (0.51) mg/kg in fat.

In the study in laying hens three groups of hens were treated for 34 days by capsule with iprodione at actual dose levels of 10, 31 and 103 ppm. The total residues in eggs reached a plateau between day 16–24 of the treatment at 0.53 mg/kg, 1.46 mg/kg and 6.19 mg/kg at the three feeding levels, respectively.

The total mean (and highest) residues in muscle, liver, and skin+fat from the 10-ppm feeding level at day 34 were 0.24 (0.30), 2.91 (3.65) and 0.54 (0.73) mg/kg respectively. The total mean residues in muscle, liver, and skin/fat from the 31-ppm feeding level at day 34 were 0.84 (1.06), 6.4 (9.94) and 1.59 (1.86) mg/kg respectively. At the highest dose level (103 ppm) residues were 2.92 (3.37), 15.54 (16.03), 6.43 (7.45) mg/kg, respectively in muscle, liver and skin/fat. The decline of residues in eggs and tissues was not investigated.

Farm animal dietary burden

Not possible, because no residue definition for enforcement purposes was derived.

Animal commodity maximum residue levels

No maximum residue levels were estimated, because no residue definition for enforcement could be derived in the absence of a suitable analytical method for determining targeted residues of iprodione in animal matrices.

FUTURE WORK OR INFORMATION

Desirable:

- A metabolism study in root crops;

- A targeted analytical method for enforcement of iprodione residues in animal commodities
- Storage stability data for high protein crops;
- A hydrolysis study representing the standard processing conditions of pasteurization, baking/brewing/boiling and sterilization;
- Processing studies where all relevant metabolites (including 3,5-DCA) are analysed;
- Feeding studies in livestock with targeted analyses.

RECOMMENDATIONS

Based on the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

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

Definition of the residue for compliance with the MRL for animal commodities: *not concluded.*

Definition of the residue for dietary risk assessment for animal commodities: *iprodione + 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide (RP302490) + N-(3,5-dichloro-4-hydroxyphenyl)-2-carbamoylacetamide (RP36114).*

Table 9: Residue levels suitable for establishing maximum residue limits and for IEDI and IESTI assessments

CCN	Commodity	Recommended Maximum residue level (mg/kg)		HR or HR-P (mg/kg)	STMR or STMR-P (mg/kg)
		New	Previous		
TN 0660	Almond	0.3	0.2	0.17	0.0395
AM 0660	Almond hulls	50 (dw)	2	n.a.	14.85 (ar)
FP 0226	Apple (in 1994 10 Po was withdrawn)	-	-	-	-
GC 0640	Barley	W	2	-	-
AL 0061	Bean, hay and/or straw *(phaseolus* spp)	20 (dw)	100	highest: 7.72 (ar)	median: 3.7 (ar)
VD 0071	Beans (*phaseolus* spp) - dry	W	0.1	-	-
VP 0061	Beans with pods (*phaseolus* spp) - immature pods and succulent seeds	1.5	-	0.81	0.31
FB 0264	Blackberries	W	30	-	-
VB 0400	Broccoli [a]	40	25	24	9.4
FB 2005	Cane berries, subgroup of	50	-	22.6	13.5
VR 0577	Carrot	W	10 (Po)	-	-
FS 0013	Cherries, subgroup of	0.3	10	0.14	0.042
VP 2845	Common bean (pods and/or immature seeds)	W	2	-	-
VC 0424	Cucumber	W	2	-	-
FB 0269	Grapes	W	10	-	-

CCN	Commodity	Recommended Maximum residue level (mg/kg)		HR or HR-P (mg/kg)	STMR or STMR-P (mg/kg)
		New	Previous		
FI 0341	Kiwifruit	W	5	-	-
VL 0482	Lettuce, head	W	10	-	-
VL 0483	Lettuce, leaf	W	25	-	-
VA 0385	Onion, bulb	0.15	0.2	0.11	0.05
FS 2001	Peaches (including nectarines and apricots), Subgroup of	0.05*	-	0.05	0.05
FS 0247	Peaches	W	10	-	-
FP 0009	Pome fruits (group)	W	5 (Po)	-	-
VR 0589	Potato	0.05*	-	0.05	0.05
VR 0589	Potato culls	0.15	-	n.a.	0.10
DV 0589	Potato flakes/granules	0.05*	-	-	0.0145
SO 0495	Rape seed	W	0.5	-	-
FB 0272	Raspberries, red, black	W	30	-	-
GM 0649	Rice, husked	W	10	-	-
HS 0193	Spices, roots and rhizomes	W	0.1	-	-
HS 0190	Spices, seeds	W	0.05 (*)	-	-
FB 0275	Strawberry	W	10	-	-
VR 0596	Sugar beet	W	0.1 (*)	-	-
SO 2091	Sunflower seed	W	0.5	-	-
VO 0448	Tomato	W	5	-	-
VL 2832	Witloof chicory (sprouts)	W	1	-	-
	Potato chips	-	-	n.a.	0.023

(ar) – as received; (dw) – dry weight; n.a. = not applicable

[a] On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of iprodione for the consumption of broccoli may present a public health concern

Table 6: Residue levels for feed

CCN	Commodity	Recommended Maximum residue level (mg/kg)		HR or HR-P (mg/kg)	STMR or STMR-P (mg/kg)
		New	Previous		
AL 1030	Bean, forage (*phaseolus* spp)	n.a.	-	12.2 (ar)	7.4 (ar)
VR 0589	Potato culls	0.15	-	n.a.	0.10

(ar) – as received; (dw) – dry weight; n.a. = not applicable

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for iprodione is 0–0.06 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for iprodione were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2020 JMPR

Report.

The IEDIs ranged from 0 to 3 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of iprodione from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for iprodione is 0.6 mg/kg bw. The International Estimate of Short-Term Intakes (IESTIs) for iprodione were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs varied from 0 to 190 percent of the ARfD for children (toddler, the Netherlands) and 0–60 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of iprodione from uses considered by the present Meeting may present a public health concern.

Possible refinement when the international estimate of short-term intakes exceeds the ARfD

The Meeting concluded that the estimated acute dietary exposure to residues of iprodione for the consumption of broccoli by children may present a public health concern.

As no alternative GAP data were available to the Meeting to estimate lower HR values for these commodities, no refinement of the acute dietary exposure estimates was possible. International estimate of short-term intakes can be refined if alternative GAP data become available in the future.

The ARfD of 0.6 mg/kg bw established by the 2023 JMPR was derived from a threshold dose of 60 mg/kg bw for effects after 6 days of exposure in the developmental study in rabbits. As the study was considered adequate and the LOAEL is just over three times the NOAEL, it is unlikely that the ARfD can be refined significantly.

Threshold of toxicological concern (TTC) consideration for metabolites

During the 2023 JMPR Meeting, the WHO concluded that the metabolites RP30228, RP36112, RP36221, RP25040, 3,5-DCA (-conjugate), RP37176, RP44247, and DCHPU could be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day). Since, within the currently assessed uses, RP25040 was only observed in feed commodities, it was not assessed against the TTC III.

[refer to background/WHO text where relevant]

The 2023 Meeting estimated the following dietary exposures:

RP30228 (plant* + processed** + animal)	0.29 µg/kg bw per day
RP36112 (plant* + animal)	0.30 µg/kg bw per day
RP36221 (plant* + animal)	0.037 µg/kg bw per day
3,5-DCA-(conjugate) (plant* + processed** + animal)	0.09 µg/kg bw per day

RP44247 (animal)	0.12 µg/kg bw per day
DCHPU (animal, mammalian only)	0.37 µg/kg bw per day
RP37176 (processed** only)	0.17 µg/kg bw per day

* Not in food commodities for which maximum residue levels are estimated by the current Meeting

** Assuming formation of 30 percent RP30228, 20 percent RP37176, and 5.5 percent 3,5-DCA during processing.

The Meeting concluded that the estimated dietary exposure to residues of iprodione from uses considered by the JMPR is below the TTC for Cramer Class III compounds and is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.20 Isocycloseram (334) (T,R)*

TOXICOLOGY

Isocycloseram is the ISO-approved common name for 4-[5-(3,5-dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-*N*-(2-ethyl-3-oxo-1,2-oxazolidin-4-yl)-2-methylbenzamide (IUPAC), with the Chemical Abstracts Service number 2061933-85-3. The substance is a new insecticide and miticide belonging to the chemical group of isoxazolines. It binds the GABA receptor, blocking inhibitory neurotransmission results in hyperexcitation and finally death of target insects. It is intended for control of a variety of pests in agricultural and ornamental crops but may also play a role in vector control, for example to prevent transmission of malaria. However, suitability of this compound for the latter purpose is beyond the scope of this evaluation.

Isocycloseram has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR). All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with current test guidelines, unless otherwise specified. Public scientific literature that might complement the toxicological studies is scarce.

Biochemical aspects

Based on toxicokinetic investigations, a quantitatively similar elimination of radioactivity in faeces after oral and intravenous administration, and evidence of nearly complete metabolism in excreta, the oral absorption of low doses of isocycloseram of up to 3 mg/kg body weight (bw) was moderately fast and nearly complete. At 10 mg/kg bw absorption was above 80 percent. Some saturation of oral absorption became apparent at much higher dose levels as also shown by blood level measurements in apical toxicological studies. Distribution was wide, with highest organ concentrations after 168 hours in kidneys, followed by spleen, liver and adrenals. The predominant route of elimination was via the bile, accounting for up to 50 percent of total radioactivity within 72 hours of dosing. Urinary excretion was very limited, less than 4 percent of administered dose (AD). There was evidence of significant nonbiliary excretion into the intestinal lumen which contributed to the total faecal excretion of about 90 percent of AD. Elimination was slow overall with 6–10 percent of AD still retained in the carcass, organs and gastrointestinal tract (GIT) after 168 to 192 hours, and 16 percent after 72 hours, but based on data from repeated administration of radiolabelled compound there was no evidence of accumulation.

Metabolism in the rat was extensive with a large number of metabolites identified, most of which occurred only at low levels in the various compartments. Major metabolic pathways comprised ring-opening of the isoxazole ring, ring-opening and cleavage of the oxazolidinone ring, oxidative defluorination and glucuronic acid conjugation. Metabolite SYN549543 was the most abundant in bile, accounting for up to 11 percent of AD after low-dose administration. Metabolite SYN549436, together with its glucuronide (metabolite C), made up around 10 percent of AD in the bile of female rats. In addition, it was the main circulating metabolite in plasma.

In a comparative in vitro study, biotransformation of isocycloseram by human and rat liver microsomes was investigated. Human and rat metabolism appeared qualitatively similar but there were minor quantitative differences.

In general the impact of species, sex, repeated administration and position of the radiolabel on the toxicokinetics and metabolism of isocycloseram was low.

Toxicological data

The acute oral median lethal dose (LD_{50}) of isocycloseram in the rat was >4500 mg/kg bw. The dermal LD_{50} in rats was greater than 5000 mg/kg bw. The acute median lethal inhalation concentration (LC_{50}) was greater than 4.62 mg/L. Isocycloseram was not irritating to the skin of rabbits, but was minimally to slightly irritating to rabbits' eyes. A positive result was observed in a local lymph node assay (LLNA), whereas the compound proved negative in the less sensitive Buehler test in Guinea pigs.

In repeat-dose studies of toxicity in rodents, target organs were the adrenals, testes, liver and intestines, but effects were mostly not very pronounced. In dogs the critical effect was body weight loss.

In a 28-day oral toxicity study in mice the dietary concentrations were 0, 100, 300, 700 or 1000 ppm (equal to 0, 17.4, 55.9, 132 and 172 mg/kg bw per day for males, 0, 20.9, 60.5, 142 and 176 mg/kg bw per day for females). The no-observed-adverse-effect level (NOAEL) was 100 ppm (equal to 17.4 mg/kg bw per day), based on histopathological findings in liver, spleen and duodenum as observed at the lowest-observed-adverse-effect level (LOAEL) of 300 ppm (equal to 55.9 mg/kg bw per day).

In a 90-day study in mice, dietary concentrations of 0, 50, 300 or 700 ppm (equal to 0, 8.0, 48.8 and 117 mg/kg bw per day for males, 0, 9.9, 51.6 and 140 mg/kg bw per day for females) were administered. The NOAEL was 50 ppm (equal to 8 mg/kg bw per day), based on histopathological findings in adrenals and spleen at the next highest dose level of 300 ppm (equal to 48.8 mg/kg bw per day) and supported by alterations in clinical chemistry parameters.

In a 28-day feeding study in rats, the test substance was administered at dietary concentrations of 0, 50, 200, 350 or 500 ppm (equal to 0, 4.3, 16.3, 26.8 and 37.0 mg/kg bw per day) to male animals. Females received isocycloseram at dose levels of 0, 50 or 700 ppm (equal to 0, 4.5 and 50.1 mg/kg bw per day). Doses above 700 ppm were not tolerated and animals were terminated prematurely on day 11 due to mortality and severe clinical signs, and not further examined. The NOAEL of 50 ppm (equal to 4.3 mg/kg bw per day) was based on histopathological findings in the adrenals of males at the LOAEL of 200 ppm (equal to 16.3 mg/kg bw per day) and on clinical signs, reductions in body weight gain and food consumption, and on microscopic findings in adrenals, liver, and kidneys in females at the LOAEL of 700 ppm (50.1 mg/kg bw per day).

In a 90-day feeding study in rats, isocycloseram was fed at dietary concentrations of 0, 50, 150 or 300 ppm (equal to 0, 3.9, 11.2 and 22.0 mg/kg bw per day for males, 0, 4.4, 13.4 and 24.0 mg/kg bw per day for females). The NOAEL was 50 ppm (equal to 3.9 mg/kg bw per day). The LOAEL was 150 ppm (equal to 11.2 mg/kg bw per day) in males, based on higher kidney weight and histopathological findings in testis and epididymis.

In a 28-day study using capsule administration, dogs received isocycloseram at dose levels of 0, 10, 50 or 150 mg/kg bw per day (later reduced to 80 mg/kg bw per day) in males, and 0, 10, 35 or 70 mg/kg bw per day in females. Toxicity in both males and females was excessive at the highest dose and resulted in premature terminations which were not further examined. The NOAEL was 10 mg/kg bw per day, based on body weight losses at higher dose levels.

In a 90-day feeding study in dogs, the dose levels were 0, 5, 15, and initially 35 mg/kg bw per day. The high dose caused marked body weight losses, therefore, it was reduced to 25 mg/kg bw per day. The NOAEL was 15 mg/kg bw per day, based on body weight losses and reduced food intake at the top dose of 35/25 mg/kg bw per day.

The overall NOAEL for dogs was 15 mg/kg bw per day, based on body weight loss and reduced food intake at higher doses.

In an 18-month carcinogenicity study in mice, isocycloseram was administered at dietary concentrations of 0, 15, 60 or 200 ppm (equal to 0 1.7, 6.7 and 23.1 mg/kg bw per day for males, 0, 1.8, 7.1 and 24.4 mg/kg bw per day for females). A NOAEL of 15 ppm (equal to 1.7 mg/kg bw per day) was identified based on increased plasma cell infiltration in the mesenteric lymph nodes at the LOAEL of 60 ppm (equal to 6.7 mg/kg bw per day). A mode of action (MOA) could not be elucidated from these findings. No increase in neoplastic lesions was seen and, accordingly, the highest dietary concentration of 200 ppm (equal to 23.1 mg/kg bw per day) was the NOAEL for carcinogenicity.

In a combined chronic toxicity and carcinogenicity study in rats, isocycloseram was fed over 24 months at dietary concentrations of 0, 20, 50 or 150 ppm (equal to 0, 0.9, 2.3 and 7.0 mg/kg bw per day for males, 0, 1.2, 3.0 and 9.2 mg/kg bw per day for females). The NOAEL for long-term toxicity of 50 ppm (equal to 2.3 mg/kg bw per day) was based on histopathological findings in the testes and epididymides of males at 150 ppm. The respective LOAEL was 150 ppm (equal to 7.0 mg/kg bw per day). There was no evidence of carcinogenicity and so accordingly the carcinogenicity NOAEL in this study was 150 ppm (equal to 7.0 mg/kg bw per day), the highest dose tested.

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

Isocycloseram was tested in an adequate range of studies in which no genotoxic potential was revealed.

The Meeting concluded that isocycloseram is unlikely to be genotoxic.

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

In a two-generation reproductive toxicity study, isocycloseram was administered to rats at dietary concentrations that were adjusted weekly to provide dose levels of 0, 1.5, 4 or 12 mg/kg bw per day. The reproductive NOAEL was 4 mg/kg bw per day, based on a significant increase in post-implantation loss and impaired pup viability over the first four postnatal days (PNDs) at 12 mg/kg bw per day. The NOAEL of 4 mg/kg bw per day for both parental and

offspring toxicity was based on organ weight changes (adrenals, kidney and liver) and histopathological findings in intestines and testes in adult rats of both generations at 12 mg/kg bw per day, and further supported by a more equivocal delay in male sexual maturation and a decrease in ovarian follicle count in the F1 generation at this same dose.

In a developmental toxicity study in rats, isocycloseram was administered by oral gavage from gestation day (GD) 6 to GD 19 at dose levels of 0, 3.5, 7.5 or 15 mg/kg bw per day. The maternal NOAEL was 15 mg/kg bw per day, the highest dose tested. The embryo/fetal NOAEL of 7.5 mg/kg bw per day was based on the occurrence of bifid sternebrae (a rare skeletal anomaly) in two fetuses from two litters and supported by a slight overall increase in skeletal variations at 15 mg/kg bw per day. Since it is known that effects on sternal development have a relatively narrow critical sensitivity window in rodents, the resulting NOAEL of 7.5 mg/kg bw per day should for this reason be taken into consideration when deriving an acute reference dose.

In a developmental toxicity study in rabbits, isocycloseram was administered by oral gavage at doses of 0, 3.5, 7.5 or 15 mg/kg bw per day from GD 6 to GD 27. The maternal NOAEL was 7.5 mg/kg bw per day based on a slightly lower mean body weight gain in the does at the LOAEL of 15 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 15 mg/kg bw per day, the highest dose tested.

The Meeting concluded that isocycloseram is not teratogenic since the occurrence of bifid sternebrae is not considered a malformation.

In an acute neurotoxicity study in rats, doses of 0, 50, 200 or 1000 mg/kg bw were administered by oral gavage. The systemic NOAEL was 50 mg/kg bw per day based on lower body weight gain, reduced food consumption and transiently depressed activity at higher doses. The LOAEL for these effects was 200 mg/kg bw per day. The NOAEL for acute neurotoxicity was 1000 mg/kg bw, the highest dose tested. No evidence of specific neurotoxic potential was observed and the highest tested dose of 1000 mg/kg bw was considered the NOAEL for neurotoxicity.

In a 90-day feeding study the neurotoxic potential of isocycloseram was investigated in rats that received daily dietary concentrations of 0, 50, 150 or 300 ppm (equal to 3.9, 13.2 and 24.8 mg/kg bw per day for males, 5.5, 15.6 and 32.7 mg/kg bw per day for females). The NOAELs for both systemic effects and neurotoxicity were 300 ppm (equal to 24.8 mg/kg bw per day), the highest dose tested.

The Meeting concluded that isocycloseram is not neurotoxic.

No specific study to investigate the immunotoxicity of isocycloseram was available, but no evidence of immunotoxicity was reported in routine toxicological studies with isocycloseram.

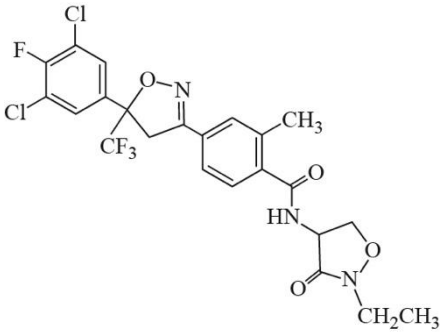
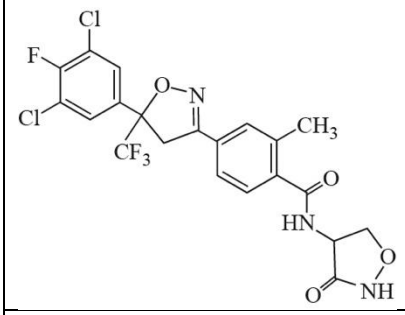
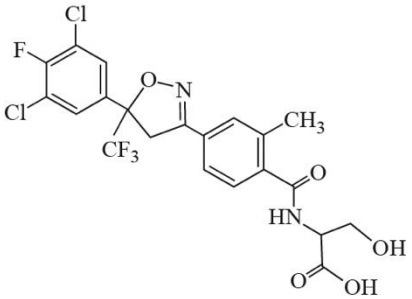
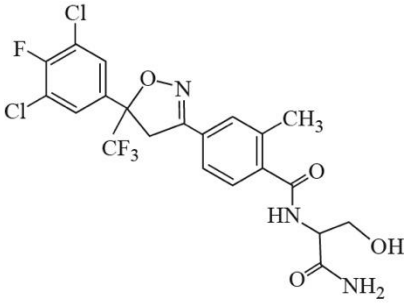
The Meeting concluded that isocycloseram is unlikely to be immunotoxic.

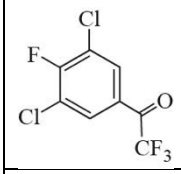
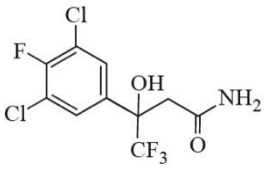
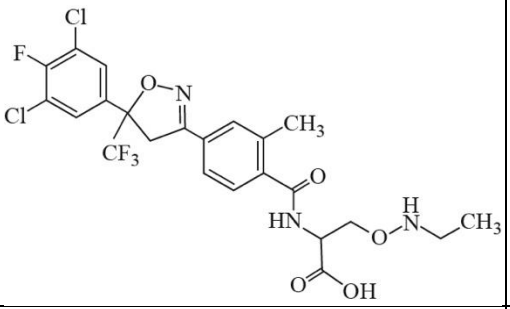
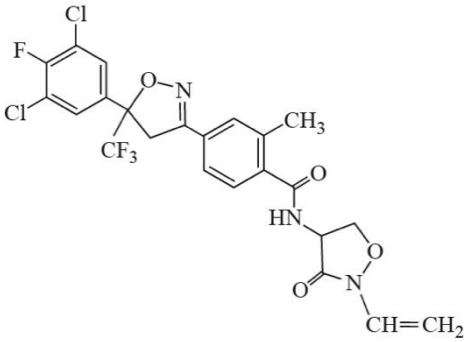
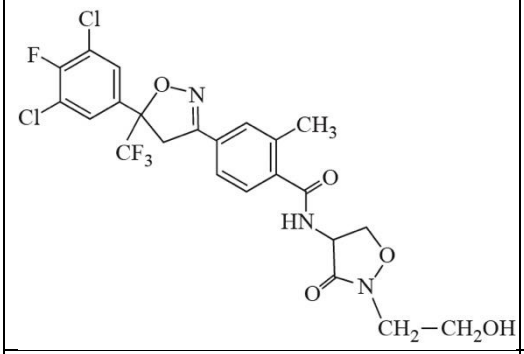
Toxicological data on metabolites and/or degradates

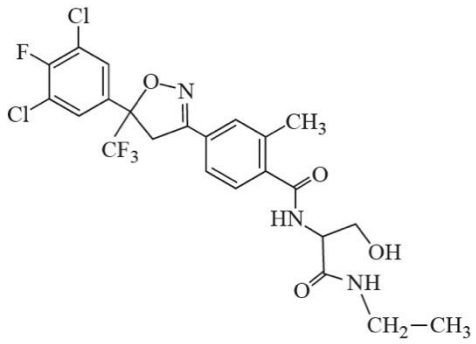
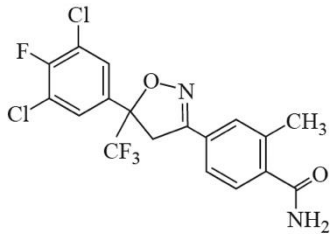
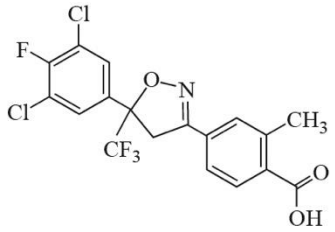
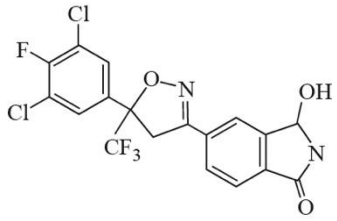
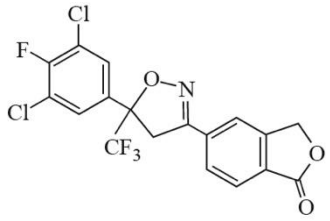
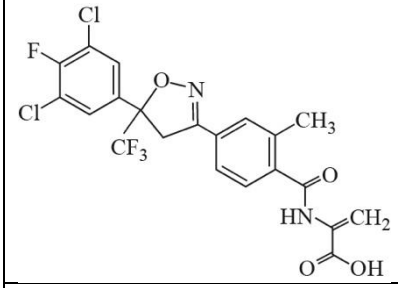
Information on metabolites was scarce. A grouping concept was developed and provided by the sponsor, together with predictions for genotoxicity and general toxicity based on in silico analyses. Experimental data is only available for one metabolite, SYN548569 (CA5697A), which

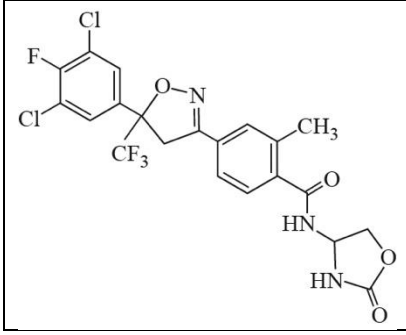
has a very different structure from the parent, is not part of rat metabolism, but was detected in livestock matrices and rotational crops. A summary of what is known on metabolites of isocycloseram is shown in the table below.

Summary on toxicological characterization of metabolites of isocycloseram in plants, livestock and processed commodities

Compound, code, structure	Major rat metabolite (>10% AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Toxicological reference values
Isocycloseram 	Parent	Negative, (full experimental dataset)	Full dataset	ADI: 0–0.02 mg/kg bw ARfD: 0.08 mg/kg bw (females of child-bearing age); 0.5 mg/kg bw (general population)
SYN549436 	Major	Negative (QSAR, RA)	Covered by parent	Parent ADI and ARfD
SYN549543 	Major	Negative (QSAR, RA)	Covered by parent	Parent ADI and ARfD
SYN549544 	Minor	Negative (QSAR, RA)	Indirectly covered by parent (it is a precursor of SYN 549543)	Parent ADI and ARfD

SYN548569 (CA5697A) 	Not found	Negative (data)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN552188 	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN551203 	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN551475 	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN550402 	Not found	Negative (QSAR)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN550737	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day

				
SYN549431 	Minor	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN549107 	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN551479 	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN551474 	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN551485 	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value: 1.5 µg/kg bw per day
SYN551583	Not found	Negative (QSAR, RA)	No data	TTC Cramer class III value:

	1.5 µg/kg bw per day

TTC: Threshold of toxicological concern; RA: Read-across; QSAR: Quantitative structural–activity relationship
ADI: Acceptable daily intake; ARfD: Acute reference dose

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of isocycloseram residues on the human intestinal microbiome.

Human data

From very limited observations on the health of manufacturing personnel, no adverse effects had been reported. No information on poisoning incidents was available. As expected for a new compound, human data is very scarce.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.02 mg/kg bw for isocycloseram based on the NOAEL of 1.7 mg/kg bw per day in the long-term study in mice and the NOAEL of 2.3 mg/kg bw per day in the two-year study in rats. A safety factor of 100 was used.

This ADI is considered applicable also to the dietary metabolites SYN549436, SYN549543 and SYN549544.

The Meeting established an ARfD for females of child-bearing age of 0.08 mg/kg bw based on the embryo/fetal NOAEL of 7.5 mg/kg bw in the developmental toxicity study in rats, applying a safety factor of 100.

The Meeting established an ARfD for the general population of 0.5 mg/kg bw based on the NOAEL of 50 mg/kg bw in the acute neurotoxicity study in rats, applying a safety factor of 100.

Both ARfDs are applicable to dietary metabolites SYN549436, SYN549543 and SYN549544.

A toxicological monograph was prepared.

Levels relevant to risk assessment of isocycloseram

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity[a]	Toxicity	15 ppm, equal to 1.7 mg/kg bw per day	60 ppm, equal to 6.7 mg/kg bw per day
		Carcinogenicity	200 ppm, equal to 23.1 mg/kg bw per day[c]	-
Rat	Acute neurotoxicity study[b]	Neurotoxicity	1000 mg/kg bw[c]	-
		Systemic effects	50 mg/kg bw	200 mg/kg bw
	Two-year studies of toxicity and carcinogenicity[a]	Toxicity	50 ppm, equal to 2.3 mg/kg bw per day	150 ppm, equal to 7.0 mg/kg bw per day
		Carcinogenicity	150 ppm, equal to 7.0 mg/kg bw per day[c]	-
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	4 mg/kg bw per day	12 mg/kg bw per day
		Parental toxicity	4 mg/kg bw per day	12 mg/kg bw per day
		Offspring toxicity	4 mg/kg bw per day	12 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	15 mg/kg bw per day[c]	-
		Embryo/fetal toxicity	7.5 mg/kg bw per day	15 mg/kg bw per day
Rabbit	Developmental toxicity study[b]	Maternal toxicity	7.5 mg/kg bw per day	15 mg/kg bw per day
		Embryo/fetal toxicity	15 mg/kg bw per day [c]	-
Dog	90-day study[a]	Toxicity	15 mg/kg bw per day	25 mg/kg bw per day

[a] Dietary administration

[b] Gavage administration

[c] Highest dose tested

*Acceptable daily intake (ADI)**

0–0.2 mg/kg bw

*Acute reference dose (ARfD) for females of child bearing age**

0.08 mg/kg bw

*Acute reference dose (ARfD) for the general population**

0.5 mg/kg bw

* Applies to isocycloseram and metabolites SYN549436, SYN549543 and SYN549544

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 isocycloseram

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Moderately rapid (T_{max} 6–8 hours) but nearly complete at low dose of 1 mg/kg bw; above 80% at high dose of 10 mg/kg bw
Dermal absorption	No data
Distribution	Widely distributed, highest residues in kidneys, followed by spleen, liver, and adrenals
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Mainly via faeces (up to 90% in total) but not complete within 7–8 days (6–10% remaining in carcass and organs); Significant part excreted within 72 hours via bile (46–50% at low dose); urinary excretion low (≤4%); Exhalation negligible
Metabolism in animals	Extensive with a large number of metabolites mostly occurring at low levels Major rat metabolites SYN549436 and its glucuronide and SYN549543 Main pathways comprising opening of isoxazole ring, opening and cleavage of oxazolidinone ring, oxidative defluorination, and glucuronidation
Toxicologically significant compounds in animals and plants	Parent isocycloseram, SYN548569 (CA5697A) SYN549436, SYN549543 and SYN549544
Acute toxicity	
Rat, LD_{50}, oral	4500 mg/kg bw
Rat, LD_{50}, dermal	>5000 mg/kg bw
Rat, LC_{50}, inhalation	>4.62 mg/L (four-hour nose only exposure)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Minimally to slightly irritating
Dermal sensitization	Sensitizing (LLNA)
Short-term studies of toxicity	
Target/critical effect	Histological lesions in liver, spleen, adrenals, intestines, testis and epididymis in rodents; higher kidney weight in rats; body weight loss in dogs

Lowest relevant oral NOAEL	3.9 mg/kg bw per day (rat)
Lowest relevant dermal NOAEL	100 mg/kg bw per day (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Plasma cell infiltration of mesenteric lymph nodes in mice; histopathological findings in testes/epididymides in rats
Lowest relevant NOAEL	1.7 mg/kg bw per day (mouse)
Carcinogenicity	Not carcinogenic in mice or rats
Genotoxicity	No genotoxic potential
Reproductive toxicity	
Target/critical effect	*Reproductive toxicity*: increase in post-implantation loss *Offspring toxicity*: microscopic lesions in testes, liver, duodenum; organ weight changes; delay in male sexual maturation and lower ovarian follicle count, and decreased postnatal viability of pups *Parental toxicity:* microscopic lesions in testes, and duodenum; organ weight changes
Lowest relevant parental NOAEL	4 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	4 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	4 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	*Maternal toxicity*: slightly reduced body weight gain in rabbits *Developmental:* rare anomaly of bifid sternebrae and slight overall increase in skeletal variations in rat fetuses at highest dose of 15 mg/kg bw per day
Lowest relevant maternal NOAEL	7.5 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	7.5 mg/kg bw per day (rat)
Neurotoxicity	
Acute neurotoxicity NOAEL	No evidence of a specific neurotoxic potential up to highest dose of 1000 mg/kg bw, but systemic effects at 200 mg/kg bw and above (rat)
Subchronic neurotoxicity NOAEL	24.8 mg/kg bw per day, highest dose tested in a 90-day study (rat) No evidence of neurotoxicity or systemic effects
Developmental neurotoxicity NOAEL	No data, not necessary
Other toxicological studies	
Immunotoxicity	No data
Phototoxicity	No data
Mechanistic studies	No data

Studies on toxicologically relevant metabolites

SYN548569 (CA5697A)	Negative Ames test but positive in vitro micronucleus assay, negative bone marrow micronucleus assay in mice
Microbiology data	No data submitted
Human data	Not available for this new compound, at least no evidence of health effects in manufacturing plant personnel

Summary

	Value	Study	Safety factor
ADI	0–0.02 mg/kg bw	18-month study in mice, two-year study in rats	100
ARfD for females of child-bearing age	0.08 mg/kg bw	Developmental toxicity study in rats	100
ARfD for the general population	0.5 mg/kg bw	Acute neurotoxicity study in rats	100

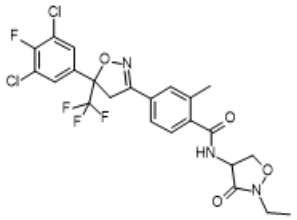
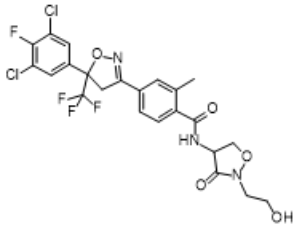
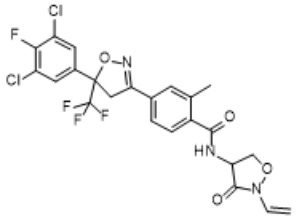
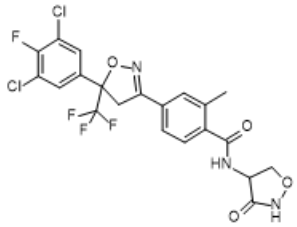
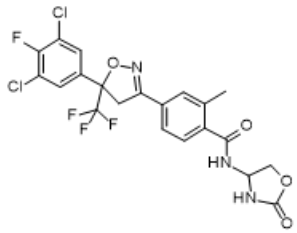
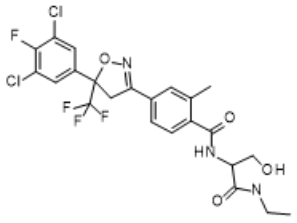
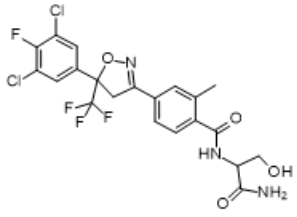
RESIDUE AND ANALYTICAL ASPECTS

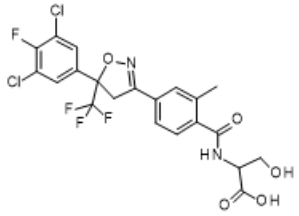
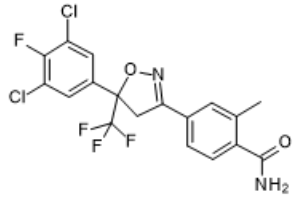
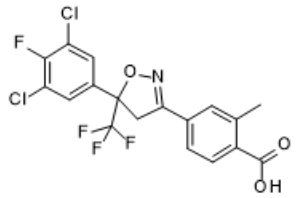
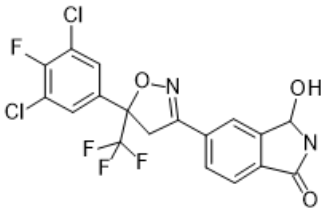
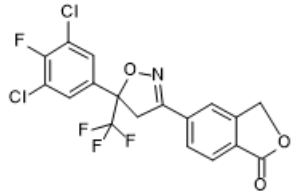
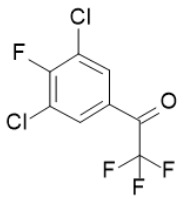
Isocycloseram (4-[5-(3,5-dichloro-4-fluorophenyl)-4,5-dihydro-5-(trifluoromethyl)-3-isoxazolyl]-N-(2-ethyl-3-oxo-4-isoxazolidinyl)-2-methylbenzamide) is a new active ingredient that has not previously been evaluated by the JMPR.

Isocycloseram is an insecticide belonging to IRAC group 30 (allosteric modulators of chlorine channels mediated by GABA) which acts by inhibiting the glutamate nerve receptor in the insects; it has contact and ingestion effect on eggs (some species), immature stages (larvae and nymphs) and adults. Isocycloseram is also a broad-spectrum insecticide controlling pests such as spider mites, leaf miners, trips, weevils, coffee borer, bed bugs, frog spits, lepidopteran larvae and others.

Isocycloseram was scheduled at the Fifty-second Session of the CCPR for evaluation as a new compound in 2022 . All relevant information in terms of chemical identity, physical and chemical properties, metabolism and environmental fate, methods of residue analysis, storage stability, intended use patterns, supervised residue trials, fate of residues upon processing, and farm animal feeding studies were submitted for evaluation by the 2023 JMPR to support the evaluation of isocycloseram as a new compound.

The chemical structures of isocycloseram and its metabolites/degradates relevant for the appraisal are shown below.

Compound code (Other names)	Description	Chemical structure
Isocycloseram	4-[5-(3,5-dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-N-(2-ethyl-3-oxo-1,2-oxazolidin-4-yl)-2-methyl-benzamide	
SYN550402	4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-N-[2-(2-hydroxyethyl)-3-oxo-isoxazolidin-4-yl]-2-methyl-benzamide	
SYN551475	4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-N-(3-oxo-2-vinyl-isoxazolidin-4-yl)benzamide	
SYN549436	4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-N-(3-oxoisoxazolidin-4-yl)benzamide	
SYN551583	4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-N-(2-oxooxazolidin-4-yl)benzamide	
SYN550737	4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-N-[2-(ethylamino)-1-(hydroxymethyl)-2-oxo-ethyl]-2-methyl-benzamide	
SYN549544	N-[2-amino-1-(hydroxymethyl)-2-oxo-ethyl]-4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-benzamide	

Compound code (Other names)	Description	Chemical structure
SYN549543	2-[[4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-benzoyl]amino]-3-hydroxy-propanoic acid	
SYN549431	2-[[4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-benzoyl]amino]-3-hydroxy-propanoic acid	
SYN549107	4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-benzoic acid	
SYN551479	5-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-3-hydroxy-isoindolin-1-one	
SYN551474	5-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-3H-isobenzofuran-1-one	
SYN548569	1-(3,5-dichloro-4-fluoro-phenyl)-2,2,2-trifluoro-ethanone	

Based on the information on physical and chemical properties, isocycloseram is not volatile and is lipid soluble with a log Pow of approximately five. Isocycloseram is hydrolytically stable at environmental pH and has the potential to be moderately persistent under aerobic field conditions. Photodegradation is unlikely to be a major degradation pathway of isocycloseram in the environment.

Plant metabolism

The Meeting received studies describing the metabolism of isocycloseram in fruiting vegetables (tomato), oilseeds (soya bean), leafy crops (mustard greens) and cereals (rice). The isocycloseram structure with four rings containing two phenyl-, one oxoisoxazolidinyl- and one oxazole-ring, requires the evaluation of the metabolic behaviour of the active ingredient labelled in the different ring systems separately. Therefore, a [halophenyl-U-^{14}C]-radiolabel, a [methylphenyl-U-^{14}C]-radiolabel and an [oxoisoxazolidinyl-4,5-^{14}C]-radiolabel were used for all metabolism studies. In general, all three radiolabels yielded similar results across the metabolism studies.

Tomato

Isocycloseram was formulated as an SC and applied to tomato plants grown outdoors. The metabolic fate of ^{14}C-isocycloseram was examined following three separate, foliar applications of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram at a nominal application rate of 120 g ai/ha. The three applications were performed at approximately BBCH 51, BBCH 72, and BBCH 85.

The commodities were collected at a suitable harvest time for leaves and mature fruits (BBCH 88, 3 days after the third application) and leaves, immature and mature fruits (BBCH 106, 21 days after the third application). The total radioactive residue (TRR), mg ai equivalents per kg of commodity, were measured in each commodity sampled. In addition, TRR was determined from the organic solvent washes of fruits.

Residues in leaves and fruits were 6.814 and 0.021 (halophenyl-labelled), 6.954 and 0.032 (methylphenyl-labelled)and 6.023 and 0.022 (oxoisoxazolidinyl-labelled) mg eq/kg respectively at 3 days after last application and 6.203 and 0.003 (halophenyl-labelled), 5.207 and 0.004-0.005 (methylphenyl-labelled) and 5.340 and 0.011 (oxoisoxazolidinyl-labelled) mg eq/kg respectively at 21 days after last application.

The extractability of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram with acetonitrile:water was good at 92 to 96 percent TRR (tomato leaves) and 87 to 95 percent TRR (mature tomato fruits) across all radiolabels. The extractability of [methylphenyl-U-^{14}C]-isocycloseram was good at 88 percent TRR for immature tomato fruit.

Following foliar application, parent isocycloseram was detected as the most abundant component in all tomato samples, ranging from 65 to 95 percent TRR (tomato leaves) and 51 to 83 percent TRR (mature tomato fruit) across all radiolabels. Parent isocycloseram was detected in immature tomato fruit at 74 percent in the methyphenyl-label only. SYN549431 was the only major metabolite, ranging from 7.6 to 15 percent TRR (tomato leaves) and 2.7 to 6.0 percent TRR (mature tomato fruit) across all radiolabels. It was not detected in the 21 DAT immature fruit (methylphenyl-labelled).

Soya bean

Isocycloseram was formulated as an SC and applied to soya beans grown outdoors. The metabolic fate of ^{14}C-isocycloseram was examined following three separate foliar applications of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram at a nominal application rate of 80 g ai/ha. Three applications were performed at approximately BBCH 23, BBCH 71, and BBCH 79.

The aerial portion of the crop was collected at a suitable harvest time for forage (BBCH 51, 37 days after the first application), hay (BBCH 71, 69 days after the first application), and beans at maturity (BBCH 89, 30 days after the third application). In the case of soya bean hay and beans, the harvested raw material was further dried near the plots to simulate agricultural hay practice and to remove residual moisture from beans prior to threshing.

Residues forage and hay were 1.200 and 0.025, (halophenyl-labelled). The [halophenyl-U-^{14}C]-isocycloseram was not detected in bean samples. Residues forage, hay, and beans were 0.226, 0.022, and 0.016 (methylphenyl-labelled) and 0.407, 0.020, and 0.087 (oxoisoxazolidinyl-labelled) mg eq/kg respectively.

The extractability of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram with acetonitrile:water was good at 91 to 95 percent TRR (soya bean forage) and 55 to 71 percent TRR (soya bean hay) across all radiolabels. The extractability of [methylphenyl-U-^{14}C]-isocycloseram and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram was good at 59 to >99 percentTRR for soya bean beans.

Following foliar application, parent isocycloseram was detected as the most abundant component in all soya bean forage samples, ranging from 42 to 67 percent RR across all radiolabels. Parent isocycloseram was detected at low levels in soya bean seed samples at 7.2 percent (methyphenyl-labelled only) and in soya bean hay samples from 2.1 to 15 percent TRR (halophenyl-label and oxoisoxazolidinyl-labelled). SYN549431 was the only major metabolite, ranging from 5.8 to 10 percent TRR in soya bean forage samples and 0.7—10 percent TRR in soya bean hay samples (methylphenyl- and halophenyl-labelled). SYN549431 was detected at 0.7 percent TRR in soya bean seed samples (methyphenyl-labelled only).

Mustard greens

Isocycloseram was formulated as an SC and applied to mustard greens grown outdoors. The metabolic fate of ^{14}C-isocycloseram was examined following separate foliar applied and in-furrow applications of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram a nominal application rate of 150 and 60 g ai/ha for in-furrow or foliar treatment, respectively. A single treatment in-furrow or three foliar applications were performed at approximately BBCH 15, BBCH 18, and BBCH 48.

The commodity was collected at immature greens (BBCH 18, 7 days after the first application) and mature greens (BBCH 49, 5 days after the third application) growth stages.

Residues in immature and mature greens were 1.071 and 1.945 (halophenyl-labelled), 1.154 and 2.041 (methylphenyl-labelled) and 1.197 and 2.150 (oxoisoxazolidinyl-labelled) mg eq/kg, respectively.

The extractability of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram with acetonitrile:water was good at 92-96 percent TRR (immature mustard greens) and 94.7–96.5 percent TRR (mature mustard greens) across all radiolabels resulting from foliar applications.

Following foliar applications, parent isocycloseram was the most abundant component ranging from 88 to 99 percent TRR (mature mustard greens) and 74 to 86 percent TRR (immature mustard greens) across all radiolabels.

SYN549431 was identified at 2.7–2.9 percent TRR in immature mustard greens (halophenyl- and methylphenyl-labelled) and 3.1 percent TRR in mature mustard greens (methylphenyl-labelled only).

Additional low-level metabolites, SYN549543 and SYN549436, were also present in foliar applied mustard greens, each accounting for ≤0.8 percent TRR (≤0.009 mg eq/kg).

Following in-furrow treatment, residues in mature greens were 0.008 mg eq/kg (halophenyl-labelled). Residues in immature greens were 0.006 (methylphenyl-labelled) and 0.004 (oxoisoxazolidinyl-labelled) mg eq/kg, respectively.

The extractability of [methylphenyl-U-^{14}C]-isocycloseram and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram was good at 59–63 percent TRR (immature mustard greens) and the extractability of [halophenyl-U-^{14}C]-isocycloseram was good at 66 percent TRR (mature mustard greens).

Parent isocycloseram was also detected as most abundant component in immature mustard greens samples from in-furrow applications for methylphenyl- and oxoisoxazolidinyl-labelled experiments, ranging from 38 to 45 percent TRR, but was less abundant in the mature sample of the halophenyl-labelled experiment, accounting for 2.3 percent TRR. SYN549431 was also detected at 7.7 percent TRR in immature mustard greens from the in-furrow application (methylphenyl-labelled only).

Paddy rice

Isocycloseram was formulated as an SC and applied to paddy rice grown outdoors. The metabolic fate of ^{14}C-isocycloseram was examined following three separate applications of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram at a nominal application rate of 100 g ai/ha. Three applications were performed at approximately BBCH 27, BBCH 33, and BBCH 83.

The commodity was collected at the appropriate crop growth stage corresponding to rice commodities. The aerial portion of the crop was collected at forage (BBCH 33, 13 days after the first application), hay (BBCH 60, 57 days after the second application), and mature crops (straw, husks and grain) (BBCH 89, 21 days after the third application) growth stages.

Residues forage, hay, straw, grain, and husks were 1.837, 2.079, 2.596, 0.144, and 3.744 (halophenyl-labelled), 1.559, 2.497, 2.486, 0.186, and 3.507 (methylphenyl-labelled) and 1.707, 1.251, 3.851, 0.176, 4.118 (oxoisoxazolidinyl-labelled) mg eq/kg, respectively.

The extractability of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram with acetonitrile:water was good at 93 to 94 percent TRR (rice forage), 92 to 98 percent TRR (rice hay), 86 to 94 percent TRR (rice grain), 92 to 94 percent TRR (rice straw), and 94 to 96 percent TRR (rice husks) across all radiolabels.

Following foliar applications, parent isocycloseram was the most abundant component ranging from 80 to 90 percent TRR (rice forage), 62 to 76 percent TRR (rice hay), 82 to 86 percent TRR (rice grain), 87 to 94 percent RR (rice straw), and 93 to 96 percent TRR (rice husks) across all radiolabels.

SYN549431 was identified at 1.3 to 11 percent TRR (rice forage), 20 to 25 percent TRR (rice hay), 2.9 to 3.7 percent TRR (rice grain), 5.6 to 6.0 percent TRR (rice straw) in the halophenyl- and methylphenyl-labels and at 1.4 percent TRR in risk husks (halophenyl-labelled only).

Plant metabolism summary and conclusions

Primary crop metabolism of isocycloseram has been investigated in crops from four representative groups, namely pulses and oilseeds (soya bean), fruit (tomatoes), leafy vegetables (mustard greens) and rice grown under paddy conditions.

Metabolism was investigated using foliar applications representative of the agricultural use patterns in all foliar crops. Additional experiments incorporating an in-furrow application were included in the mustard greens study to determine whether unique soil metabolites would be taken up by the plant.

The biotransformation pathways in all four crops tested was similar. The most predominant metabolite of isocycloseram, SYN549431, was generated via loss of the oxoisoxazolidine ring.

Environmental fate

The Meeting received studies investigating the behaviour of isocycloseram following photodegradation, hydrolytic degradation, and aerobic soil degradation. The Meeting also received studies investigating the aerobic degradation of SYN550738 and SYN549107 in soil.

Photodegradation

Isocycloseram degraded slowly under irradiated conditions in both dry and moist layers, whereas minimal degradation was observed in the respective dark controls. In the dry layer incubation, isocycloseram degraded with a half-life (DT_{50}) of 45.8 days of artificial sunlight which corresponds to 85.1 days natural sunlight at 30°N to 50°N. Degradation in moist soil showed a

DT50 of 61.2 days under artificial sunlight. This corresponds to 111.6 days natural sunlight at 30°N to 50°N.

The predominant degradation product observed was SYN549431, reaching a level of about 6 percent AR. No other degradate was observed at levels of >5 percent AR in any of the radiolabels.

The Meeting determined that photolysis is not likely a significant route of degredation for isocycloseram.

Hydrolytic degradation

Degradation of isocycloseram was faster at pH 7 than pH 4. DT50 values ranged from 1.36 to 1290 days across all pHs at 25°C. Three degradates were observed at >10 percent AR. SYN551203 was present in both methylphenyl- and oxoisoxazolidinyl-labelled samples. At 50°C, levels of SYN551203 increased throughout the incubation period reaching a maximum of up to 57.0 percent AR by 21 – 29 DAT. At 60 and 70°C, SYN551203 reached maximum amounts of 60.1 percent AR (OXO label) and 63.1 percent AR (MP label) by 9 and 2 DAT, respectively, before declining to ≤23.7 percent and ≤2.7 percent AR, respectively. SYN551485 was also present in both methylphenyl- and oxoisoxazolidinyl-labelled samples. It reached maximum levels of 21.8 percent AR (oxoisoxazolidinyl-labelled), 57.7 percent AR (methylphenyl-labelled) and 77.3 percent AR (oxoisoxazolidinyl-labelled) at 50, 60 and 70°C, respectively. SYN549107 was present in methylphenyl-labelled samples only and reached up to 11.4 percent AR by the end of the incubation period at 70°C but was not detected at any significant level (≤1.0 percent AR) at the lower temperatures.

The Meeting determined isocycloseram is hydrolytically stable at environmental pH.

Terrestrial field dissipation

Isocycloseram degraded with a DT50 values ranging from 20.9 to 437 days (Geometric Mean: 80.2 days).

The Meeting determined that isocycloseram has the potential to be moderately persistent under aerobic field conditions. Particularly, Isocycloseram was found to be more persistent when applied by broadcast application on bare soil than when applied on turf plots.

Confined rotational crops

The Meeting received two studies examining the nature of the residue in rotational crops were provided.

In the first study, [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram was applied once to bare soil at a nominal rate of 360 g ai/ha. In the second study, [methylphenyl-U-^{14}C]-isocycloseram and [halophenyl-U-^{14}C]-isocycloseram were applied once to separate bare soil plots, also at a nominal rate of 360 g ai/ha.

In both studies, lettuce, wheat, and radish were planted ca. 30, 120, and 273 days after treatment. Crops were harvested at the appropriate growth stage for immature and mature lettuce; wheat forage, hay, straw, and grain; radish roots; and radish leaves.

Total radioactive residues in immature and mature lettuce were 0.006 and 0.002 (halophenyl-labelled) and 0.005 and 0.007 (methylphenyl-labelled) mg/kg respectively at 30-day plant-back intervals (PBIs), 0.005 and 0.002 (halophenyl-labelled) and 0.014 and 0.015 (methylphenyl-labelled) mg/kg respectively at 120-day PBIs, and 0.001 and 0.001 (halophenyl-labelled) and 0.004 and 0.002 (methylphenyl-labelled) mg/kg respectively at 273-day PBIs.

Residues in immature lettuce were 0.033 mg/kg (oxoisoxazolidinyl-labelled) at 30-day PBIs. Residues of immature and mature lettuce were 0.004 and 0.004 (oxoisoxazolidinyl-labelled) mg/kg respectively at 120-day PBIs.

The extractability of [methylphenyl-U-^{14}C]-isocycloseram was good at >99 percent TRR for both immature and mature lettuce resulting from a single soil directed application.

Residues in radish leaves and radish roots were 0.004 and 0.057 (halophenyl-labelled) and 0.016 and 0.074 (methylphenyl-labelled) mg/kg respectively at 30-day PBIs, 0.002 and 0.006 (halophenyl-labelled) and 0.018 and 0.074 (methylphenyl-labelled) mg/kg respectively at 120-day PBIs, and 0.002 and 0.015 (halophenyl-labelled) and 0.005 and 0.018 (methylphenyl-labelled) mg/kg respectively at 273-day PBIs.

The extractability of [methylphenyl-U-14C]-isocycloseram was good at >90 percent TRR for radish roots and >92 percent TRR for radish leaves resulting from a single soil directed applications.

Residues in wheat forage, hay, straw, and grain were 0.043, 0.155, 0.125, and0.003 (halophenyl-labelled) and 0.008, 0.017, 0.035, and 0.002 (methylphenyl-labelled) mg/kg, respectively, at 30 day PBIs, 0.015, 0.084, 0.089, and 0.004 (halophenyl-labelled) and 0.006, 0.015, 0.031, and 0.002 (methylphenyl-labelled) mg/kg, respectively, at 120 day PBIs, and 0.004, 0.009, 0.021, and 0.001 (halophenyl-labelled) and 0.003, 0.002, 0.005, and 0.001 (methylphenyl-labelled) mg/kg, respectively, at 273 day PBIs.

The extractability of [methylphenyl-U-^{14}C]-isocycloseram was good at >82 percent TRR for wheat straw and >58 percent TRR for wheat hay resulting from a single soil directed applications. The extractability of [halophenyl-U-14C]-isocycloseram was good at >90 percent TRR for wheat straw, >97 percent TRR for wheat hay, and > 78 percent TRR for wheat forage resulting from a single soil directed applications.

Total radioactive residues generally decreased with increasing PBIs. At PBIs of 30 days, isocycloseram was the predominant residue in most cases, followed by residues or SYN551288 and SYN549431.Proportions of the metabolites SYN552188 and/or SYN549431 becoming increasingly predominant at longer PHIs. Concentrations of those residues in human foods were low (typically <0.01 mg eq/kg; radish root, 30-day PBI is an exception at 0.059 mg/kg isocycloseram).

Parent isocycloseram was identified as the most abundant component in 30 DAT wheat hay (34.0 percent TRR, 0.025 mg/kg), 30 DAT wheat straw (30.8 percent TRR, 0.021 mg/kg), 120

DAT wheat hay (42.4 percent TRR, 0.08 mg/kg), 120 DAT wheat straw (50.8 percent TRR, 0.008 mg/kg), 273 DAT wheat straw (34.1 percent TRR, 0.006 mg/kg) and radish roots (54.0 percent TRR, 0.007 mg/kg). It was not identified in other analysed commodities.

Field rotational crops

The Meeting received a study investigating residues in field rotational crops grown in the United States during the 2017 and 2018 growing seasons.

At each study site, isocycloseram was applied as three applications to bare soil at a nominal rate of 120 g ai/ha on a 7-day interval. Adjuvants were included in the spray solution. Leafy vegetables (mustard greens, lettuce, or spinach), root vegetables (radish or turnip), and a cereal grain (wheat) were planted into treated soil ca. 30, 90, 120, 180, and 270 days (wheat only) after the last application. Note: lettuce leaves were not analysed and are not further discussed herein.

Samples were harvested at commercial maturity, except for wheat forage (BBCH 30-40) and wheat hay (BBCH 40-85).

Residues of isocycloseram, SYN549431 and SYN548569 were <0.01 mg/kg in all samples except for isocycloseram in radish leaves at PBIs of 30 (one sample; 0.024 mg eq/kg) and 90 (one sample; 0.015 mg eq/kg) days.

Based on results of the field rotational crop study, residues in rotational crops are expected to be <0.01 mg/kg at PBIs greater than 90 days for leaves of root/tuber vegetables and 30 days for all other crops.

Environmental fate and rotational crops summary and conclusions

The reported DT_{50} values of isocycloseram showed great variability (20.9 to 437 days) across all environmental fate studies. Overall, the field studies support a classification of isocycloseram as persistent in soil. Based on results of the field rotational crop study, residues in rotational crops are expected to be <0.01 mg/kg at PBIs greater than 30 days (90 days for leaves of root/tuber vegetables) and are not of concern.

Animal metabolism

The Meeting received studies describing the metabolism of isocycloseram in lactating goats and laying hens.

Lactating goats

The metabolism and excretion of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram was investigated in lactating goats as a model for ruminants.

Each radiolabelled test compound was orally administered in a capsule, separately, to one goat at nominal rate of 30 mg eq/kg dietary dry matter, corresponding to 38.7 ppm (dry) (methylphenyl-labelled), 35.5 ppm (dry) (halophenyl-labelled), and 41.5 ppm (dry) (oxoisoxazolidinyl-labelled). The goats received seven doses at 24-hour intervals and were sacrificed 11–12 hours after the last dosing. Milk was collected twice daily. TRR was determined in each individual milk sample and daily pooled milk sample; in tissues of muscle (composite loin and flank), fat (composite perirenal, subcutaneous, and omental), kidney, and liver; and in urine, faeces, bile, GI tract and contents, and cage wash. Radioactivity in carcasses were not measured.

The total recovery of dosed radioactivity was 82.3 percent with the majority of this associated with faeces (53.8 percent), gastrointestinal tract and contents (16.4 percent), urine (6.0 percent), and milk and tissues (5.9 percent).

In milk, TRR was consistently higher in evening samples compared to morning samples. Evening and morning samples were pooled on all days except day 7, where only evening milk was collected and not pooled. TRR did not reach a plateau in the methylphenyl-labelled and halophenyl-labelled experiments. In the oxoisoxazolidinyl-labelled study, TRR reached a plateau of 0.91 mg eq/kg following 5 days. Whole milk was separated into skim milk and cream samples daily. Comparison in skim milk and cream showed preference for the cream fraction, with TRR ranging from 0.03 to 0.09 mg eq/kg (methylphenyl-labelled), 0.02 to 0.09 mg eq/kg (halophenyl-labelled), and 0.004-0.23 mg eq/kg (oxoisoxazolidinyl-labelled) in skim milk and 2.7 to 9.8 mg eq/kg (methylphenyl-labelled), 3.07 to 10.5 mg eq/kg (halophenyl-labelled), and 4.5-15.6 mg eq/kg (oxoisoxazolidinyl-labelled) in cream.

In liver, TRR in tissues samples amounted to 6.4 mg eq/kg (methylphenyl-labelled), 8.7 mg eq/kg (halophenyl-labelled), and 13.1 mg eq/kg (oxoisoxazolidinyl-labelled).

In composite (perirenal, subcutaneous, and omental) fat TRR in tissues samples amounted to 4.1 mg eq/kg (methylphenyl-labelled), 5.9 mg eq/kg (halophenyl-labelled), and 9.0 mg eq/kg (oxoisoxazolidinyl-labelled).

In kidney, TRR in tissue samples amounted to 4.1 mg eq/kg (methylphenyl-labelled), 3.9 mg eq/kg (halophenyl-labelled), and 10.0 mg eq/kg (oxoisoxazolidinyl-labelled).

In composite (loin and flank) muscle, TRR in tissues samples amounted to 0.89 mg eq/kg (methylphenyl-labelled), 1.0 mg eq/kg (halophenyl-labelled), and 1.3 mg eq/kg (oxoisoxazolidinyl-labelled).

Extractability of milk, liver, kidney, fat and muscle was very good at > 97 percent, >93 percent, 89 percent, 99, and 97 percent TRR, respectively.

Parent isocycloseram was detected as the most abundant component in all tissues, accounting for 45.7 percent TRR (5.985 mg/kg) in liver, 22.0 TRR (2.197 mg/kg) in kidney, 70.7 percent TRR (0.908 mg/kg) in muscle, 60.4 percent TRR (0.499 mg/kg) in milk and 81.8 percent TRR (7.386 mg/kg) in fat.

No single metabolite accounted for >1.4 percent TRR in fat or milk, except for SYN551475, which was detected at 5.2 percent TRR (0.469 mg/kg) and 6.6 percent TRR (0.055 mg/kg) in fat and milk, respectively.

SYN549436, SYN549544, and SYN550737 were the most abundant metabolites detected in liver (20.5 percent TRR, 2.685 mg/kg, 11.5 percent TRR, 1.506 mg/kg, and 5.8 percent TRR, 0.760 mg/kg respectively) and kidney (19.1 percent TRR and 1.907 mg/kg, 12.6 percent TRR, 1.258 mg/kg, and 4.6 percent TRR, 0.459 mg/kg, respectively). SYN549544 was also detected in the muscle (4.8 percent TRR, 0.062 mg/kg). SYN550402 (4.1 percent TRR, 0.053 mg/kg) and SYN551475 (5.9 percent TRR, 0.076 mg/kg) were abundant in muscle. No tissue unique metabolites were detected.

Laying hens

The metabolism and excretion of [methylphenyl-U-^{14}C]-isocycloseram, [halophenyl-U-^{14}C]-isocycloseram, and [oxoisoxazolidinyl-4,5-^{14}C]-isocycloseram was investigated in laying hens as a model for poultry.

Each radiolabelled test compound was orally administered in a capsule, separately, to six hens at nominal rate of 12 mg eq/kg dietary dry matter, corresponding to 24.0 ppm (dry) (methylphenyl-labelled), 21.9 ppm (dry) (halophenyl-labelled), and 22.1 ppm (dry) (oxoisoxazolidinyl-labelled). The hens received 14 doses at 24-hour intervals and were sacrificed 12 hours after the last dosing. Eggs were collected twice daily. TRR was determined in each daily (pooled) egg white and egg yolk sample; in tissues of muscle (composite breast and leg/thigh), fat (composite skin with fat and peritoneal), and liver; and in excreta and cage wash. Radioactivity in carcasses, GI tract, GI contents, bile, and blood were not measured.

The total recovery of the administered radioactivity was 83.5 percent, 80.1 percent and 81.2 percent or the [methylphenyl-U-14C]-isocycloseram, [halophenyl-U-14C]-isocycloseram and [oxoisoxazolidinyl-4,5-14C]-isocycloseram experiments, respectively.

In egg whites, TRR reached a plateau of 0.25 mg eq/kg following 6 days (methylphenyl-labelled), 0.25 mg eq/kg following 5 days (halophenyl-labelled), and 0.24 mg eq/kg following 5 days (oxoisoxazolidinyl-labelled). In egg yolks, TRR reached a plateau of 13.0 mg eq/kg after 12 days (methylphenyl-labelled), 12.9 mg eq/kg after 12 days (halophenyl-labelled), and 7.9 mg eq/kg after 9 days (oxoisoxazolidinyl-labelled).

In liver, TRR in tissues samples amounted to 6.2 mg eq/kg (methylphenyl-labelled), 7.0 mg eq/kg (halophenyl-labelled), and 4.9 mg eq/kg (oxoisoxazolidinyl-labelled).

In composite (skin and peritoneal) fat, TRR in tissue samples amounted to 4.7 mg eq/kg (methylphenyl-labelled), 5.3 mg eq/kg (halophenyl-labelled), and 2.8 mg eq/kg (oxoisoxazolidinyl-labelled).

In composite (breast and leg) muscle, TRR in tissue samples amounted to 0.79 mg eq/kg (methylphenyl composite (breast and leg) muscle), 0.80 mg eq/kg (halophenyl composite (breast and leg) muscle), and 0.61 mg eq/kg (oxoisoxazolidinyl composite (breast and leg) muscle).

Extractability of muscle, liver, fat, egg whites, and egg yolks was very good at > 96 percent, >94 percent, 93 percent, 97 percent, and 95 percent TRR, respectively.

In egg whites, SYN549544, SYN549436, and SYN549431 were detected as the abundant metabolites accounting for 7.6-16.3 percent TRR (0.02-0.042 mg eq/kg), 9.4-22.6 percent TRR (0.024-0.057 mg eq/kg), and 0-27.2 percent TRR (0-0.07 mg eq/kg) across all radiolabels. Metabolites SYN551479, SYN551583, and SYN551474 were also detected in but were less abundant (<9.0 percent TRR).

In egg yolk, SYN549544, SYN551479, SYN551583 and SYN549431 were detected as the abundant metabolites accounting for 8.3-15.5 percent TRR (1.169-1.361 mg eq/kg), 0-17.0 percent TRR (0-2.3 mg eq/kg), 3.0-10.0 percent TRR (0.411-1.041 mg eq/kg), and 0-27.8 percent TRR (0-3.548 mg eq/kg) across all radiolabels. Metabolites SYN549436, SYN551475, SYN551474, SYN548569, and SYN549543 were also detected in but were less abundant <5.0 percent TRR).

In whole eggs (calculated from residues in egg whites and egg yolks, assuming 60 percent whites and 40 percent yolks), SYN549544, SYN551479, SYN551583 and SYN549431 were detected as the abundant metabolites accounting for 22.0-27.7 percent TRR (1.216-1.635 mg eq/kg), 10.2-13.3 percent TRR (0.485-0.556 mg eq/kg), 6.0-14.4 percent TRR (0.058-0.170 mg eq/kg), and 0-27.3 percent TRR (0-1.497 mg eq/kg) across all radiolabels. Metabolites SYN549436, SYN551475, SYN551474, SYN548569, and SYN549543 were also detected in but were less abundant (<9.0 percent TRR).

In muscle, SYN549431 was detected as the most abundant metabolite at 0-30.2 percent TRR (0-0.240 mg eq/kg). SYN549107, SYN549544, SYN551479, SYN551583, SYN551475, SYN551474, and SYN549543 were also detected but were less abundant (<8.0 percent TRR).

In fat, SYN549431 and SYN551475 were detected as the abundant metabolites accounting for 0-10.5 percent TRR (0-0.500 mg eq/kg) and 14.8-19.1 percent TRR (0.531-0.810 mg eq/kg), respectively. SYN551583, SYN551474, SYN549544, and SYN551479 were also detected but were less abundant (<9.0 percent TRR).

In liver, SYN548569, SYN549544, SYN551583 and SYN549431 were detected as the abundant metabolites accounting for 0-15.6 percent TRR (0-1.090 mg eq/kg), 16.5-26.1 percent TRR (1.270-1.430 mg eq/kg), 6.3-13.8 percent TRR (0.440-0.680 mg eq/kg), and 0-24.5 percent TRR (0-1.559 mg eq/kg) across all radiolabels. Metabolites SYN549543, SYN549107, SYN551479, SYN551475, SYN551474, and SYN549436 were also detected in but were less abundant <9.0 percent TRR).

Animal metabolism summary and conclusions

The metabolism of isocycloseram was evaluated in lactating goats and laying hens.

The distribution and elimination of isocycloseram appeared to be similar in the lactating goat, laying hen, and rat. Radioactivity was consistently observed at highest levels in the liver, followed by lower (rat and goat) or similar (hen) levels in kidney, followed by fat. Muscle incurred the lowest level of radioactivity in the goat and hen. Faeces was the primary route of excretion.

The biotransformation pathway of isocycloseram in ruminants and poultry is well understood and consistent with that observed in the rat.

The metabolite SYN550402 was formed via hydroxylation on the N-ethyl moiety. Subsequent elimination led to the formation of SYN551475. SYN549436 was formed via N-de ethylation. Further metabolism of SYN549436 led to the formation of SYN551583 and SYN549544 via oxidation/rearrangement of the isooxazolidine ring and opening of the isooxazolidine ring, respectively. SYN550737 was formed from parent via isoxazolidine ring opening. De-ethylation also led to the formation of SYN549544. Hydrolysis of the amide bond present in SYN549544 led to the formation of SYN549543. The cleavage of the oxoisoxazolidine ring resulted in the formation of the amide SYN549431.

Hydrolysis of SYN549431 resulted in the formation of the acid metabolite SYN549107 and subsequent formation of the lactone SYN551474. SYN549431 was also metabolized to SYN551479 by oxidation (at methyl group in methylphenyl moiety) and subsequent cyclization. Oxidation of the methylphenyl ring (via an epoxide) to form a catechol and nitrile, followed by hydrolysis of the resulting nitrile led to the formation of the amide, SYN552188, and subsequent retro-aldo reaction formed SYN548569. Cleavage of the isoxazoline ring also resulted in the formation of SYN548569.

Analytical methods

The Meeting received several analytical methods for quantitation of isocycloseram and various metabolites.

Isocycloseram-specific methods are available for the analysis of isocycloseram and relevant metabolites in crop and animal matrices. The QuEChERS multi-residue method is suitable for the determination of isocycloseram and metabolites SYN549431 and SYN548569 in plant commodities (high water, high starch, high oil, high protein, high acid, dry crop). The QuEChERS analytical method is suitable for the determination of isocycloseram and metabolites SYN549431, SYN548569, SYN549436, SYN549544, SYN551583 and SYN551475 in representative animal commodities (poultry egg, poultry muscle, poultry fat, poultry liver, bovine milk, bovine cream, bovine muscle, bovine fat, bovine liver, and bovine kidney). All methods submitted to the Meeting had an LOQ of 0.01 mg/kg.

Storage stability

The Meeting received several studies investigating the stability of isocycloseram, SYN549431, and SYN548569 in various commodities under frozen storage conditions.

Residues of isocycloseram were stable in plants (mean recoveries greater than 70 percent) at all sampling intervals. Therefore, isocycloseram is considered to be stable in diverse crop matrices for a period of at least 24 months at -18°C.

Residues of SYN549431 were stable in plants (mean recoveries greater than 70 percent) at all sampling intervals. Therefore, SYN549431 is considered to be stable in diverse crop matrices for a period of at least 24 months at -18°C.

Isocycloseram is stable in all animal matrices tested for at least 90 days, except for poultry liver where it was only stable until the analysis on day 32. Metabolites SYN549431, SYN551583, and SYN551475 were stable for at least 90 days in all matrices tested. Metabolites SYN549544, and SYN548569 were generally stable for at least 90 days in all matrices tested.

For plants and animals, the storage stability data support the storage durations and conditions of the submitted studies.

Residue definition

Plant commodities

The metabolism of isocycloseram was similar in the submitted crops (foliar: tomato, soya bean, mustard greens, and paddy rice and in-furrow: mustard greens).

Following foliar application, parent isocycloseram was detected in all matrices and accounted for 2.1–98.7 percent TRR across all commodities and radiolabels for foliar treatments and 2.3–44.8 percent TRR in mature and immature mustard greens across all radio labels for in-furrow treatments. SYN549431 was the major metabolite identified in all studies and accounted for 0.7–6.0 percent TRR (food commodities) and 0.7-25 percent (feed commodities) across all commodities and radiolabels for foliar treatments. SYN549431 was also at 7.7 percent TRR in immature mustard greens from the in-furrow application (methylphenyl-labelled only).

Additional low-level metabolites, SYN549543 and SYN549436, were also present in foliar applied mustard greens, each accounting for ≤0.8 percent TRR (≤0.009 mg eq/kg).

In studies on rotational crops reflecting uptake from soil, total radioactive residues generally decreased with increasing PBIs. At PBIs of 30 days, isocycloseram was the predominant residue in most cases, with increasing proportions of the metabolites SYN552188 and/or SYN549431 becoming predominant at longer PHIs. Concentrations of those residues in human foods were low (typically <0.01 mg eq/kg; radish root, 30-day PBI is an exception at 0.059 mg/kg isocycloseram).

In supervised field trials, isocycloseram and SYN549431 were the most frequently detected residues. Residues of SYN549431 were always lower than parent isocycloseram residues and were, on average, <8 percent compared to parent residues. This ratio was consistent across all processed fractions analysed, demonstrating that with respect to parent no significant concentration or changes were observed with processing. Therefore, the Meeting determined that SYN549431 can be considered a minor metabolite.

Residues of SYN548569 were typically not observed above 0.01 mg/kg with limited exceptions in processed commodities.

The Meeting concluded that isocycloseram was a suitable marker for enforcement purposes.

A suitable analytical method using LC-MS/MS is available to determine residues of isocycloseram in plant commodities.

The Meeting recommended the following definition of the residue for compliance with the MRL for plant commodities: *isocycloseram.*

In deciding which compounds should be included in the residue definition for risk assessment for plants, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates: isocycloseram and SYN549431.

The Meeting determined that SYN549431 does not have similar toxicity to parent isocycloseram and is covered by the HBGVs for isocycloseram. The Meeting considered that SYN549431 could be assessed using the threshold of toxicological concern for Cramer Class III compounds of 1.5 µg/kg bw per day.

The estimated exposure based on metabolism studies, resulted in the following maximum long-term exposures:

SYN549431 0.134 µg/kg bw per day.

The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The Meeting concluded that SYN549431 is unlikely to present a dietary exposure concern from the uses evaluated by the current Meeting.

The Meeting recommended the following definition of the residue for dietary risk assessment for plant commodities: *isocycloseram*.

Animal commodities

Regarding the residue definition for animal commodities, the metabolism of isocycloseram in lactating goats and laying hens was qualitatively similar.

In lactating goats, parent isocycloseram was detected as the most abundant component in all animal matrices, accounting for 45.7 percent TRR (5.985 mg/kg) in liver, 22.0 percent TRR (2.197 mg/kg) in kidney, 70.7 percent TRR (0.908 mg/kg) in muscle, 60.4 percent TRR (0.499 mg/kg) in milk and 81.8 percent TRR (7.386 mg/kg) in fat.

In fat and milk, no single metabolite accounted for >1.4 percent TRR in fat or milk, except for SYN551475, which was detected at 5.2 percent TRR (0.469 mg eq/kg) and 6.6 percent TRR (0.055 mg eq/kg) in fat and milk, respectively.

In liver and kidney, SYN549436, SYN549544, and SYN550737 were the most abundant metabolites detected at 20.5 percent TRR, 2.685 mg eq/kg, 11.5 percent TRR, 1.506 mg eq/kg, and 5.8 percent TRR, 0.760 mg eq/kg respectively and 19.1 percent TRR and 1.907 mg eq/kg, 12.6 percent TRR, 1.258 mg eq/kg, and 4.6 percent TRR, 0.459 mg eq/kg, respectively.

In muscle, SYN549544 was also detected at 4.8 percent TRR, 0.062 mg eq/kg and SYN550402 at 4.1 percent TRR, (0.053 mg eq/kg) and SYN551475 at 5.9 percent TRR (0.076 mg eq/kg) were abundant.

No tissue unique metabolites were detected.

In laying hens, parent isocycloseram was detected as the most abundant component across all commodities analysed, accounting for 26.3–34.7 percent TRR (0.163–0.275 mg/kg) in muscle, 8.6–14.8 percent TRR (0.600–0.755 mg/kg) in liver, 45.2-63.7 percent TRR (2.139–2.566 mg/kg) in fat, 21.6–38.5 percent TRR (2.977-3.336 mg/kg) in egg yolks, and 16.6–25.3 percentTRR (0.043-0.066 mg eq/kg)in egg whites.

The Meeting concluded that isocycloseram was a suitable marker for enforcement purposes.

A suitable analytical method using LC-MS/MS is available to determine residues of isocycloseram in animal commodities.

The Meeting recommended the following definition of the residue for compliance with the MRL for animal commodities: *isocycloseram*.

In egg whites, SYN549544, SYN549436, and SYN549431 were detected as the abundant metabolites accounting for 7.6–16.3 percent TRR (0.02–0.042 mg eq/kg), 9.4–22.6 percent TRR (0.024–0.057 mg eq/kg), and 0–27.2 percent TRR (0–0.07 mg eq/kg) across all radiolabels. Metabolites SYN551479, SYN551583, and SYN551474 were also detected in but were less abundant (<9.0 percent TRR).

In egg yolk, SYN549544, SYN551479, SYN551583 and SYN549431 were detected as the abundant metabolites accounting for 8.3–15.5 percent TRR (1.169–1.361 mg eq/kg), 0–17.0 percent TRR (0–2.3 mg eq/kg), 3.0–10.0 percent TRR (0.411–1.041 mg eq/kg), and 0–27.8 percent TRR (0–3.548 mg eq/kg) across all radiolabels. Metabolites SYN549436, SYN551475, SYN551474, SYN548569, and SYN549543 were also detected in but were less abundant <5.0 percent TRR).

In whole eggs (calculated from residues in egg whites and egg yolks, assuming 60 percent whites and 40 percent yolks), SYN549544, SYN551479, SYN551583 and SYN549431 were detected as the abundant metabolites accounting for 22.0–27.7 percent TRR (1.216–1.635 mg eq/kg), 10.2–13.3 percent TRR (0.485-0.556 mg eq/kg), 6.0–14.4 percent TRR (0.058–0.170 mg eq/kg), and 0–27.3 percent TRR (0-1.497 mg eq/kg) across all radiolabels. Metabolites SYN549436, SYN551475, SYN551474, SYN548569, and SYN549543 were also detected in but were less abundant (<9.0 percent TRR).

In muscle, SYN549431 was detected as the most abundant metabolite at 0–30.2 percent TRR (0-0.240 mg eq/kg). SYN549107, SYN549544, SYN551479, SYN551583, SYN551475, SYN551474, and SYN549543 were also detected but were less abundant (<8.0 percent TRR).

In fat, SYN549431 and SYN551475 were detected as the abundant metabolites accounting for 0-10.5 percent TRR (0–0.500 mg eq/kg) and 14.8–19.1 percent TRR (0.531–0.810 mg eq/kg),

respectively. SYN551583, SYN551474, SYN549544, and SYN551479 were also detected but were less abundant (<9.0 percent TRR).

In liver, SYN548569, SYN549544, SYN551583 and SYN549431 were detected as the abundant metabolites accounting for 0–15.6 percent TRR (0–1.090 mg eq/kg), 16.5–26.1 percent TRR (1.270–1.430 mg eq/kg), 6.3-13.8 percent TRR (0.440–0.680 mg eq/kg), and 0–24.5 percent TRR (0-1.559 mg eq/kg) across all radiolabels. Metabolites SYN549543, SYN549107, SYN551479, SYN551475, SYN551474, and SYN549436 were also detected in but were less abundant <9.0 percent TRR).

Animals are also potentially exposed through the diet to residues of parent isocycloseram and SYN549431.

Supervised residue trial data where SYN549431 was analysed indicate negligible residues of SYN549431 in animal feed and as such the livestock dietary burden for SYN549431 is also estimated to be negligible.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates: isocycloseram, SYN549543, SYN548569, SYN549544, SYN549436, SYN550402, SYN550737, SYN550402, SYN549431, SYN551583, SYN551474, SYN551475, SYN551479, SYN548569, and SYN4549107.

Similar toxicity to parent isocycloseram is assumed for the minor metabolites SYN549543, SYN549436, and SYN549544 and it is assumed they are covered by the HBGVs for isocycloseram.

Using estimates of livestock dietary burden for each of the compounds and assuming the same transfer rate to animal commodities as for isocycloseram, the Meeting noted that the metabolites SYN549544 and SYN549436 could make a significant contribution to overall consumer exposure. Residues of SYN549544 were greater than 10 percent TRR relative to parent in almost all tissue samples in the animal metabolism studies. In addition, the Meeting determined that the submitted feeding studies showed residues of SYN549436 were found at similar levels to residues of SYN549544.

The Meeting considered that it was not necessary to include SYN549431 in the residue definition for risk assessment for animal commodities as it was only occasionally detected in the field trials on feed commodities.

The Meeting recommended the following definition of the residue for dietary risk assessment for animal commodities: *isocycloseram and the metabolites* N-[2-amino-1-(hydroxymethyl)-2-oxo-ethyl]-4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-benzamide *and* 4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-N-(3-oxoisoxazolidin-4-yl)benzamide *(expressed as isocycloseram).*

In deciding whether the residue for compliance monitoring is regarded as fat-soluble, the Meeting noted that residue levels in the lactating goat study were 0.908 mg/kg in muscle and 7.386 mg/kg in fat. In addition, comparison between in skim milk and cream in the lactating goat metabolism study showed preference for the cream fraction, with TRR ranging from 0.03 to 0.09

mg eq/kg (methylphenyl-labelled), 0.02 to 0.09 mg eq/kg (halophenyl-labelled), and 0.004–0.23 mg eq/kg (oxoisoxazolidinyl-labelled) in skim milk and 2.7 to 9.8 mg eq/kg (methylphenyl-labelled), 3.07 to 10.5 mg eq/kg (halophenyl-labelled), and 4.5-15.6 mg eq/kg (oxoisoxazolidinyl-labelled) in cream.

In the laying hen metabolism study, residues were 0.275 mg/kg in muscle and 2.566 mg/kg in composite skin and fat and residues were 0.066 mg/kg in egg whites and 3.336 mg/kg in egg yolks.

The Meeting considers the residue should be classified as fat-soluble.

Consideration of metabolites using TTC approach

The Meeting determined that metabolites SYN548569, SYN550402, SYN550737, SYN550402, SYN549431, SYN551583, SYN551474, SYN551475, SYN551479, SYN548569, and SYN4549107 do not have similar toxicity to parent isocycloseram and not are covered by the HBGVs for isocycloseram. The Meeting considered that these metabolites could be assessed using the threshold of toxicological concern for Cramer Class III compounds of 1.5 µg/kg bw per day.

The estimated exposure based on metabolism studies, resulted in the following maximum long-term exposures:

SYN548569 0.0164 µg/kg bw per day,
SYN550402 0.0031 µg/kg bw per day,
SYN550737 0.0094 µg/kg bw per day,
SYN551583 0.0031 µg/kg bw per day,
SYN551474 0.0006 µg/kg bw per day,
SYN551475 0.0006 µg/kg bw per day,
SYN551479 0.0000 µg/kg bw per day,
SYN4549107 0.0000 µg/kg bw per day.

The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The Meeting concluded that SYN548569, SYN550402, SYN550737, SYN550402, SYN549431, SYN551583, SYN551474, SYN551475, SYN551479, SYN548569, and SYN4549107 were unlikely to present a dietary exposure concern from the uses evaluated by the current Meeting.

Results of supervised trials on crops

The Meeting received magnitude of the residue studies for isocycloseram in/on fruits (citrus, pome, and stone), bulb vegetables (onion), brassica vegetable (head brassica and flowerhead brassica), cucurbit, fruiting vegetables (inedible and edible peel), non-cucurbit, fruiting vegetables (tomato, pepper, eggplant), pulses (soya bean), root and tuber vegetables (potato), cereal grains (maize), oilseeds (cotton seed), and seed for beverages and sweets (coffee beans).

Citrus

Supervised residue trials on oranges, grapefruits, lemons, and tangerines were available from the United States.

The cGAP for citrus from Paraguay is two foliar applications at 90 g ai/ha followed by two applications at 30 g ai/ha with a nominal retreatment interval (RTI) of 7 days and a pre-harvest-interval (PHI) of 7 days.

Oranges

In nine independent trials from the United States approximating the cGAP from the Republic of Paraguay, residues of isocycloseram in/on oranges were (n=9): 0.012, 0.034, 0.040, 0.053, 0.064, 0.14, 0.16, 0.17, 0.20 mg/kg (highest individual analytical result 0.221 mg/kg).

The Meeting estimated a maximum residue level of 0.4 mg/kg for subgroup of oranges, sweet, sour (including orange-like hybrids) (FC 0004).

The HR and the STMR are 0.22 mg/kg and 0.064 mg/kg, respectively, based on whole fruit.

Grapefruit

In six independent trials from the United States approximating the cGAP from Paraguay, residues of isocycloseram in/on grapefruits were (n=6): 0.039, 0.045, 0.057, 0.072, 0.079, 0.13 mg/kg (highest individual analytical result 0.146 mg/kg).

The Meeting estimated a maximum residue level of 0.3 mg/kg for Subgroup of Pummelo and Grapefruits (including shaddock-like hybrids, among others grapefruit) (FC 0005).

The HR and the STMR are 0.15 mg/kg and 0.0645 mg/kg, respectively, based on whole fruit.

Lemon

In five independent trials from the United States approximating the cGAP from Paraguay, residues of isocycloseram in/on lemon were (n=5): 0.031, 0.051, 0.052, 0.088, 0.25 mg/kg (highest individual analytical result 0.251 mg/kg).

The Meeting estimated a maximum residue level of 0.5 mg/kg for subgroup of lemons and limes (including citron) (FC 0002).

The HR and the STMR for are 0.25 mg/kg and 0.052 mg/kg, respectively, based on whole fruit.

Mandarin

In four independent trials from the United States approximating the cGAP from Paraguay, residues of isocycloseram in/on mandarin were (n=4): 0.082, 0.12, 0.13, 0.18 mg/kg (highest individual analytical result 0.186 mg/kg).

The Meeting determined that there are insufficient trials on mandarins to estimate a maximum residue level, however, the Meeting has previously reviewed residues in lemons and mandarins and noted that residues in lemons and mandarins are similar and that residues in lemons can be used to support a maximum residue for mandarins.

The Meeting noted that the cGAP covers citrus and that median residues of lemons and mandarins are within a 5-fold difference. The Mann-Whitney test suggests the distributions are similar and the Meeting decided to combine the residues for estimating a maximum residue level.

In nine independent trials approximating the cGAP, residues of isocycloseram in/on lemons and mandarins were (n=9): 0.031, 0.051, 0.052, 0.082, 0.088, 0.116, 0.134, 0.184, 0.245 mg/kg (highest individual analytical result 0.251 mg/kg).

The Meeting estimated a maximum residue level of 0.4 mg/kg for subgroup of mandarins (including mandarin-like hybrids) (FC0003).

The HR and the STMR are 0.25 mg/kg and 0.088 mg/kg, respectively, based on whole fruit.

Pome fruits

Supervised residue trials on apples and pears are available from the United States and Canada.

The cGAP for pome fruit from Paraguay is three foliar applications at 90 g ai/ha with a nominal RTI of 7 days and a PHI of 14 days.

Apples

In 18 independent trials from the United States and Canada approximating the cGAP from Paraguay, residues of isocycloseram in/on apple were (n=18): 0.040, 0.054, 0.064, 0.076, 0.083, 0.092, 0.096, 0.104, 0.107, 0.11, 0.112, 0.114, 0.119, 0.12, 0.131, 0.143, 0.181, 0.20 mg/kg

Pears

In 12 independent trials from the United States and Canada approximating the cGAP from Paraguay, residues of isocycloseram in/on pears were (n=12): 0.052, 0.057, 0.081, 0.098, 0.100, 0.10, 0.119, 0.12, 0.196, 0.207, 0.21, 0.24 mg/kg (highest individual analytical result 0.27 mg/kg).

The Meeting noted that the cGAP covers pome fruits and that median residues of apples and pears are within a 5-fold difference. A Mann-Whitney U-Test demonstrate that populations of apple and pear are not significantly different and therefore can be combined. Combined residues of isocycloseram were (n=30): 0.040, 0.052, 0.054, 0.057, 0.064, 0.076, 0.081, 0.083, 0.092, 0.096, 0.098, 0.10 (3), 0.11 (4), 0.119 (2), 0.12 (2), 0.13, 0.14, 0.18, 0.20 (2), 0.21(2), 0.24 mg/kg (highest individual analytical result 0.27 mg/kg).

The Meeting estimated a maximum residue level of 0.4 mg/kg for the group of pome fruits (FP 0009).

The HR and the STMR for pome fruits are 0.27 mg/kg and 0.105 mg/kg, respectively.

Stone fruits

Cherry

Supervised residue trials on stone fruits (including peach, nectarine, cherry, and apricot) are available from the United States and Canada.

The cGAP for stone fruit from Paraguay is three foliar applications at 90 g ai/ha with a nominal RTI of 7 days and a PHI of 14 days.

Cherry

In 10 independent trials from the United States and Canada approximating the cGAP from Paraguay, residues of isocycloseram in/on cherry were (n=10): 0.20, 0.223, 0.230, 0.27, 0.317, 0.371, 0.38, 0.418, 0.420, 0.62 mg/kg

The Meeting estimated a maximum residue level of 1 mg/kg for subgroup of cherries (FS 0013).

The HR and the STMR are 0.62 mg/kg and 0.344 mg/kg, respectively.

Peach

In 12 independent trials from the United States and Canada approximating the cGAP from Paraguay, residues of isocycloseram in/on peach were (n=12): 0.037, 0.059, 0.060, 0.073, 0.084, 0.087, 0.11 (2), 0.12, 0.14, 0.16, 0.17 mg/kg (highest individual analytical result 0.233 mg/kg).

The Meeting estimated a maximum residue level of 0.3 mg/kg for subgroup of peaches (including Nectarine and Apricots) (FS 2001).

The HR and the STMR are 0.23 mg/kg and 0.0985 mg/kg, respectively.

Plum

In independent trials approximating the cGAP, residues of isocycloseram in/on plum were (n=10): 0.010, 0.017, 0.024, 0.055, 0.056, 0.086, 0.093, 0.11, 0.112, 0.229 mg/kg

The Meeting estimated a maximum residue level of 0.4 mg/kg and for subgroup of plums (including fresh prunes) (FS 0014).

The HR and the STMR are 0.32 mg/kg and 0.071 mg/kg, respectively.

Onion

Supervised residue trials on bulb onions and spring onions were available from the United States and Canada.

The cGAP for bulb onions and chives from Guatemala is three foliar applications at 120 g ai/ha with a nominal RTI of 7 days and a PHI of 7 days.

Bulb onion

In 10 independent trials from the United States and Canada approximating the cGAP from Guatemala, residues of isocycloseram in/on bulb onion were (n=16): <0.01 (10) mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg for onion, bulb (VA 0385).

The HR and the STMR are 0.01 mg/kg.

Head brassica

Supervised residue trials on head cabbage (with and without leaves) and Brussels sprouts were available from the United States.

The cGAP for cabbage and Brussels sprouts from Guatemala is three foliar applications at 60 g ai/ha with a nominal RTI of 7 days and a PHI of 1 day.

In 10 independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram in/on head cabbage with wrapper leaves were (n=10): 0.12, 0.21, 0.28, 0.30, 0.37, 0.41, 0.46, 0.47, 0.67, 2.7 mg/kg.

In 10 independent trials from the United States approximating the cGAP Guatemala, residues of isocycloseram in/on head cabbage without wrapper leaves were (n=10): 0.019, 0.023 (2), 0.030, 0.038, 0.039, 0.069, 0.081, 0.092, 0.86 mg/kg (highest individual analytical result 1.199 mg/kg).

In four ten independent trials from the United States approximating the cGAP Guatemala, residues of isocycloseram in/on Brussels sprouts were (n=4): 0.032, 0.038, 0.11, 0.72 mg/kg.

The Meeting noted that while the cGAP covers head cabbage and Brussels sprouts that median residues of head cabbage (with leaves) and Brussels sprouts are not within a 5-fold difference. The Meeting determined that there is too much variability within the dataset and the group is not sufficiently homogeneous to make a group recommendation.

The Meeting estimated a maximum residue level of 4 mg/kg for cabbages, head (VB 0041).

The HR and the STMR for head cabbage without wrapper leaves (for consumer intake calculations) are 1.2 mg/kg and 0.0385 mg/kg, respectively.

The highest residue and the median residue for head cabbage with wrapper leaves (for livestock dietary burden calculations) are 2.7 mg/kg and 0.574 mg/kg, respectively.

The Meeting estimated a maximum residue level of 2 mg/kg for Brussels sprouts (VB 0402).

The HR and the STMR for Brussels sprouts are 0.81 mg/kg and 0.072 mg/kg, respectively.

Flowerhead brassica

Supervised residue trials for broccoli and cauliflower were available from the United States.

The cGAP for broccoli and cauliflower from Guatemala is three foliar applications at 60 g ai/ha with a nominal RTI of 7 days and a PHI of 1 day.

Broccoli

In 10 independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram were (n=10): 0.089, 0.127, 0.150, 0.155, 0.173, 0.249, 0.262, 0.274, 0.369, 0.405 mg/kg (highest individual analytical result 0.462 mg/kg).

The Meeting estimated a maximum residue level of 0.7 mg/kg for broccoli (VB 0400).

The HR and the STMR are 0.46 mg/kg and 0.211 mg/kg, respectively.

Cauliflower

In 10 independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram were (n=10): 0.01 (2), 0.011, 0.045, 0.050, 0.051, 0.084, 0.168, 0.170, 0.282 mg/kg (highest individual analytical result 0.316 mg/kg).

The Meeting estimated a maximum residue level of 0.5 mg/kg for cauliflower (VB 0404).

The HR and the STMR are 0.32 mg/kg and 0.051 mg/kg, respectively.

Cucurbits – edible peel

Supervised residue trials for cucumbers and summer squash are available from the United States.

The cGAP for cucumber and summer squash from Guatemala is three foliar applications at 60 g ai/ha with a nominal RTI 7 days and a of PHI of 3 days.

Cucumber

In eight independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram in/on cucumber were (n=8): <0.01, 0.013, 0.014, 0.017, 0.031, 0.032, 0.045, 0.056 mg/kg (highest individual analytical result 0.063 mg/kg).

The Meeting estimated a maximum residue level of 0.1 mg/kg for cucumber (VC 0424).

The HR and the STMR are 0.063 mg/kg and 0.024 mg/kg, respectively.

Summer squash

In eight independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram in/on summer squash were (n=8): <0.01 (3), 0.010, 0.013, 0.017, 0.023, 0.060 mg/kg (highest individual analytical result 0.063 mg/kg).

The Meeting estimated a maximum residue level of 0.09 mg/kg for squash, summer (VC 0431).

The HR and the STMR are 0.063 mg/kg and 0.012 mg/kg, respectively.

Cucurbits – inedible peel

Supervised residue trials for melons are available from the United States.

The cGAP for melon from Guatemala is three foliar applications at 60 g ai/ha with a nominal RTI 7 days and a of PHI of 3 days.

Melon

In eight independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram in/on melon were (n=8): <0.01, 0.013, 0.014, 0.017, 0.031, 0.032, 0.045, 0.056 mg/kg (highest individual analytical result 0.078 mg/kg).

The Meeting estimated a maximum residue level of 0.15 mg/kg for melons, except watermelon (VC 0046).

The HR and the STMR are 0.078 mg/kg and 0.024 mg/kg, respectively.

Fruiting vegetables, other than cucurbits

Supervised residue trials for tomatoes, peppers (sweet and chilli), and eggplants are available from the United States.

The cGAP for tomato, pepper (sweet and chilli), and eggplant from Guatemala is three foliar applications at 120 g ai/ha with a nominal RTI of 7 days and a of PHI 1 day.

Tomato

In 16 independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram were (n=16): 0.016, 0.047, 0.054, 0.067, 0.082, 0.086, 0.090, 0.10 (2), 0.11, 0.12, 0.13, 0.16c, 0.22 c, 0.24 c, 0.41 c mg/kg (highest individual analytical result 0.431 mg/kg).

The Meeting estimated a maximum residue level of 0.5 mg/kg for tomato (VO 0448).

The HR and the STMR are 0.43 mg/kg and 0.10 mg/kg, respectively.

Pepper, sweet

In eight independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram were (n=8): 0.037, 0.059, 0.087 (2), 0.10 (2), 0.14 (2) mg/kg (highest individual analytical result 0.180 mg/kg).

The Meeting estimated a maximum residue level of 0.3 mg/kg for the peppers, sweet (VO 0445).

The HR and the STMR are 0.18 mg/kg and 0.0935 mg/kg, respectively.

Pepper, chilli

In eight independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram were (n=8): 0.068, 0.093, 0.14 (2), 0.16, 0.120, 0.30, 0.36 mg/kg (highest individual analytical result 0.395 mg/kg).

The Meeting estimated a maximum residue level of 0.6 mg/kg for peppers, chilli (VO 0444).

The HR and the STMR are 0.40 mg/kg and 0.15 mg/kg, respectively.

Using the default concentration factor of 7 for deriving residues in dried chilli pepper from data on fresh chilli peppers, the Meeting estimated a maximum residue level of 4.2 mg/kg and a HR and a STMR of 2.8 mg/kg and 1.1 mg/kg, respectively for peppers, chilli, dried (HS 0444).

Eggplant

[c] Indicates cherry tomato

In four independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram were (n=4): 0.022, 0.027, 0.035, 0.053 mg/kg.

The Meeting determined that there are insufficient trials on eggplants to estimate a maximum residue level, however, the Meeting has previously reviewed residues in peppers, sweet and eggplants and noted that residues in peppers, sweet and eggplants are similar and that residues in peppers, sweet can be used to support a maximum residue for eggplants.

The Mann-Whitney test suggests the distributions are similar and the Meeting decided to combine the residues for estimating a maximum residue level.

In 12 independent trials approximating the cGAP, residues of isocycloseram in/on peppers, sweet and eggplants were (n=12): 0.022, 0.027, 0.035, 0.037, 0.053, 0.059, 0.087 (2), 0.10 (2), 0.14 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for eggplant (VO 0440).

The HR and the STMR are 0.18 mg/kg and 0.070 mg/kg, respectively.

Soya beans, dry

Supervised residue trials are available from the United States.

The cGAP for soya bean from Paraguay is three foliar applications at 75 g ai/ha with a nominal RTI of 7 days and a PHI of 14 days.

In 21 independent trials from the United States approximating the cGAP from Paraguay, residues of isocycloseram in/on soya beans, dry were (n=21): <0.01, 0.010, 0.012 (2), 0.013, 0.014, 0.016, 0.018, 0.019, 0.020 (2), 0.022, 0.023 (2), 0.024, 0.027, 0.029, 0.046, 0.061, 0.063, 0.099 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for soya bean (dry) (VD 0541).

The STMR is 0.0225 mg/kg, respectively.

Potato

Supervised residue trials on potatoes are available from the United States.

The cGAP for potato from Guatemala is three applications at 60 g ai/ha with a nominal RTI of 7 days and a PHI of 14 days.

In 26 independent trials from the United States approximating the cGAP from Guatemala and at higher (5x) application rates, residues of isocycloseram in/on potatoes were (n=26): <0.01 (26) mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg for potato (VR 0589).

The HR and the STMR are both 0 mg/kg.

Maize and sweet corn

Supervised residue trials are available from the United States.

The cGAP for maize and sweet corn from Guatemala is one in-furrow at-planting application at 150 g ai/ha followed by two foliar applications at 30 g ai/ha at an interval of 7 days and a nominal PHI of 21 days.

In 27 independent trials from the United States approximating the cGAP from Guatemala, residues of isocycloseram in/on maize grain were (n=27): <0.01 (27) mg/kg.

The Meeting estimated a maximum residue level of 0.01 mg/kg for maize (GC 0645).

The STMR is 0.01 mg/kg.

Cotton seed

Supervised residue trials are available from the United States.

The cGAP for cotton from Paraguay is four foliar applications at 75 g ai/ha with a nominal RTI of 7 days and PHI of 14 days.

In 11 independent trials from the United States approximating the cGAP from Paraguay, residues of isocycloseram in/on cotton seed were (n=11): 0.013, 0.060, 0.077 (2), 0.084, 0.11, 0.12 (2), 0.14, 0.23, 0.27 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg for cotton seed (SO 0691).

The STMR is 0.11 mg/kg, respectively.

Coffee bean

Supervised residue trials are available from Brazil.

The cGAP for coffee from Guatemala is three foliar applications at 60 g ai/ha with a nominal RTI of 30 days and a PHI of 40 days.

In 12 independent trials from Brazil approximating the cGAP from Brazil, residues of isocycloseram were (n=12): <0.01 (4), 0.01 (4), 0.02 (4) mg/kg.

The Meeting estimated a maximum residue level of 0.04 mg/kg for coffee bean (SB 0716).

The STMR is 0.01 mg/kg.

Residues in animal feed

Supervised residue trials are available from the United States.

Soya bean

The cGAP for soya bean from Paraguay is three foliar applications at 75 g ai/ha with a nominal RTI of 7 days and PHI of 14 days.

Forage

In 21 independent trials from the United States approximating the cGAP from Paraguay, isocycloseram residues in soya bean forage (as received) were (n=21): 0.75, 0.80, 0.83, 0.90, 0.91, 0.93, 1.2, 1.5, 1.6, 1.7 (2), 1.8, 1.9, 2.1, 2.4, 2.6 (2), 2.8, 2.9, 3.4, 4.8 mg/kg.

The median residue for risk assessment for soya bean forage is 1.7 mg/kg (as received).

The highest residue for risk assessment for soya bean forage is 4.8 mg/kg (as received).

Hay

In independent trials approximating the cGAP, isocycloseram residues in soya bean hay (as received) were (n=21): 1.5, 1.7, 2.1, 3.0, 3.1, 3.7, 3.8, 4.2, 4.3, 4.5 (2), 5.4, 6.7 (2), 6.8, 6.9, 7.8, 8.0, 8.8, 11, 12 mg/kg.

Residues in soya bean hay were adjusted for percent dry matter in the study submissions.

In independent trials approximating the cGAP, isocycloseram residues in soya bean hay were (n=21): 1.8, 2.0, 2.5, 3.5, 3.6, 4.4, 4.5, 4.9, 5.1, 5.3 (2), 6.4, 7.9 (2), 8.0, 8.1, 9.2, 9.4, 10, 13, 14 mg/kg (dw).

The Meeting estimated a maximum residue level of 20 mg/kg (dw) for soya bean, hay and/or straw (AL 0541).

The highest residue and the median residue are 14 mg/kg (dw) and 5.3 mg/kg (dw), respectively.

Maize

The cGAP for maize hay and maize forage from Guatemala is one in-furrow at-planting application at 150 g ai/ha followed by two foliar applications at 30 g ai/ha at an interval of 7 days and a nominal PHI of 21 days.

Forage

In independent trials approximating the cGAP, isocycloseram residues were (n=23): 0.13 (2), 0.16 (2), 0.17 (2), 0.19, 0.21, 0.23 (2), 0.27 (2), 0.30, 0.31, 0.33 (2), 0.35, 0.39, 0.43, 0.44, 0.46, 0.66, 1.6 mg/kg.

The median for risk assessment for maize forage is proposed to be 0.27 mg/kg.

The highest residue for risk assessment for maize forage is 1.6 mg/kg.

Stover

In independent trials approximating the cGAP, isocycloseram residues in maize hay (as received) were (n=27): 0.21, 0.23, 0.27, 0.28, 0.29 (2), 0.30, 0.31, 0.33, 0.35, 0.36 (2), 0.38 (2), 0.40, 0.42, 0.45, 0.47, 0.50, 0.51 (2), 0.53, 0.54, 0.62, 0.63, 0.72, 0.83 mg/kg.

Residues in maize hay were adjusted for percent dry matter in the study submissions.

In independent trials approximating the cGAP, isocycloseram residues were (n=27): 0.25, 0.28, 0.33 (2) 0.35 (2), 0.37 (2), 0.40, 0.42, 0.43 (2), 0.46 (2), 0.48, 0.50, 0.55, 0.57, 0.61 (3), 0.64, 0.65, 0.75 (2), 0.86, 1.0 mg/kg (dw).

The Meeting estimated a maximum residue level of 1.5 mg/kg (dw) for maize, stover (AL 3558).

The highest residue and the median residue for maize stover on a DM base are 1.0 mg/kg and 0.46 mg/kg, respectively.

Cotton gin by-products

The cGAP for cotton from Paraguay is four applications at 75 g ai/ha with a nominal RTI of 7 days and a PHI of 14 days.

In independent trials approximating the cGAP, isocycloseram residues in cotton gin by-products (as received) were (n=3): 1.6, 3.4, 5.0 mg/kg

The Meeting considered the number of trials insufficient for estimating a maximum residue level for cotton gin by-products.

Fate of residues during processing

High temperature hydrolysis

The Meeting received one study evaluating the hydrolytic stability of [halophenyl-U-^{14}C]-isocycloseram under conditions representative of food processing. The study demonstrated that isocycloseram is hydrolytically stable in buffer at pH 4 at a temperature simulating pasteurization (90°C). At pH 5, at a temperature simulating baking/brewing/boiling (100°C), isocycloseram accounted for 95.9 percent of the residue and SYN549431 (0.7 percent AR) and SYN551485 (3.1 percent AR) were found. At pH 6, at a temperature simulating sterilization (120°C), isocycloseram accounted for 79.6 percent of the residue and SYN549431 (0.5 percent AR), SYN551203 (14.1 percent AR) and SYN551485 (4.0 percent AR) were found.

In addition, The Meeting received one study evaluating the hydrolytic stability of [methylphenyl-U-14C]-SYN549106 (S-isomer of SYN549431) under conditions representative of food processing. The study demonstrated that [Methylphenyl-U-^{14}C]-SYN549106 was found to be hydrolytically stable in buffer solutions at pH 4, 5 and 6 at temperatures simulating pasteurization (90°C), baking/brewing/boiling (100°C) and sterilization (120°C), respectively.

Residues in processed commodities

The Meeting studies evaluating the effect of processing on isocycloseram and SYN549431 in citrus, apple, plum, tomato, soya bean, potato, maize, and cotton. Isocycloseram was applied at 3X-5X the cGAP application rate.

Calculated processing factors indicated with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation in these cases is based on the LOQ (0.01 mg/kg) of the analytical method and the residue concentration of the RAC. The STMR-P and median-P values are calculated by multiplying the PF with the RAC STMR or RAC median value.

Raw commodity (STMR)	**Processed commodity**	**Individual processing factors**		**Processing factor (median)**	**STMR-P (mg/kg)**
Isocycloseram					
Orange (0.064 mg/kg)	Peel	2.8	3.9	3.3	0.21
	Pulp, dry	4.4	8.4	6.4	0.41
	Juice	<0.018	0.17	<0.10	0.0064
	Oil	256	127	200	13
	Meal	4.9	9.1	7.0	0.45
	Molasses	0.11	<0.17	0.14	0.0090
	Marmalade	0.14	<0.17	0.16	0.010
Apple (0.105 mg/kg)	Juice	0.06	0.16	0.11	0.012
	Pomace, wet	2.8	1.9	2.4	0.25
	Sauce	<0.02	0.03	<0.02	0.0021
	Canned	<0.02	<0.02	<0.02	0.0021
	Dried	0.02	<0.02	0.02	0.0021
Plum (0.071 mg/kg)	Juice	0.04	<0.05	0.05	0.0036
	Puree	0.14	0.3	0.22	0.016
	Plum, Dried	2.6	3.7	3.1	0.22
Tomato (0.10 mg/kg)	Peeled	<0.03	<0.10	<0.06	0.006
	Juice	0.14	0.15	0.15	0.015
	Canned tomato	<0.03	<0.10	<0.06	0.006
	Pomace, wet	18	13	16	1.6

	Pomace, dry		90		53		72	7.2
	Paste		0.67		0.70		0.68	0.068
	Puree		0.24		0.27		0.25	0.025
	Dried tomato		3.1		3.2		3.2	0.32
Soya Bean, Dry (0.0225 mg/kg)	AFG		370	800	460	560	550	12
	Hulls		3.3	2.8	6.2	6.2	6.2	0.14
	Meal		0.09	0.16	0.11	<0.20	0.20	0.0045
	Flour		0.08	0.14	<0.08	<0.20	0.20	0.0045
	Milk		0.06	0.09	<0.08	<0.20	0.20	0.0045
	Tofu		0.19	0.27	0.24	<0.20	0.20	0.0045
	Soy sauce		<0.03	<0.09	<0.08	<0.20	<0.20	0.0045
	Miso		<0.03	<0.09	<0.08	<0.20	<0.20	0.0045
	Pollard		0.40	0.50	0.51	<0.48	0.48	0.011
	Crude oil		0.83	1.9	0.89	1.1	1.1	0.025
	Refined oil		<0.03	<0.09	<0.08	<0.20	<0.20	0.0045
Cotton Seed (0.11 mg/kg)	SC,DC formulation	Meal	<0.01	<0.03	<0.01	<0.03	<0.02	0.0022
		Hulls	0.06	0.09	0.07	0.09	0.08	0.0088
		Refined oil	<0.01	<0.03	<0.01	<0.03	<0.02	0.0022

The Meeting estimated maximum residue levels of isocycloseram of 80 mg/kg in citrus oil (OR 0001), 3 mg/kg in oranges, dried pulp (AB 0004), 1 mg/kg in apple pomace, wet (AB 1230), 1.5 mg/kg in prune, dried (DF 0014), 8 mg/kg in tomato, pomace (DM 3525), 2 mg/kg in tomato, dried (DV 0448), and 1 mg/kg in soya bean hulls (AL 3533).

The Meeting estimated HR-P values of isocycloseram of 1.4 mg/kg in tomato, dried.

Animal feeding studies

Ruminant

The Meeting received a residue transfer study in cattle was conducted in the United States in 2020. The purpose of this study was to determine the magnitude of residues of isocycloseram and metabolites SYN549431, SYN548569, SYN59436, and SYN549544 in milk and tissues (muscle, fat, kidney, and liver) from lactating dairy cows at three oral dose levels (4.4, 13.2, and 44 ppm) of isocycloseram for a minimum of 28 consecutive days.

In whole milk residues of isocycloseram reached a plateau by day three of dosing.

Residues of isocycloseram in whole milk samples were below the LOQ prior to dosing and ranged from <0.01 to 0.20 mg eq/kg over the course of the dosing period. Residues of SYN549431 in whole milk samples remained below the LOQ throughout the duration of the study.

Residues of isocycloseram in cream samples ranged from 0.015 to 0.29 mg eq/kg over the course of the dosing period. Residues of SYN549431 in cream remained below the LOQ throughout the duration of the study.

Residues of isocycloseram and SYN549431 in skim milk samples remained below the LOQ throughout the duration of the study.

Residues of isocycloseram in muscle samples ranged from <0.01 to 0.026 mg eq/kg. Residues of the metabolite SYN549431 in muscle samples remained below the LOQ throughout the duration of the study.

In perirenal fat samples, parent isocycloseram residues ranged from 0.035 to 0.16 mg eq/kg. Residues of the metabolite SYN549431 remained below the LOQ throughout the duration of the study.

In omental fat samples, parent isocycloseram residues ranged from 0.011 to 0.43 mg eq/kg. Residues of the metabolite SYN549431 remained below the LOQ throughout the duration of the study.

In subcutaneous fat samples, parent isocycloseram residues ranged from <0.01 to 0.065 mg eq/kg. Residues of the metabolite SYN549431 remained below the LOQ throughout the duration of the study.

In liver samples, parent isocycloseram residues were in the range of 0.018–0.23 mg eq/kg, while residues of metabolites SYN549431, SYN548569, SYN549436, and SYN549544 were in the range of 0.011–0.14 mg eq/kg, 0.025–0.23 mg eq/kg, 0.017–0.15 mg eq/kg, and 0.023–0.22 mg eq/kg, respectively.

In kidney samples, parent isocycloseram residues were in the range of <0.01–0.085 mg eq/kg, while residues of metabolites SYN549431, SYN549436, and SYN549544 residues were in the range of <0.01–0.020 mg eq/kg, 0.015–0.21 mg eq/kg, and 0.012–0.12 mg eq/kg, respectively. Residues remained <below the LOQ for SYN548569 throughout the duration of the study.

Poultry

The Meeting residue transfer study in laying hens was conducted in the United States in 2020. The study determined the magnitude of residues of isocycloseram and metabolites SYN549431, SYN549544, SYN551583, SYN551475, and SYN548569 in eggs and tissues (muscle, fat, and liver).

Laying hens were fed diets containing isocycloseram at four feeding levels (0.037, 0.11, 0.36 and 1.7 ppm) for a minimum of 28 consecutive days.

In whole egg residues of isocycloseram reached a plateau between 13 to 16 days.

In whole egg samples, residues of isocycloseram, SYN549431, and SYN549544 ranged from <0.01 to 0.057 mg eq/kg, <0.01–0.034 mg eq/kg, and <0.01–0.013 mg eq/kg, respectively.

In egg white samples, residues of isocycloseram, SYN549431, and SYN549544 remained below the LOQ throughout the duration of the study.

In egg yolk samples, residues of isocycloseram, SYN549431, and SYN549544 ranged from 0.020 to 0.16 mg eq/kg, 0.010 - 0.078 mg eq/kg, and <0.01–0.031 mg eq/kg, respectively.

In muscle samples, residues of isocycloseram ranged from <0.01 to 0.014 mg eq/kg. Residues of the metabolite SYN549431 in muscle samples remained below the LOQ throughout the duration of the study.

In fat samples, residues of isocycloseram, SYN549431, and SYN549544 ranged from <0.01 to 0.16 mg eq/kg, from <0.01 to 0.016 mg eq/kg, and from <0.01 to 0.053 mg eq/kg, respectively.

In liver samples, isocycloseram residues ranged from <0.01 to 0.068 mg eq/kg while residues of metabolites SYN549431, SYN549544, SYN548569, and SYN551583 residues ranged from <0.01 to 0.015 mg eq/kg, from <0.01 to 0.082 mg eq/kg, from <0.01 to 0.040 and from <0.01 to 0.048 mg eq/kg, respectively.

Residues in animal commodities

Farm animal dietary burdens

Those commodities and their input values used in estimating livestock dietary burdens are listed in the Recommendations Tables.

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR by the current Meeting. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarized below.

Residues in animal commodities were estimated for residues of isocycloseram.

	USA-Canada		**EU**		**Australia**		**Japan**	
	Max	**Mean**	**Max**	**Mean**	**Max**	**Mean**	**Max**	**Mean**
Beef cattle	1.381	0.785	6.8	0.154	14.89[1]	0.955[2]	0.024	0.024
Dairy cattle	5.186	0.103	6.108	0.133	9.388	0.923	2.01	0.016
Poultry – broiler	0.014	0.014	0.022	0.022	0.005	0.005	0.01	0.01
Poultry - layer	0.014	0.014	2.567	0.022	0.005	0.005	0.012	0.01

[1] Highest maximum beef or dairy cattle dietary burden used for mammalian milk and tissue MRL calculations.
[2] Highest mean beef or dairy cattle dietary burden used for mammalian milk and tissue STMR estimates.

Cattle

Tissue residue estimates are based on the wort-case dietary burdens from either beef or dairy cattle. Milk residue estimates are based on the dietary burdens for dairy cattle.

Residues were calculated as isocycloseram only for enforcement and for isocycloseram plus the minor metabolites (SYN549543 and SYN549436) which are covered by the HBGVs for isocycloseram in line with the proposed residue definition for risk assessment for mammals.

	Feed level (ppm DM)	Isocycloseram residues4 (mg/kg)				
		Muscle	Fat	Liver	Kidney	Milk3
		Maximum residue levels and estimated HRs in mammals				
Feeding study[1]	13.20	0.010	0.345	0.091	0.026	0.048
	44.00	0.026	0.662	0.230	0.085	0.198
Dietary burden and residue estimate	14.89	0.011	0.362	0.099	0.029	-
	9.388	-	-	-	-	0.042
		Mean residue levels and estimated STMRs in mammals				
Feeding study[2]	4.40	0.010	0.105	0.021	0.010	0.010
Dietary burden and residue estimate	0.955	0.0022	0.024	0.0043	0.0022	-
	0.923	-	-	-	-	0.0021

[1]Highest residues for tissues.
[2]Mean residues for tissues and milk.
[3] Average during plateau phase (day three).
[4]Sum of Isocycloseram, SYN549543 and SYN549436.

	Feed level (ppm DM)	Sum of Isocycloseram, SYN54954 and SYN549436 residues[4] (mg/kg)				
		Muscle	Fat	Liver	Kidney	Milk[3]
		Maximum residue levels and estimated HRs in mammals				
Feeding study[2]	13.20	0.010	0.345	0.243	0.139	0.049
	44.00	0.026	0.662	0.597	0.419	0.205
Dietary burden and residue estimate	14.89	0.011	0.362	0.266	0.154	-
	9.388	-	-	-	-	0.043
		Mean residue levels and estimated STMRs in mammals				
Feeding study[2]	4.40	0.010	0.105	0.064	0.045	0.010
Dietary burden and residue estimate	0.955	0.0022	0.024	0.013	0.011	-
	0.923	-	-	-	-	0.0021

[1]Highest residues for tissues
[2]Mean residues for tissues and milk
[3] Average during plateau phase (day three)
[4]Sum of Isocycloseram, SYN549543 and SYN549436

The Meeting estimated the following maximum residue levels: milk 0.05 mg/kg; meat (mammalian except marine mammals) 0.02 mg/kg; mammalian fat (except milk fat) 0.4 mg/kg and edible offal 0.3 mg/kg.

The Meeting estimated the following HRs: mammalian meat 0.011 mg/kg; mammalian fat 0.37 mg/kg; liver 0.27 mg/kg; kidney 0.16 mg/kg; and milk 0.043 mg/kg and STMRs: mammalian meat 0.0022 mg/kg; mammalian fat 0.024 mg/kg; liver 0.013 mg/kg; kidney 0.011 mg/kg; and milk 0.0021 mg/kg.

Poultry

The Meeting noted that the maximum dietary burden for poultry (2.566) is more than 150 percent max dose rate (1.7) and determined that the study is unsuitable for the estimation of residues levels based on the uses considered by the Meeting.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

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

Definition of the residue for compliance with the MRL for animal commodities: *isocycloseram*.

Definition of the residue for dietary risk assessment for animal commodities: the sum of *isocycloseram and metabolites* N-[2-amino-1-(hydroxymethyl)-2-oxo-ethyl]-4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-benzamide and 4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-*N*-(3-oxoisoxazolidin-4-yl)benzamide (expressed as isocycloseram).

The residue is fat-soluble.

Desirable: a feeding study estimating the dietary burden for poultry.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

c

The ADI for isocycloseram is 0–0.02 mg/kg bw was established by the current JMPR. The IEDIs for isocycloseram were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 1 to 4 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of isocycloseram from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfDs for isocycloseram of 0.5 mg/kg bw (general population) and 0.08 mg/kg bw (child-bearing population) were established by the current JMPR. The IESTIs for isocycloseram were calculated for all commodities and their processed foods for which STMRs and STMR-Ps were estimated by the current Meeting. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs for children varied from 0 to 9 percent of the ARfD and the IESTIs for the general population varied from 0 to 6 percent. The IESTIs varied from 0 to 40 percent of the ARfD for the child-bearing population. The Meeting concluded that acute dietary exposure to residues of isocycloseram from uses considered by the present Meeting is unlikely to present a public health concern.

Consideration of metabolites using TTC approach

The Meeting determined that metabolites SYN549431, SYN548569, SYN550737, SYN550402, SYN551583, SYN551474, SYN551475, SYN551479, and SYN4549107 do not have similar toxicity to parent isocycloseram and not are covered by the HBGVs for isocycloseram. The Meeting considered that these metabolites could be assessed using the threshold of toxicological concern for Cramer Class III compounds of 1.5 µg/kg bw per day.

The estimated exposure based on metabolism studies, resulted in the following maximum long-term exposures:

SYN549431	0.1314 µg/kg bw per day,
SYN548569	0.0164 µg/kg bw per day,
SYN550402	0.0031 µg/kg bw per day,
SYN550737	0.0094 µg/kg bw per day,
SYN551583	0.0031 µg/kg bw per day,
SYN551474	0.0006 µg/kg bw per day,
SYN551475	0.0006 µg/kg bw per day,
SYN551479	0.0000 µg/kg bw per day,
SYN4549107	0.0000 µg/kg bw per day.

The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The Meeting concluded that SYN549431, SYN548569, SYN550402, SYN550737, SYN551583, SYN551474, SYN551475, SYN551479, and SYN4549107 were unlikely to present a dietary exposure concern from the uses evaluated by the current Meeting.

5.21 Isoflucypram (330) (T,R)

TOXICOLOGY

Isoflucypram (BCS-CN88460) is the ISO-approved common name for *N*-(5-chloro-2-isopropylbenzyl)-*N*-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-*1H*-pyrazole-4-carboxamide, with the Chemical Abstracts Service number 1255734-28-1. Isoflucypram is a novel broad-spectrum fungicide. It belongs in the chemical class of *N*-cyclopropyl-*N*-benzylpyrazole carboxamides and it is a succinate dehydrogenase inhibitor.

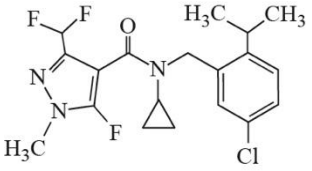
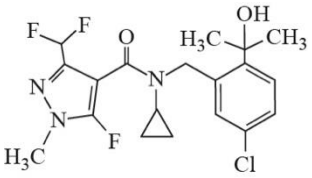
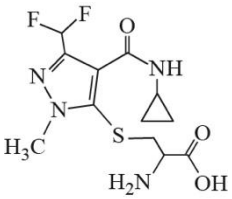
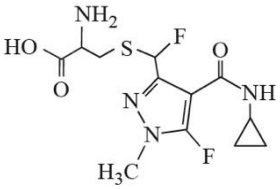
Isoflucypram was evaluated for the first time by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2022, when an ADI of 0–0.06 mg/kg body weight (bw) was established for isoflucypram. An ARfD was considered unnecessary. Dietary risk assessments could not be conducted at JMPR 2022 as the Meeting was unable to recommend residue definitions for dietary risk assessment of plant and animal commodities due to genotoxic prediction for two metabolites. Additional information on these metabolites in the form of quantitative structure–activity relationship (QSAR) analyses of genotoxicity were supplied to the current Meeting by the sponsor. The information included new data on the genotoxicity of several metabolites evaluated at JMPR 2022. As the information provided may affect the dietary risk assessment, isoflucypram was evaluated at the current Meeting. There was no other new information on the toxicology of this compound.

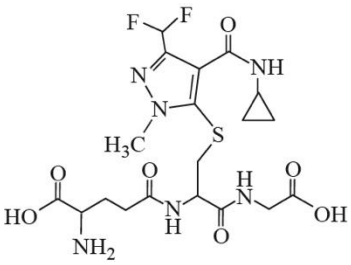
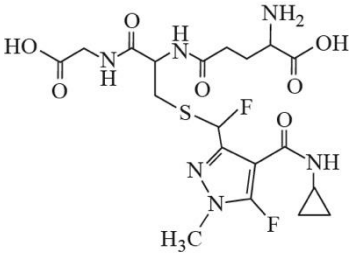
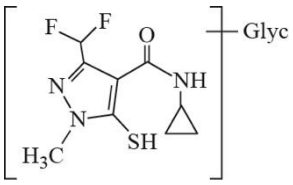
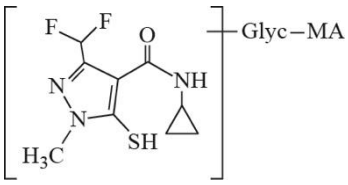
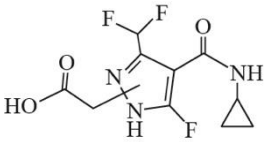
Toxicological data on metabolites and/or degradates

In silico analysis for genotoxic potential was conducted on 12 metabolites of isoflucypram: M02, M44, M45, M46, M47, M48, M52, M54, M55, M56, M57 and M68. The parent and the major rat metabolite M58 were also analyzed for comparison with the other metabolites. The analysis included metabolites with known or partially characterized structures and conjugated metabolites. Metabolites that were not fully structurally characterized were assessed for all their possible structures. Conjugated metabolites were assessed using their respective deconjugated forms. No concern with regard to genotoxic potential was raised for any of the metabolites assessed.

A summary of the toxicological evaluation of metabolites requested for residue definition is shown below in the table below.

Summary of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	**Major rat metabolite** (>10% AD)	**Genotoxicity assessment** (data, QSAR, read-across)	**General toxicity**	**Toxicological reference values**
Isoflucypram (BCS-CN88460) 	Parent	Not genotoxic (data)	Full dataset	ADI: 0–0.06 mg/kg bw ARfD: Unnecessary
M02 Isoflucypram-2-propanol 	No	Not genotoxic in (QSAR and RA)	No data but covered by the parent (Structural similarity)	Parent ADI
M52* Isoflucypram-desfluoro-*N*-methyl-cyclopropyl-pyrazole-carboxamide-OH-Cys **a**  **b** 	No <2% in rat bile	Not genotoxic (QSAR and RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day

M54* Isoflucypram-desfluoro-*N*-methyl-cyclopropyl-pyrazole-carboxamide-OH-GSH **a**  **b** 	No <2% in rat bile	Not genotoxic (QSAR and RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
M56** Isoflucypram-desfluoro-*N*-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc 	Not found in rats	Not genotoxic (QSAR and RA)#	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
M57** Isoflucypram-desfluoro-*N*-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc-MA 	Not found in rats	Not genotoxic (QSAR and RA)	No information	TTC Cramer class III value: 1.5 µg/kg bw per day
M68 Isoflucypram-cyclopropyl-pyrazole-carboxamide-acetic acid 	Not found in rats Structural similarity to M58; a major metabolite in mice, rats, rabbits and dogs	Not genotoxic (QSAR and RA)	No data but covered by the parent (Structural similarity to M58)	Parent ADI

QSAR: Quantitative structure–activity relationship; RA: Read-across; TTC: Threshold of toxicological concern;

ADI: Acceptable daily intake; ARfD: Acute reference dose;

Data from JMPR evaluation in 2022

* Showing the most likely structures of M52 and M54

** As for M56 and M57, three possible chemical structures were not provided, therefore their Markush formats are shown in this table. SMILEs codes of their most likely structures were as follow:

For M56: Cn1nc(C(F)F)c(C(=O)N(C2CC2)C3OC(CO)C(O)C(O)C3O)c1S,
Cn1nc(C(F)F)c(C(=O)NC2CC2)c1SC3OC(CO)C(O)C(O)C3O or
Cn1nc(C(F)F)c(\C(=N/C2CC2)\OC3OC(CO)C(O)C(O)C3O)c1S

For M57: Cn1nc(C(F)F)c(C(=O)N(C2CC2)C3OC(COC(=O)CC(=O)O)C(O)C(O)C3O)c1S,
Cn1nc(C(F)F)c(C(=O)NC2CC2)c1SC3OC(COC(=O)CC(=O)O)C(O)C(O)C3O or
Cn1nc(C(F)F)c(\C(=N/C2CC2)\OC3OC(COC(=O)CC(=O)O)C(O)C(O)C3O)c1S

In silico analysis on genotoxicity of the two possible aglycons was conducted; both aglycons can be the cleavage product of these six possible conjugates.

Toxicological evaluation

The 2022 Meeting established an ADI of 0–0.06 mg/kg bw for isoflucypram based on a NOAEL of 6.27 mg/kg bw per day in the long-term study in rats and applying a safety factor of 100. The current Meeting concluded that the parent ADI applies to M01, M02, M11, M12, M62, M66, M67, M68 and M69.

The 2022 Meeting concluded that it was not necessary to establish an ARfD for isoflucypram and this conclusion applies to all the metabolites assessed at the present Meeting.

An addendum to the toxicological monograph was prepared.

ADI applies to isoflucypram and metabolites M01, M02, M11, M12, M62, M66, M67, M68 and M69, expressed as isoflucypram

0–0.06 mg/kg bw

Acute reference dose (ARfD)

Unnecessary

RESIDUE AND ANALYTICAL ASPECTS

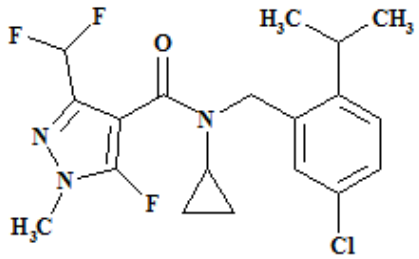
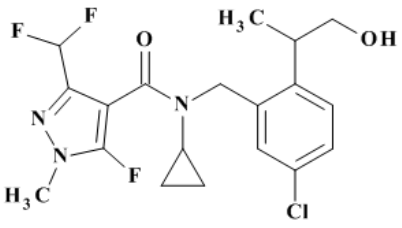
Isoflucypram was first evaluated by the JMPR in 2022. The 2022 Meeting established an ADI of 0—0.06 mg/kg bw/day and determined that an ARfD was unnecessary.

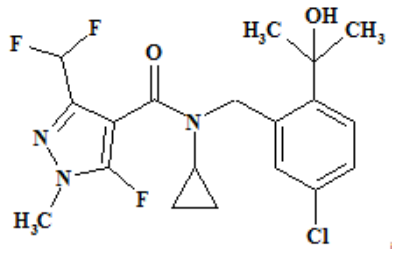
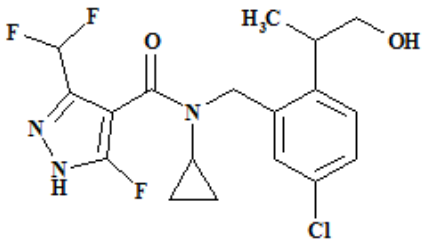
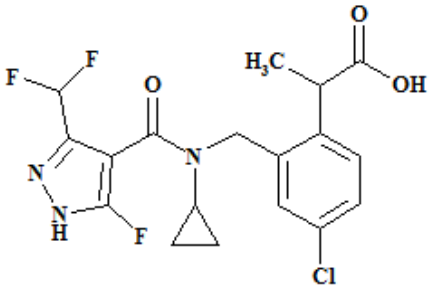
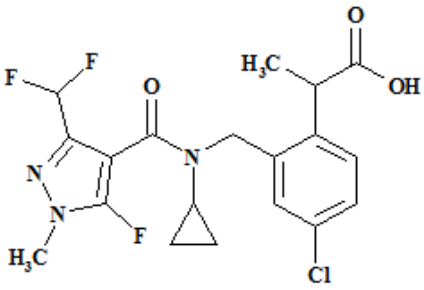
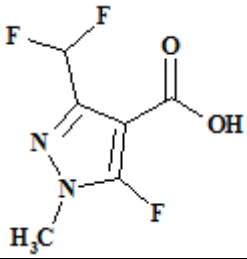
The 2022 Meeting concluded that the residue definition for compliance with MRLs for plant and animal commodities is isoflucypram and the residue definition for animal commodities for dietary risk assessment is the sum of isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, and isoflucypram-desmethyl-carboxylic acid, expressed as isoflucypram. The 2022 Meeting did not reach a conclusion about the residue definition for dietary risk assessment for plants.

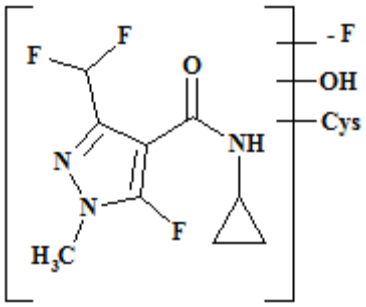
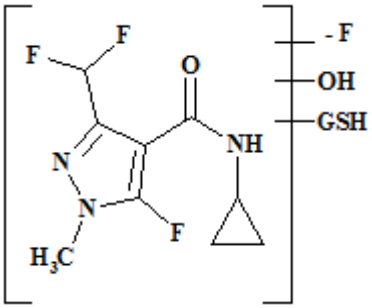
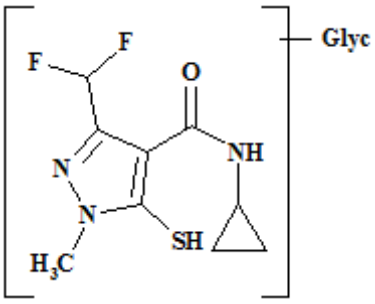
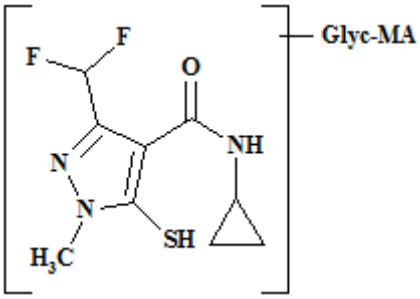
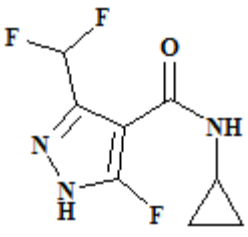
The 2022 Meeting concluded that isoflucypram-desmethyl-propanol (free and conjugated) and isoflucypram-2-propanol (free and conjugated) are assessed using the threshold of toxicological concern (TTC) approach without concern for genotoxicity (Cramer Class III 1.5 µg/kg bw/day).

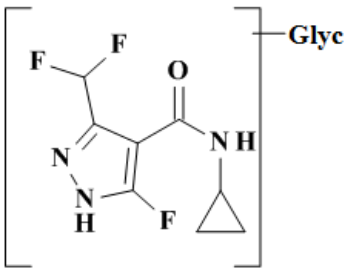
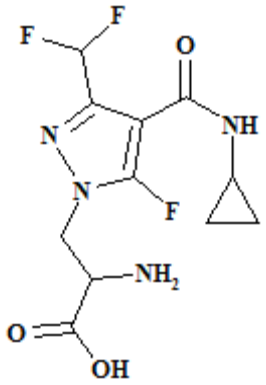
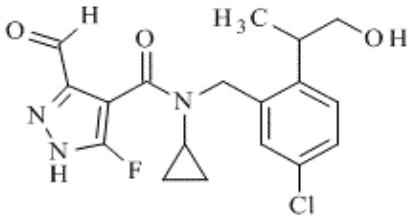
The 2023 Meeting received additional information on the structure of two metabolites observed in the confined rotational crop study, residue analytical methods, and barley processed commodities. The 2023 Meeting reclassified the toxicological assessment for several metabolites.

The chemical structures of isoflucypram and its metabolites/degradates relevant for the appraisal are shown below.

Code Name	Chemical Identity (IUPAC)	Structure
Isoflucypram	N-(5-chloro-2-isopropylbenzyl)-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide	
M01 Isoflucypram-propanol	N-[5-chloro-2-(1-hydroxypropan-2-yl)benzyl]-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazole-4-carboxamide	

Code Name	Chemical Identity (IUPAC)	Structure
M02 Isoflucypram-2-propanol	2-{4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)-methyl]phenyl}propan-2-yl	
M06 Isoflucypram-desmethyl-propanol	N-[5-chloro-2-(1-hydroxypropan-2-yl)benzyl]-N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1H-pyrazole-4-carboxamide	
M11 Isoflucypram-desmethyl-carboxylic acid	2-{4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1H-pyrazol-4-yl]carbonyl}amino)methyl]phenyl}propanoic acid	
M12 Isoflucypram-carboxylic acid	2-{4-chloro-2-[(cyclopropyl{[3-(difluoromethyl)-5-fluoro-1-methyl-1H-pyrazol-4-yl]-carbonyl}amino)-methyl]phenyl}-propanoic acid	
M50 Isoflucypram-N-methyl-pyrazole-carboxylic acid	3-(difluoromethyl)-5-fluoro-1-methyl-pyrazole-4-carboxylic acid	

Code Name	Chemical Identity (IUPAC)	Structure
M52 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-Cys	-	
M54 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-GSH	-	
M56 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc	-	
M57 Isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc-MA	-	
M58 Isoflucypram-cyclopropyl-pyrazole-carboxamide	N-cyclopropyl-3-(difluoromethyl)-5-fluoro-1H-pyrazole-4-carboxamide	

Code Name	Chemical Identity (IUPAC)	Structure
M62 Isoflucypram-cyclopropyl-pyrazole-carboxamide-Glyc (isomer 1 and 2)	-	
M66 Isoflucypram-cyclopropyl-pyrazole-carboxamide-Ala	3-[4-(cyclopropylcarbamoyl)-3-(difluoromethyl)-5-fluoro-1H-pyrazol-1-yl]alanine	
M77 Isoflucypram-desmethyl-propanol-aldehyde	N-[5-chloro-2-(1-hydroxypropan-2-yl)benzyl]-N-cyclopropyl-5-fluoro-3-formyl-1H-pyrazole-4-carboxamide	

Confined rotational crops

The 2022 Meeting evaluated confined rotational crop data for isoflucypram. In the pyrazole study, all identified metabolites contained only the pyrazole ring. Many metabolites shared structural similarities with sugar and/or amino acid conjugates. No extract hydrolysis data were provided. The 2022 Meeting assigned metabolites to one of the following groups based on structural similarities.

- Compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure (*including isoflucypram-cyclopropyl-pyrazole-carboxamide-Ala and isoflucypram-cyclopropyl-pyrazole-carboxamide-Glyc isomers 1 and 2)*
- Compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-OH structure *(including isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-Cys and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-GSH)*

- Compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide-OH structure *(including isoflucypram-cyclopropyl-pyrazole-carboxamide-OH-lactic acid isomers 1 and 2)*
- Compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure *(including isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc-MA)*

The 2023 Meeting received additional information about the structures of M52 and M54 which indicated those two metabolites do not contain the hydroxy adduct as originally concluded.

Due to similarity in structure and toxicological properties, the 2023 Meeting regrouped the metabolites that should be assessed together as follows:

- Compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure (*including isoflucypram-cyclopropyl-pyrazole-carboxamide-Ala and isoflucypram-cyclopropyl-pyrazole-carboxamide-Glyc isomers 1 and 2)*
- Compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide-OH structure *(including isoflucypram-cyclopropyl-pyrazole-carboxamide-OH-lactic acid isomers 1 and 2)*
- Compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure *(including isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc, isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc-MA, isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-Cys, and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-GSH)*

Confined rotational crops summary and conclusions

In the confined rotational crops study, the only metabolites or group of metabolites equal to or greater than 0.010 mg eq/kg in food commodities was the group containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure at a concentration up to 0.010 mg eq/kg in rotational turnip tops and 0.015 mg eq/kg in rotational mature Swiss chard.

In the confined rotational crops study, the only metabolites or groups of metabolites that exceeded 0.050 mg eq/kg in livestock feed items were compounds containing the isoflucypram-cyclopropyl-pyrazole-carboxamide structure at a concentration up to 0.051 mg eq/kg in rotational wheat hay and compounds containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure at concentrations up to 0.052 mg eq/kg in rotational wheat straw.

The Meeting noted that, should a higher cGAP be received in the future, the expectation of residues of the pyrazole metabolites in rotational crops may need to be re-evaluated.

Analytical methods

The Meeting received analytical method description and validation data for Method 01685. The method was successfully validated for the determination of isoflucypram-desmethyl-propanol-aldehyde in tomato fruit, orange fruit, rape seed, bean dry seed, wheat straw, wheat grain, barley grain, and barley processed commodities. The LOQ is 0.01 mg/kg (isoflucypram equivalents) for all matrices tested.

Residue definition

The 2022 Meeting concluded that the residue definition for compliance with MRLs for plant and animal commodities is isoflucypram and the residue definition for animal commodities for dietary risk assessment is the sum of isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, and isoflucypram-desmethyl-carboxylic acid, expressed as isoflucypram.

The 2022 Meeting concluded that could not reach a conclusion for the residue definition for plant commodities for dietary risk assessment or for residues to be included for animal dietary burdens. The 2023 Meeting re-evaluated the data to determine these residue definitions.

Plant commodities

Dietary risk assessment

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates. No metabolites were detected in the tomato, wheat grain, soya bean seed, oilseed rape seed, and potato tuber metabolism studies. Compounds considered were isoflucypram-propanol (free and conjugated) and isoflucypram-desmethyl-propanol (free and conjugated) based on quantifiable residues in the barley and wheat supervised residue trials. Additionally, the Meeting considered the group of metabolites containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure based on residues >0.01 mg eq/kg in the confined rotational crop metabolism study.

Based on toxicological properties, isoflucypram-propanol (free and conjugated) is assumed to be covered by the isoflucypram HBGV. In supervised residue trials matching the cGAP, isoflucypram-propanol (free and conjugated) was quantifiable in cereal grains in three of 39 trials at concentrations of 0.011 (wheat), 0.014 (barley), and 0.019 (wheat) mg eq/kg with corresponding isoflucypram residues of 0.019, <0.01, and <0.01 mg/kg, respectively. Isoflucypram-propanol concentrates in brewer's grain, pearl barley, and barley bran by factors of 1.1x, 1.8x, and 2.1x, respectively. The Meeting concluded that free/conjugated isoflucypram-propanol should be considered in the residue definition for dietary risk assessment.

The Meeting concluded that isoflucypram-desmethyl-propanol (free and conjugated) could be assessed using the TTC approach without concern for genotoxicity (Cramer Class III 1.5 µg/kg bw/day).

The Meeting concluded that the metabolites containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure could be assessed using the TTC approach without concern for genotoxicity (Cramer Class III 1.5 µg/kg bw/day).

The Meeting therefore concluded that for plants, the residue definition for dietary risk assessment is the sum of isoflucypram and free/conjugated isoflucypram-propanol, expressed as isoflucypram.

Animal commodities

The 2023 Meeting reclassified isoflucypram-2-propanol (free and conjugated) as covered by the isoflucypram HBGV. In the metabolism studies, the sum of isoflucypram-2-propanol and its GlucA conjugate accounted for 5.0—20.3 percent TRR (correlating to 29—470 percent the concentration of parent isoflucypram) in ruminant matrices and was not detected in poultry matrices. In the ruminant feeding study, isoflucypram-2-propanol (free) was recovered at 0.009 mg eq/kg in in the high-dose (47.13 ppm) cream fraction and isoflucypram-2-propanol (free and conjugated) was recovered in the mid- (15.54 ppm) and high-dose (48.13 ppm) liver fractions at concentrations of 0.027 and 0.069 mg eq/kg, respectively. Isoflucypram-2-propanol was not quantifiable in the poultry feeding study. The Meeting concluded that free/conjugated isoflucypram-2-propanol should be considered in the residue definition for dietary risk assessment.

The Meeting therefore concluded that for animal commodities, the residue definition for dietary risk assessment is the sum of isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated), expressed as isoflucypram.

<u>Animal Dietary Burden (Cereal hay and straw)</u>

For construction of animal dietary burdens, the Meeting considered residues observed in animal commodities or residues that potentially convert to residues observed in animal commodities.

For hay and straw of cereal crops, the Meeting noted that the metabolite isoflucypram-propanol (free and conjugated) was a prominent residue in the hydrolysed extract in the wheat hay and straw metabolism studies, accounting for 42.8—50.2 percent of the concentration of parent isoflucypram in wheat hay and 15.7—20.9 percent of the concentration of parent isoflucypram in wheat straw. In supervised residue trials matching the cGAP, most barley and wheat hay and straw samples contained quantifiable residues of isoflucypram-propanol (free and conjugated). The Meeting concluded that free/conjugated isoflucypram-propanol should be considered in the animal dietary burdens.

In supervised residue trials matching the cGAP, most barley and wheat hay and straw samples contained quantifiable residues of isoflucypram-desmethyl-propanol (free and conjugated). The Meeting concluded that isoflucypram-desmethyl-propanol (free and

conjugated) could be assessed using the TTC approach without concern for genotoxicity (Cramer Class III 1.5 µg/kg bw/day).

The Meeting therefore concluded that for cereal hay and straw, the residues to be included for dietary burden calculation are the sum of isoflucypram and isoflucypram-propanol (free and conjugated), expressed as isoflucypram.

As soya bean feed items followed a different metabolic pathway than for cereal grains, The Meeting concluded that the residues to be considered for animal dietary burdens would be re-evaluated if uses were to expand to soya beans. The Meeting noted that hydrolysis data for the soya bean extracts would be informative for concluding whether or not the metabolites observed in soya bean feeds are of interest for animal dietary burden calculations.

Conclusion

Based on the above, the 2023 Meeting recommended the following additional residue definitions for isoflucypram:

Definition of the residue for dietary risk assessment for plant commodities: *Sum of isoflucypram and isoflucypram-propanol (free and conjugated), expressed as isoflucypram*.

Definition of the residue for dietary risk assessment for animal commodities: *Sum of isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated), expressed as isoflucypram.*

Residues to be include for calculation of dietary burdens (cereal hay and straw): *Sum of isoflucypram and isoflucypram-propanol (free and conjugated), expressed as isoflucypram.*

Results of supervised trials on crops

The Meeting received supervised field trial data to support isoflucypram uses on wheat and barley.

In this appraisal, the following residue summaries are given:

- *Isoflucypram:* For maximum residue level estimation in plant and animal commodities (grain, hay, and straw)
- *Sum of isoflucypram and isoflucypram-propanol (free and conjugated)*: For dietary risk assessment calculations (grain, hay, and straw)
- *Isoflucypram-desmethyl-propanol (free and conjugated):* For isoflucypram-desmethyl-propanol TTC approach (grain)
- *Sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated):* For dietary burdens for isoflucypram-desmethyl-propanol TTC approach (grain, hay, and straw).

All metabolites are expressed in parent equivalents in the following text. Therefore, no conversion factors are needed.

Cereal grains

Supervised residue trials are available from multiple European countries and New Zealand.

Barley

The cGAP for barley grain from New Zealand is one application at 75 g ai/ha up to BBCH 61 (56-day pre-harvest interval (PHI)).

In independent trials approximating the cGAP, residues of isoflucypram were (n=21): <0.010(19), 0.013, and 0.10 mg/kg.

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) were (n=10): <0.020(8), 0.023, and 0.024 mg eq/kg.

In independent trials approximating the cGAP, residues of isoflucypram-desmethyl-propanol (free and conjugated) were (n=10): <0.010(4), 0.011, 0.012, 0.014, 0.018, 0.019, and 0.029 mg eq/kg.

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) were (n=10): <0.020(4), 0.021, 0.022, 0.024, 0.028, 0.032, and 0.039 mg eq/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg for barley grain. The Meeting estimated a median value for animal dietary burdens for maximum residue level calculation of 0.010 mg/kg (isoflucypram only).

The Meeting estimated a supervised trial median residue (STMR) value for dietary risk assessment and for animal dietary burden calculations for dietary risk assessment of 0.020 mg eq/kg (isoflucypram and free/conjugated isoflucypram-propanol).

The Meeting estimated a median value for isoflucypram-desmethyl-propanol TTC assessment of 0.012 mg eq/kg (free/conjugated isoflucypram-desmethyl-propanol only).

The Meeting estimated a median value for animal dietary burdens to isoflucypram-desmethyl-propanol TTC assessment of 0.022 mg/kg (sum of isoflucypram and free/conjugated isoflucypram-desmethyl-propanol).

Wheat

The cGAP for wheat grain from New Zealand is one application at 75 g ai/ha up to BBCH 69 (42-day PHI).

In independent trials approximating the cGAP, residues of isoflucypram were (n=42): <0.010(39), 0.015, 0.019, and 0.042 mg/kg.

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) were (n=29): <0.020(26), 0.025, 0.029, 0.030 mg eq/kg.

In independent trials approximating the cGAP, residues of isoflucypram-desmethyl-propanol (free and conjugated) were (n=29): <0.010(29) mg eq/kg.

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) were (n=29): <0.020(27), 0.025, and 0.029 mg eq/kg.

The Meeting estimated a maximum residue level for wheat grain of 0.05 mg/kg. The Meeting estimated a median value for animal dietary burdens for maximum residue level calculation of 0.010 mg/kg (isoflucypram only).

The Meeting estimated an STMR value for dietary risk assessment and for animal dietary burden calculations for dietary risk assessment of 0.020 mg eq/kg (isoflucypram and free/conjugated isoflucypram-propanol).

The Meeting estimated a median value for isoflucypram-desmethyl-propanol TTC assessment of 0.010 mg eq/kg (free/conjugated isoflucypram-desmethyl-propanol only).

The Meeting estimated a median value for animal dietary burdens to isoflucypram-desmethyl-propanol TTC assessment of 0.020 mg eq/kg (sum of isoflucypram and free/conjugated isoflucypram-desmethyl-propanol).

As the use pattern covers triticale, the Meeting decided to extrapolate the wheat grain maximum residue level, median residue level, and STMR to triticale.

Residues in animal feed

Supervised residue trials are available from multiple European countries and New Zealand.

The barley and wheat supervised residue trials included residue data on commodities defined as “forage” and “green material.”

The Meeting noted that the percent dry matter in these samples collected at the cGAP PHI ranged from 29 to 91 percent for wheat and from 43 to 85 percent for barley, well above what the Meeting considers forage. Further, the BBCH growth stages for wheat and barley crops were 75—89, which is more closely related to the growth stage for hay (BBCH 40-85) than for forage (up to BBCH 30). The Meeting therefore considers this crop hay as opposed to forage.

Barley, hay and/or straw

Barley hay

The cGAP for barley hay from New Zealand is one application at 75 g ai/ha up to BBCH 61 (42-day PHI).

Residues in barley hay were adjusted for percent dry matter in the study submissions.

In independent trials approximating the cGAP, isoflucypram residues were (n=8): 0.094, 0.11, 0.24, 0.32 (2), 0.37, 0.48, and 0.51 and mg/kg (dw).

In independent trials at ca 1.5X the cGAP application rate, isoflucypram residues were (n=2): 0.23 and 0.14 mg/kg (dw).

Isoflucypram residues proportioned (factors of 0.65-1.0X) to the cGAP application rate were (n=10): 0.094, 0.097, 0.11, 0.15, 0.24, 0.32(2), 0.37, 0.47, and 0.50 mg/kg (dw).

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) were (n=4): 0.20, 0.46, 0.61, and 0.88 mg eq/kg (dw).

In independent trials at ca 1.5X the cGAP application rate, residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) were (n=2): 0.64 and 1.0 mg eq/kg (dw).

Residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) proportioned (factors of 0.65-1.0X) to the cGAP application rate were (n=6): 0.20, 0.45, 0.46, 0.61, 0.67, and 0.88 mg eq/kg (dw).

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) were (n=4): 0.15, 0.35, 0.44, and 0.57 mg eq/kg (dw).

In independent trials at ca 1.5X the cGAP application rate, residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) were (n=2): 0.28 and 0.42 mg eq/kg (dw).

Residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) proportioned (factors of 0.65-1.0X) to the cGAP application rate were (n=6): 0.15, 0.20, 0.27, 0.35, 0.44, and 0.57 mg eq/kg (dw).

Barley straw

The cGAP for barley straw/stubble from New Zealand is one application at 75 g ai/ha up to BBCH 61 (56-day PHI).

Residues in barley straw were adjusted for percent dry matter. For some trials, percent dry matter was reported and residues were corrected in the study submissions. For all other trials, a percent dry matter of 89 percent was assumed and corrected by the Meeting.

In independent trials approximating the cGAP, residues of isoflucypram were (n=20): 0.055, 0.088, 0.16, 0.18(3), 0.22, 0.26, 0.27(3), 0.33, 0.36, 0.38, 0.45, 0.46, 0.69, 0.96, 1.1(2) mg/kg (dw).

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) were (n=10): 0.43, 0.44(2), 0.54, 0.64, 0.76, 0.84, 0.87, and 1.3(2) mg eq/kg (dw).

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) were (n=10): 0.23, 0.32(2), 0.36(2), 0.40, 0.48, 0.49, 0.80, and 1.0 mg eq/kg (dw).

Barley hay and straw conclusions

The following recommendations are for the higher of hay and straw data.

For animal dietary burdens for maximum residue level estimation, residues of isoflucypram only are considered. The Meeting estimated a median residue of 0.28 mg/kg and a highest residue of 1.1 mg/kg for barley hay and straw.

For animal dietary burdens for dietary risk assessment, the sum of isoflucypram and free/conjugated isoflucypram-propanol are considered. The Meeting estimated a median residue of 0.70 mg eq/kg for barley hay and straw.

For animal dietary burdens for the free/conjugated isoflucypram-desmethyl-propanol TTC dietary risk assessment, the sum of isoflucypram and free/conjugated isoflucypram-desmethyl-propanol are considered. The Meeting estimated a median residue of 0.38 mg eq/kg for barley hay and straw.

Wheat, hay and/or straw

Wheat hay

The cGAP for wheat hay from New Zealand is one application at 75 g ai/ha up to BBCH 69 (28-day PHI).

Residues in wheat hay were adjusted for percent dry matter. For 34 of the trials conducted according to cGAP, percent dry matter was reported and residues were corrected by the Meeting. For the remaining eight trials, percent dry matter was not reported. A percent dry matter of 54 percent was assumed and corrected by the Meeting, based on the average percent dry matter from the 34 trials above.

In independent trials approximating the cGAP, isoflucypram residues were (n=42): <0.010, 0.14(2), 0.16, 0.17, 0.19(2), 0.20(2), 0.22, 0.26, 0.29(2), 0.31(2), 0.33(3), 0.36, 0.38, 0.41, 0.44, 0.50, 0.62, 0.86, 0.90, 0.91, 0.95, 1.1(3), 1.2(4), 1.3(2), 1.5(3), 1.7, and 3.3 mg/kg (dw).

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) were (n=15): 0.24, 0.25, 0.29, 0.31, 0.50, 0.55, 0.72, 1.1, 1.2, 1.3, 1.4, 1.5, 1.7, 2.6, and 3.6 mg eq/kg (dw).

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) for TTC dietary burdens were (n=15): 0.17, 0.22, 0.26, 0.31, 0.39, 0.44, 0.49, 0.57, 1.0, 1.1, 1.2(2), 1.3, 1.9, and 3.4 mg eq/kg (dw).

Wheat straw

The cGAP for wheat straw/stubble from New Zealand is one application at 75 g ai/ha up to BBCH 69 (42-day PHI).

Residues in wheat straw were adjusted for percent dry matter. For some trials, percent dry matter was reported and residues were corrected in the study submissions. For all other trials, a percent dry matter of 88 percent was assumed and corrected by the Meeting.

In independent trials approximating the cGAP, residues of isoflucypram were (n=37): <0.010, 0.061, 0.081, 0.13, 0.14(3), 0.17, 0.22, 0.25(2), 0.27, 0.32, 0.35, 0.43, 0.44, 0.45, 0.47, 0.55, 0.60, 0.73, 0.93, 1.1, 1.3(2), 1.4, 1.5, 1.6(3), 1.8(2), 1.9, 2.2(2), 2.7, and 3.6 mg/kg (dw).

In independent trials approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-propanol (free and conjugated) were (n=27): <0.020, 0.12, 0.21, 0.23, 0.25(2), 0.27, 0.44, 0.45, 0.50, 0.53, 0.58, 0.60, 0.65, 0.86(2), 1.1, 1.5, 1.6, 1.7, 2.1(3), 2.2(2), 3.1, and 3.9 mg eq/kg (dw).

In independent trial approximating the cGAP, residues of the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) were (n=27): <0.020, 0.078, 0.11, 0.23(2), 0.25, 0.28, 0.30, 0.34, 0.38, 0.43, 0.47, 0.50(2), 0.59, 0.66, 0.95, 1.3, 1.4, 1.6(2), 1.7, 1.8, 1.9(2), 2.8, and 3.8 mg eq/kg (dw).

Wheat hay and straw conclusions

The following recommendations are for the higher of hay and straw data.

For animal dietary burdens for maximum residue level estimation, residues of isoflucypram only are considered. The Meeting estimated a median residue of 0.55 mg/kg and a highest residue of 3.6 mg/kg for wheat hay and straw.

For animal dietary burdens for dietary risk assessment, the sum of isoflucypram and free/conjugated isoflucypram-propanol are considered. The Meeting estimated a median residue of 1.1 mg eq/kg for wheat hay and straw.

For animal dietary burdens for the free/conjugated isoflucypram-desmethyl-propanol TTC dietary risk assessment, the sum of isoflucypram and free/conjugated isoflucypram-desmethyl-propanol are considered. The Meeting estimated a median residue of 0.57 mg eq/kg for wheat hay and straw.

Barley and wheat hay and straw conclusions

'Barley hay and straw' and 'wheat hay and straw', as commodities moving in trade, may not always be readily distinguishable from each other. Consequently, the Meeting considered it

preferable that the two commodities have the same Codex MRL. The Meeting agreed to use the wheat straw data (dw) for the maximum residue level estimation for both 'barley hay and/or straw (dw)' and 'wheat hay and/or straw (dw)'.

The Meeting estimated a maximum residue level of 5 mg/kg for isoflucypram in/on wheat hay and/or straw (dw), and barley hay and/or straw (dw).

As the use pattern covers triticale hay and straw, the Meeting decided to extrapolate the estimated maximum residue level, median residue levels, and highest residue levels from wheat hay and straw to triticale hay and straw.

Fate of residues during processing

Residues in processed commodities

The 2022 and 2023 Meetings studies received evaluating the effect of processing on isoflucypram, isoflucypram-propanol, isoflucypram-desmethyl-propanol, and isoflucypram-desmethyl-propanol-aldehyde in wheat and barley. Isoflucypram was applied at 4X-5X the cGAP application rate.

Calculated processing factors indicated with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation in these cases is based on the LOQ (0.01 mg/kg) of the analytical method and the residue concentration of the RAC. The STMR-P and median-P values are calculated by multiplying the PF with the RAC STMR or RAC median value.

All residues of isoflucypram-desmethyl-propanol-aldehyde in RAC and processed commodity samples were <LOQ. Therefore, isoflucypram-desmethyl-propanol-aldehyde residues are excluded from Table 1.

For each barley processed fraction, residues of parent isoflucypram, isoflucypram-propanol, and isoflucypram-desmethyl-propanol either all concentrated in the processed fraction or all decreased in the processed fraction; therefore, the Meeting concluded that no interconversion of analytes occurred during processing.

Table 1. Processing factors for isoflucypram, isoflucypram-propanol, and isoflucypram-desmethyl-propanol

Raw Commodity (STMR)	Processed Commodity	Individual Processing Factors	Processing Factor (Median)	STMR-P or Median-P = $STMR_{RAC}$ or $Median_{RAC}$ X PF (mg eq/kg)	Reference(s)
Isoflucypram					
Barley grain (0.010 mg/kg)	Brewer's grain	<0.67, 1.7, 1.8	1.7	Median: 0.017	15-3407 E20PR001-01
	Beer	<0.67, <0.061, <0.16	<0.16	0.0016	15-3407 E20PR001-01
	Pearl Barley	<0.67, 0.088, <0.16	<0.16	0.0016	15-3407 E20PR001-01
	Flour	1.8, 1.5	1.7	0.017	E20PR001-01
	Bran	4.9, 3.7	4.3	Median: 0.043	E20PR001-01
Wheat grain (0.010 mg/kg)	Bran	1.2	1.2	0.012	15-3407

Raw Commodity (STMR)	Processed Commodity	Individual Processing Factors	Processing Factor (Median)	STMR-P or Median-P = $STMR_{RAC}$ or $Median_{RAC}$ X PF (mg eq/kg)	Reference(s)
	Germ	1.1	1.1	0.011	15-3407
	AGF	148	148	Median: 1.5	15-3407
	Gluten	0.94	0.94	0.0094	15-3407
Isoflucypram-propanol					
Barley grain (0.010 mg eq/kg)	Brewer's grain (dried)	0.96, 1.3	1.1	Median: 0.011	E20PR001-01
	Beer	<0.20, <1.0	0.60	0.0060	E20PR001-01
	Pearl barley	<0.20, <1.0	0.60	0.0060	E20PR001-01
	Flour	1.9, 1.6	1.8	0.018	E20PR001-01
	Bran	0.45, 3.8	2.1	Median: 0.021	E20PR001-01
Isoflucypram-desmethyl-propanol					
Barley grain (0.012)	Brewer's grain (dried)	1.7, 1.7	1.7	Median: 0.020	E20PR001-01
	Beer	<0.16, <0.44	0.60	0.0072	E20PR001-01
	Pearl barley	0.23, <0.46	0.35	0.0042	E20PR001-01
	Flour	2.0, 2.2	2.1	0.025	E20PR001-01
	Bran	2.9, 3.0	3.0	Median: 0.036	E20PR001-01

The Meeting estimated maximum residue levels of 0.02 mg/kg in barley flour, 0.05 mg/kg in barley bran, and 0.015 mg/kg in wheat germ and wheat bran.

The Meeting estimated STMR-P values of 0.035 mg eq/kg for barley flour and 0.0076 mg eq/kg for beer and pearl barley (sum of isoflucypram and free/conjugated isoflucypram-propanol).

For animal dietary burden calculation for maximum residue levels, the Meeting estimated median-P values of 1.5 mg/kg for AGF, 0.043 mg/kg for barley bran, 0.017 mg/kg for barley brewer's grain, 0.0094 mg/kg for wheat gluten, and 0.011 mg/kg for wheat milled byproducts (isoflucypram).

For animal dietary burden calculation for dietary risk assessment, the Meeting estimated median-P values of 0.064 mg eq/kg for barley bran and 0.028 mg eq/kg for barley brewer's grain (sum of isoflucypram and free/conjugated isoflucypram-propanol).

For isoflucypram-desmethyl-propanol TTC assessment, the Meeting estimated median-P values of 0.025 mg eq/kg for barley flour, 0.0072 mg eq/kg for beer, and 0.0042 mg eq/kg for pearl barley (free/conjugated isoflucypram-desmethyl-propanol only).

For dietary burdens for the isoflucypram-desmethyl-propanol TTC assessment, the Meeting estimated median-P values of 0.079 mg eq/kg for barley bran and 0.037 mg eq/kg for brewer's grain (sum of isoflucypram and free/conjugated isoflucypram-desmethyl-propanol).

Residues in animal commodities

Farm animal dietary burdens

Dietary burdens were calculated for beef cattle, dairy cattle, broilers, and laying poultry based on feed items evaluated by the JMPR by the current Meeting. The dietary burdens, estimated using the most recent version of the OECD livestock dietary burden calculator, are presented in Annex 6 and summarized below.[17]

Separate dietary burdens were calculated for:

- Isoflucypram for maximum residue level estimation in animal commodities (Table 2)
- Sum of isoflucypram and isoflucypram-propanol (free and conjugated) for dietary risk assessment to animal commodities (Table 3)
- Sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) for isoflucypram-desmethyl-propanol TTC approach (Table 4).

Table 2. Animal dietary burden for maximum residue level calculation

	Livestock dietary burden, isoflucypram, ppm of dry matter diet			
	Japan	US-Canada	EU	Australia
	Max	Max	Max	Max
Beef cattle	0.019	0.64	0.84	3.6[a]
Dairy cattle	0.015	0.73	0.84	2.5[b]
Poultry – broiler	0.002	0.015	0.013	0.012
Poultry – layer	0.006	0.012	0.37[c]	0.009

[a] Highest maximum beef cattle dietary burden suitable for maximum residue level estimates for mammalian tissues.
[b] Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk.
[c] Highest maximum poultry dietary burden suitable for maximum residue estimates for poultry eggs and tissues.

Table 3. Animal dietary burden for dietary risk assessment

	Livestock dietary burden, sum of isoflucypram and isoflucypram-propanol (free and conjugated), ppm of dry matter diet			
	Japan	US-Canada	EU	Australia
	Mean	Mean	Mean	Mean
Beef cattle	0.031	0.18	0.31	1.1[a]
Dairy cattle	0.021	0.23	0.30	0.78[b]
Poultry – broiler	0.002	0.023	0.019	0.016
Poultry – layer	0.004	0.017	0.13[c]	0.012

[a] Highest mean beef cattle dietary burden suitable for STMR estimates in mammalian tissues.
[b] Highest mean dairy cattle dietary burden suitable for STMR estimates in milk.
[c] Highest mean poultry dietary burden suitable for STMR estimates in eggs and poultry tissues.

Table 4. Animal dietary burden for isoflucypram-desmethyl-propanol (free and conjugated) TTC approach

	Livestock dietary burden, sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated), ppm of dry matter diet			
	Japan	US-Canada	EU	Australia
	Mean	Mean	Mean	Mean
Beef cattle	0.038	0.098	0.17	0.57[a]
Dairy cattle	0.026	0.13	0.17	0.41[b]
Poultry – broiler	0.003	0.026	0.022	0.016

[17] http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/

Poultry – layer	0.004	0.019	0.081[c]	0.013

[a] Highest mean beef cattle dietary burden suitable for isoflucypram-desmethyl-propanol (free and conjugated) TTC approach for mammalian tissues.
[b] Highest mean dairy cattle dietary burden suitable for isoflucypram-desmethyl-propanol (free and conjugated) TTC approach for milk.
[c] Highest mean poultry dietary burden suitable for isoflucypram-desmethyl-propanol (free and conjugated) TTC approach for eggs and poultry tissues.

Animal commodity estimations of maximum residue levels and dietary risk assessment

Mammals (other than marine mammals)

The isoflucypram maximum dietary burdens for beef cattle and dairy cattle are 3.6 and 2.5 ppm, respectively.

Table 5 shows the anticipated isoflucypram residues in beef and dairy cattle for maximum residue level estimation.

Table 5. Anticipated residue of isoflucypram in mammals other than marine mammals for maximum residue level estimation

	Feed level (ppm) for milk residues	Isoflucypram residue (mg/kg) in milk	Feed level (ppm) for tissue residues	Isoflucypram residue (mg/kg) in tissues			
				Muscle	Liver	Kidney	Fat
MRL beef or dairy cattle							
Feeding study	4.18	<0.005	4.18	<0.01	<0.01	<0.01	<0.01
Dietary burden and residue estimate	2.50	<0.005[a]	3.60	<0.01	<0.01	<0.01	<0.01

[a] Residue of <0.005 mg/kg at the 15.5 ppm feeding level was used for the determination of the residue in milk fats.

The Meeting estimated the following maximum residue levels: 0.005* mg/kg for milks and milk fats (based on residue of <0.005 mg/kg at the 15.5 ppm feeding level) and 0.01* mg/kg for meat (from mammals other than marine mammals), fat (from mammals other than marine mammals), and edible offal (mammalian).

The mean dietary burdens to the sum of isoflucypram and isoflucypram-propanol (free and conjugated) for beef and dairy cattle are 1.1 and 0.78 ppm, respectively.

Table 6 shows the anticipated isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) residues in beef and dairy cattle commodities for dietary risk assessment.

Table 6. Anticipated residues of isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) in mammals other than marine mammals for dietary risk assessment

	Feed level (ppm) for milk residues	Isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) (mg eq/kg) in milk	Feed level (ppm) for tissue residues	Isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) (mg eq/kg) in tissues			
				Muscle	Liver	Kidney	Fat
STMR beef or dairy cattle							
Feeding study	1.61	<0.025	1.61	<0.05	<0.05	<0.05	<0.05
Dietary burden and residue estimate (Total Isoflucypram)	0.78	<0.012	1.1	<0.034	<0.034	<0.034	<0.034

The Meeting estimated the following STMRs: 0.012 mg eq/kg for milks, 0.034 mg eq/kg for fat (from mammals other than marine mammals) and edible offal (mammalian), and 0.034 mg eq/kg for meat.

The mean dietary burdens to the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) for beef and dairy cattle are 0.57 and 0.41 ppm, respectively.

Table 7 shows the anticipated isoflucypram-desmethyl-propanol (free and conjugated) residues in beef and dairy cattle for the TTC approach.

Table 7. Anticipated residues of isoflucypram-desmethyl-propanol in mammals other than marine mammals for TTC approach

	Feed level (ppm) for milk residues	Isoflucypram-desmethyl-propanol residue (mg eq/kg) in milk	Feed level (ppm) for tissue residues	Isoflucypram-desmethyl-propanol residue (mg eq/kg) in tissues			
				Muscle	Liver	Kidney	Fat
Median beef or dairy cattle residue							
Feeding study	1.61	<0.005	1.61	<0.01	<0.01	<0.01	<0.01
Dietary burden and residue estimate	0.41	<0.0013	0.57	<0.0035	<0.0035	<0.0035	<0.0035

The Meeting estimated anticipated isoflucypram-desmethyl-propanol (free and conjugated) residues of 0.0013 mg eq/kg in milks, 0.0035 mg eq/kg for muscle and fat (from mammals other than marine mammals), and 0.0035 mg eq/kg for edible offal (mammalian) for the TTC approach.

Poultry

The isoflucypram maximum dietary burden for poultry is 0.37 ppm.

Table 8 shows the anticipated isoflucypram residues in poultry for maximum residue level estimation.

Table 8. Anticipated residues of isoflucypram in poultry for maximum residue level estimation

	Feed level (ppm) for egg residues	Isoflucypram residue (mg/kg) in eggs	Feed level (ppm) for tissue residues	Isoflucypram residue (mg/kg) in tissues			
				Muscle	Liver	Kidney	Fat
MRL broiler or layer poultry							
Feeding study	0.53	<0.01	0.53	<0.01	<0.01	<0.01	<0.01
Dietary burden and residue estimate	0.37	<0.01	0.37	<0.01	<0.01	<0.01	<0.01

The Meeting estimated maximum residue levels of 0.01* mg/kg for eggs, poultry meat, poultry fat, and poultry edible offal.

The dietary burden to the sum of isoflucypram and isoflucypram-propanol (free and conjugated) for poultry is 0.13 ppm.

Table 9 shows the anticipated isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) residues in poultry commodities for dietary risk assessment.

Table 9. Anticipated residues to isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) in poultry for dietary risk assessment

	Feed level (ppm) for egg residues	Isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) (mg eq/kg) in eggs	Feed level (ppm) for tissue residues	Isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated) (mg eq/kg) in tissues		
				Muscle	Liver	Fat
STMR broiler or layer poultry						
Feeding study	0.53	<0.05	0.53	<0.05	<0.05	<0.05
Dietary burden and residue estimate (Total Isoflucypram)	0.13	<0.012	0.13	<0.012	<0.012	<0.012

The Meeting estimated STMRs of 0.012 mg eq/kg for eggs, poultry fat, and poultry edible offal, and 0.012 mg eq/kg for poultry meat.

The mean dietary burden to the sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) is 0.081 mg eq/kg.

Table 10 shows the anticipated isoflucypram-desmethyl-propanol (free and conjugated) residues in poultry commodities for the TTC approach.

Table 10. Anticipated residues to isoflucypram-desmethyl-propanol (free and conjugated) in poultry for TTC approach

	Feed level (ppm) for egg residues	Isoflucypram-desmethyl-propanol residue (mg eq/kg) in eggs	Feed level (ppm) for tissue residues	Isoflucypram-desmethyl-propanol residue (mg eq/kg) in tissues			
				Muscle	Liver	Kidney	Fat
Median beef or dairy cattle residue							
Feeding study	0.53	<0.01	0.53	<0.01	<0.01	<0.01	<0.01
Dietary burden and residue estimate	0.081	<0.0015	0.081	<0.0015	<0.0015	<0.0015	<0.0015

The Meeting estimated anticipated isoflucypram-desmethyl-propanol (free and conjugated) residues of 0.0015 mg eq/kg in eggs, poultry meat, poultry fat, and poultry edible offal for the TTC approach.

Future work or information

Desirable information

- Hydrolysis data on the soya bean metabolism study extracts
- If uses for crops not covered by the available metabolism studies are submitted in the future, then metabolism studies for those crops will be needed.

RECOMMENDATIONS

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

Definition of the residue for dietary risk assessment for plant commodities: *sum of isoflucypram and isoflucypram-propanol (free and conjugated), expressed as isoflucypram.*

Definition of the residue for dietary risk assessment for animal commodities: *sum of isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated), expressed as isoflucypram.*

The residue is fat-soluble.

Residue levels suitable for establishing maximum residue levels and for IEDI assessments

		Recommended maximum residue level (mg/kg)			
CCN	**Commodity**	**Existing**	**Proposed**	**STMR or STMR-P (mg eq/kg)**	**HR or HR-P (mg eq/kg)**
GC 0640	Barley	-	0.1	0.020	-
GC 0653	Triticale	-	0.05	0.020	-
GC 0654	Wheat	-	0.05	0.020	-
AS 0640	Barley, hay and/or straw	-	5	Median: 0.70 (dw)	-
AS 0653	Triticale, hay and/or straw	-	5	Median: 1.1 (dw)	-
AS 0654	Wheat, hay and/or straw	-	5	Median: 1.1 (dw)	-
ML 0106	Milks	-	0.005*	0.012	-
FM 0183	Milk fats	-	0.005*	-	-
MM 0095	Meat (from mammals other than marine mammals)	-	0.01*	Muscle: 0.034 Fat: 0.034	-
MF 0100	Mammalian fats (except milk fats)	-	0.01*	0.034	-
MO 0105	Edible offal (mammalian)	-	0.01*	0.034	-
PE 0112	Eggs	-	0.01*	0.012	-
PM 0110	Poultry meat	-	0.01*	Muscle: 0.012 Fat: 0.0012	-
PF 0111	Poultry fats	-	0.01*	0.012	-
PO 0111	Poultry, edible offal of	-	0.01*	0.012	-
-	Barley brewer's grain	-	-	Median: 0.028	-
-	Barley beer	-	-	0.0076	-
-	Pearl barley	-	-	0.0076	-
CF 3511	Barley flour	-	0.02	0.035	-
CM 3510	Barley bran, unprocessed	-	0.05	Median: 0.064	-
CF 1210	Wheat germ	-	0.015	-	-
-	Wheat bran, unprocessed	-	0.015	-	-

Isoflucypram residues in livestock feeds

CCN	Commodity	Median/ Median-P (mg/kg)	Highest (mg/kg)
GC 0640	Barley	0.010	-
GC 0653	Triticale	0.010	-
GC 0654	Wheat	0.010	-
AS 0640	Barley, hay and/or straw	0.28	1.1
AS 0653	Triticale, hay and/or straw	0.55	3.6
AS 0654	Wheat, hay and/or straw	0.55	3.6
-	Barley brewer's grain	0.017	-
CM 3510	Barley bran, unprocessed	0.043	-
-	Wheat aspirated grain fractions	1.5	-
CF 1210	Wheat germ	0.011	-
-	Wheat gluten	0.0094	-

Sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) residues, expressed as isoflucypram, in feeds.

CCN	Commodity	Median/ Median-P (mg eq/kg)
GC 0640	Barley	0.022
GC 0653	Triticale	0.020
GC 0654	Wheat	0.020
AS 0640	Barley, hay and/or straw	0.38
AS 0653	Triticale, hay and/or straw	0.57
AS 0654	Wheat, hay and/or straw	0.57
-	Barley bran, unprocessed	0.079
-	Barley brewer's grain	0.037

Isoflucypram-desmethyl-propanol (free and conjugated), expressed as isoflucypram, in foods.

CCN	Commodity	Median (mg eq/kg)
GC 0640	Barley	0.012
GC 0653	Triticale	0.010
GC 0654	Wheat	0.010
ML 0106	Milks	0.0013
MM 0095	Meat (from mammals other than marine mammals)	0.0035
MF 0100	Mammalian fats (except milk fats)	0.0035
MO 0105	Edible offal (mammalian)	0.0035
PE 0112	Eggs	0.0015
PM 0110	Poultry meat	0.0015
PF 0111	Poultry fats	0.0015
PO 0111	Poultry, edible offal of	0.0015
-	Barley beer	0.0072
-	Pearl barley	0.0042
-	Barley flour	0.025

Metabolites of containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure, expressed as isoflucypram, in rotational crops.

CCN	Commodity	Median (mg eq/kg)
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	0.010
VL 2050	Subgroup of leafy greens	0.015
VL 0054	Subgroup of leaves of Brassicaceae, raw	0.015

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for isoflucypram is 0—0.06 mg/kg bw/day. The International Estimated Daily Intakes (IEDI) for isoflucypram was estimated for the 17 GEMS/Food cluster diets using the STMR or STMR-P values estimated by the previous and current Meetings. The results are shown in Annex 3. The IEDIs are 0—1 percent of the maximum ADI. The Meeting concluded that the long-term intake of isoflucypram from uses that have been considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2022 JMPR determined that an ARfD for isoflucypram was unnecessary. Therefore, the Meeting concluded that the acute dietary exposure to residues of isoflucypram from the uses considered is unlikely to present a public health concern.

Threshold for toxicological concern (TTC) consideration for metabolites

The Meeting concluded metabolites isoflucypram-desmethyl-propanol (free and conjugated) and the group of metabolites containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure (including isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc, isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto-Glyc-MA, isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-Cys, and isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-GSH) could be assessed using the TTC approach (Cramer Class III threshold of 1.5 µg/kg bw per day).

The current Meeting estimated dietary exposures for isoflucypram-desmethyl-propanol (free and conjugated) of 0.0097-0.093 µg/kg bw/day and the group of metabolites containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure of 0.0013-0.030 µg/kg bw/day.

The Meeting concluded that the estimated dietary exposure to residues of isoflucypram-desmethyl-propanol (free and conjugated) and the group of metabolites containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure from uses considered by the JMPR is below the TTC for Cramer Class III compounds and is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.

5.22 Isotianil (335) (T,R)*

TOXICOLOGY

Isotianil is the ISO-approved name for 3,4-dichloro-*N*-(2-cyanophenyl)-1,2-thiazole-5-carboxamide, for which the Chemical Abstracts Service number is 224049-04-1. Isotianil is a monocarboxylic acid amide fungicide of the thiodiazole-carboxamide chemical class (Fungicide Resistance Action Committee Group class P03, salicylic acid-like). Isotianil-induced fungal control is exerted via the induction in the plant of pathogenesis-related proteins, leading to increased systemic acquired resistance in uninfected plant parts.

Isotianil has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR). All critical studies, except where stated, contained statements of compliance with good laboratory practice (GLP) and generally complied with currently accepted test methods. In a search of published scientific literature, no relevant peer reviewed published scientific papers were identified.

Overall, the Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

In rats the radioactivity derived from orally gavaged isotianil was rapidly absorbed, however the time to reach maximum concentration (T_{max})was dose-dependent and increased from 0.3 hours in males and 0.6 hours in females following dosing at 4 mg/kg body weight (bw), to 3.3 hours in males and 0.9 hours in females following dosing at 200 mg/kg bw.

Over the dose range 4–200 mg/kg bw, values for total plasma area under the concentration–time curve ($AUC_{0\rightarrow\infty)}$ and maximum concentration (C_{max}) increased with dose, but these increases were less than dose proportional. In this dose range, higher plasma exposure, based on $AUC_{0\rightarrow\infty}$ and C_{max}, occurred in females than in males. Estimated oral absorption, based on elimination via the faeco-biliary and urinary pathways in rodent mass balance studies at 4 mg/kg bw, was 72.5 percent of administered radioactivity (AR) or greater.

The highest levels of isotianil-derived radioactivity following oral dosing occurred in the stomach, intestine, kidney and liver, reflecting the routes of administration and excretion. Concentrations of isotianil-derived radioactivity in most tissues were maximal after 0.25–0.5 hours, depending on dose. After 168 hours total residues in tissues were below 0.2 percent of AR and total residues in the carcass were 0.12 percent of AR or less. The ratio of radioactivity excreted in the faeces compared to that in the urine varied with dose, a larger fraction of the AR being excreted in the faeces at higher dose levels. Based on a bile duct cannulation study in rats, biliary excretion was extensive (greater than 46 percent of AR) with the biliary pathway being the major route of excretion and urinary excretion being a minor pathway after oral dosing at 4 mg/kg bw.

Based on in vitro comparative metabolite studies using pooled, mixed sex, human, rat, dog, and rabbit liver microsomes there appeared to be no human-specific metabolites.

The following major (greater than 10 percent of the administered radioactivity and/or greater than 10 percent of the area under the HPLC curve) in vivo metabolites were identified in rats following oral dosing with 4 or 200 mg/kg bw of isotianil:

- 4'-OH-isotianil (kidney, plasma),
- glucuronide of 4'-OH-isotianil (kidney),
- 4',5'-di-OH-isotianil, plus 3',4'-di-OH-isotianil (kidney and plasma),
- DCIT-acid (liver, kidney and plasma), and
- sulphate of 2-amino 5-hydroxybenzonitrile (liver, kidney, plasma).

Based on samples collected from the rat biliary excretion study three major metabolites were identified in the excreta: DCIT-acid, 4'-OH-isotianil, the glucuronide of 4'-OH-isotianil and tri-OH-isotianil. Metabolism of isotianil in rats predominantly involves hydroxylation followed by glucuronidation in the case of 4'-OH-isotianil.

Toxicological data

The acute oral median lethal dose (LD_{50}) of isotianil in rats was greater than 2000 mg/kg bw. The acute dermal (occlusive) LD_{50} of isotianil in rats was greater than 2000 mg/kg bw, and the acute median lethal concentration (LC_{50}) for inhalation was greater than 5 mg/L. Isotianil was not irritant to the skin or eyes of rabbits. Isotianil was non-toxic but sensitizing in the Guinea pig maximization test (Magnusson & Kligman).

The repeat daily dose oral (dietary) toxicological properties of isotianil were evaluated in mice, rats and dogs. The key effects were on body weight parameters, the liver, the kidney and the lung.

In a 92-day oral toxicity study, isotianil was administered to groups of mice at concentrations of 0, 150, 1000 or 7000 ppm (equal to 0, 33.1, 204.1 and 1309.5 mg/kg bw per day for males, 0, 54.8, 401.1 and 2474.6 mg/kg bw per day for females). The study NOAEL was 7000 ppm (equal to 1309.5 mg/kg bw per day), the highest dose tested.

In a 90-day oral toxicity study isotianil was administered via the diet to groups of rats at concentrations of 0, 100, 500, 2500 or 20 000 ppm (equal to 0, 6.7, 34, 166 and 1441 mg/kg bw per day for males, 0, 7.7, 39, 187 and 1560 mg/kg bw per day for females). Additional groups of ten rats per sex were treated with 0 and 20 000 ppm for 13 weeks. The NOAEL was 20 000 ppm (equal to 1441 mg/kg bw per day), the highest dose tested.

In a second 90-day rat oral toxicity study, isotianil was administered via the diet to groups of rats at concentrations of 0, 20, 500, 2500 or 20 000 ppm (equal to 0, 1.18, 29.7, 148 and 1238 mg/kg bw per day for males, 0, 1.39, 35.1, 178 and 1398 mg/kg bw per day for females). The NOAEL was 20 000 ppm (equal to 1238 mg/kg bw per day), the highest dose tested.

The combined NOAEL for the two 90-day dietary studies in rats was 1441 mg/kg bw per day, the highest dose tested.

In a 91 to 94-day toxicity study, isotianil was administered via the diet to groups of dogs at concentrations of 0, 500, 2000 or 8000 ppm (equal to 0, 12.2, 51.1 and 200 mg/kg bw per day for males, 0, 13.4, 54.4 and 211 mg/kg bw per day for females). The NOAEL was 2000 ppm (equal to 51.1 mg/kg bw per day) due to the presence of hepatotoxicity at 8000 ppm (equal to 200 mg/kg bw per day).

In a 1-year toxicity study, isotianil was administered via the diet to groups of dogs at concentrations of 0, 200, 1000 or 5000/3000 ppm (equal to 0, 5.22, 27.2 and 107 mg/kg bw per day for males, 0, 5.33 26.9 and 110 mg/kg bw per day for females). The high dose was reduced to 3000 ppm after week 31 (males) and week 30 (females), due to hepatotoxicity and decreased food consumption. The NOAEL was 200 ppm (equal to 5.22 mg/kg bw per day) due to the presence of hepatotoxicity in males at 1000 ppm (equal to 2.72 mg/kg bw per day).

In a combined chronic/carcinogenicity study, isotianil was administered for 78-weeks via the diet to groups mice at concentrations of 0, 70, 700 or 7000 ppm (equal to 0, 6.89, 71.5 and 706 mg/kg bw per day for males, 0, 6.66, 67.2 and 667 mg/kg bw per day for females). The NOAEL for systemic toxicity and carcinogenicity was 7000 ppm (equal to 667 mg/kg bw per day), the highest dose tested.

In a 1-year chronic toxicity study isotianil was administered for 52 weeks via the diet to groups of rats at concentrations of 0, 60, 600, 6000 or 20 000 ppm (equal to 0, 2.83, 27.9, 291 and 979 mg/kg bw per day for males, 0, 3.70, 37.3, 381 and 1254 mg/kg bw per day for females). The NOAEL was 6000 ppm (equal to 291 mg/kg bw per day) due to increased incidences of acicular urinary crystals that correlated with renal proximal tubule changes, alveolar wall bronchiolization and diffuse hepatocyte hyperplasia at 20 000 ppm (equal to 979 mg/kg bw per day).

In a carcinogenicity study isotianil was administered ad libitum for 104 weeks via the diet to groups of rats at concentrations of 0, 2000, 6000 or 20 000 ppm (equal to 0, 79.2, 242 and 823 mg/kg bw per day for males, 0, 105, 311 and 1052 mg/kg bw per day for females). The NOAEL for carcinogenesis was 20 000 ppm (equal to 823 mg/kg bw per day), the highest dose tested. The NOAEL for systemic toxicity was 2000 ppm (equal to 79.2 mg/kg bw per day) due to an increased incidence of lung alveolar wall bronchiolization in males at 6000 ppm (equal to 242 mg/kg bw per day).

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

Isotianil did not induce genotoxicity in an adequate range of in vitro and in vivo assays.

The Meeting concluded that isotianil is unlikely to be genotoxic.

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

In a multigenerational study isotianil was administered to groups of rats (the F0 generation) at dietary concentrations of 0, 50, 1000 or 10 000 ppm (equal to mean isotianil intakes for the F0 males, F1 males, F0 females, and F1 females, in that order, of 0 mg/kg bw per

day, then 2.97, 3.42, 4.87 and 5.13 mg/kg bw per day for the 50 ppm group; 59.7, 68.2, 97.6 and 103 mg/kg bw per day for the 1000 ppm group; and 590, 695, 976 and 1027 mg/kg bw per day for the 10 000 ppm group) The parental systemic NOAEL was 10 000 ppm (equal to 590 mg/kg bw per day), the highest dose tested. The reproductive NOAEL was 10 000 ppm (equal to 590 mg/kg bw per day), the highest dose tested. The offspring NOAEL was 1000 ppm (equal to 68.2 mg/kg bw per day) based on decreased pup body weight in both the F1 and F2 generations at 10 000 ppm (equal to 695 mg/kg bw per day).

In a prenatal developmental toxicity study, isotianil was administered via oral gavage to rats on gestation days (GDs) 6–19 at 0, 99.5, 300 or 1180 mg/kg bw per day. The NOAEL for both maternal and embryo/fetal toxicity was 1180 mg/kg bw per day, the highest dose tested.

In a prenatal developmental toxicity study, isotianil was administered orally (gavage) to rabbits at doses of 0, 100, 300 or 1000 mg/kg bw per day from GD 6 to GD 27. The maternal NOAEL was 300 mg/kg bw per day due to reduced maternal body weight gain over GDs 6–21 and reduced placental weights, at 1000 mg/kg bw per day, the highest dose tested. The embryo/fetal NOAEL was 300 mg/kg bw per day due to reduced fetal weights at 1000 mg/kg bw per day.

The Meeting concluded that isotianil is not teratogenic.

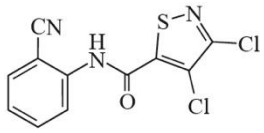
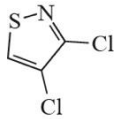
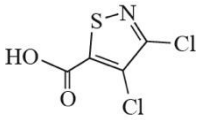
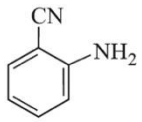
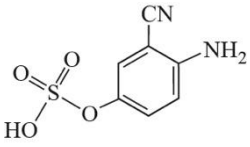
No neurotoxicity studies were submitted for evaluation. Based on the currently available database the meeting concluded that isotianil is unlikely to be neurotoxic.

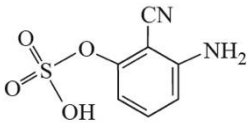
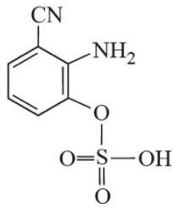
No immunotoxicity studies were submitted for evaluation. Based on the currently available database the meeting concluded that isotianil is unlikely to be immunotoxic.

Toxicological data on metabolites and/or degradates

A summary of the results for plant and livestock metabolites of isotianil is shown in the table below.

Summary of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	Major rat metabolite (>10% AD)	Genotoxicity assessment (data, QSAR, read across)	General toxicity	Toxicological reference values
Isotianil 				ADI: 0–0.05 mg/kg bw ARfD: Unnecessary
DCIT (3,4-Dichloro-1,2-thiazole; 3,4-dichloro-isothiazole) 	No	Negative (bacterial reverse mutation assay)	No data	Cramer Class III TTC: 1.5 µg/kg bw per day
DCIT-acid (3,4-Dichloroisothiazole -5-carboxylic acid) 	Yes	Negative (bacterial reverse mutation assay)	Acute oral LD_{50} > 300 < 2000 mg/kg bw Skin corrosive, severe eye irritant, skin sensitizer 28-day rat oral toxicity NOAEL 417 mg/kg bw per day (highest dose tested) 90-day rat oral toxicity NOAEL 133 mg/kg bw per day Rat prenatal developmental toxicity, maternal NOAEL 10 mg/kg bw per day; developmental NOAEL 50 mg/kg bw per day	More toxic than parent Key effect in repeat oral studies (rodents) on body weight, likely secondary to irritancy and therefore not relevant to dietary risk assessment Major rat metabolite; parent ADI is adequately protective
2-Aminobenzonitrile 	No	Negative (bacterial reverse mutation assay)	Acute rat oral LD_{50} > 300 < 2000 mg/kg bw. Neurotoxicity (tremor, ataxic gait, and prone position) 300 mg/kg bw; lateral position, hypothermia, lacrimation, red tears, ptosis, and decrease in spontaneous activity at 2000 mg/kg)	Cramer Class III TTC: 1.5 µg/kg bw per day
No name provided 	No	Based on QSAR genotoxic potential cannot be categorically excluded	No data	TTC for genotoxicity: 0.0025 µg/kg bw per day

No name provided 	No	Based on QSAR genotoxic potential cannot be categorically excluded	No data	TTC for genotoxicity: 0.0025 µg/kg bw per day
No name provided 	No	Based on QSAR genotoxic potential cannot be categorically excluded	No data	TTC for genotoxicity: 0.0025 µg/kg bw per day

QSAR: Quantitative structure–activity relationship; TTC: Threshold of toxicological concern; AD: Administered dose
ADI: Acceptable daily intake; ARfD: Acute reference dose

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of isotianil residues on the human intestinal microbiome.

Human data

In reports on manufacturing plant personnel, no adverse health effects were noted.
The Meeting concluded that the existing database on isotianil was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting established an ADI for isotianil of 0–0.05 mg/kg bw, based on a NOAEL of 5.22 mg/kg bw per day in the one-year oral (dietary exposure) toxicity study in dogs. A safety factor of 100 was used.

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

A toxicological monograph was prepared.

Levels relevant to risk assessment of isotianil

Species	Study	Effect	NOAEL	LOAEL
Mouse	92-day toxicity study[a]	None	7000 ppm, equal to 1309.5 mg/kg bw per day[c]	-
	78-week study of toxicity and carcinogenicity[a]	Toxicity	7000 ppm, equal to 667 mg/kg bw per day[c]	-
		Carcinogenicity	7000 ppm, equal to 667 mg/kg bw per day[c]	-
Rat	90-day toxicity studies[a, d]	No adverse tox effects observed	20 000 ppm, equal to 1441 mg/kg bw per day[c, d]	-
	One-year toxicity study[a]	Toxicity	6000 ppm, equal to 291 mg/kg bw per day	20 000 ppm, equal to 979 mg/kg bw per day
	104-week carcinogenicity study[a]	Toxicity	2000 ppm, equal to 79.2 mg/kg bw per day	6000 ppm, equal to 242 mg/kg bw per day
		Carcinogenicity	20 000 ppm, equal to 823 mg/kg bw per day[c]	-
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	10 000 ppm equal to 590 mg/kg bw per day[c]	-
		Parental toxicity	10 000 ppm, equal to 590 mg/kg bw per day[c]	-
		Offspring toxicity	1000 ppm, equal to 68.2 mg/kg bw per day	10000 ppm, equal to 695 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	1180 mg/kg bw per day[c]	-
		Embryo/fetal toxicity	1180 mg/kg bw per day[c]	-
Rabbit	Developmental toxicity study[b]	Maternal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
		Embryo/fetal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
Dog	91 to 94-day toxicity study[a]	Toxicity	2000 ppm, equal to 51.1 mg/kg bw per day	8000 ppm, equal to 200 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
	One-year toxicity study[a]	Toxicity	200 ppm, equal to 5.22 mg/kg bw per day	1000 ppm, equal to 29.6 mg/kg bw/day
	One-year toxicity study[a]	Toxicity	200 ppm, equal to 5.22 mg/kg bw per day	1000 ppm, equal to 29.6 mg/kg bw/day
3,4-Dichloroisothiazole-5-carboxylic acid (DCIT-acid) [e]				
Rat	28-day study of toxicity[a]	Toxicity	6000 ppm, equal to 417 mg/kg bw per day[c]	-
	90-day study of toxicity[a]	Toxicity	2000 ppm, equal to 133 mg/kg bw per day	6500 ppm, equal to 478 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	10 mg/kg bw per day	50 mg/kg bw per day
		Embryo/fetal toxicity	50 mg/kg bw per day	250 mg/kg bw per day

[a] Dietary administration [b] Gavage administration [c] Highest dose tested; [d] Two or more studies combined [e] Major metabolite in rats

Acceptable daily intake (ADI) applies to isotianil and DCIT-acid, expressed as isotianil

0–0.05 mg/kg bw

An acute reference dose (ARfD)

Unnecessary

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

Investigation of the mode of action of hepatotoxicity in dogs; information on the genotoxicity of the sulphates of 2-aminohydroxybenzonitrile.

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

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of oral absorption	Rapid, sub- proportional to dose, 72.5%–73.4% (estimated)
Dermal absorption	No data
Distribution	Wide; highest concentrations in stomach, intestine, liver and kidney reflecting the routes of administration and excretion
Potential for accumulation	No evidence of accumulation

Rate and extent of excretion	Predominantly faeco–biliary with urine as a minor pathway Rapid and essentially complete by 168 hours
Metabolism in animals	Predominantly hydroxylation followed, in some cases, by glucuronidation; the major enzymes involved in metabolism were not identified
Toxicologically significant compounds in animals and plants	Isotianil, DCIT, DCIT-acid, anthranilonitrile
Acute toxicity	
Rat, LD_{50}, oral	>2000 mg/kg bw
Rat, $LD_{50,}$ dermal	>2000 mg/kg bw
Rat, LC_{50}, inhalation	>5 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea pig, dermal sensitization	Sensitizing (Magnussen & Kligmann)
Short-term studies of toxicity	
Target/critical effect	Liver (dog)
Lowest relevant oral NOAEL	5.22 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rat)b
Lowest relevant inhalation NOAEC	>5mg/L
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Lung alveolar wall bronchiolization in male rats
Lowest relevant NOAEL	79.2 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic[a]
Genotoxicity	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Reductions in preweaning body weight
Lowest relevant parental NOAEL	590 mg/kg bw per day (rat)[b]
Lowest relevant offspring NOAEL	68.2 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	590 mg/kg bw per day (rat)[b]
Developmental toxicity	
Target/critical effect	Reduced fetal and placental weights
Lowest relevant maternal NOAEL	300 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	300 mg/kg bw per day (rabbit)

Neurotoxicity	
Acute neurotoxicity NOAEL	No data
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No evidence from routine studies.
Studies on toxicologically relevant metabolites	
DCIT	Acute oral LD_{50}: no data 28-day NOAEL: no data Not genotoxic (Ames, in vitro micronucleus test)
DCIT-acid (3,4-dichloroisothiazole-5-carboxylic acid)	Acute oral LD_{50}: >300 < 2000 mg/kg bw (rat) Skin irritancy: corrosive (in vitro epidermal reconstruct) Eye irritancy: severe (in vitro ICE) Skin sensitizer: EC3 = 3% 28-day NOAEL: 417 mg/kg bw per day (rat)b 90-day NOAEL: 133 mg/kg bw per day (rat) Not genotoxic (Ames, micronucleus in vitro) Prenatal developmental maternal NOAEL: 10 mg/kg bw per day developmental NOAEL: 50 mg/kg bw per day
Anthranilonitrile	Acute oral LD_{50}: > 300 < 2000 mg/kg bw Not genotoxic (bacterial reverse mutation assay)
Microbiological aspects	No data submitted
Human data	No clinical cases or poisoning incidents have been recorded No adverse effects in workers involved in the production of isotianil

[a] Unlikely to pose a carcinogenic risk to humans via exposure from the diet

[b] Highest dose tested

Summary

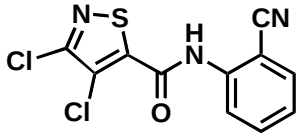
	Value	Study	Safety factor
ADI	0–0.05 mg/kg bw [a]	One-year study of toxicity in dogs	100
ARfD	Unnecessary		

[a] Applies to isotianil and DCIT-acid, expressed as isotianil

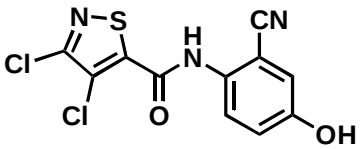
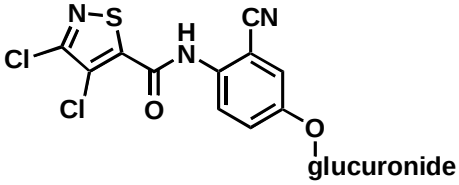
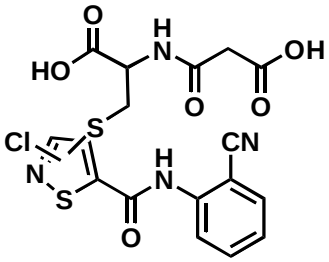
Isotianil is a thiadiazole carboxamide fungicide and belongs to the group of plant activator compounds, which induce the host plant defence. At the Fifty-second Session of CCPR it was scheduled for the evaluation as a new compound in 2022 and rescheduled to the 2023 JMPR.

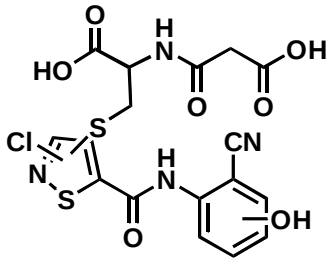
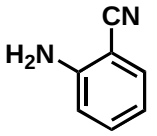
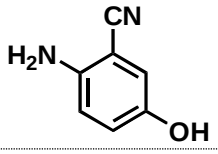
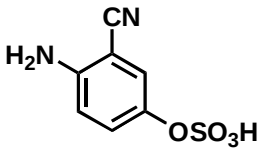
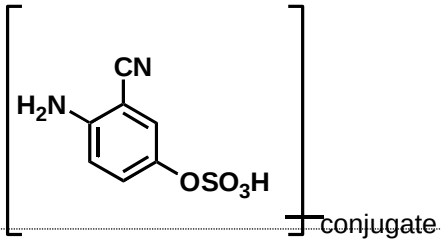
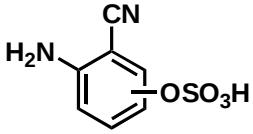
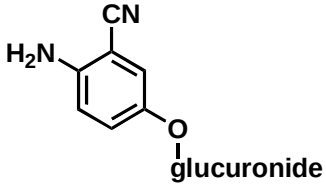
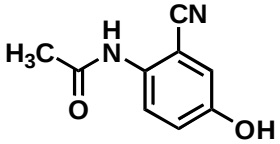
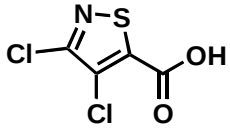
The Meeting received information on the metabolism of isotianil in lactating goats and laying hens, lemon, tomato, potato and rice, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials on citrus and banana as well as livestock feeding studies (lactating cow, laying hen).

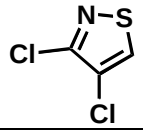
Isotianil is 3,4-dichloro-2'-cyano-1,2-thiazole-5-carboxanilide.



The following abbreviations are used for the major metabolites discussed below:

Chemical Name	Chemical Structure
4'-OH-isotianil	
Glucuronide of 4'-OH-isotianil	
Malonyl-cysteinyl-isotianil	

Chemical Name	Chemical Structure
Malonyl-cysteinyl-OH-isotianil	
2-aminobenzonitrile	
2-amino-5-hydroxy-benzonitrile	
Sulphate of 2-amino-5-hydroxy-benzonitrile	
Conjugate of sulphate of 2-amino-5-hydroxy-benzonitrile	
Sulphate of 2-amino-hydroxy-benzonitrile	
Glucuronide of 2-amino-5-hydroxy-benzonitrile	
Acetyl-2-amino-5-hydroxy-benzonitrile	
DCIT-acid	

Chemical Name	Chemical Structure
DCIT	

Based on the information on physical and chemical properties, isotianil is not volatile and is lipid soluble with a log Pow of around 3. Isotianil is hydrolytically moderately persistent at environmental pH. Aqueous photolysis is likely to be a major degradation pathway of isotianil in the environment.

Metabolism

Isotianil is typically used for three different situations (exclusively or in combination):

- incorporation into the soil prior to or at planting
- as a foliar spray to the growing crop
- for paddy rice application to soil at transplanting with flooding followed by application to paddy water.

The Meeting received plant metabolism studies with isotianil following soil application (lemon, potato), foliar application (lemon, tomato, potato) and rice paddy application. The crops studied are representative of fruit (lemon, tomato), root and tuber vegetables (potato) and cereals (rice).

The metabolism of isotianil in plants, animals and soils was investigated using [phenyl-U-^{14}C]-isotianil ([Ph]-label) and [isothiazole-3-^{14}C, carboxamide-^{14}C]-isotianil ([IC]-label).

Plant metabolism

Some scientific studies were also located in the literature that are relevant to plant metabolism. In a study on the translocation of isotianil and 2-aminobenzonitrile in tomato leaves, isotianil remained fixed at its application site, even after 14 days, though the amount of isotianil declined to 50 percent over the duration of the study. 2-aminobenzonitrile levels in the leaf surrounding the application area rose steadily up to day 10, before receding. Translocation of 2-aminobenzonitrile from treated leaves towards untreated leaves was observed.

In a separate study the uptake and movement of isotianil and DCIT-acid was investigated on adaxial leaf surfaces of tomato and banana and following uptake via the roots in tomato and wheat plants. Uptake of isotianil via the roots (tomato, wheat) led to a systemic distribution in the plant. Isotianil was not taken up via the leaf (tomato, banana), however DCIT-acid showed rapid uptake and movement within the plant.

For studies on metabolism of crops maintained in a greenhouse, the particular glass in the greenhouse allowed transmission of wavelengths of light characteristic of natural sunlight and can be considered equivalent to plants maintained in the field.

Soil treatments

Lemon

The metabolic fate of ^{14}C-isotianil in lemon trees maintained in a greenhouse was examined following four applications to the soil at 200 g ai/ha at BBCH 73-89 and at 45-day intervals. Fruit and leaves were harvested 1 day or 29 days after the last application.

Residues fruit and leaves were 0.003 and 0.055 [Ph]-label and 0.016 and 0.273 [IC]-label mg eq/kg respectively at 1 day after last application and 0.002 and 0.069 [Ph]-label and 0.017 and 0.253 [IC]-label mg eq/kg respectively at 29 days after last application.

The extractability of ^{14}C with acetonitrile/water was good for lemon fruit and leaves (≥88 percent TRR)

Isotianil parent compound was the major component of the ^{14}C in whole fruit harvested at 1-day (58 percent TRR, 0.002 mg/kg [Ph]-label, 39 percent TRR, 0.006 mg/kg [IC]-label) but was a relatively minor component of ^{14}C at 29-days (2 percent TRR <0.001 mg/kg [Ph]-label, 11 percent TRR 0.002 mg/kg [IC]-label). Isotianil was the major component in leaves at 1-day (90 percent TRR 0.049 mg/kg [Ph]-label, 57 percent TRR 0.156 mg/kg [IC-label]) and 29-days (45 percent TRR 0.114 mg/kg [IC-label). The only other compound identified in leaves was DCIT-acid in the 29-day [IC]-label experiment at 15 percent TRR (0.038 mg eq/kg).

Potato

In a study on the metabolism of isotianil in potato (maintained in greenhouse) was examined following two soil applications, the first was applied at planting at 350 g ai/ha with the second at 226 g ai/ha 28 days prior to harvest.

Residues tubers and vines were 0.008 and 0.769 [Ph]-label and 0.056 and 1.33 [IC]-label mg eq/kg respectively at 28 days after last application.

The extractability of ^{14}C in vines with acetonitrile/water was good for both labels (≥82 percent TRR). The extractability of ^{14}C in tubers with acetonitrile/water was good from the IC-label experiments (69 percent TRR) with an additional 10 percent released on microwave assisted extraction with acetonitrile/H_2O/formic acid and a further 21 percent TRR released by acid hydrolysis using 5 percent trifluoroacetic acid (TFA). The overall extractability of ^{14}C in tubers (sum of acetonitrile/H_2O, microwave assisted acetonitrile/H_2O/formic acid, 5 percent TFA) was almost 100 percent TRR. Levels of ^{14}C were too low in the tubers from the [Ph]-label experiment for analysis.

Isotianil was the only compound identified in the [Ph]-label vines at 90 percent TRR (0.692 mg/kg). Isotianil was also detected in the [IC]-label tubers at 2.5 percent TRR (0.001 mg/kg) and in vines at 78 percent TRR (1.037 mg/kg). The main component identified in tubers was DCIT-acid at 34.8 percent TRR (0.019 mg eq/kg). DCIT-acid was a minor component of the residues in vines (4.2 percent TRR 0.056 mg eq/kg).

Foliar treatment

Lemon

The metabolic fate of ^{14}C-isotianil in lemon trees maintained in a greenhouse was examined following four foliar applications of an SC formulation at BBCH 73-89 at 150 g ai/ha and at 21 day intervals. Fruit and leaves were harvested 1 day after the last application.

Residues in fruit and leaves were 1.059 and 96.75 [Ph]-label and 1.037 and 106.2 [IC]-label mg eq/kg respectively.

The extractability of ^{14}C with acetonitrile/water was good for lemon fruit (99 percent TRR with 73 percent TRR recovered in the initial surface rinse) and leaves (98 percent TRR).

Isotianil parent compound was the major component of the ^{14}C in whole fruit (91-92 percent TRR both labels, 0.948-0.974 mg/kg) with low levels of malonyl cysteinyl-OH-isotianil (2 percent TRR 0.020 mg eq/kg [Ph]-label) and malonyl cysteinyl-isotianil (5 percent TRR both labels 0.048-0.057 mg eq/kg) also detected. Isotianil was the only compound identified in leaves and represented 95-98 percent TRR (94.9 mg/kg).

Tomato

The uptake and metabolism of ^{14}C-isotianil applied in an SC formulation to greenhouse grown tomato plants was studied following three foliar applications at BBCH 51 (inflorescence emergence: first inflorescence visible [first bud erect]), BBCH 71-79 (development of fruit: first fruit cluster: first fruit has reached typical size till nine or more fruit clusters with fruits of typical size), and BBCH 88 (ripening of fruit and seed: 80 percent of fruits show typical fully ripe colour). The nominal application rate was 200 g ai/ha per spray. Fruit was harvested 7 days after the last application.

Residues fruit were 0.233-0.347 [Ph]-label and 0.078-0.220 [IC]-label mg eq/kg.

The extractability of ^{14}C in fruit with acetonitrile:water was good for tomatoes (>97 percent TRR), the majority of which was located on the surface of the fruit (≥78 percent TRR).

Isotianil parent compound was the major component of the ^{14}C in whole fruit (91-92 percent TRR, 0.212-0.320 mg/kg [Ph]-label and 75.7-79.5 percent TRR, 0.167-0.301 mg/kg [IC]-label)) with low levels of 2-aminobenzonitrile (1.8-4.1 percent TRR, 0.006-0.009 mq eq/kg [Ph]-label) and DCIT-acid (6.7-8.9 percent TRR, 0.019-0.025 mg eq/kg [IC]-label) also detected.

Potato

The metabolism of ^{14}C-isotianil in potato (var Kennebec) was reported following four foliar applications of an SC formulation, at 7-day intervals and at 300 g ai/ha. The plants were maintained in a greenhouse. Potato tubers and vines were collected 28 days after the last application.

Residues tubers and vines were 0.038 and 34.5 [Ph]-label and 0.116 and 49.1 [IC]-label mg eq/kg respectively at 28 days after the last application.

The extractability of ^{14}C in vines with acetonitrile/water was good for both labels (97 percent TRR). The extractability of ^{14}C in tubers with acetonitrile/water was good (41 percent TRR [Ph]-label, 65 percent TRR [IC]-label) with additional ^{14}C released on microwave assisted extraction with acetonitrile/H_2O/formic acid (5 percent TRR [Ph]-label, 8 percent TRR [IC]-label) and further ^{14}C released by acid hydrolysis using 5 percent TFA (45 percent TRR [Ph]-label, 27 percent TRR [IC]-label). The overall extractability of ^{14}C in tubers (sum of acetonitrile/H_2O, microwave assisted acetonitrile/H_2O/formic acid, 5 percent TFA) was ≥91 percent TRR.

Isotianil was the only compound identified in the [Ph]-label experiment at 11 percent TRR (0.004 mg/kg) in tubers and 97 percent TRR (33.5 mg/kg) in vines.

Isotianil was not detected in tubers from the [IC]-label experiment but was present in vines 92.8 percent TRR (45.6 mg/kg) in vines. The main component identified in tubers was DCIT-acid at 35.5 percent TRR (0.041 mg eq/kg) but which was a minor component of the residues in vines (4.1 percent TRR, 2.0 mg eq/kg).

Paddy rice

The metabolism of ^{14}C-isotianil in paddy rice plants grown in a greenhouse was studied following three applications of a granular formulation. The first application was made as a nursery box treatment on the day of transplanting at 4-5 leaf stage (126 days before harvest) into loam soil and flooded with water followed by two paddy water treatments performed at 76- and 30-days before harvest. The single application rates were 300 g ai/ha, resulting in a total application rate of 900 g ai/ha. Immature rice plants were collected 7 days after the second application. At maturity rice plants were harvested, and the plants were separated into whole-grain and straw (leaf/stem). The whole-grain was further processed to give husked rice (brown rice) and hulls.

Residues immature plants, husked rice, hulls and straw were 0.264, 0.057, 0.315 and 1.299mg eq/kg for the [Ph]-label experiment and 1.032, 0.160, 0.546 and 4.127 mg eq/kg for the [IC]-label experiment.

The extractability of ^{14}C in husked rice with acetonitrile/water (4:1) was 29-30 percent TRR with additional ^{14}C released on extraction with acetonitrile/water (1:1) (8.8 percent TRR [Ph]-label, 23.2 percent TRR [IC]-label), acetonitrile/water (4:1) Soxhlet (4.9 percent TRR [Ph]-label, 1.9 percent TRR [IC]-label) and acetonitrile/water /0.1M HCl (0 [Ph]-label, 1.2 percent TRR [IC]-label). Further ^{14}C was released following more aggresive treatments, acid hydrolysis using 1+6M HCl (27.4 percent TRR [Ph]-label, 26.0 percent TRR [IC]-label) and base hydrolysis using 1+6M NaOH (25.6 percent TRR [Ph]-label, 15.6 percent TRR [IC]-label). The overall extractability of ^{14}C in husked rice was 96.3 percent TRR [Ph]-label and 97.1 percent TRR [IC]-label. A similar pattern for extraction of ^{14}C was observed for the other matrices analysed.

Isotianil was extensively metabolized in rice. Isotianil was a minor component of the ^{14}C in husked rice (1.8-5.3 percent TRR; 0.003 mg/kg), hulls (4.5-5.4 percent TRR; 0.014-0.030 mg/kg) and immature rice plants (0.5-5.9 percent TRR; 0.005-0.016 mg/kg) and was present at approximately 11 percent TRR in the straw (9.4-11.0 percent TRR; 0.123-0.454 mg/kg).

The major metabolites identified in the extracts of immature rice plants were DCIT-acid (6.8 percent TRR; 0.070 mg eq/kg) in the [IC]-label experiment; and 2-aminobenzonitrile (9.2 percent TRR; 0.024 mg eq/kg) in the [Ph]-label experiment. A polar region characterized using ion-exchange chromatography is most likely ^{14}C associated with water soluble natural products ([Ph]-label: 11.7 percent TRR, 0.031 mg eq/kg; [IC]-label: 38.9 percent TRR, 0.401 mg eq/kg).

The major metabolites identified in the extracts of husked rice were DCIT-acid (6.1 percent TRR; 0.010 mg eq/kg) in the [IC]-label experiment; glucose from incorporation of ^{14}C-units into natural products ([Ph]-label: 8.2 percent TRR, 0.005 mg eq/kg; [IC]-label: 25.5 percent

TRR, 0.041 mg eq/kg); and 2-aminobenzonitrile (16.2 percent TRR; 0.009 mg eq/kg) in the [Ph]-label experiment.

The major metabolites identified in the extracts of hulls were DCIT-acid (17.3 percent TRR; 0.095 mg eq/kg) in the [IC]-label experiment; glucose from incorporation of ^{14}C-units into natural products ([Ph]-label: 12.6 percent TRR, 0.040 mg eq/kg; [IC]-label: 27.2 percent TRR, 0.149 mg eq/kg); and 2-aminobenzonitrile (14.6 percent TRR; 0.046 mg eq/kg) in the [Ph]-label experiment.

The major metabolites identified in the extracts of straw were DCIT-acid (18.2 percent TRR; 0.752 mg eq/kg) in the [IC]-label experiment; glucose from incorporation of ^{14}C-units into natural products ([Ph]-label: 12.9 percent TRR, 0.0168 mg eq/kg; [IC]-label: 21.2 percent TRR, 0.874 mg eq/kg); and 2-aminobenzonitrile (13.7 percent TRR; 0.178 mg eq/kg) in the [Ph]-label experiment.

In summary, following soil application to lemon and potato, isotianil was the major residue identified in lemon fruit at 1-day and 29 days after last application and in potato vines 28 days after application while in potato tubers DCIT-acid was the major residue identified.

Following foliar application to lemon (1 DALA) and tomato (7 DALA), the majority of the radioactivity in fruit is found in the surface wash. Unchanged isotianil was the major ^{14}C residue. In potato following foliar application, the major residue identified in tubers 28-DALA was DCIT-acid while in vines it was isotianil.

Following application to rice at transplanting and flooding, and subsequently to paddy water, the major residues identified in husked rice, hulls, straw and immature plants were 2-aminobenzonitrile and DCIT-acid with lower levels of isotianil also detected.

The metabolism was found to be similar across each crop and involves cleavage of the amide bond to form DCIT-acid and 2-aminobenzonitrile. Additionally, a minor route of metabolism involves hydroxylation of the phenyl ring and/or conjugation with glutathione leading to the formation of a malonyl-cysteinyl adduct at the 3 or 4 position on the isothiazole-carboxamide ring. For rice, significant degradation of the moiety and incorporation of ^{14}C units into natural products was also observed.

Rotational crop metabolism

No studies on rotational crops were made available to the Meeting. Should future uses of isotianil include crops that are routinely rotated, studies on residues in follow crops will be needed to determine if residues will transfer from soil.

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hens dosed with isotianil.

Rats

Metabolism of isotianil in rats was evaluated by the WHO Core Assessment Group of the 2023 JMPR. Metabolites identified in rats included: DCIT-acid and 4'-OH-isotianil (both free and

glucuronide conjugates), 4’5’-di-OH-isotianil, 3’4’-di-OH-isotianil and the sulphate of 2-amino-5-hydroxybenzonitrile.

Lactating goats

Lactating goats were orally dosed by gavage once daily following morning milking for five consecutive days with ^{14}C-isotianil at doses equivalent to 33.1 [Ph]-label or 20.2 [IC]-label ppm in the diet and sacrificed within 6 hours of the last dose.

By 6 hours after the last dose, the majority of the ^{14}C was recovered in faeces (24.9-42.0 percent of the administered dose (AD)) and urine (18.6-29.8 percent AD). Milk accounted for 0.019-0.025 percent AD while tissues accounted for 0.15-0.18 percent AD. The material balance was 69.3-84.2 percent AD and the poor accountability may in part be explained by radioactivity in the cage wash not being reported.

Residues in milk reached a plateau by 2–4 days of the start of dosing and showed lower levels in morning compared to evening milk suggesting rapid elimination.

TRR were highest for kidney, followed by liver; fat and muscle had low residues; TRR were 0.227–0.236 mg eq/kg in kidney, 0.137-0.217 mg eq/kg in liver, 0.0.007–0.014 mg eq/kg in fat and 0.005–0.007 mg eq/kg in muscle.

Extractability of ^{14}C from tissues with acetonitrile:water was good for kidney (88—92 percent TRR), muscle (6372 percent TRR), and fat (80–94 percent TRR) and Day 4—6 milk (85—87 percent TRR) but poor for liver (32—47 percent TRR). Additional radioactivity was released from liver post-extraction solids using microwave assisted acetonitrile:water extraction (26 percent TRR), microwave assisted acetonitrile/water/formic acid extraction followed by protease (21 percent TRR) and refluxing with 2M HCl for 20 hours (21 percent TRR).

For the [Ph]-label dosed goat, the majority of radioactive residues in milk was identified and/or characterized (87 percent TRR) and kidney (80 percent TRR). Only 8 percent TRR was identified in liver while TRR residues in muscle and fat were <0.01 mg eq/kg and not analysed further.

Isotianil (parent) was not detected in tissues or milk. The phenyl-derived metabolites identified included the sulphate of 2- amino-5-hydroxybenzonitrile (69 percent TRR 0.016 mg eq/kg milk day 5, 39 percent TRR 0.088 mg eq/kg kidney), sulphate of 2-amino-hydroxybenzonitrile (18 percent TRR 0.004 mg eq/kg milk day 5) and glucuronide of 2- amino-5-hydroxybenzonitrile (17.0 percent TRR 0.038 mg eq/kg kidney, 3 percent TRR 0.007 mg eq/kg liver). 4-OH-Isotianil and its glucuronide were also detected (sum 24 percent TRR 0.056 mg eq/kg kidney, 5 percent TRR 0.011 mg eq/kg liver). Several minor unidentified metabolites were detected, none of which individually were greater than 8 percent TRR in milk, liver and kidney.

For the [IC]-label dosed goat, the majority of radioactive residues in milk was identified (73 percent TRR), fat (94 percent TRR) and kidney (88 percent TRR). Identification of radioactive residues was lower in liver (29 percent TRR) and muscle (45 percent TRR).

Isotianil (parent) was not detected in tissues and milk. DCIT-acid was the major component of the ^{14}C (72.9 percent TRR 0.011 mg eq/kg milk d5, 19.8 percent TRR 0.027 mg eq/kg liver, 76.7 percent TRR 0.181 mg eq/kg kidney, 44.9 percent 0.003 mg eq/kg muscle, 81.8

percent TRR 0.011 mg eq/kg fat). 4-OH-isotianil and its glucuronide were also detected (combined 11.7 percent TRR 0.028 mg eq/kg kidney, 9.2 percent TRR 0.012 mg eq/kg liver, 12 percent TRR 0.002 mg eq/kg fat). Several minor unidentified metabolites were detected, none of which individually were greater than 0.006 mg eq/kg.

Laying hens

The metabolism of ^{14}C-isotianil was studied in laying hens. Hens were dosed orally *via* capsules, once a day for 14 consecutive days with ^{14}C-isotianil at doses equivalent to 17.7 [Ph] or 20.6 [IC] ppm in the diet. Hens were sacrificed 6 hours after the final dose.

Radioactivity plateaued in whole eggs within 8 days from the start of dosing at ca. 0.038 mg eq/kg in the [Ph]-label and within 7 days at ca. 0.083 mg eq/kg in the [IC]-label experiment.

By 6 hours after the last dose, the majority of the ^{14}C was recovered in excreta (94.4—95.1 percent AD). Eggs accounted for 0.08—0.18 percent AD while tissues accounted for 0.25—0.63 percent AD. Levels of ^{14}C were highest in liver (0.776—1.021 mg eq/kg) and kidney (0.229—1.731 mg eq/kg) with only low levels in fat (0.044—0.074 mg eq/kg), skin (0.064—0.077 mg eq/kg), and muscle (0.011—0.077 mg eq/kg).

Extractability with acetonitrile/water was good at 67.2—93.0 percent TRR [Ph-^{14}C] and 78.1—93.4 percent TRR [IC-^{14}C] from whole eggs and tissues (except liver). Recovery from liver was 31.0 percent TRR [Ph] and 45.1 percent TRR [IC]. Further radioactivity was released from egg and liver post-solvent extraction solids on sequential treatment with microwave assisted acetonitrile/water, aqueous formic acid and with hydrochloric acid. At the end ≤3 percent TRR from eggs or liver remained in the solids.

The majority of radioactive residues (67—100 percent TRR) was identified and/or characterized in tissues and eggs from the [Ph]- and [IC]-label dosed hens.

In the [Ph]-label experiment, isotianil was a major [^{14}C] residue in fat, accounting for 69—76 percent TRR (0.025—0.052 mg/kg) but was either not detected (liver) or a minor residue in other tissues and egg (egg 5.1 percent TRR 0.002 mg/kg, muscle 8.9 percent TRR 0.001 mg/kg). 4'-OH-isotianil accounted for 3.9—8.6 percent TRR (0.003 mg eq/kg) in fat, 6.6 percent TRR (0.051 mg eq/kg) in liver, 13 percent TRR (0.002 mg eq/kg) in muscle and 16 percent TRR (0.006 mg eq/kg) in eggs.

The phenyl-label specific metabolites included 2-amino-5-hydroxy-benzonitrile (liver 10.5 percent TRR 0.082 mg eq/kg), sulphate of 2-amino-5-hydroxy-benzonitrile (egg 9.8 percent TRR 0.004 mg eq/kg, leg muscle 21 percent TRR 0.003 mg eq/kg, liver 0.6 percent TRR 0.004 mg eq/kg), acetyl-2-amino-5-hydroxy-benzonitrile (liver 4 percent TRR 0.031 mg eq/kg), conjugate of sulphate of 2-amino-5-hydroxy-benzonitrile (liver 4.1 percent TRR 0.031 mg eq/kg), and 2-aminobenzonitrile (liver 14.2 percent TRR 0.110 mg eq/kg). A compound releasing 2-aminobenzonitrile on acid treatment accounted for 1.5 percent (0.011 mg eq/kg) in liver to 17.6 percent TRR (0.007 mg eq/kg) in egg. Bis-cysteinyl-isotianil was detected at 1.6 percent TRR in liver (0.012 mg eq/kg). Several other minor unidentified metabolites were also detected, none of which individually were greater than 8.9 percent TRR, which combined accounted for 8.9-15 percent TRR in eggs and tissues.

In the [IC]-label experiment, isotianil was a major [^{14}C] residue in fat, accounting for 39-45 percent TRR (0.024-0.046 mg/kg) but was either not detected (liver, muscle) or a minor residue in egg (2.7 percent TRR 0.002 mg/kg). 4'-OH-isotianil accounted for 5.3-18 percent TRR (0.005-0.011 mg eq/kg) in fat, 5.3 percent TRR (0.054 mg eq/kg) in liver, and 8 percent TRR (0.007 mg eq/kg) in eggs.

The [IC]-label specific metabolite DCIT-acid comprised the major part of [^{14}C] residue (34-89 percent TRR) in eggs (49.5 percent TRR 0.041 mg eq/kg), fat (35-43 percent TRR 0.021-0.045 mg eq/kg), muscle (88 percent TRR 0.048-0.086 mg eq/kg) and liver (34 percent TRR 0.348 mg eq/kg). Bis-cysteinyl-isotianil was detected at 0.8 percent TRR in liver (0.008 mg eq/kg). Several minor unidentified metabolites were also detected, none of which individually were greater than 6.7 percent TRR, which combined accounted for up to 15.7 percent TRR in eggs and tissues.

The metabolism of [^{14}C]-isotianil was similar in lactating goats and laying hens. Hydrolysis of the amide bond of isotianil occurs leading to DCIT-acid and 2-aminobenzonitrile, hydroxylation of the phenyl moiety, leading to 4'-OH-isotianil; hydrolysis of the amide bond of 4'-OH-isotianil leading to the formation of 2-amino-5-hydroxy-benzonitrile followed by conjugation with sulfuric acid and acetylation of 2-amino-5-hydroxy-benzonitrile leading to acetyl-2-amino-5-hydroxy-benzonitrile. Additionally, dechlorination of the isothiazole-ring by conjugation with glutathione and subsequent degradation of the glutathione leading to bis-cysteinyl-isotianil and the formation of small polar compounds were also observed.

Environmental fate

The Meeting received aqueous and soil photolysis, aqueous hydrolysis and aerobic soil studies for isotianil.

In laboratory aerobic soil degradation studies on isotianil the major soil degradate was DCIT-acid (up to 81 percent applied radioactivity, peaking between 3 and 14 days) with mineralization to CO_2 reaching up to 89 percent applied radioactivity by 120 days incubation at 25°C. The laboratory DT_{50} values for isotianil degradation in different soils were 0.8 days (n=8, 0.1-2.7 days) and for DCIT-acid 15.8 days (n=4, 10-23.7 days).

The DT_{50} values indicate isotianil and DCIT-acid are not persistent in soil.

In a study on aqueous hydrolysis, isotianil was moderately persistent and was hydrolysed at environmental pHs with a DT_{50} at pH 7 and 25°C in the dark of 66.1 days. The major degradation products were DCIT-acid and 2-aminobenzonitrile.

Aqueous photolysis is fast and may be a significant route of degradation with a laboratory DT_{50} value in distilled water of 2.2 days or 7.4–9.4 days when adjusted to conditions in Tokyo, Japan. The major degradate observed was 2-aminobenzonitrile (max 14.5 percent applied radioactivity) with DCIT-acid only detected in the dark control samples. Photolysis may contribute to the degradation of isotianil in the environment.

Isotianil does not undergo significant photolytic degradation on moist soil when exposed to artificial sunlight. Photo-transformation of isotianil on soil surface is unlikely to contribute significantly to the degradation in the environment. No isotianil exclusive photodegradates of are formed.

Degradation of isotianil in flooded soil systems is moderate and isotianil is not expected to persist in water or sediment. DT_{50} values for water/sediment in two flooded soil studies were 42.7 and 53.9 days for isotianil and 22.7 and 33.3 days for DCIT-acid.

Methods of analysis

The Meeting received information on analytical methods for isotianil in plant and animal matrices. The methods are suitable for analysis of isotianil and metabolites DCIT-acid and 2-aminobenzonitrile in plant and isotianil and metabolites DCIT-acid, 2-aminobenzonitrile (free and conjugated), and 2-amino-5-hydroxybenzonitrile (free and conjugated) in animal matrices.

Isotianil and its metabolites DCIT-acid and 2-aminobenzonitrile were extracted from homogenized plant matrices using a mixture of acetonitrile and water (4:1 v/v). Processing of the extract differs for isotianil/DCIT-acid and 2-aminobenzonitrile. For isotianil and DCIT-acid the extract is acidified (0.25M HCl). For clean-up the extract is concentrated and loaded onto a Chromabond XTR (diatomaceous earth) cartridge and isotianil and DCIT-acid eluted with cyclohexane/ethyl acetate (85/15 v/v), evaporated to dryness and reconstituted for analysis by reverse phase LC-MS/MS in electrospray negative mode. For 2-aminobenzonitrile, the extract is acidified (1M HCl) and concentrated before addition of 5M NaOH and water. For clean-up the extract is loaded onto a Chromabond XTR (diatomaceous earth) cartridge and 2-aminobenzonitrile eluted with dichloromethane and toluene, the dichloromethane removed by evaporation and the 2-aminobenzonitrile derivatized by addition of acetonitrile and benzoyl chloride before analysis by reverse phase LC-MS/MS in electrospray positive mode.

The LOQs for plant commodities are typically 0.01 mg/kg expressed as isotianil, for each compound. The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure isotianil, DCIT-acid and 2-aminobenzonitrile in plant commodities.

Analysis of plant commodities for parent isotianil using QuEChERS was validated for a range of commodities but not for DCIT-acid.

For animal commodities, the method involved two extractions with acetonitrile/water. After centrifuging, an aliquot of the extract was analysed for isotianil and DCIT-acid by reversed phase LC-MS/MS. A second aliquot was derivatized with benzoyl chloride, and subsequently analysed by reversed phase LC-MS/MS for “free” 2-aminobenzonitrile and 2-amino-5-hydroxybenzonitrile. A third aliquot was enzymatically treated with β-glucuronidase/arylsulphatase to cleave potential glucuronide and sulphate conjugates of 2-aminobenzonitrile and 2-amino-5-hydroxybenzonitrile, cleaned up, derivatized with benzoyl chloride, and subsequently analysed by reversed phase LC-MS/MS for 2-aminobenzonitrile and 2-amino-5-hydroxybenzonitrile. The LOQ for isotianil and its metabolites DCIT-acid and 2-aminobenzonitrile was 0.01 mg/kg per analyte expressed as isotianil in milk, cream, whey, eggs, muscle, fat, kidney, and liver. For 2-amino-5-hydroxybenzonitrile and conjugates hydrolysable to 2-amino-5-hydroxybenzonitrile, the LOQ was 0.01 mg/kg (expressed as isotianil) in milk, cream, whey, eggs, muscle, and fat; 0.1 mg/kg for cattle liver; and 0.025 mg/kg for cattle kidney. The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure isotianil, DCIT-acid, 2-aminobenzonitrile (free and conjugated) and 2-amino-5-hydroxybenzonitrile (free and conjugated) in animal commodities.

Stability of pesticide residues in stored analytical samples

The Meeting received information on storage stability of isotianil and metabolites (DCIT-acid, 2-aminobenzonitrile) in raw/processed plant commodities.

Isotianil residues are stable for at least 24 months in high-water-content fruit (apple), high-acid-content fruit (lemon), high-protein-content seed (kidney bean seed) and high-starch-content grain (wheat grain) commodities stored under frozen conditions (≤-18°C). Isotianil residues were also stable for at least 22 months in high-oil-content seed (soya bean seed) commodities stored under frozen conditions (≤-18°C).

DCIT-acid residues are stable for at least 24 months in high-water-content fruit (apple), high-acid-content fruit (lemon), high-starch-content grain (wheat grain), at least 23 months in high-protein-content seed (kidney bean seed), and at least 22 months in high-oil-content seed (soya bean seed) commodities stored under frozen conditions (≤-18°C).

2-Aminobenzonitrile residues are stable for up to 6 months in high-water-content fruit (apple), up to 1 month in high-acid-content fruit (lemon), up to 24 months in high-protein-content seed (kidney bean seed), at least 18 months in high-starch-content grain (wheat grain), and for at least 22 months in high-oil-content seed (soya bean seed) commodities stored under frozen conditions (≤-18°C).

Samples of banana and citrus fruit from the supervised residue and processing trials were stored for a maximum of 23 months prior to analysis.

Freezer storage stability studies were not available for animal commodities. All analyses in the feeding trials for ruminants and poultry were conducted within <30 days of sampling and samples not analysed within 24 hours of sampling were stored deep frozen until analysis.

Definition of the residue

Plant commodities

The metabolism of isotianil was similar in the submitted crops (soil: lemon, potato; foliar: lemon, tomato, potato; as well as to soil and water in paddy rice).

In summary, following foliar application to lemon, tomato, and potato unchanged isotianil was a major ^{14}C residue (lemon fruit 91-92 percent TRR day 1, 0.95-0.97 mg/kg; tomato fruit 76-91 percent TRR 0.167-0.320 mg/kg 7 days; potato tubers 11 percent TRR 0.004 mg/kg 28 days). The major residue identified in potato tubers was DCIT-acid (35.5 percent TRR, 0.041 mg eq/kg) while in vines it was isotianil (93-97 percent TRR, 33.5-45.6 mg/kg).

Following soil application to lemon and potato, isotianil was the major residue identified in lemon fruit at 1d and 29 d after last application (39-58 percent TRR, 0.002-0.006 mg/kg at 1 day, 2-11 percent TRR, <0.001-0.002 mg/kg at 29 days) and in potato vines 28 d after application (78-90 percent TRR, 0.692-1.037 mg/kg) while in potato tubers DCIT-acid was the major residue identified (34.8 percent TRR, 0.019 mg eq/kg).

Following application to rice at transplanting followed by flooding and subsequently to paddy water, isotianil was a significant component of the identified residues (husked rice 1.8-5.3 percent TRR 0.003 mg/kg, immature plants 0.5-5.9 percent TRR 0.005-0.016 mg/kg, hulls 4.5-5.4 percent TRR 0.014-0.030 mg/kg, straw 9.4-11 percent TRR 0.123-0.454 mg/kg). The major residues identified in husked rice, hulls, straw and immature plants were 2-aminobenzonitrile (husked rice 16.2 percent TRR 0.009 mg eq/kg, immature plants 9.2 percent TRR 0.024 mg eq/kg, hulls 14.6 percent TRR 0.046 mg eq/kg, straw 13.7 percent TRR 0.178 mg eq/kg) and DCIT-acid

(husked rice 6.1 percent TRR 0.010 mg eq/kg, immature plants 6.8 percent TRR 0.070 mg eq/kg, hulls 17.3 percent TRR 0.095 mg eq/kg, straw 18.2 percent TRR 0.752 mg eq/kg).

In supervised field trials on citrus and bananas, isotianil was the most frequently detected residue with DCIT-acid generally occurring at levels much lower than isotianil for citrus and not detected in bananas. The exception is soil application citrus trials where residues are infrequent and where detected, DCIT-acid occurred more frequently than isotianil. 2-aminobenzonitrile was not detected in any trials on citrus following foliar or soil application or banana following foliar application.

Isotianil and DCIT-acid are the most significant residues among the commodities investigated and validated analytical methods are available for their determination.

Parent isotianil occurs in all commodities. The Meeting decided the residue definition for compliance with MRLs in plants should be isotianil.

In deciding which compounds should be included in the residue definition for risk assessment the Meeting considered the likely occurrence of the compounds present at 10 percent of the parent compound (isotianil) and the toxicological properties of the candidates. Compounds considered were 2-aminobenzonitrile (rice) and DCIT-acid (lemon, potato, rice).

Similar toxicity to parent isotianil is assumed for the major degradate/metabolite DCIT-acid and it is assumed to be covered by the HBGVs for isotianil.

DCIT-acid was a significant component of the ^{14}C residues following foliar application to tomato (6.7-8.9 percent TRR 0.019-0.025 mg eq/kg), potato tubers (28 DALA, 35.5 percent TRR 0.041 mg eq/kg), potato vines (28 DALA, 4.1 percent TRR 2.0 mg eq/kg), potato tubers following soil application (34.8 percent TRR 0.019 mg eq/kg) and paddy rice commodities (brown rice 6.1 percent TRR 0.010 mg eq/kg, immature plants 6.8 percent TRR 0.070 mg eq/kg, hulls 17.3 percent TRR 0.095 mg eq/kg, straw 18.2 percent TRR 0.752 mg eq/kg).

The Meeting agreed that the residue definition for dietary risk assessment should be the sum of isotianil and DCIT-acid (expressed as isotianil).

2-Aminobenzonitrile was a significant metabolite in rice commodities (husked rice 16.2 percent TRR 0.009 mg eq/kg, immature plants 9.2 percent TRR 0.024 mg eq/kg, hulls 14.6 percent TRR 0.046 mg eq/kg, straw 13.7 percent TRR 0.178 mg eq/kg).

Insufficient toxicological data was available for 2-aminobenzonitrile, and the Meeting considered it could be assessed using the threshold of toxicological concern (TTC) approach (Cramer class III 1.5 µg/kg bw/day).

Animal commodities

Regarding the residue definition for livestock commodities, the metabolism of isotianil in lactating goats and laying hens was qualitatively similar. Isotianil was a major component of the residue in the fat of laying hens (38.7-76.3 percent TRR 0.024-0.052 mg/kg), a minor component in eggs (2.7-5.1 percent TRR 0.002 mg eq/kg) and not detected in laying hen liver or milk and tissues of lactating goats.

The predominant residue in the lactating goat and laying hen metabolism studies with [IC]-isotianil was DCIT-acid (goat: muscle 44.9 percent 0.003 mg eq/kg, fat 81.8 percent 0.011 mg eq/kg, kidney 76.7 percent 0.181 mg eq/kg, liver 19.8 percent 0.027 mg eq/kg, milk 72.9 percent 0.011 mg eq/kg; hen: egg 49.5 percent 0..041 mg eq/kg, muscle 87.8-88.5 percent 0.048-

0.086 mg eq/kg, fat 35.1-42.9 percent 0.021-0.045 mg eq/kg, liver 34.1 percent 0.348 mg eq/kg). The sum of 4'-OH-isotianil and its glucuronide conjugate was also present at >10 percent TRR (goat: liver 5-9.2 percent 0.011-0.012 mg eq/kg, kidney 11.7-24 percent 0.028-0.056 mg eq/kg, fat 0-12 percent 0.002 mg eq/kg, hen: egg 8-16.2 percent, 0.006-0.007 mg eq/kg, muscle 13.1 percent 0.002 mg eq/kg, fat 3.9-18.2 percent 0.003-0.011 mg eq/kg, liver 5.3-6.6 percent 0.051-0.054 mg eq/kg).

The predominant residue in the lactating goat metabolism study with [Ph]-isotianil was conjugates of 2-amino-hydroxybenzonitrile: the sulphate of 2-amino-5-hydroxybenzonitrile (milk 69 percent 0.016 mg eq/kg, kidney 39 percent 0.088 mg eq/kg), the glucuronide of 2-amino-5-hydroxybenzonitrile (kidney 17 percent 0.038 mg eq/kg, liver 3 percent 0.007 mg eq/kg) and the sulphate of 2-amino-hydroxybenzonitrile (milk 18 percent 0.004 mg eq/kg). Small amounts of 2-aminobenzonitrile were detected in the laying hen study (eggs 6.2 percent 0.002 mg eq/kg, fat 12.9-13.4 percent 0.005-0.009 mg eq/kg, liver 14.2 percent 0.110 mg eq/kg) but not the lactating goat study.

Methods are available for the determination of isotianil, DCIT-acid, 2-aminobenzonitrile (free and conjugated), 2-amino-5-hydroxybenzonitrile (free and conjugated) in tissues, milk and eggs.

The Meeting agreed the residue for compliance monitoring for tissues, milk and eggs should be the sum of isotianil and DCIT-acid (expressed as isotianil).

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates: isotianil, 4'-OH-isotianil (free and conjugated), DCIT-acid, 2-amino-5-hydroxybenzonitrile, sulphate of 2-amino-5-hydroxybenzonitrile (free and conjugated), acetyl-2-amino-5-hydroxybenzonitrile, sulphate of 2-amino-hydroxybenzonitrile, and 2-aminobenzonitrile (free and conjugated).

Using estimates of livestock dietary burden, the Meeting noted that residues of isotianil and metabolites are not expected (<0.01 mg/kg).

The Meeting agreed that the residue definition for dietary risk assessment for tissues and milk should be the sum of isotianil and DCIT-acid (expressed as isotianil).

The Meeting noted that while parent isotianil is not regarded as genotoxic, possibility of genotoxicity could not be excluded for the sulphate conjugates of 2-amino-hydroxybenzonitrile, due to the lack of toxicological information on these metabolites and quantification of metabolites in rat metabolism. The Meeting considered that these metabolites could be assessed using the TTC approach for genotoxic compounds (0.0025 µg/kg bw/day).

If the use of isotianil is expanded to crops fed to livestock, the residue definition may need to be revisited.

The Meeting recommended the following residue definitions for isotianil:

- Definition of the residue for compliance with the MRL for plant commodities: *isotianil*
- Definition of the residue for compliance with the MRL for animal commodities: *sum of isotianil, DCIT-acid, expressed as isotianil*
- Definition of the residue for dietary risk assessment for plant and animal commodities: *sum of isotianil, DCIT-acid, expressed as isotianil.*

In deciding whether the residue for compliance monitoring is regarded as fat-soluble, the Meeting noted mean residues at the highest dose level in the laying hen transfer study, residues in the highest dose group were <0.02 mg/kg in muscle and 0.020 mg/kg in fat and 0.046 mg/kg in skin+fat.

The Meeting considers the residue should be classified as not fat-soluble.

Results of supervised residue trials on crops

Supervised trials were available for the use of isotianil on citrus (orange, lemon, grapefruit, mandarin) and banana crops.

When calculating the sum of isotianil and DCIT-acid, values below the LOQ were assumed to be at the LOQ. Examples are shown below:

Isotianil (mg/kg)	DCIT-acid (mg eq/kg)	Sum (mg/kg)
<0.01	<0.01	<0.02
0.02	<0.01	0.03
<0.01	0.02	0.03

The residue concentrations in the evaluation tables are expressed in terms isotianil equivalents.

In evaluating the crop residue data, a range of values are required to be derived. Estimates are made for residues of:

- Isotianil for estimation of maximum residue levels for plant commodities
- Total residues (isotianil+DCIT-acid) for estimation of maximum residue levels for animal commodities and for estimation of STMR and HR values for plant and animal commodities

Citrus

The critical GAP for isotianil on citrus in Cambodia is five foliar applications at 0.075 kg ai/ha (maximum season 0.375 kg ai/ha) at 21-day intervals with a PHI of 1 day.

Trials conducted on citrus in the United States were made available to the Meeting. At each trial site separate plots were treated with four soil applications or five foliar applications or a single soil application followed by four foliar applications. At some trial locations, residues at the PHI were higher in the plots with a single soil application followed by four foliar applications than the plots matching cGAP. The Meeting considered the initial soil application at >100 days prior to harvest will not contribute to the residues detected at harvest and that it is the last two foliar applications that drive the residues. The Meeting agreed to use the higher of the plots with five foliar or one soil plus four foliar applications for estimating maximum residue levels, STMR and HR levels.

The Meeting noted that when measured, residues in pulp were all <0.01 mg/kg for isotianil and <0.02 mg/kg for total residues). A conservative estimate of the ratio of residues in pulp to whole fruit can be obtained from the metabolism study on lemons following foliar application where total residues in pulp were 9.8 percent of total residues in whole fruit. The Meeting agreed to use a factor of 0.098 to convert **total residues** in whole fruit to **total residues** in pulp, the edible portion.

Oranges:

Residues of **isotianil** matching cGAP were (n=9): 0.032, 0.036, 0.067, 0.098, 0.10, 0.11, 0.12, 0.14, 0.21 mg/kg.

The median **isotianil** residue for use in estimating median residues in citrus pulp on processing is 0.10 mg/kg.

Total residues in whole fruit matching cGAP were (n=9): 0.042, 0.046, 0.077, 0.11, 0.12, 0.13, 0.13, 0.17, 0.23 mg/kg (highest individual analytical result 0.24 mg/kg).

The median **total residue** for use in estimating median residues in citrus pulp on processing is 0.12 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR (edible portion) of 0.012 (0.12×0.098) mg/kg for isotianil in the subgroup of oranges, sweet, sour (including orange-like hybrids).

Lemons:
Residues of **isotianil** matching cGAP were (n=5): 0.015, 0.054, 0.11, 0.11, 0.24 mg/kg.

Total residues matching cGAP were (n=5): 0.025, 0.064, 0.12, 0.12, 0.29 mg/kg (highest individual analytical result 0.31 mg/kg).

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR (edible portion) of 0.012 (0.12×0.098) mg/kg for isotianil in the subgroup of lemons and limes (including citron).

Mandarins:
Residues of **isotianil** matching cGAP were (n=4): 0.086, 0.12, 0.14, 0.21 mg/kg.

Total residues matching cGAP were (n=4): 0.096, 0.14, 0.16, 0.24 mg/kg (highest individual analytical result 0.24 mg/kg).

There are insufficient trials on lemons to estimate a maximum residue level however, the Meeting has previously reviewed residues in lemons and mandarins and noted that residues in lemons and mandarins are similar and that residues in lemons can be used to support a maximum residue for mandarins. The Mann-Whitney test suggests the distributions are similar and the Meeting decided to combine the residues for estimating a maximum residue level.

Residues of **isotianil** matching cGAP were (n=9): 0.015, 0.054, 0.086, 0.11, 0.11, 0.12, 0.14, 0.21, 0.24 mg/kg.

Total residues matching cGAP were (n=9): 0.025, 0.064, 0.096, 0.12, 0.12, 0.14, 0.16, 0.24, 0.29 mg/kg (highest individual analytical result 0.31 mg/kg).

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR (edible portion) of 0.012 (0.12×0.098) mg/kg for isotianil in the subgroup of mandarins (including mandarin-like hybrids).

Grapefruit:
Residues of **isotianil** matching cGAP were (n=6): 0.038, 0.055, 0.058, 0.065, 0.070, 0.11 mg/kg.

Total residues matching cGAP were (n=6): 0.048, 0.065, 0.068, 0.075,0.080, 0.13 mg/kg (highest individual analytical result 0.13 mg/kg).

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR (edible portion) of 0.00715 (0.0715×0.098) mg/kg for isotianil in the subgroup of pummelo and grapefruits (including shaddock-like hybrids, among others grapefruit).

Bananas

The critical GAP for isotianil on **bagged banana** in Australia, Colombia, Guatemala, Honduras, Panama and the Dominican Republic is four foliar applications at 0.05 kg ai/ha (maximum season 0.2 kg ai/ha) with a retreatment interval of 56 days, do not apply after 8-leaf stage in Australia, 3 months (90 days) for the last two applications central America and 42 days in Colombia. The PHI is 0 days or not required when used as directed.

In supervised trials on banana, the number of applications was eight at intervals of 28 days compared with the cGAP which is a maximum of four applications at intervals ranging from not specified to 90 days for countries of central America. The Meeting noted that the trials involved exaggerated number of applications and that in all cases residues were <LOQ.

Residues of **isotianil** approximating cGAP were (n=12): <u>≤0.01</u> (12) mg/kg

Total residues approximating cGAP were (n=12): <u>≤0.02</u> (12) mg/kg

The Meeting estimated a maximum residue level of 0.01* mg/kg, and an STMR of 0.02 mg/kg for isotianil in banana.

Fate of residues during processing

The Meeting received information on the fate of isotianil residues following hydrolysis under conditions simulating commercial processing.

The hydrolytic stability of isotianil and DCIT-acid was studied in sterile aqueous buffers at pH 4 at 90 °C for 20 minutes, pH 5 at 100 °C for 60 minutes and pH 6 at 120 °C for 20 minutes to simulate commercial processing practices (pasteurization, baking/brewing/boiling and sterilization).

Isotianil was not significantly degraded during the simulation of pasteurization (pH 4, 90 °C) and baking/brewing/boiling (pH 5, 100 °C) with isotianil representing ≥96 percent AR at the end of the experiment. In contrast, significant degradation occurred during sterilization (pH 6, 120 °C) with isotianil accounting for 58-59 percent AR at the end of the experiment, 2-aminobenzonitrile for 42 percent AR ([Ph]-label) and DCIT-acid for 36 percent AR ([IC]-label).

The effect of processing of DCIT-acid was also studied. DCIT-acid was also not degraded during the simulation of pasteurization (pH 4, 90 °C) and baking/brewing/boiling (pH 5, 100 °C) with only minor degradation occurring during sterilization (pH 6, 120 °C). DCIT-acid accounted for ≥87 percent AR at the end of the experiment with DCIT present at 13 percent AR.

The Meeting received information on the fate of isotianil residues during processing of oranges.

Processing factors and median and highest residue values for isotianil – used for estimation of plant commodity maximum residue levels.

Processed commodity	Raw commodity median residue (highest) (mg/kg)	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)
Orange juice	0.10	<0.11 <0.19	0.11	0.011
Orange oil	(0.24)	67 104	85.5	8.55

Processed commodity	Raw commodity median residue (highest) (mg/kg)	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg/kg)
Orange peel processed		1.1 2.4	1.75	0.175
Orange pomace dried		0.25 0.93	0.59	0.059
Orange pomace wet		<0.19 0.23	0.21	0.021
Orange pulp dry		0.22 1.1	0.66	0.066
Marmalade		<0.11 <0.19	0.11	0.011

Processing factors and median and highest residue values for **Total residues** (sum of isotianil and DCIT-acid) – used for STMR and median estimation and for livestock dietary burdens.

Processed commodity	Raw commodity median residue (highest) (mg eq/kg)	Individual processing factors	Median or best estimate processing factor	Median residue-P (mg eq/kg)
Orange juice	0.12	<0.17 <0.32	0.17	0.0204
Orange oil	(0.31)	56 75	65.5	7.86
Orange peel processed		1.1 2.5	1.8	0.216
Orange pomace dried		0.53 1.4	0.965	0.1158
Orange pomace wet		<0.32 0.34	0.33	0.0396
Orange pulp dry		0.46 1.4	0.93	0.1116
Marmalade		<0.17 <0.32	0.17	0.0204

Using the estimated maximum residue level of 0.4 mg/kg for the group of citrus and applying the processing factors of 85.5 for orange oil for residues of isotianil and 65.5 for total residues, the Meeting estimated a maximum residue level of 40 mg/kg for citrus oil, and a median residue of 7.86 mg/kg for total residues.

Residues in animal commodities

Farm animal feeding studies

The Meeting received a study on the transfer of isotianil to tissues and milk of dairy cows following oral dosing.

Groups of lactating cows were dosed once daily with isotianil at the equivalent of 1.01, 3.40, 9.18, and 34.48 ppm in the feed for 28 days with sacrifice within 24 hours of the last dose. Samples of milk and tissues were analysed for isotianil, DCIT-acid, 2-aminobenzonitrile, 2-aminobenzonitrile conjugates, 2-amino-5-hydroxybenzonitrile and 2-amino-5-hydroxybenzonitrile conjugates.

No residues of isotianil or metabolites were detected in milk at the dose levels studied (max 34.48 ppm).

No residues of isotianil, 2-aminobenzonitrile or 2-aminobenzonitrile conjugates were detected in any tissue samples. DCIT-acid was only detected at the 9.18 and 34.48 ppm dose levels while 2-amino-5-hydroxybenzonitrile and 2-amino-5-hydroxybenzonitrile conjugates were only detected in kidney at the 34.48 ppm dose level. Mean DCIT-acid residues in kidney were 0.015 and 0.051 mg/kg for the 9.18 and 34.48 ppm feed levels, respectively. Mean 2-amino-5-hydroxybenzonitrile residues in kidney were <0.025 mg/kg for the 34.48 ppm feed level, while mean 2-amino-5-hydroxybenzonitrile conjugate residues in kidney were 0.045 mg/kg.

A laying hens transfer study for isotianil was made available to the Meeting. Hens were dosed orally daily for 28 days at the equivalent of 1.04, 3.12 and 10.59 ppm in the diet with sacrifice within 6 hours of the last dose. Samples of milk and tissues were analysed for isotianil, DCIT-acid, 2-aminobenzonitrile, 2-aminobenzonitrile conjugates, 2-amino-5-hydroxybenzonitrile and 2-amino-5-hydroxybenzonitrile conjugates.

No residues of isotianil or metabolites were detected in eggs at the dose levels studied (max 10.59 ppm).

Of the tissues, isotianil was only detected in fat and only at the highest dose level with mean residues 0.01 mg/kg.

No residues of 2-aminobenzonitrile, 2-aminobenzonitrile conjugates, 2-amino-5-hydroxybenzonitrile or 2-amino-5-hydroxybenzonitrile conjugates were detected in any tissue samples. DCIT-acid was only detected at the 3.12 ppm dose level in liver (mean 0.017 mg/kg) and skin with adhering fat (0.011 mg/kg) and 10.59 ppm dose levels in fat (0.010 mg/kg), liver (0.057 mg/kg), muscle (0.018 mg/kg) and skin with adhering fat (0.036 mg/kg).

Farm animal dietary burden

Those commodities and their input values used in estimating livestock dietary burdens are listed in the Recommendations Tables (citrus pulp, dry).

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR by the current Meeting. The dietary burdens, estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarized below.

Residues in animal commodities were estimated for the total residues (sum of isotianil and DCIT-acid) for use in estimating maximum residue levels and for dietary risk assessment.

Estimated maximum and mean dietary burdens of farm animals (isotianil+DCIT-acid)

	Animal dietary burden: isotianil+DCIT-acid, ppm of dry matter diet							
	US-Canada		**EU**		**Australia**		**Japan**	
	max	**mean**	**max**	**mean**	**max**	**mean**	**max**	**mean**
Beef cattle	0.013	0.013	0.006	0.006	0.038□	0.038□		
Dairy cattle	0.013	0.013	0.025	0.025	0.038□	0.038□		

□ Highest maximum beef or dairy cattle dietary burden suitable for MRL and HR estimates for mammalian tissues and milk.
□ Median beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.

Animal commodity maximum residue levels

Cattle

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

Total residues (sum of isotianil+DCIT-acid)

	Feed Level (ppm) for milk residues	Isotianil +DCIT-acid residues (mg/kg) in milk	Feed Level (ppm) for tissue residues	Isotianil+DCIT-acid residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
Highest residue for maximum residue level estimation (beef or dairy cattle)							
Feeding Study	34.48	<0.02	34.48	<0.02	<0.02	0.061	<0.02
Dietary burden and estimate of highest residue	0.038	0.000022	0.038	0.000022	0.000022	0.000067	0.000022

The Meeting estimated the following maximum residue levels: milk *0.02 mg/kg; meat (mammalian except marine mammals) *0.02 mg/kg, mammalian fat (except milk fat) *0.02 mg/kg and edible offal *0.02 mg/kg. The Meeting estimated the following STMRs: mammalian meat 0 mg/kg; mammalian fat 0 mg/kg; liver 0 mg/kg, kidney 0 mg/kg and milk 0 mg/kg.

Poultry

There is no dietary burden for poultry. The Meeting estimated the following maximum residue levels for poultry commodities: eggs *0.02 mg/kg; poultry meat *0.02 mg/kg, poultry fat *0.02 mg/kg and poultry edible offal *0.02 mg/kg to replace its previous recommendations.

The Meeting estimated the following STMRs: poultry meat 0 mg/kg; poultry fat 0 mg/kg; liver 0 mg/kg and eggs 0 mg/kg.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

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

Definition of the residue for compliance with the MRL for animal commodities and for dietary risk assessment for plant and animal commodities: *sum of isotianil and 3,4-dichloro-1,2-thiazole-5-carboxylic acid (DCIT-acid)*.

The residue is not fat-soluble.

Desirable: should uses expand to crops that are rotated, studies relevant to residues in rotated crops.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for isotianil is 0–0.05 mg/kg bw. The IEDIs for isotianil were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs was less than 1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of isotianil from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The current Meeting determined that the establishment of an acute reference dose is unnecessary for isotianil. The Meeting concluded that the acute dietary exposure to residues of isotianil, from uses considered by the present Meeting, is unlikely to present a public health concern.

Consideration of metabolites using TTC approach

The Meeting considered 2-aminobenzonitrile could be assessed using the TTC for Cramer Class III compounds of 1.5 µg/kg bw per day.

The estimated exposure based on metabolism and processing studies, resulted in the following maximum long-term exposure:
2-aminobenzonitrile 0.0375 µg/kg bw per day.

The estimated exposure is below the TTC for Cramer Class III compounds. The Meeting concluded that 2-aminobenzonitrile is unlikely to present a dietary exposure concern from the uses evaluated by the current Meeting. Should further uses be considered in the future, this conclusion may need to be re-evaluated.

The Meeting also considered the sulphate conjugates of 2-aminohydroxybenzonitrile could be assessed using the TTC for genotoxic compounds of 0.025 µg/kg bw per day.

The estimated exposure based on metabolism studies, resulted in the following maximum long-term exposure:

sulphate conjugates of 2-aminohydroxybenzonitrile 0.00002834 µg/kg bw per day.

The estimated exposure is below the TTC for genotoxic compounds. The Meeting concluded that sulphate conjugates of 2-aminohydroxybenzonitrile are unlikely to present a dietary exposure concern from the uses evaluated by the current Meeting. Should further uses be considered in the future, this conclusion may need to be re-evaluated.

5.23 Mepiquat chloride (336) (T,R)*

TOXICOLOGY

Mepiquat chloride is the ISO-approved common name for 1,1-dimethylpiperidinium chloride (IUPAC), Chemical Abstracts Service number 24307-26-4. Mepiquat chloride is a quaternary ammonium compound which acts by inhibition of gibberellin biosynthesis, used as a plant growth regulator to restrict vegetative growth.

Mepiquat chloride has not previously been evaluated by Joint FAO/WHO Meeting on Pesticide Residue (JMPR) and was reviewed by the present Meeting at the request of the Codex Committee on Pesticide Residues (CCPR).

All critical studies contained statements of compliance with good laboratory practice (GLP), unless otherwise indicated. It is noted that, due to the hygroscopic nature of the pure substance a number of the studies were conducted using a test material of low and variable purity, in which the test substance was complexed with water. Limited additional information was identified in the literature that complemented the toxicological information submitted for the current evaluation.

Biochemical aspects

Mepiquat chloride was rapidly and extensively absorbed after an oral dose of [*2,6*-^{14}C]mepiquat chloride at either 1.2 or 12 mg/kg body weight (bw). The maximum concentration (C_{max}) at 1.2 mg/kg bw was reached 40 minutes after dosing, and 60 minutes after dosing at 12 mg/kg bw.

Levels were slightly higher (18–20 percent) in both the blood and plasma of females at the low dose than in that of males. Radiolabel was identified mainly in the gastrointestinal (GI) tract after eight hours, with levels dropping over subsequent time periods. Levels were also high in kidney after eight hours, and the urinary bladder at 24 hours. Levels in other tissues were low in all time periods. Mepiquat chloride was eliminated predominantly in urine, in part by active secretion, with up to 87.7 percent of the radiolabel eliminated via this route after a low oral dose of 1.2 mg/kg bw, or 81.5 percent of the radiolabel after a higher oral dose of 12 mg/kg bw.

Elimination via the faeces accounted for around 10–15 percent of the radiolabel. Less than 1 percent of the radiolabel was excreted in bile over 24 hours.

Metabolism of mepiquat chloride was extremely limited. No metabolites of mepiquat chloride were detected in urine, faeces or tissue samples during in vivo studies. In an in vitro comparative metabolism study with mouse, rat, dog and human liver microsomes, trace evidence of a hydroxylated metabolite was seen at the highest concentration in the rat and dog, and no unique human metabolites were identified.

Toxicological data

The acute oral median lethal dose (LD_{50}) of mepiquat chloride in mice was 780 mg/kg bw, and in rats it was 464 mg/kg bw; the dermal LD_{50} was greater than 2000 mg/kg bw. The inhalation median lethal concentration (LC_{50}) of mepiquat chloride was greater than 4.89 mg/L. Mepiquat

chloride was not irritating to skin or eyes of rabbits, and it was not skin sensitizing in either the mouse local lymph node assay (LLNA), nor in a non-guideline guinea pig maximization test.

In repeat-dose dietary studies in mice, rats and dogs, effects in mice and rats were limited to decreased body weight gain, associated with decreased food consumption. In dogs, salivation, sedation and neurological signs were seen at high doses, with deposition of iron pigment in the liver and spleen observed after 12 months.

In a 90-day dietary study in mice, mepiquat chloride was administered at 0, 300, 900, 1700 or 8100 ppm (equal to 0, 60, 186, 526 and 1731 mg/kg bw per day for males, 0, 83, 265, 705 and 2422 mg/kg bw per day for females). The no-observed-adverse-effect level (NOAEL) was 8100 ppm in the diet (equal to 1731 mg/kg bw per day), the highest dose tested.

In a 4-week dietary toxicity study in rats, mepiquat chloride was administered at 0, 500, 2000 or 8000 ppm (equal to 0, 44, 175 and 633 mg/kg bw per day for males, 0, 48, 191 and 688 mg/kg bw per day for females). The NOAEL was 8000 ppm (equal to 633 mg/kg bw per day), the highest dose tested.

In a 90-day dietary toxicity study (not GLP) in rats, mepiquat chloride was administered at 0, 100, 300, 1000 or 3000 ppm (equal to 0, 9.2, 27.6, 91.8 and 275.5 mg/kg bw per day for males, 0, 8.9, 26.7, 91.2 and 278.8 mg/kg bw per day for females). The NOAEL was 1000 ppm (equal to 91.2 mg/kg bw per day) based on reduced food consumption and body weight gain at 3000 ppm (equal to 275.5 mg/kg bw per day) as well as decreased weight of heart, lungs, spleen and kidney in males.

In a second 90-day dietary toxicity study in the same facility, mepiquat chloride was administered at 0, 145, 579, 2316 or 4632 ppm (equal to 0, 10, 40, 163 and 319 mg/kg bw per day for males, 0, 12, 47, 188 and 372 mg/kg bw per day for females). The NOAEL was 4632 ppm (equal to 319 mg/kg bw per day), the highest dose tested.

In a subsequent 90-day toxicity study in rats with doses of mepiquat chloride of 0 and 12 000 ppm, (equal to 0 and 826 mg/kg bw per day), systemic toxicity was seen at 12 000 ppm, and effects included impaired behaviour, tremors, impaired gait, ataxia, posture abnormalities, abnormal respiration and vocalizations. Effects were considered to be related to effects on the nicotinic acetylcholine-activated receptors. The lowest-observed-adverse-effect level (LOAEL) in this study was 12 000 ppm (equal to 826 mg/kg bw per day) the only dose tested.

Overall, the NOAEL for short-term effects in rats was 4632 ppm (equal to 319 mg/kg bw per day), a value that incorporated all available short-term studies in rats, based on a LOAEL of 12 000 ppm (equal to 826 mg/kg bw per day).

In a 90-day dietary toxicity study in dogs, mepiquat chloride was administered at 0, 100, 300, 1000 or 3000 ppm (equal to 0, 3.3, 9.8, 32.4 and 95.3 mg/kg bw per day). The NOAEL for toxicity was 1000 ppm (equal to 32.4 mg/kg bw per day) based on signs of sedation progressing to periodic lateral positioning and tonic–clonic spasms, as well as decreases in haemoglobin, erythrocytes and haematocrit after six and 13 weeks at 3000 ppm (equal to 95.3 mg/kg bw per day).

In a 12-month dietary study in dogs at dose levels of 0, 200, 600 or 1800 ppm (equal to 0, 6.3, 19.9 and 58.4 mg/kg bw per day) the NOAEL was 600 ppm (equal to 19.9 mg/kg bw per day) based on the deposition of iron pigment in the spleen and liver at 1800 ppm (equal to 58.4 mg/kg bw per day).

In a second 12-month dietary study in dogs, mepiquat chloride was initially administered in the diet at 0 or 8000 ppm, reduced to 6000 ppm (equal to 0 and 166 mg/kg bw per day). The LOAEL was 6000 ppm, equal to 166 mg/kg bw per day based on salivation, haematological changes, weight changes in kidneys, thyroid and adrenal glands, along with histopathological findings in the kidneys and spleen. It was noted that the haematological effects observed in the 90-day study and the increase in iron pigment stored in the spleen and liver in the 12-month study were likely to have been due to related effects. Overall, the NOAEL for effects in dogs was 1000 ppm (equal to 32.4 mg/kg bw per day) based on the deposition of iron pigment in spleen and liver at 1800 ppm (equal to 58.4 mg/kg bw per day).

In a chronic toxicity and carcinogenicity dietary study mice were fed mepiquat chloride for up to 104 weeks at 0, 500, 2000 or 7500 ppm (equal to 0, 74, 297 and 1140 mg/kg bw per day in males, 0, 85, 328 and 1348 mg/kg bw per day in females). No differences in the type or incidence of tumours were observed during the study, and there were no treatment-related changes in haemotology or pathology. The NOAEL for chronic toxicity was 2000 ppm (equal to 297 mg/kg bw per day) based on a decrease in body weight at 7500 ppm. The NOAEL for carcinogenicity was 7500 ppm (equal to 1140 mg/kg bw per day) the highest dose tested.

In a second toxicity and carcinogenicity study, mice were administered the test article at 0, 100, 300, 1000 or 3000 ppm (equal to 0, 16, 48.9, 169.4 and 513.5 mg/kg bw per day in males, 0, 21.7, 65.3, 226.1 and 689.4 mg/kg bw per day in females). The NOAELs for toxicity and carcinogenicity were both 3000 ppm (equal to 513.5 mg/kg bw per day), the highest dose tested.

The overall NOAEL for chronic toxicity in mice was 3000 ppm (equal to 513.5 mg/kg bw per day). The overall NOAEL for carcinogenicity was 7500 ppm (equal to 1140 mg/kg bw per day), the highest dose tested.

In a chronic study in rats, mepiquat chloride was fed for 24 months at dietary levels of 0, 290, 2316 or 5790 ppm (equal to 0, 13, 106 and 268 mg/kg bw per day for males, 0, 18, 146 and 371 mg/kg bw per day for females). The NOAEL for toxicity was 2316 ppm (equal to 106 mg/kg bw per day) based on reduced food consumption, decreased body weight and body weight gain and an increase in urinary crystals at 5790 ppm (equal to 268 mg/kg bw per day). While there were no signs of carcinogenicity at any dose, the study was not considered a suitable one from which to draw conclusions on carcinogenicity because of the small group size, consisting of just 20 rats of each sex per group.

In a chronic toxicity and carcinogenicity dietary study, mepiquat chloride was fed to rats for 24 months at 0, 290, 2316 or 5790 ppm (equal to 0, 13, 106 and 268 mg/kg bw per day for males, 0, 18, 146 and 371 mg/kg bw per day for females). The NOAEL for chronic toxicity was 2316 ppm (equal to 106 mg/kg bw per day), based on decreased body weight at 5790 ppm (equal to 268 mg/kg bw per day). The NOAEL for carcinogenicity was 5790 ppm (equal to 268 mg/kg bw per day), the highest dose tested.

In a combined chronic toxicity and carcinogenicity study, rats were fed mepiquat chloride in the diet for 104 weeks at 0, 100, 300, 1000, 3000 or 9000 ppm (equal to 0, 6. 18, 62, 186 and 684 mg/kg bw for males, 0, 7, 21, 72, 212 and 670 mg/kg bw per day for females). The NOAEL for chronic toxicity was 3000 ppm (equal to 186 mg/kg bw per day) based on depressed body weight compared to controls at 9000 ppm (equal to 670 mg/kg bw per day). The NOAEL for carcinogenicity was 9000 ppm (equal to 670 mg/kg bw per day), the highest dose tested.

Overall, the NOAEL for chronic toxicity in rats was 3000 ppm (equal to 186 mg/kg bw per day) based on effects on body weight at 5790 ppm (equal to 268 mg/kg bw per day). The overall NOAEL for carcinogenicity was 9000 ppm (equal to 670 mg/kg bw per day), the highest dose tested.

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

Mepiquat chloride was tested for genotoxicity in an adequate range of in vitro and in vivo assays. No evidence of genotoxicity was found.

The meeting concluded that mepiquat chloride is unlikely to be genotoxic.

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

In a multigeneration reproductive toxicity study, mepiquat chloride was administered to rats in the diet at 0, 500, 1500 or 5000 ppm, (equivalent to 0, 52, 155 and 500 mg/kg bw per day). The NOAEL for parental and offspring toxicity was 1500 ppm (equal to 155 mg/kg bw per day) based on decreased food consumption and body weight, as well as tremors during lactation in the dams, and decreased pup body weight, at 5000 ppm (equivalent to 500 mg/kg bw per day). The NOAEL for reproductive toxicity was 5000 ppm (equal to 500 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study, rats were administered mepiquat chloride by gavage at 0, 50, 150 or 300 mg/kg bw per day from gestation day (GD) 6 to GD 15. The NOAEL for maternal toxicity was 150 mg/kg bw per day, based on clinical signs of toxicity including tremors, piloerection, unsteady gait and hypersensitivity, as well as decreased body weight gain at 300 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 300 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study, mepiquat chloride was administered by gavage to rabbits at dose levels of 0, 50, 100 or 150 mg/kg bw per day from GD 7 to GD 19. The NOAEL for maternal toxicity was 50 mg/kg bw per day based on reduced body weight gain at 100 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 150 mg/kg bw per day, the highest dose tested.

The Meeting concluded that mepiquat chloride is not teratogenic.

In an acute neurotoxicity study, rats were dosed by gavage with mepiquat chloride as a single oral dose of 0, 58, 174 or 697 mg/kg bw. The NOAEL was 58 mg/kg bw, based on signs of toxicity in the functional observation battery and slightly decreased motor activity at 174 mg/kg bw.

In a subchronic neurotoxicity study, rats were fed mepiquat chloride in the diet for 13 weeks at concentrations of 0, 943, 3770 or 7540 ppm (equal to 0, 65.6, 259 and 517 mg/kg bw per day for males, 0, 79.4, 367, and 617 mg/kg bw per day for females). The NOAEL for neurotoxicity was 7540 ppm (equal to 517 mg/kg bw per day), the highest dose tested. The NOAEL for overall toxicity was 943 ppm, (equal to 66 mg/kg bw per day), based on decreased body weight gain at 3770 ppm (equal to 259 mg/kg bw per day).

The potential for developmental neurotoxicity was investigated with mepiquat chloride being administered to pregnant female rats at 0, 15, 30 or 60 mg/kg bw per day from GD 6 to post partum day (PPD) 10. Mepiquat chloride was then administered to pups at the same dose levels from PPDs 11 to 21. The NOAEL for development neurotoxicity was 60 mg/kg bw per day, the highest dose tested. The NOAEL for systemic toxicity in pups was 30 mg/kg bw per day, based on lethality at 60 mg/kg bw per day, primarily during the first three days of direct dosing.

The action of mepiquat chloride on nicotinic and muscarinic acetylcholine receptors was investigated. These studies indicate a specific, though slight, effect (ca 1% of acethylcholine effect) on nicotinic acetylcholine-activated receptors, and a measurable but very low and unselective affinity to muscarinic receptors.

The Meeting concluded that mepiquat chloride was neurotoxic only at doses that produced systemic toxicity.

The potential for immunotoxic effects was investigated in rats at dietary doses of mepiquat chloride of 0, 972, 2981 or 9000 ppm (equal to 0,82, 258 and 744 mg/kg bw per day) for four weeks. The NOAEL for systemic toxicity was 2981 ppm (equal to 258 mg/kg bw per day) based on decreased body weight at the highest dose of 9000 ppm (equal to 744 mg/kg bw per day). The NOAEL for immunotoxicity was 9000 ppm (equal to 744 mg/kg bw per day), the highest dose tested.

The Meeting concluded that mepiquat chloride is not immunotoxic.

Toxicological data on metabolites and/or degradates

4-Hydroxy-mepiquat chloride

In an acute oral toxicity test in rats, the LD_{50} for 4-hydroxy-mepiquat chloride was greater than 464 mg/kg bw.

Metabolite 4-hydroxy-mepiquat chloride was negative for mutagenicity in Salmonella typhimurium strains TA1535, TA100, TA1537, TA98 and *Escherichia coli* strain WP2 uvrA in the presence and absence of metabolic activation.

An in-silico comparison of mepiquat chloride and 4-hydroxy-mepiquat chloride was carried out using Derek Nexus and OECD QSAR Toolbox. All SAR alerts identified for 4-hydroxy-mepiquat chloride were also present for mepiquat chloride.

N-methyl piperidine

Metabolite *N*-methyl piperidine is a residual impurity detected in mepiquat chloride and was negative for mutagenicity in an Ames test.

The Meeting concluded that 4-hydroxy-mepiquat chloride is toxicologically relevant, and of no greater potency than the parent**.**

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of mepiquat chloride residues on the human intestinal microbiome.

Human data

No information was provided on the health of workers involved in the manufacture or use of mepiquat chloride. No information on accidental or intentional poisoning in humans was available.

The Meeting concluded that the existing database on mepiquat chloride was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The meeting established an ADI for mepiquat chloride of 0–0.3 mg/kg bw based on the overall NOAEL of 32.4 mg/kg bw per day in the 90-day and 12-month dog studies, and using a safety factor of 100. This ADI is considered applicable also to 4-hydroxy-mepiquat chloride.

The meeting established an ARfD of 0.6 mg/kg bw, based on the NOAEL of 58 mg/kg bw in the rat acute neurotoxicity study. A safety factor of 100 was used. This ARfD is considered applicable also to 4-hydroxy-mepiquat chloride.

A toxicological monograph was prepared.

Levels relevant to risk assessment of mepiquat chloride

Species	Study	Effect	NOAEL	LOAEL
Mouse	104-week studies of toxicity and carcinogenicity [a, d]	Toxicity	3000 ppm, equal to 513.5 mg/kg bw per day	7500 ppm, equal to 1140 mg/kg bw per day
		Carcinogenicity	7500 ppm, equal to 1140 mg/kg bw per day [c]	-
Rat	Acute neurotoxicity study [b]	Toxicity	58 mg/kg bw per day	174 mg/kg bw per day [e]
	90-day dietary studies [a]	Toxicity	4632 ppm, equal to 319 mg/kg bw per day	12 000 ppm, equal to 826 mg/kg bw per day
	Two-year studies of chronic toxicity and carcinogenicity [a, d]	Toxicity	3000 ppm, equal to 186 mg/kg bw per day	5790 ppm, equal to 268 mg/kg bw per day
		Carcinogenicity	9000 ppm, equal to 670 mg/kg bw per day [c]	-
	Two-generation study of reproductive toxicity [a]	Parental toxicity	5000 ppm, equal to 500 mg/kg bw per day [c]	-
		Offspring toxicity	1500 ppm, equal to 155 mg/kg bw per day	5000 ppm, equal to 500 mg/kg bw per day
		Maternal toxicity	1500 ppm, equal to 155 mg/kg bw per day	5000 ppm, equal to 500 mg/kg bw per day
	Developmental toxicity study [b]	Embryo/fetal toxicity	150 mg/kg bw per day	300 mg/kg bw per day
		Maternal toxicity	300 mg/kg bw per day [c]	-
Rabbit	Developmental toxicity study [b]	Embryo/fetal toxicity	50 mg/kg bw per day	100 mg/kg bw per day
		Toxicity	150 mg/kg bw per day [c]	-
Dog	13-week and 1 year studies of toxicity [a,d]		1000 ppm, equal to 32.4 mg/kg bw per day	1800 ppm, equal to 58.4 mg/kg bw per day

[a] Dietary administration;

[b] Gavage administration;

[c] Highest dose tested;

[d] Two or more studies combined;

[e] Lowest dose tested;

Acceptable daily intake (ADI), applies to mepiquat chloride and 4-hydroxy-mepiquat chloride, expressed as mepiquat chloride

0–0.3mg/kg bw

Acute reference dose (ARfD), applies to mepiquat chloride and 4-hydroxy-mepiquat chloride, expressed as mepiquat chloride

0.6 mg/kg bw

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

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

Critical end-points for setting guidance values for exposure to mepiquat chloride

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Mepiquat chloride was rapidly and extensively absorbed after oral dosing; absorption > 80% of AD
Dermal absorption	Absorbed, followed by urinary excretion
Distribution	Widely distributed, with highest levels in gastrointestinal tract, urinary bladder, liver and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid and nearly complete, with around 85% of administered radioactivity excreted via urine, and up to 15% in faeces; very limited excretion (<1%) via bile
Metabolism in animals	Extremely limited, with no metabolites detected in urine or faeces in in vivo studies Limited quantities of 4-hydroxy-mepiquat chloride detected in an in vitro comparative metabolism study
Toxicologically significant compounds in animals and plants	Mepiquat chloride and 4-hydroxy-mepiquat chloride
Acute toxicity	
Rat, LD_{50}, oral	464 mg/kg bw
Rat, LD_{50}, dermal	>2000 mg/kg bw
Rat, LC_{50}, inhalation	>4.89 mg/L
Rabbit, dermal irritation	Not irritating

Rabbit, ocular irritation	Not irritating
Mouse, dermal sensitization	Not sensitizing
Guinea pig, dermal sensitization	Not sensitizing
Short-term studies of toxicity	
Target/critical effect	Decreased body weight gain and food consumption (rat, dog) Effects on erythrocytes, along with increased haemosiderin in the spleen (dog)
Lowest relevant oral NOAEL	32.4 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Decreased body weight
Lowest relevant NOAEL	186 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic in mice or rats[a]
Genotoxicity	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Decreased body weight gain and food consumption
Lowest relevant parental NOAEL	155 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	155 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	500 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	Decreased body weight gain and food consumption, associated with delayed fetal development
Lowest relevant maternal NOAEL	50 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	150 mg/kg bw per day (rabbit)
Neurotoxicity	Signs of systemic toxicity were seen in a number of neurotoxicity studies, with specifically neurotoxic effects observed only in the presence of general toxicity
Acute neurotoxicity NOAEL	58 mg/kg bw (systemic toxicity relevant for ARfD)
Subchronic neurotoxicity NOAEL	517 mg/kg bw per day, highest dose tested (rat)

Developmental neurotoxicity NOAEL	60 mg/kg bw per day, highest dose tested (rat)
Other toxicological studies	
Immunotoxicity NOAEL	>744 mg/kg bw per day, the highest dose tested (rat)
Studies on toxicologically relevant metabolites	
4-Hydroxy-mepiquat chloride	Acute oral LD_{50}: >464 mg/kg bw (rat) Not genotoxic (Ames) In silico comparison with mepiquat chloride indicated comparable alerts
Microbiological aspects	No data submitted
Human data	No clinical cases or poisoning incidents have been recorded

[a] Unlikely to pose a carcinogenic risk to humans via exposure from the diet

Summary

	Value	Study	Safety factor
ADI	0–0.3 mg/kg bw [a]	Overall NOAEL in 90 day and 12-month studies (dog)	100
ARfD	0.6 mg/kg bw [a]	Acute neurotoxicity study, based on signs of systemic toxicity (rat)	100

[a] Applies to mepiquat chloride and 4-hydroxy-mepiquat chloride, expressed as mepiquat chloride

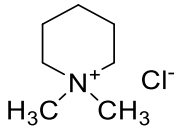
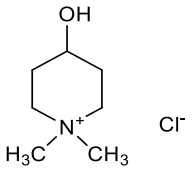
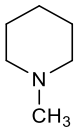
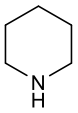
RESIDUE AND ANALYTICAL ASPECTS

Mepiquat chloride, a quaternary ammonium compound, is registered on a variety of crops worldwide, acting as a plant growth regulator by inhibiting the biosynthesis of gibberellic acid to reduce lodging in oilseed and to increase size of grape berries.

At the Fifty-second Session of CCPR (2021), mepiquat chloride was scheduled for consideration by the 2022 JMPR as a new compound for the use in cotton and grape, and the evaluation was carried over to the 2023 JMPR. The Meeting received the data for mepiquat chloride on plant and animal metabolism, environmental fate, methods of analysis, use pattern, residues resulting from supervised trials in grape and cotton, fate of residues in storage and processing, and residue in animal products.

Structures of compounds in this appraisal are as follows:

Name IUPAC-name	Structure	Name IUPAC-name	Structure

Mepiquat chloride 1,1-dimethylpiperidinium chloride		4-Hydroxymepiquat 4-hydroxy-1,1-dimethylpiperidinium chloride	
Methyl piperidine		Piperidine	

With respect to the physical and chemical properties that may impact on residues in crops, mepiquat chloride is not regarded as volatile, and it is highly water-soluble (log Pow is <-3).

Plant metabolism

The Meeting received information on the fate of mepiquat chloride in grape, wheat, barley, cotton and rape. The compound may exist in solution as mepiquat cation, but values for the parent compound is expressed as mepiquat chloride. In the metabolism studies, total radioactive residues (TRR) are expressed in mg mepiquat chloride equivalents/kg.

In the metabolism study on grape, [^{14}C]-mepiquat chloride was applied twice to grape plant in outdoor condition as foliar spray at rates of 1.1 kg ai/ha with an interval of 28 days. Grape berries harvested 98 days after the last treatment (DALA) were homogenized and extracted by 0.01 mol/L HCl in methanol (96 percent TRR, 1.0 mg eq/kg). The major component in the extract was mepiquat-chloride (80 percent TRR, 0.85 mg/kg).

In the metabolism study on wheat, [^{14}C]-mepiquat chloride was applied once to wheat as foliar spray at a rate of 0.70 kg ai/ha. Wheat grain harvested at 71 days after treatment (DAT) was homogenized and sequentially extracted by methanol (59 percent TRR, 0.46 mg eq/kg) and then water (3.0 percent TRR, 0.023 mg eq/kg). All of the extracted components by methanol and water were identified as mepiquat chloride (59 percent TRR, 0.46 mg/kg and 3.0 percent TRR, 0.023 mg/kg, respectively). Additional radioactive residues were released by extraction with 10 g/L aqueous ammonia (5.5 percent TRR, 0.043 mg eq/kg), followed by enzyme hydrolysis with macerozyme (19 percent TRR, 0.15 mg eq/kg) and then amylase/amyloglucosidase (2.4 percent TRR, 0.019 mg eq/kg). TRRs in final unextracted residue were 5.0 percent (0.039 mg eq/kg). After the exhaustive extraction, 9.1 percent TRR (0.071 mg eq/kg) of mepiquat chloride was released, and 18 percent TRR (0.14 mg eq/kg) was found in polar HPLC peaks.

In wheat chaff (2.4 mg eq/kg) and straw (10 mg eq/kg) at 71 DAT, sequential extraction with methanol and water resulted in 43 percent and 70 percent TRR (1.0 and 7.0 mg eq/kg), respectively, of which 42 percent and 66 percent TRR (1.0 and 6.6 mg/kg), respectively, were mepiquat chloride. The abovementioned exhaustive extraction of unextracted residue resulted in additional mepiquat chloride (12 percent TRR, 0.28 mg eq/kg and 16 percent TRR, 1.6 mg eq/kg, respectively). Further investigation on wheat chaff after the exhaust extraction indicated that 2.0 percent TRR (0.048 mg eq/kg) was found in lignin fraction.

In a metabolism study on barley, [^{14}C]-mepiquat chloride was applied once to barley plant in a greenhouse as foliar spray at a rate of 0.91 kg ai/ha. Barley grain harvested at 52 DAT was homogenized and extracted by 0.01 mol/L HCl in methanol (67 percent TRR, 1.2 mg eq/kg),

followed by 0.1 mol/L of aqueous HCl at reflux for 1 h (29 percent TRR, 0.54 mg eq/kg). Major component was parent mepiquat chloride in HCl-methanol extract (63 percent TRR, 1.2 mg/kg) and aqueous HCl extract (18 percent TRR, 0.33 mg eq/kg). The radioactivity in straw (5.1 mg eq/kg) was extracted by 0.01 mol/L HCl in methanol (71 percent TRR, 3.6 mg/kg) followed by 0.1 mol/L of aqueous HCl at reflux for 1 h (8.0 percent TRR, 0.42 mg eq/kg). The major component was parent mepiquat-chloride in HCl-methanol extract (69 percent TRR, 3.5 mg/kg) and in aqueous HCl extract (5.0 percent TRR, 0.26 mg/kg). Methyl piperidine and piperidine were not detected in the residue from any part of the plant.

In the metabolism study on cotton, [^{14}C]-mepiquat-chloride was applied once to cotton plant in outdoor condition as a foliar spray at a rate of 0.16 kg ai/ha. Cotton seed harvested at 67 DAT was homogenized and sequentially extracted by hexane (1.2 percent TRR, 0.010 mg eq/kg), 0.1 mol/L HCl in methanol (86 percent TRR, 0.82 mg eq/kg) and 10 g/L of aqueous NaCl at reflux (7.8 percent TRR, 0.075 mg eq/kg). Major components were parent mepiquat chloride in methanol extract (90 percent TRR, 0.85 mg/kg) and in aqueous NaCl extract (3.9 percent TRR, 0.037 mg eq/kg). In forage (15 DAT) and straw (67 DAT), most of the radioactivity was mepiquat chloride (91 percent TRR, 0.38 mg/kg and 91 percent TRR, 0.79 mg/kg, respectively).

In the metabolism study on rape, [14C]-mepiquat-chloride was applied twice to rape under glass roof as foliar spray at rates of 0.30 kg ai/ha with an interval of 154 days. Rapeseeds harvested at 63 DALA were homogenized and sequentially extracted by cyclohexane (0.8 percent TRR, 0.10 mg eq/kg), methanol (67 percent TRR, 8.8 mg eq/kg) and water (18 percent TRR, 2.3 mg eq/kg) (methanol and water used contain 1 mmol/L of hexanesulfonic acid). All of the extracted component in methanol and water were identified as parent mepiquat chloride (67 percent TRR, 8.8 mg/kg in methanol and 18 percent TRR, 2.3 mg eq/kg in water). Additional radioactive residues were released by extraction with 10 g/L of aqueous ammonia (3.8 percent TRR, 0.50 mg eq/kg), followed by treatment with macerozyme (containing pectinase, cellulase and hemicellulose; 8.3 percent TRR, 1.1 mg eq/kg), of which all were mepiquat chloride (3.8 percent TRR, 0.50 mg/kg and 8.3 percent TRR, 1.1 mg/kg, respectively). In straw (63 DALA, 3.8 mg eq/kg) and hulls (63 DALA, 9.5 mg eq/kg), most of radioactivity was identified as mepiquat chloride (98 percent TRR, 3.7 mg/kg and 96 percent TRR, 9.2 mg/kg, respectively).

In summary, the mepiquat chloride residues were 81 percent TRR, 1.5 mg eq/kg in barley; 94 percent TRR, 0.89 mg eq/kg in cotton; 80 percent TRR, 0.85 mg eq/kg in grape; 97 percent TRR, 13 mg eq/kg in rapeseed; and 72 percent TRR, 0.56 mg eq/kg in wheat, and no other metabolites were identified. The Meeting concluded that the metabolic pathways in barley, cotton, grape, rapeseed and wheat were qualitatively similar and that metabolism of mepiquat chloride, which could be adsorbed to plant components or incorporated into natural products such as lignin, is slow.

Animal metabolism

The Meeting received animal metabolism studies on rats, lactating goats and laying hen. The compound may exist in solution as mepiquat cation, but values for the parent compound is expressed as mepiquat-chloride. The metabolism of mepiquat chloride in rats was reviewed in the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2023 JMPR.

Three metabolism studies on lactating goats were available to the Meeting.

In the first study, a lactating goat received [14C]-mepiquat-chloride orally at 0.95 g/day (equivalent to 800 ppm) for 5 consecutive days, and then it was sacrificed 6 hours after the last dose. Majority of radioactivity was excreted during the study (76 percent AR, except gastrointestinal (GI) tract content). Radioactivity in milk reached a plateau level of 0.39 mg eq/kg at the day 3. Among tissues, radioactivity was found in kidney (18 mg eq/kg), liver (12 mg eq/kg), muscle (1.8-2.8 mg eq/kg) and fat (0.14-0.19 mg eq/kg). Identification of residues in milk and tissue indicated that main component was mepiquat chloride (44 percent TRR, 0.15 mg/kg and 79-95 percent TRR, 0.12-19 mg/kg, respectively). Methyl piperidine was detected in tissues, with the highest concentration in kidney (1.3 percent TRR, 0.26 mg eq/kg), but not in milk. Piperidine was detected only in omental fat (3.1 percent TRR, 0.005 mg eq/kg).

In the second study, a lactating goat received [^{14}C]-mepiquat-chloride orally at 1.0 g/day (equivalent to 840 ppm) for 5 consecutive days, and then it was sacrificed 6 hours after the last dose. Majority of radioactivity was excreted (93 percent AR including GI tract and its content). Radioactivity in milk did not reach plateau, increasing during the study period to 0.27 mg eq/kg. Residues in tissue were not reported. In the milk, 15 percent TRR (0.031 mg/kg) was identified as mepiquat chloride. Further characterization of components in milk showed that TRR associated with proteins, fat and carbohydrates were 8.7, 7.7 and 36 percent TRR (0.018, 0.017 and 0.076 mg eq/kg), respectively. Incubation of the deproteinized milk with galactosidase and yeast (*Saccharomyces cerevisiae*) followed by reaction with dipicrylamine resulted in galactose conjugate of 4-hydroxymepiquat-chloride (23 percent TRR, 0.049 mg eq/kg).

In the third study, a lactating goat received [^{14}C]-mepiquat-chloride orally at 1.0 g/day (equivalent to 830 ppm) for 8 consecutive days, and then it was sacrificed 6 hours after the last dose. Majority of radioactivity was excreted (96 percent AR, including GI tract and its content). Radioactivity in milk did not reach plateau, increasing throughout the study period to 0.35 mg eq/kg. Radioactivity in tissue was 17 mg eq/kg in kidney, 16 mg eq/kg in liver, 3.6 mg eq/kg in muscle and 1.4 mg eq/kg in fat. Mepiquat chloride was identified in tissues (82 percent TRR, 14 mg/kg in kidney; 41 percent TRR, 6.6 mg/kg in liver; 74 percent TRR, 2.7 mg/kg in muscle; and 84 percent TRR, 1.2 mg/kg in fat) and milk (19 percent TRR, 0.08 mg/kg). After hydrolysis of liver extract and milk by aqueous HCl at reflux (1 mol/L, 4 hours), 4-hydroxymepiquat-chloride was released (40 percent TRR, 6.9 mg eq/kg and 24 percent TRR, 0.081 mg eq/kg, respectively). Further investigation suggested that 4-hydroxymepiquat in liver was glycerophosphate conjugate and diacetate derivative, and that in milk was galactose conjugate.

Two metabolism studies on laying hens were available to the Meeting.

In the first study, 15 laying hens received [14C]-mepiquat-chloride orally at 36 mg/day (equivalent to 254 ppm) for 6 consecutive days, and then they were sacrificed 6 hours after the last dose. Majority of AR (90 percent) was excreted. Radioactivity in egg did not reach plateau, increasing during the study to 1.0 mg eq/kg. In tissues, radioactive residue was found in kidney (2.8 mg eq/kg), liver (1.4 mg eq/kg), skin (0.53 mg eq/kg), muscle (0.30-0.32 mg eq/kg) and fat (0.28 mg eq/kg). After extraction by methanol or water, the major component was mepiquat chloride in tissues (85 percent TRR, 2.4 mg/kg in kidney; 61 percent TRR, 0.83 mg/kg in liver; 72 percent TRR, 0.20 mg/kg in fat; 60-65 percent TRR, 0.19 mg/kg in muscle; and 31 percent TRR, 0.16 mg/kg in skin) and eggs (70 percent TRR, 0.64 mg/kg). Methyl piperidine was detected only in muscle (6.5-7.1 percent TRR, 0.02 mg eq/kg) and skin (1.3 percent TRR, 0.007 mg eq/kg).

In the second study, five laying hens received [^{14}C]-mepiquat-chloride orally at 36 mg/day (equivalent to 300 ppm) for 5 consecutive days, and then they were sacrificed 6 hours after the last dose. Radioactivity in egg did not reach plateau, increasing during the study to 0.78 mg eq/kg. Among tissues, radioactivity was found in kidney (2.8 mg eq/kg), liver (1.2 mg eq/kg), muscle (0.25 mg eq/kg) and fat and skin (1.1-4.3 mg eq/kg after removal of lipid layer by centrifugation). In the extraction by saturated aqueous NaCl (after removal of lipid layer for fat and skin), the major component was mepiquat chloride in tissues (90 percent TRR, 2.5 mg/kg in kidney; 89 percent TRR, 0.96 mg/kg in liver; 92 percent TRR; 98 percent TRR, 0.24 mg/kg in muscle; and 87-92 percent TRR, 0.97-3.8 mg/kg in fat and skin after removal of lipid layer by centrifugation) and egg (86 percent TRR, 0.87 mg/kg). No further identification was conducted.

In summary, mepiquat chloride was metabolized to methyl piperidine and piperidine in goat and hen. In goat, it was also metabolized to 4-hydroxymepiquat chloride, and its conjugate was observed in milk and liver. The metabolism pathways in goat and hen were qualitatively similar.

Environmental fate

The Meeting received information on degradation in solution and confined rotational crops. Study on aerobic soil photodegradation or aerobic degradation was not available to the Meeting.

Hydrolytic degradation in aqueous solution

Mepiquat chloride was stable to hydrolysis at 25 °C in the dark between pH 3-9 for at least 30 days (≈100 percent left).

Photochemical degradation in aqueous solution

Mepiquat chloride was stable in aqueous photochemical degradation studies with and without photosensitizer for at least 23 days (> 84 percent and ≈100 percent left, respectively).

Study on confined rotational crops

[^{14}C]-mepiquat-chloride was applied to soil at 0.70 kg ai/ha under greenhouse conditions, and following crops of lettuce (leafy crop), radish (root crop) and wheat (cereal crop) were planted at plant back intervals (PBI) of 29, 120 and 365 days. Crops were harvested at maturity, with the exception of wheat forage, homogenized and extracted by methanol and then water.

TRR at PBI of 29 and 120 days were 0.003—0.011 mg eq/kg in lettuce, 0.015—0.026 mg eq/kg in radish root, 0.018—0.040 mg eq/kg in radish top, 0.074—0.082 mg eq/kg in wheat forage, 0.28—0.36 mg eq/kg in wheat straw, 0.27—0.42 mg eq/kg in wheat chaff and 0.32—0.44 mg eq/kg in wheat grain. TRRs in crops of PBI 365 days were < 0.01 mg eq/kg except in wheat straw and chaff (0.016 and 0.018 mg eq/kg, respectively).

Crops at PBI of 29 and 120 days were extracted with methanol and then water (76—82 percent, 42—60 percent and 37—92 percent TRR from lettuce, radish root and radish top, respectively). In wheat forage, straw, chaff and grain at PBI of 29 and 120 days, low percentages

of radioactivity were extracted with methanol and then water (40-41 percent in forage, 16 percent in chaff and 11 percent in grain).

In wheat grain of PBI of 29 and 120 days after extraction with methanol and water, additional TRR were released by sequential treatment of beta-glucosidases/hesperidinase (5.3—14 percent TRR, 0.023—0.046 mg eq/kg), cellulase/macerozyme (24—40 percent TRR, 0.11–0.13 mg eq/kg) and amylase/amyloglucosidase (10–19 percent TRR, 0.032—0.083 mg eq/kg). In wheat straw and chaff, TRR were released by 0.1 kg/L NaOH (22—24 percent TRR, 0.060—0.086 mg eq/kg and 29–37 percent TRR, 0.098—0.12 mg eq/kg, respectively) and found in lignin (6.7–9.8 percent TRR, 0.019—0.035 mg eq/kg and 12—16 percent TRR, 0.044—0.051 mg eq/kg, respectively). It was suggested that in wheat, significant amounts of radioactivity were incorporated into natural components.

Parent mepiquat chloride was detected in some crops at PBI of 29 and 120 days but at low level (≤0.011 mg/kg) and not detected in wheat straw and chaff at PBI of 365 days. No further identification was conducted.

Conclusion

The Meeting considered that levels of free form of mepiquat chloride in following crops were insignificant. However, the information on possible presence of bound mepiquat cation in rotational crop commodities was not available. The Meeting also noted that when considering new uses on other crops, information on aerobic degradation and soil photodegradation will be necessary.

Methods of analysis

The Meeting received information on five methods of analysis for mepiquat chloride in plant products (No. 505/0, No. A9106, 12C-G030, 19C-G066 and No. P3366G), two methods in animal products (No. 286 and No. A9104), one method in both plant and animal products (No. 23) and one method for enforcement (No. P3367G). In these methods, mepiquat chloride was extracted with methanol-aqueous HCl or acetone-water (ratio depends on method), cleaned up, and analysed using LC-MS, LC-MS/MS, ion chromatography-conductive detector or gas chromatography-nitrogen phosphorus detection (GC-NPD).

The Meeting confirmed that the following methods were validated for mepiquat chloride: Method No. 505/0 (LC-MS/MS) for wheat forage, barley grain, maize straw, grape, apple and rapeseed with an LOQ of 0.05 mg/kg; Method No. A9106 (ion chromatography) for cotton with an LOQ of 0.1 mg/kg; Methods 12C-G030 (LC-MS) and 19C-G066 (LC-MS/MS) for grapes with an LOQ of 0.01 mg/kg; Method No. P3366G (LC-MS/MS) for tomato, orange, wheat grain and rapeseed with an LOQ of 0.01 mg/kg; Method No. 23 (GC-NPD) for grapes with an LOQ of 0.05 mg/kg; Method No. 286 (ion chromatography) for egg, muscle, liver, skin, fat, milk and kidney with an LOQ of 0.05 mg/kg; and Method P3367G (LC-MS/MS) for milk, muscle, liver, egg and fat with an LOQ of 0.01 mg/kg.

With regards to Method No. A9104 (ion chromatography), the method validation data were not sufficient. The Meeting, however, confirmed the validity of the method for muscle, fat, liver,

kidney, milk and egg with an LOQ of 0.05 mg/kg because the method was similar to a validated method (Method No. 286) and procedural recovery data were within an acceptable range.

The Meeting also received information on a method for 4-hydroxymepiquat-chloride in animal products (No. 322). Samples after homogenization and extraction with methanol were mixed with aqueous HCl (1 mol/L) and refluxed for 4 hours (same conditions as that in the animal metabolism study) to release 4-hydroxymepiquat-chloride from conjugates, and then analysed by ion chromatography. The Meeting confirmed that Method No. 322 was validated for conjugated 4-hydroxymepiquat-chloride in liver and milk with an LOQ of 0.05 mg/kg.

Stability of residues in stored analytical samples

Stability studies on mepiquat chloride residues in plant commodities (grape, wheat and cotton) and animal tissues were available. Mepiquat chloride was stable for at least 18 months in grapes (High acid content and high water content), 25 months in cottonseed (oil seeds), 22 months in cotton hulls, 23 months in cotton meal, and 28 months in cotton oil (crude and refined) and soapstock when stored at ≤ -5 °C. Mepiquat chloride was also stable for at least 24 months in wheat (grain, forage and straw; High starch and/or protein content and low water and fat content) when stored at ≤ -20 °C.

In animal commodities, mepiquat chloride was stable for at least 26 months in kidney, muscle, fat and eggs, 27 months in liver and 38 months in milk when stored at ≤ -5 °C.

In supervised trials received at the current Meeting, all samples were kept frozen at ≤ -5 °C and analysed within 6 months after harvest.

Definition of the residue

Plant commodities

In the metabolism studies on grape, wheat, barley, cotton and rape, parent mepiquat cation was found in all crops analysed (100 percent TRR in grape, 63 percent TRR in barley, 62 percent in wheat, 90 percent TRR in cottonseed, and 85 percent TRR in rapeseed). The Meeting noted that suitable analytical methods exist to determine mepiquat cation in plant commodities. The Meeting considered that parent mepiquat cation was a suitable marker for enforcement.

These metabolism studies indicated that mepiquat cation was partially bound (18 percent TRR in barley, 3.9 percent TRR in cottonseed, 12 percent TRR in rapeseed and 9.1 percent TRR in wheat). Total TRR of mepiquat cation was 81 percent in barley, 71 percent in wheat and >90 percent for other commodities.

No other significant metabolites were found in all plant metabolism studies.

Animal commodities

Parent mepiquat cation was found in all commodities in metabolism studies on lactating goat (42-80 percent TRR in liver, 95-96 percent TRR in kidney, 76-93 percent TRR in muscle, 76-79 percent TRR in fat and 20-44 percent TRR in milk) and laying hen (61-89 percent TRR in liver, 85-90 percent TRR in kidney, 60-98 percent TRR in muscle, 72-92 percent TRR in fat, 31-95 percent

TRR in skin and 70-86 percent TRR in eggs). The Meeting noted that suitable analytical methods exist to determine mepiquat cation in animal commodities. The Meeting considered that parent mepiquat cation was a suitable marker for enforcement.

The fact that mepiquat chloride residues in muscle were higher than those in fat (1.9-2.7 mg/kg vs 0.12-0.18 mg/kg in the first study and 2.6 mg/kg vs 1.4 mg/kg in the third study on goat) suggested that the residue is not fat-soluble.

According to the animal metabolism studies, the following compounds were identified and could be included in the residue definition for dietary risk assessment: methylpiperidine, piperidine and 4-hydroxymepiquat cation (after hydrolysis).

In the metabolism studies on goat, methylpiperidine was found in liver (0.4 percent TRR, 0.052 mg eq/kg), kidney (1.3 percent TRR, 0.26 mg eq/kg), muscle (0.6-2.0 percent TRR, 0.012-0.061 mg eq/kg) and fat (2.1-9.1 percent TRR, 0.003-0.018 mg eq/kg) but not detected in milk. In the metabolism studies on hen, methylpiperidine was found in muscle (6.5-7.1 percent TRR, 0.02 mg eq/kg) and skin (1.3 percent TRR, 0.007 mg eq/kg) but not detected in liver, kidney, fat and eggs. The ratios of methylpiperidine residue to parent mepiquat chloride were the highest in renal fat of goat (11 percent) and muscle of hen (11 percent) and lower (< 3 percent) in other commodities.

The Meeting concluded that methylpiperidine was not genotoxic but could not conclude on the toxicological relevance of methylpiperidine. On this basis, the Meeting agreed to apply the TTC approach within Cramer Class III (1.5 µg/kg bw/d) for toxicity.

Piperidine was detected only in omental fat of goat (3.1 percent TRR, 0.005 mg eq/kg). The Meeting considered that the level of piperidine was not significant and concluded that there was no need to include piperidine in the residue definition.

4-Hydroxymepiquat cation was found in liver and milk in the metabolism study on goat (24 percent TRR, 4.1 mg eq/kg and 23 percent TRR, 0.10 mg eq/kg, respectively). The Meeting concluded that 4-hydroxymepiquat chloride is of no greater potency than mepiquat-chloride and its toxicity is covered by the HBGVs of the parent compound. The Meeting considered that the levels of 4-hydroxymepiquat cation was significant (74 percent of parent in liver and 100-160 percent of parent in milk) and concluded that 4-hydroxymepiquat cation should be included in the residue definition. The Meeting noted that there was no need to include the compound in the residue definition for poultry commodities because most of the residues (≥ 89 percent) were identified as mepiquat cation or methyl piperidine in poultry studies, suggesting that it is unlikely that significant level of 4-hydroxymepiquat cation exists in poultry commodities.

Conclusion

The Meeting established residue definition for mepiquat chloride as follows:

Definition of the residue for compliance with the MRL for plant and animal commodities: mepiquat cation.

Definition of the residue for dietary exposure assessment for plant commodities: mepiquat cation

Definition of the residue for dietary exposure assessment for animal commodities: sum of mepiquat cation and 4-hydroxy-1,1-dimethylpiperidinium cation (4-hydroxymepiquat cation, free and conjugated), expressed as mepiquat cation.

The residue is not fat-soluble.

Results of supervised trials on crops

Plant metabolism studies on grape and cotton indicated that >95 percent TRR was extracted with weak acid. In the methods of analysis used in the supervised trials, mepiquat chloride was extracted by stronger acid than that was used in the plant metabolism study. The Meeting considered that the amount of unextracted mepiquat chloride in the supervised trials was insignificant and that mepiquat chloride, including adsorbed, was properly analysed in the study.

The analytical values of mepiquat chloride were converted into that of mepiquat cation by the ratio of their molecular weights (x 0.763).

Berries and other small fruits

Grapes

The critical GAP for mepiquat chloride on grapes in Japan is two foliar applications at 88 g ai/hL at (1) 7-11 shoot leaves or pre-flowering stage and (2) 10–20 days after full bloom and a PHI of 60 days. In trials, the first application timing matched the Japanese GAP, but the second application timing was later (fruit enlargement to fruit colouring stage or 60—80 days after full bloom). The Meeting noted that although the trials were not conducted in strict accordance with the GAP in terms of the timing of the second application, it agreed that the trials likely reflect the cultivation practice for faster growing varieties and that the trials could be used to support a recommendation.

In the trials, residues of mepiquat cation in grape were (n=8): 0.49, 0.51, 0.53, 0.63, 0.78, 1.0, 1.4 and 2.6 mg/kg.

The Meeting estimated maximum residue level, STMR and HR for mepiquat cation in grapes of 4, 0.705 and 2.6 mg/kg.

Oilseeds

Cotton seed

The critical GAP of mepiquat chloride on cotton in Greece is one foliar application at a rate of 75 g ai/kg at BBCH 69. In independent trials matching the Greek GAP, residues of mepiquat cation in cotton seed were (n=8): 0.31, 0.66, 0.86, 1.2, 1.4, 1.5, 1.9 and 2.4 mg/kg.

The Meeting estimated maximum residue level and STMR for mepiquat cation in cotton seed of 4 and 1.3 mg/kg, respectively.

Fates of residues during processing

Stability study

Mepiquat chloride in aqueous solutions was stable (>97 percent TRR) during simulating pasteurization (pH 4, for 20 min at 90 °C), brewing, baking and boiling (pH 5, for 60 min at 100 °C) and sterilization (pH 6, for 20 min at 120 °C).

Processing

The Meeting estimated processing factors for mepiquat cation as follows.

Commodity	Processing factor	STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)	Maximum residue level (mg/kg)
Grapes (RAC)		*0.705*	*2.6*	*4*
Grape pomace, wet	1.1	0.78		
Grape pomace, dried	2.6	1.8		15
Grape juice	0.91	0.64		
Grape, dried (=currants, raisins and sultanas)	3.9	2.7	10	20
Cotton seed (RAC)		*1.3*		*4*
Delinted seed	1.2	1.6		
Cotton hulls	0.28	0.36		
Cotton meal	1.9	2.5		8
Cotton seed oil, crude	0.043	0.056		
Cotton seed oil, edible	0.040	0.052		

Residues in animal commodities

Farm animal feeding studies

A dairy cow feeding study was available to the Meeting. Three groups of lactating cows (three per dose group) received mepiquat chloride on grain in a gelatine capsule at rates of 13, 65 and 195 ppm per a day for 28 days (9.9, 50 and 150 ppm as mepiquat cation). The residue levels of mepiquat chloride in milk at plateau were 0.050 mg/kg (0.038 mg/kg as mepiquat cation) from cows fed at 13 and 65 ppm and 0.10 mg/kg (0.076 mg/kg as mepiquat cation) from cows fed at 195 ppm. Among tissues, the highest residue level was observed in kidney (0.15 mg/kg), followed by liver (0.14 mg/kg), muscle (<0.05 mg/kg) and fat (<0.05 mg/kg) from cows fed at 13 ppm of mepiquat-chloride (0.11, 0.11, <0.038 and <0.038 mg/kg as mepiquat cation, respectively).

A feeding study on hen was available to the Meeting. Three groups of laying hens (15 per dose group) received mepiquat chloride by oral bolus at rates of 1.0, 5.0 and 15 ppm per a day for 28 days (0.76, 3.8 and 11 ppm based on mepiquat cation). The mean residue levels in eggs were consistently <0.05 mg/kg (< 0.038 mg/kg as mepiquat cation) for groups treated at 1.0 and 5.0 ppm and up to 0.074 mg/kg (0.056 mg/kg as mepiquat cation) for the group treated at 15 ppm. Residue levels in any tissues from all groups were <0.05 mg/kg (liver, muscle, fat and skin)(< 0.038 mg/kg as mepiquat cation).

Farm animal dietary burden

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 included in the list below.

The mepiquat chloride concentrations were converted into mepiquat cation by the ratio of their molecular weights (x 0.763).

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the Meeting. The dietary burdens, estimated using the OECD

diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarized below.

Animal dietary burden for mepiquat cation

	Animal dietary burden, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	Mean	max	mean	max	mean	max	mean
Beef cattle	0.16	0.16	0.14	0.14	2.4❶	2.4❸	-	-
Dairy cattle	0.46	0.46	0.32	0.32	1.8❷	1.8❹	-	-
Poultry – broiler	0.56❺	0.56❻	0.14	0.14	0.28	0.28	-	-
Poultry – layer	0.56❼	0.56❽	0.14	0.14	0.28	0.28		

❶ Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues
❷ Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk
❸Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues
❹ Highest mean dairy cattle dietary burden suitable for STMR estimates for milk
❺Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues
❻Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues
❼ Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs
❽Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs

Animal commodity maximum residue levels

Cattle

Maximum residue levels of mepiquat cation in cattle commodities

	Feed Level (ppm) for milk residues	Total residues (mg/kg) in milk	Feed Level (ppm) for tissue residues	Total residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
HR level Determination (beef or dairy cattle)							
Feeding Study			9.9	<0.038	0.11	0.11	<0.038
Dietary burden and estimate of highest residue			2.4	<0.0092	0.027	0.027	<0.0092
STMR Determination (beef or dairy cattle)							
Feeding Study	9.9	0.038	9.9	<0.038	0.14	0.15	<0.038
Dietary burden and estimate of highest residue	1.8	0.0069	2.4	<0.0092	0.034	0.036	<0.0092

The Meeting estimated maximum residue levels for mepiquat cation of 0.008(*) mg/kg for milk, 0.01 mg/kg for meat (from mammals other than marine mammals) and mammalian fat (except milk fats) and 0.04 mg/kg for edible offal (mammalian).

With regards to the total residues for risk assessment, the Meeting considered that 4-hydroxymepiquat-chloride, which was not analysed but is expected at significant levels, could be estimated using the ratio of it to mepiquat chloride in the metabolism studies: in milk (x1.6) and liver (x0.74).

The Meeting estimated HRs of 0.0092 mg eq/kg for meat (from mammals other than marine mammals), 0.0092 mg eq/kg for mammalian fat (except milk fats) and 0.059 mg eq/kg for edible offal (mammalian) (0.034 x (1 + 0.74)) based on the residue in liver.

The Meeting estimated medians of 0.018 mg eq/kg for milk (0.0069 x (1 + 1.6)), 0.0092 mg eq/kg for meat (from mammals other than marine mammals), 0.0092 mg eq/kg for mammalian fat (except milk fats) and 0.047 mg eq/kg for edible offal (mammalian) (0.027 x (1 + 0.74)) based on the residue in liver.

Maximum residue levels of mepiquat cation in poultry commodities

	Feed Level (ppm) for eggs residues	Total residues (mg/kg) in eggs Expressed as mepiquat chloride (mepiquat cation)	Feed Level (ppm) for tissue residues	Total residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (poultry)							
Feeding Study	0.76	<0.038		<0.038	<0.038	<0.038	<0.038
Dietary burden and estimate of highest residue	0.56	<0.028	0.70	<0.028	<0.028	<0.028	<0.028
STMR Determination (poultry)							
Feeding Study	0.76	<0.038		<0.038	<0.038	<0.038	<0.038
Dietary burden and estimate of highest residue	0.56	<0.028	0.70	<0.028	<0.028	<0.028	<0.028

Even in the feeding study with higher concentration than 0.76 ppm of mepiquat cation (3.8 ppm for eggs and 11 ppm for tissues), the residues of mepiquat cation were <0.038 mg/kg (<0.05 mg/kg as mepiquat chloride). Using the data, residues in egg and tissues were estimated as <0.0073 mg/kg and <0.0025 mg/kg (expressed as mepiquat cation), respectively. The Meeting concluded that residues of mepiquat cation will be <0.008 mg/kg for all poultry commodities, and noting the availability of a method of analysis for mepiquat chloride with an LOQ of 0.01 mg/kg (0.008 mg mepiquat cation/kg), agreed to estimate maximum residue levels for mepiquat cation of 0.008 (*) mg/kg for eggs, poultry meat, poultry edible offal, and poultry fats.

Since residues of mepiquat cation were <0.038 mg/kg in all poultry commodities at all dose levels except eggs at a dose level of 11 ppm, and since residues of 4-hydroxymepiquat cation was each ≤ 11 percent of parent in the laying hen metabolism study, the Meeting concluded that residues of 4-hydroxymepiquat cation are insignificant in poultry commodities. Therefore, the Meeting estimated STMRs and HRs of 0 mg eq/kg, for all poultry commodities.

RECOMMENDATIONS

Definition of the residue for compliance with the MRL for plant and animal commodities: *mepiquat cation*

Definition of the residue for dietary exposure assessment for plant commodities: *mepiquat cation*

Definition of the residue for dietary exposure assessment for animal commodities: *mepiquat cation and 4-hydroxy-1,1-dimethylpiperidinium cation (4-hydroxymepiquat cation, free and conjugated), expressed as mepiquat cation.*

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on the recommendations of the current JMPR, were in the range 0-1 percent of the maximum ADI of 0.3 mg/kg bw for mepiquat chloride (or 0.229 mg/kg bw expressed as mepiquat cation). The results are shown in Annex 3 of the report.

The Meeting concluded that the long-term dietary exposure from residues of mepiquat cation, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Acute dietary exposure

The IESTI for mepiquat cation was calculated. The results are shown in Annex 4 to the Report.

The IESTIs for mepiquat cation from the intake of the residue evaluated by the Meeting were 0–∂d20 percent for general population and 0–40 percent for children of the ARfD (0.6 mg/kg bw for mepiquat chloride; or 0.458 mg/kg bw expressed as mepiquat cation). The Meeting concluded that acute dietary exposure from the residues of mepiquat chloride, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The Meeting noted that methylpiperidine was not considered to be genotoxic. As no further information was available, the Meeting agreed to apply the TTC approach (Cramer Class III, 1.5 µg/kg bw/d) for toxicity.

Methylpiperidine was found in animal metabolism study but not in plant metabolism study. In the goat metabolism study fed at 800 ppm of mepiquat chloride (610 ppm as mepiquat cation), methylpiperidine was detected at 0.052 mg mepiquat cation eq/kg in liver (0.034 mg/kg expressed as methylpiperidine using the ratio of their molecular weights of 0.661), 0.255 mg eq/kg in kidney (0.17 mg/kg), 0.061 mg eq/kg in muscle (0.040 mg/kg) and 0.018 mg eq/kg in fat (0.012 mg/kg). Methylpiperidine was not found in milk. In the hen metabolism study fed at 254 ppm (194 ppm as mepiquat cation), methylpiperidine was found only in muscle at 0.02 mg eq/kg (0.013 mg/kg).

After scaling the above levels to account for the dietary burden of the parent compound (2.4 ppm cattle, 0.56 ppm poultry), the dietary exposure to methylpiperidine calculated using the 17 cluster diets were <0.001 µg/kg bw, significantly lower than the TTC for Cramer Class III.

The Meeting concluded that the chronic dietary exposure of methylpiperidine arising from uses of mepiquat chloride considered by the Meeting is unlikely to present a public health concern.

5.24 Oxathiapiprolin (291) (R)

RESIDUE AND ANALYTICAL ASPECTS

Oxathiapiprolin is the International Organization for Standardization (ISO)-provisionally approved name for 1-(4-{4-[(5RS)-5-(2,6-difluorophenyl)-4,5-dihydroisoxazol-3-yl]thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]ethanone. Oxathiapiprolin is systemic piperidinyl thiazole isoxazoline fungicide. It was first evaluated by the JMPR in 2016 for toxicology and residues. The 2016 Meeting established an ADI of 0–4 mg/kg bw and decided that an ARfD was unnecessary. The 2016 Meeting concluded that the residue definition for enforcement in plant and animal commodities is oxathiapiprolin.

The definition of the residue for dietary risk assessment for plant and animal commodities is the sum of oxathiapiprolin, 5-(trifluoromethyl)-*1H*-pyrazole-3-carboxylic acid (IN-E8S72), and 1-ß-D-Glucopyranosyl-3-(-(trifluoromethyl)-*1H*-pyrazole-5-carboxylic acid (IN-SXS67), expressed as parent.

The 2016 Meeting further concluded that the residue is not fat-soluble.

Oxathiapiprolin was scheduled at the Fifty-second Session of the CCPR for the evaluation of additional uses by the 2022 JMPR. The 2023 Meeting received information on the registered uses and residue studies were submitted to support avocado, bush berries (blueberry), low growing berries (strawberry), hops, and tree nuts (almonds, pecans). Additional data were provided relating to analytical methods and processing.

Methods of analysis

Analytical method DuPont 30422 Supplement No.1 previously evaluated by the 2016 JMPR was used to determine oxathiapiprolin, IN-E8S72 and IN-SXS67 residues.

Stability of pesticide residues in stored analytical samples

The 2016 Meeting concluded that residues of oxathiapiprolin and metabolites IN-E8S72 and IN-SXS67 were stable for at least 18 months in representative commodities with high water content (wheat forage, tomato), high starch content (potato, wheat grain), high protein content (dry bean seed), high oil content (soya bean seed), high acid content (grape) and low moisture content (wheat straw, dry grape pomace).

The intervals of demonstrated frozen storage stability encompass the range of storage periods for samples in the supervised residue trials.

Results of supervised residue trials on crops

The Meeting received information on supervised trials for oxathiapiprolin on avocado, blueberries, strawberries, almonds and pecans, and hops.

For determining the sum of oxathiapiprolin and metabolites IN-E8S72 and IN-SXS67 (residue definition for dietary assessment), the concentration of oxathiapiprolin in each sample was added to the concentration of IN-E8S72 multiplied by 2.99 [the ratio of the molecular weights of oxathiapiprolin (539 amu) and IN-E8S72 (180 amu)] and the concentration of IN-SXS67 multiplied by 1.58 [the ratio of the molecular weights of oxathiapiprolin (539 amu) and IN-SXS67 (342 amu)]. When calculating total residues, values reported as below the LOQ were assumed to be at the LOQ.

The registered GAP requires an SC (suspension concentrate) formulation. The residue trials submitted for all crops, except for blueberries, applied oxathiapiprolin as an oil dispersion (OD) formulation. Side-by-side residue trials for the two formulations were made available to the Meeting for cucumber, brassica, potato and tobacco and demonstrated that residues following use of SC and OD formulations are equivalent. The Meeting agreed that trials using an OD formulation could be used to support estimation of maximum residue levels for oxathiapiprolin when the GAP is for an SC formulation.

Blueberry

The critical GAP for oxathiapiprolin on the United States of America EPA Bushberry subgroup 13-07B, except lowbush blueberry, in the United States is two soil applications of an SC formulation at 280 g ai/ha at a minimum interval of 7 days and a PHI of 1 day. The maximum seasonal application is 580 g ai/ha.

In eight trials matching cGAP residues of **oxathiapiprolin per se** in blueberry (highbush) were: <0.01 (6), 0.15, 0.27 mg/kg.

Total residues in eight trials matching cGAP were: <0.056 (6), 0.20, 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg and an STMR of 0.056 mg/kg for oxathiapiprolin in blueberries (highbush). The Meeting noted that blueberries are a representative crop for the subgroup and concluded the dataset for blueberries was sufficient for estimation of a maximum residue level for the subgroup of bush berries (note, in Codex the commodity blueberries refers to both lowbush and highbush blueberries).

Strawberry

The Meeting received supervised residue trials on strawberry. The critical GAP for oxathiapiprolin on Low Growing Berry Crop Subgroup 13-07G, except cranberry and blueberry, lowbush in the United States is two soil applications of an SC formulation at 157 g ai/ha at a

minimum interval of 7 days and a PHI of zero days (maximum seasonal application 325 g ai/ha) **OR** two foliar applications at 34 g ai/ha at a minimum interval of 7 days and a PHI of 0 day (maximum seasonal application 67 g ai/ha).

None of the trials matched GAP as they involved both soil and foliar applications.

Avocado

The critical GAP for oxathiapiprolin on Tropical and subtropical fruit, medium to large fruit, smooth, inedible peel, crop subgroup 24B in the United States is two soil applications of an SC formulation at 134 g ai/ha at a minimum interval of 30 days and a PHI of 30 days (maximum seasonal application 280 g ai/ha) **OR** two foliar applications at 34 g ai/ha at a minimum interval of 14 days and a PHI of 1 day (maximum seasonal application 67 g ai/ha).

In five trials with an OD formulation and approximating GAP for soil application, residues of oxathiapiprolin per se in avocado (fruit without stem or pit) were: <0.01 (5) mg/kg.

Total residues in five trials matching GAP for soil application in avocado (fruit without stem or pit) were: <0.056 (5) mg/kg.

In five trials approximating GAP for foliar application, residues of **oxathiapiprolin per se** in avocado (fruit without stem or pit) were: <0.01, <0.01, 0.0117, 0.0231, 0.0435 mg/kg.

Total residues in five trials approximating GAP for foliar application in avocado (fruit without stem or pit) were: <0.056, <0.056, 0.0575, 0.0688, 0.0892 mg/kg.

Residues are higher following foliar application.

According to the Codex classification and the FAO Manual, the commodity to be analysed is the whole avocado after removal of pit where the residue is calculated and expressed on a whole fruit basis. As the pits account for an average of 15 percent of the whole fruit weight, all residues for pitted avocadoes were adjusted by a factor of 1.15 for MRL calculation. For dietary risk assessment, no residues were reported for pulp, *per se*, therefore, the total residues reported for pitted avocadoes (peel and pulp) were considered.

The Meeting estimated a maximum residue level of 0.09 mg/kg and an STMR of 0.0575 mg/kg for oxathiapiprolin in avocado based on residues following foliar application.

Tree nuts

The Meeting received supervised residue trials on almonds and pecans. The critical GAP for oxathiapiprolin on tree nuts in the United States is two soil applications of an SC formulation at 134 g ai/ha at a minimum interval of 30 days and a PHI of 30 days (maximum seasonal application 280 g ai/ha).

In five trials using an OD formulation approximating GAP for almonds, residues of **oxathiapiprolin per se** were: <0.01 (5) mg/kg.

Total residues in five trials approximating GAP for almonds were: <0.056 (5) mg/kg.

In five trials using an OD formulation approximating GAP for pecans, residues of **oxathiapiprolin per se** were: <0.01 (5) mg/kg.

Total residues in five trials approximating GAP for pecans were: <0.056 (5) mg/kg.

The Meeting noted that almonds and pecans are representative crops for the subgroup and concluded the dataset for almonds and pecans was sufficient for estimation of a maximum residue level for the group of tree nuts.

The Meeting estimated a maximum residue level of *0.01 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.01 mg/kg for the group of tree nuts.

Hops

The Meeting received supervised residue trials on hops. The critical GAP for oxathiapiprolin on hops in the United States is one soil application of an SC formulation at 280 g ai/ha and a PHI of 7 days **OR** three foliar applications at 34 g ai/ha at a minimum interval of 7 days and a PHI of 7 days (maximum seasonal application 101 g ai/ha).

None of the trials matched GAP as they involved both soil and foliar applications. However, in trials reported by the 2016 and 2018 JMPR and over a range of crops, residues of oxathiapiprolin following soil application were all <LOQ. Residues of the metabolites in trials on hops with a soil and three foliar applications were all <LOQ for IN-SXS67 and IN-E8S72. The Meeting agreed that the contribution of the soil applications to the final residue would be minor and noted that any additional residue would lead to a slight overestimate of consumer exposure and that this would be acceptable.

In six trials conducted with an OD formulation and approximating cGAP residues of **oxathiapiprolin** were (n=6): 0.33, 0.65, 1.1, 2.0, 2.0, 2.1 mg/kg.

Total residues in trials approximating cGAP were (n=6): 0.37, 0.70, 1.1, 2.0, 2.05, 2.15 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and an STMR of 1.55 mg/kg for hops (dried).

Residues in animal feeds

Almond hulls

The Meeting received supervised residue trials on almonds. The critical GAP for oxathiapiprolin on tree nuts in the United States is two soil applications of an SC formulation at 134 g ai/ha at a minimum interval of 30 days and a PHI of 30 days (maximum seasonal application 280 g ai/ha).

In five trials approximating GAP for almonds, residues of **oxathiapiprolin per se** in hulls were: <0.01, <0.01, 0.013, 0.023, 0.024 mg/kg.

Residues of **IN-SXS67 + 1.9×IN-E8S72** in hulls in five trials approximating GAP for almonds were: <0.02, <0.02, <0.02, 0.0461, 0.0803 mg/kg (expressed as IN-SXS67).

The Meeting estimated a maximum residue level of 0.05 mg/kg, and median residues of 0.013 mg/kg for oxathiapiprolin per se and 0.02 mg/kg for IN-SXS67+1.9×IN-E8S72 in almond hulls.

Residues in animal commodities

Farm animal dietary burden

The current Meeting calculated dietary burdens based on residue estimates from previous meetings with updates to reflect feed commodities addressed by the current Meeting. Potential primary crop feed items include feedstuffs from cabbage, tomato, grape, citrus, kale, soya bean, potato, maize, and sunflower crops. For the IN-SXS67+1.9×IN-E8S72 burden, potential residues in rotated or follow crops were also considered. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO manual, are presented in Annex 6 and summarized below.

The only additional feed item arising from the current evaluation is almond hulls.

Summary of animal dietary burdens, as ppm of dry matter, for oxathiapiprolin for maximum residue level setting

	Canada and US		European Union		Australia		Japan	
Livestock	**Max**	**Mean**	**Max.**	**Mean**	**Max**	**Mean**	**Max**	**Mean**
Beef cattle	0.087	0.047	5.8	4.0	0.69	0.61	0.011	0.011
Dairy cattle	0.072	0.040	5.8	4.0	12[A,B]	8.5[C,D]	0.018	0.018
Broiler chickens	0.01	0.01	0.038	0.017	0.004	0.004	0.011	0.011
Layer hens	0.011	0.011	0.20[E]	0.068[F]	0.004	0.004	0.011	0.011

[A] Highest maximum dietary burden for beef or dairy cattle; suitable for estimating the maximum residue levels for mammalian meat, fat, and offal

[B] Highest maximum dietary burden for dairy cattle; suitable for estimating the maximum residue levels for milk

[C] Highest mean dietary burden for beef or dairy cattle

[D] Highest mean dietary burden for dairy cattle

[E] Highest maximum dietary burden for broiler chickens or laying hens; suitable for estimating the maximum residue levels for poultry meat, fat, offal, and eggs

[F] Highest mean dietary burden for laying hens

Livestock*	Canada and US		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle		0.66		1.5		1.3		0.36
Dairy cattle		0.81		1.5		2.7[A,B]		0.65

* Cattle only as residues of IN-E8S72 and IN-SXS67 were not observed in the poultry metabolism studies. A separate metabolism study dosing lactating cattle with INSXS67 is available

[A] Highest mean dietary burden for beef or dairy cattle; suitable for estimating STMRs for mammalian meat, fat, and offal

[B] Highest mean dietary burden for dairy cattle; suitable for estimating the STMR for milk

Animal commodity maximum residue levels

Almond hulls does not contribute significantly to the livestock dietary burdens which are within five percent of those estimated previously, most recently at the 2018 JMPR. Feeding studies are not available in lactating cows or laying hens.

As noted by the 2018 JMPR, the dosing level for the oxathiapiprolin lactating goat metabolism study is 1.2× the cattle dietary burden and the JMPR is unable to utilize the metabolism study to estimate maximum residue levels.

As almond hulls are not included in the dietary burdens for poultry there is no change in the estimated poultry dietary burdens. Therefore, the Meeting concluded that the previously recommended maximum residue levels adequately cover the estimated maximum residues and confirms its previous maximum residue level recommendations of 0.01(*) mg/kg for oxathiapiprolin in poultry meat, poultry offal, poultry fat and eggs and STMRs for dietary assessment of 0 mg/kg for meat, 0 mg/kg for edible offal, 0 mg/kg for fat, and 0 mg/kg for eggs.

RECOMMENDATIONS

Based on the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for International Estimated Daily Intakes (IEDIs) and IESTI assessments.

Definition of the residue for compliance with the MRL: *oxathiapiprolin.*

Definition of the residue for dietary risk assessment for plant and animal commodities: *sum of oxathiapiprolin, 5-(trifluoromethyl)-1H-pyrazole-3-carboxylic acid and 1-ß-D-glucopyranosyl-3-(-(trifluoromethyl)- H-pyrazole-5-carboxylic acid, expressed as parent equivalents*.

The residue is not fat-soluble.

Long-term dietary exposure

The ADI for oxathiapiprolin is 0–4 mg/kg bw. The IEDIs for oxathiapiprolin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 0 to <1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of oxathiapiprolin from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2016 Meeting determined that the establishment of an acute reference dose is unnecessary for oxathiapiprolin. The Meeting concluded that the acute dietary exposure to residues of isotianil, from uses considered by the present Meeting, is unlikely to present a public health concern.

5.25 Permethrin (120) (T,R)**

TOXICOLOGY

Permethrin was evaluated by the present Joint FAO/WHO Meeting on Pesticide Residues (JMPR) within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). A toxicity data package on permethrin was received by the Meeting and a draft toxicological monograph was prepared. However, the Meeting concluded that insufficient information from public literature, known to be extensive and relevant, was submitted and therefore the dossier for permethrin did not permit a substantive re-evaluation to be performed.

The Meeting re-emphasized the importance of a timely and complete submission of all relevant data to enable JMPR to perform a state-of-knowledge risk assessment.

(See also General consideration: 2.5 on the rolling submission of data)

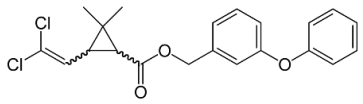
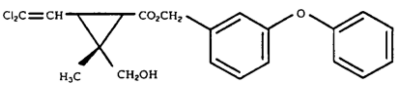
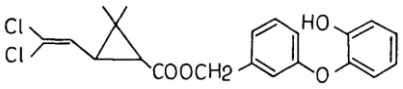
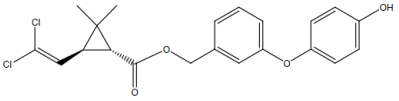
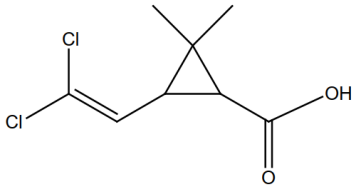
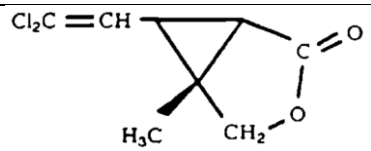
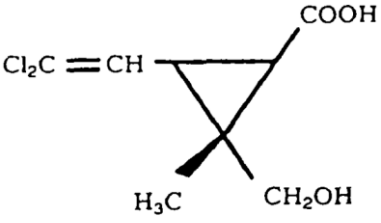
RESIDUE AND ANALYTICAL ASPECTS

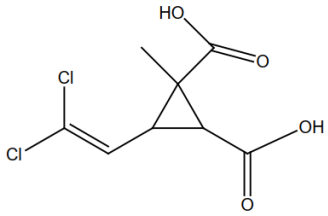
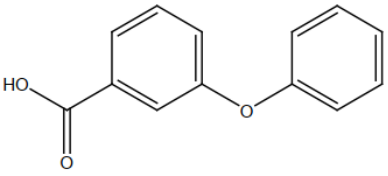
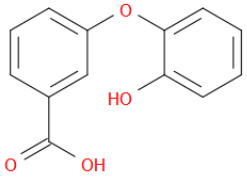
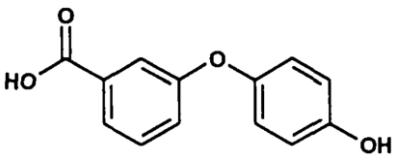
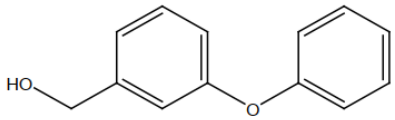
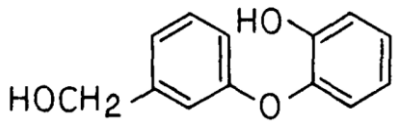
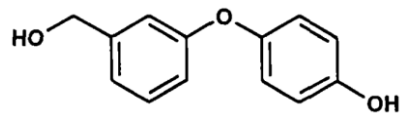
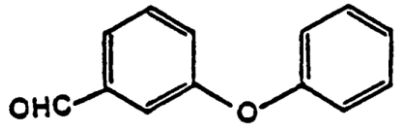
Permethrin is a synthetic pyrethroid insecticide that was first reviewed by the JMPR for toxicology and residues in 1979 (T, R). Further residue evaluations for additional uses were conducted over multiple years between 1980 and 1992, as well as in 2004 (R). Further evaluations for toxicology were conducted in 1981, 1986, 1987, and 1999. A periodic review for toxicology was conducted by the JMPR in 1999. Permethrin was listed by the Fifty-third Session of the CCPR for periodic review by the 2023 JMPR.

The Meeting received information on identity, physical and chemical properties; plant and animal metabolism, environmental fate, methods of residue analysis, storage stability, GAP information, supervised residue trials, processing studies, as well as livestock feeding studies.

Permethrin was specified by the FAO under the new compound programme in 2019.

Chemical name, abbreviation, and structure of compounds discussed below.

Chemical name	Abbreviation	Found in	Structure
Permethrin 3-phenoxybenzyl(1RS)-*cis-trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate MW: 391.3 g/mol	Permethrin	All radioactive labels from the plant and animal metabolism studies	
Hydroxypermethrin 3-phenoxylbenzyl-1-(*RS*)-*cis-trans*-3-(2,2-dichlorovinyl)-2-hydroxymethyl-2-methylcyclopropanecarboxylate	OH-permethrin	Cyclopropyl and phenyl labels from the animal metabolism studies	
2'-hydroxy-permethrin 3-(2-hydroxyphenoxy)benzyl-1-(*RS*)-*cis-trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	2'-OH-permethrin	Acid and alcohol labels from the snap bean metabolism study	
4'-hydroxy-permethrin 3-(4-hydroxyphenoxy)benzyl-1-(*RS*)-*cis-trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	4'-OH-permethrin	Acid and alcohol labels from the snap bean metabolism study and the animal metabolism studies	
Dichlorovinyl acid 1-(*RS*)-*cis-trans*-3-(2,2,dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid MW: 209.07 g/mol	DCVA	Acid and cyclopropyl labels only from the plant, animal metabolism studies, and confined rotational crop study	
3-(2,2-dichlorovinyl) cyclopropane-1,2-carbolactone	DCVA-lactone	Cyclopropyl labels from the goat metabolism study and the confined rotational crop study	
3-(2,2-Dichloroethenyl)-2-hydroxymethyl-2-methyl-1-cyclopropanecarboxylic acid	DCVA-OH	Cyclopropyl label from the confined rotational crop study	

Chemical name	Abbreviation	Found in	Structure
3-(2,2-dichlorovinyl)-2-methylcyclopropane-1,2-dicarboxylic acid	Diacid	Cyclopropyl label from the aerobic soil metabolism and confined rotational crop studies	
3-phenoxybenzoic acid MW: 214.22 g/mol	3-PBA	Alcohol and phenyl labels from the plant and animal metabolism studies, and the confined rotational crop study	
3-(2-hydroxyphenoxy)benzoic acid	2'-OH-3-PBA	Alcohol and phenyl labels from the plant metabolism studies and the confined rotational crop study	
4'-hydroxy-3-phenoxybenzoic acid	4'-OH-3-PBA	Alcohol and phenyl labels from the plant and animal metabolism studies, and the confined rotational crop study	
3-phenoxybenzyl alcohol MW: 200.24 g/mol	3-PBAlc	Alcohol and phenyl labels from the plant metabolism studies and the confined rotational crop study	
3-(2-hydroxyphenoxy)benzyl alcohol	2'-OH-3-PBAlc	Alcohol and phenyl labels from the plant metabolism studies and the confined rotational crop study	
3-(4-hydroxyphenoxy)benzyl alcohol	4'-OH-3-PBAlc	Alcohol and phenyl labels from the plant and animal metabolism studies, and the confined rotational crop study	
3-phenoxybenzyladehyde	3-PBAld	Methylene label from the aquatic photolysis study	

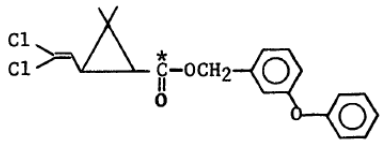
Permethrin is a mixture of two isomers (cis and trans) that are present in a ratio of approximately 40:60 (FAO specifications, 2019). Based on its physical and chemical properties, permethrin is not volatile (cis-permethrin = 2.15 × 10^{-8} mm Hg at 25°C; trans-permethrin = 0.69 × 10^{-8} at 25 °C), has low solubility in water (0.13 – 0.2 mg/L), but is highly soluble in organic solvents. It is likely to sequester to fatty matrices based on its Log P_{ow} (6.1). Hydrolysis and

aqueous photolysis are unlikely to be important routes of degradation at environmentally relevant pH levels but hydrolyses more rapidly under basic conditions and at higher temperatures.

Plant metabolism

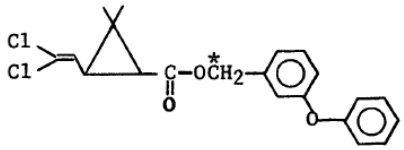
Permethrin metabolism data were submitted for foliar application to soya bean, cotton (including direct treatment of the seed), cabbage, sweet corn, and snap bean.

Figure 1. Location of label in compounds used in metabolism and environmental studies.



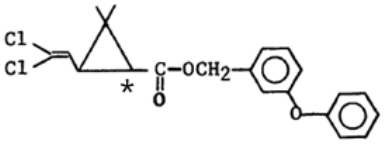
[^{14}C-acid]- permethrin

Cotton, cabbage, soya bean, sweet corn, and Snap bean



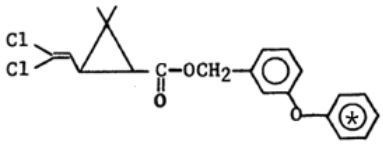
[^{14}C-alcohol]- permethrin

Cotton, cabbage, soya bean, sweet corn, and Snap bean



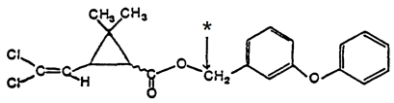
[^{14}C-cyclopropyl]-permethrin

Lactating goat, laying hen, confined rotational crop, soil and aqueous photolysis



[^{14}C-phenyl]- permethrin

Lactating goat, laying hen, confined rotational crop



[^{14}C-methylene]- permethrin

Soil hydrolysis, soil photolysis, and aqueous photolysis

Soya bean

Soya bean plants (variety Lee), grown in pots under greenhouse conditions, were treated once with [^{14}C-acid] or [^{14}C-alcohol] labelled permethrin (cis/trans ratio of 40/60). One leaf on each soybean plant was treated with radiolabelled permethrin between the three lobes of the first or second trifoliate leaf. Treated leaves were collected 0, 14, 30, and 60 days after treatment (DAT). No other parts of the plant were harvested.

The amount of applied radioactivity (percent AR) recovered from treated soya bean leaves decreased over time and ranged from 89 to 91 percent AR, 67–78 percent AR, 76–79 percent AR, and 61 percent AR, 0, 14, 30, and 60 DAT, respectively.

Soya bean leaves were extracted with chloroform:methanol, and the conjugated residues in the polar phase were released by enzyme (cellulase, 4 hours at 47°C, pH 4.5) and acid hydrolyses (reflux with 1N HCl for 1 hour). Characterization and identification were carried out by thin layer chromatography (TLC) and high performance liquid chromatography (HPLC).

For the acid label study, solvent extraction released 87.5-99.9 percent of the recovered radioactivity, with the majority of the radioactivity found in the non-polar phase at 0 DAT (96.7 percent of the radioactive residue) but decreasing over time (38.0 percent of the recovered radioactivity at 60 DAT), with the majority of the recovered radioactivity being found in the polar

phase (containing the conjugated metabolites) at 60 DAT (49.5 percent of the radioactive residues). The post extraction solids (PES) ranged from 0.1 to 12.5 percent of the recovered radioactive residue and increased with time, but were not further analysed. The parent, permethrin (sum of cis and trans isomers), was the predominant residue in soya bean leaves at all timepoints, accounting for 92.6 percent of the radioactive residues at 0 DAT and decreasing to 12.6 percent of the radioactive residues at 60 DAT. The cis/trans ratio changed from approximately 40/60 at 0 DAT to approximately 75/25 at 60 DAT, suggesting that trans-permethrin degraded faster than cis-permethrin. Conjugated DCVA (sum of cis and trans isomers, 18.3-29.0 percent of the recovered radioactivity) was a major metabolite (exclusive to the acid label study) identified in soya bean leaves at 14, 30, and 60 DAT. No other compounds were identified in the acid label study.

For the alcohol label study, solvent extraction released 81.5—99.9 percent of the recovered radioactivity, with the majority of the radioactivity found in the non-polar phase at 0 DAT (96.2 percent of the radioactive residue) but decreasing over time (61.2 percent of the recovered radioactivity at 60 DAT), with the majority of the recovered radioactivity being found in the polar phase (containing the conjugated metabolites) at 60 DAT (61.8 percent of the radioactive residues). The PES ranged from 0.1 to 18.5 percent of the recovered radioactive residues and increased with time, but were not further analysed. The parent, permethrin (sum of cis and trans isomers), was the predominant residue in soya bean leaves at all time points, accounting for 95.0 percent of the radioactive residues at 0 DAT and decreasing to 23.0 percent of the radioactive residues at 60 DAT. The cis/trans ratio changed from approximately 40/60 at 0 DAT to approximately 70/30 at 60 DAT. Conjugated 3-PBAlc (17.0—21.1 percent of the recovered radioactivity) was a major metabolites identified in soya bean leaves at 14, 30, and 60 DAT. Conjugated 2'-OH-3-PBAlc was a major metabolite at 60 DAT (10.5 percent of the recovered radioactivity). All other alcohol labelled permethrin metabolites (3-PBA, 4'-OH-3-PBAlc, 2'-OH-3-PBA, and 4'-OH-3-PBA) were minor metabolites that did not exceed 8.8 percent of the radioactive residues. All metabolites identified in the alcohol labelled soya bean study are unique to this label.

The translocation of permethrin and its degradates in mature soya bean plants following foliar and pod applications was investigated in a second study where the plants (variety Pickets 71) were treated once with [^{14}C-acid] or [^{14}C-alcohol] labelled permethrin (with a cis/trans ratio of 40/60), prepared as an emulsifiable concentrate formulation, 56 days after planting. For foliar applications, one trifoliate leaf on each soybean plant was treated with radiolabelled permethrin and two plants per label were harvested 30 DAT. On each remaining plant, one different leaf was treated with radiolabelled permethrin and two plants per label were harvested 60 after the first treatment (30 day after the last application (DALA)), and the remaining plants were harvested 78 days after the first treatment (48 DALA).

For pod applications, two plants from each label from the first foliar application were treated (2 pods per plant) with radiolabelled permethrin 33 days after the initial foliar application. Thirty days after the first pod application, two different pods from the same plants were treated a second time using the same amount of treated formulation. Soya bean plants were harvested 45 days after the initial pod application.

Very low levels of ^{14}C-residues, ranging from <0.01 to 0.56 percent AR, were found in non-treated plant parts following foliar or foliar and pod applications. The highest levels of radioactivity were observed in beans from the acid label treatment (0.56 percent AR foliar

application and up to 0.46 percent AR foliar + pod application). The results suggest that there is limited translocation of permethrin within the soya bean plant.

Cotton

Cotton plants (variety Stoneville 7A), grown in disposable flats, were treated with four different methods (i.e. foliar treatment, boll treatment, lint treatment, and direct treatment of the seed), with [^{14}C-acid] or [^{14}C-alcohol] labelled permethrin (cis/trans ratio of 40/60) formulated as an emulsifiable concentrate formulation.

For foliar application, one immature leaf on each cotton plant (125 days old, all plants had flowers but no bolls) was treated with radiolabelled permethrin and 30 days after the initial application, a new leaf on each plant was retreated. After 60 days, one plant from each label was harvested, while the remaining six plants were retreated with the formulation and harvested 30 days later (90 days after the first application).

For boll treatment, one boll per plant (125 days old) was treated with radiolabelled permethrin to the entire outside surface of the boll. Thirty days after the first application, all bolls were retreated and harvested 1 month later (60 days after the first application). For lint treatment, one third of the lint surface of cotton plants (125— 145 days old) were treated and harvested 30 days later. For seed treatment, seeds from mature cotton plants (187 days old) were treated with of the formulation and harvested 21 days after. Only untreated plant parts (except for seed) were analysed.

The results indicate that low levels of radioactivity, < 2 percent AR, were found in cotton plant parts that were not directly treated with radiolabelled permethrin.

Approximately 95—96 percent of the applied radioactivity was recovered from cotton seeds harvested 21 days after a single application directly to the seeds. Cotton seeds were extracted with methanol:chloroform for characterization and identification by TLC.

For the acid label study, solvent extraction released 98.9 percent of the recovered radioactivity, with the majority of the radioactivity found in the non-polar phase (77.5 percent of the radioactive residue) while the polar phase contained 21.4 percent of the recovered radioactivity. The PES was 1.1 percent of the radioactive residues. The parent, permethrin (sum of cis and trans isomers), was the only residue identified cotton seeds, accounting for 81.5 percent of the radioactive residues. The cis/trans ratio remained unchanged (i.e. approximately 40/60).

For the alcohol label study, solvent extraction released 95.2 percent of the recovered radioactivity, with the majority of the radioactivity found in the non-polar phase (85.8 percent of the radioactive residue) while the polar phase contained 12.7 percent of the recovered radioactivity. The PES was 1.5 percent of the radioactive residues. The parent, permethrin (sum of cis and trans isomers), was the only residue identified cotton seeds, accounting for 86.8 percent of the radioactive residues. The cis/trans ratio remained unchanged.

Based on the dates provided to cover the entire period of the study, the maximum potential storage duration of any sample is 146 days (~4.8 months). As per OECD Test Guideline No. 501 (Metabolism in Crops), storage stability data are not normally necessary for samples analysed within 6 months of collection, provided evidence is given that attempts were made to limit degradation of residues by appropriate storage of matrices and extracts during the analytical portion of the study.

Head cabbage

Head cabbage plants (variety Danish ballhead), grown under greenhouse conditions, were treated with [^{14}C-acid] or [^{14}C-alcohol] labelled permethrin (cis/trans ratio of 40/60). One leaf on each cabbage plant (35 days after planting) was treated with radiolabelled permethrin to the entire foliage surface. Thirty days after the initial application, a second application was made to a different leaf of each plant. Treated leaves were collected 0 DAT, as well as 30 days after the initial application, and 60 days after the second application (90 days after the initial application).

The amount of applied radioactivity (percent AR) recovered from treated cabbage leaves decreased over time and ranged from 89 to 93 percent AR, from 49 to 59 percent AR, and from 53 to 55 percent AR, 0, 30, and 60 DAT, respectively.

Cabbage leaves were extracted with chloroform:methanol, and the conjugated residues in the polar phase were released by enzyme (cellulase, 4 hours at 47°C, pH 4.5) and acid hydrolyses (reflux with 1N HCl for 1 hour). Characterization and identification were carried out by TLC and HPLC.

For the acid label study, solvent extraction released 82.3-99.9 percent of the recovered radioactivity, with the majority of the radioactivity found in the non-polar phase at 0 DAT (97.7 percent of the radioactive residue) but decreasing over time (23.4 percent of the recovered radioactivity at 60 DAT), with the majority of the recovered radioactivity being found in the polar phase (containing the conjugated metabolites) at 60 DAT (58.9 percent of the radioactive residues). The PES ranged from 0.1 to 17.7 percent of the recovered radioactive residue and increased with time, but were not further analysed.

The parent, permethrin (sum of cis and trans isomers), was the predominant residue in cabbage leaves at all timepoints, accounting for 94.4 percent of the radioactive residues at 0 DAT and decreasing to 20.3 percent of the radioactive residues at 60 DAT. The cis/trans ratio changed from approximately 40/60 at 0 DAT to approximately 60/40 at 60 DAT, suggesting that trans-permethrin degraded faster than cis-permethrin. Conjugated DCVA (sum of cis and trans isomers, 32.2-38.3 percent of the recovered radioactivity) was a major metabolite (exclusive to the acid label study) identified in cabbage leaves at 30 and 60 DAT. No other compounds were identified in the acid label study.

For the alcohol label study, solvent extraction released 63.6—99.9 percent of the recovered radioactivity, with the majority of the radioactivity found in the non-polar phase at 0 DAT (98.2 percent of the radioactive residue) but decreasing over time (24.2 percent of the recovered radioactivity at 60 DAT), with the majority of the recovered radioactivity being found in the polar phase (containing the conjugated metabolites) at 60 DAT (61.0 percent of the radioactive residues). The PES ranged from 0.1 to 36.4 percent of the recovered radioactive residues and increased with time, but were not further analysed. The parent, permethrin (sum of cis and trans isomers), was the predominant residue in cabbage leaves at all timepoints, accounting for 96.8 percent of the radioactive residues at 0 DAT and decreasing to 67.6 percent of the radioactive residues at 60 DAT. The cis/trans ratio changed from approximately 40/60 at 0 DAT to approximately 60/40 at 60 DAT. Conjugated 3-PBAlc (19.5—22.6 percent of the recovered radioactivity) was a major metabolite identified in cabbage at 30 and 60 DAT. Conjugated 4'-OH-3-PBAlc was a major metabolite at 60 DAT (11.2 percent of the recovered radioactivity). All other alcohol labelled permethrin metabolites (3-PBA, 2'-OH-3-PBAlc, 2'-OH-3-

PBA, and 4'-OH-3-PBA) were minor metabolites that did not exceed 4.2 percent of the radioactive residues. All metabolites identified in the alcohol labelled cabbage study are unique to this label.

The results of this study were confirmed in another study in which 28 day old cabbage plants grown under greenhouse conditions were treated with [^{14}C-acid] or [^{14}C-alcohol] labelled permethrin (cis/trans ratio of 40/60) in an ethanol solution. Two leaves from each cabbage plant were treated with radiolabelled permethrin applied to the entire foliage surface. Treated leaves were collected 30 days after application. Although residue levels of the metabolites were not reported in this study due to contamination of the samples, the study report identified the metabolites cis-DCVA, trans-DCVA, 3-PBAlc, 3-PBA, and 4'-OH-3-PBAlc. The metabolites cis-DCVA, trans-DCVA, and 3-PBAlc were identified as the major metabolites of permethrin in cabbage.

Sweet corn

Sweet corn plants (variety Sweety S1), grown under field conditions (clay loam soil) in Switzerland, were treated five times with a foliar application (using a hand-held spray bottle) with [^{14}C-cyclopropyl] or [^{14}C-phenyl] labelled permethrin (cis/trans ratio not specified), as an emulsifiable concentrate formulation, at a rate of 3.64 kg ai/ha, with retreatment intervals of 20-44 days. Immature forage was harvested 1 day after the third application. Fodder, kernel, and cobs (hair and leaves removed), were harvested 1 DALA.

Total radioactive residues (TRR) in sweet corn forage, fodder, kernel, and cobs following combustion were 1.63—1.71 mg eq/kg, 33-40 mg eq/kg, 0.10—0.13 mg eq.kg, and 0.07-0.10 mg eq/kg, respectively. Extraction of sweet corn forage, fodder, kernel, and cobs with hexane, acetonitrile, acetonitrile:water, and water, released 82-85 percent TRR, 91—92 percent TRR, 61-72 percent TRR, and 61—66 percent TRR, from each matrix, respectively. The majority of the TRR were found in the aqueous phase (43.8—65.9 percent TRR) and conjugated metabolites were released by hydrolysis with cellulase (24 hours at 37°C, pH 4.8), acid hydrolysis (1N HCl at 70°C for 3 hours at pH 1, followed by 1N HCl at 95°C under reflux for 3 hours at pH 1), and base hydrolysis (2N NaOH at 70°C for 3 hours at pH 14, followed by 2N NaOH at 75°C under reflux for 3 hours at pH 14). Hydrolysis of the PES was carried out using the same processes as the hydrolysis of the aqueous phases, which released an additional 8.2–32.3 percent TRR. Unextracted residues remaining after extensive hydrolyses ranged from 0.5 to 60.3 percent TRR (0.009—0.108 mg eq/kg). Characterization and identification of compounds was carried out by TLC and HPLC.

In the cyclopropyl label study, permethrin was the major identified residue in all sweet corn matrices except kernel, accounting for 21 percent TRR (0.38 mg eq/kg) in forage, 64 percent TRR (23.5 mg eq/kg) in fodder, and 1.0 percent TRR (0.001 mg eq/kg) in cobs. No residues of permethrin were identified in the kernel. The metabolite DCVA (sum of cis and trans isomers, free and conjugated), was a major metabolite in sweet corn forage at 18 percent TRR (0.32 mg eq/kg) and was a minor metabolite in sweet corn fodder (4.6 percent TRR, 1.7 mg eq/kg). DCVA is a unique metabolite to the cyclopropyl label study. No other metabolites were identified with this label.

In the phenyl label study, permethrin was the major identified residue in all sweet corn matrices, accounting for 22 percent TRR (0.43 mg eq/kg) in forage, 69 percent TRR (20.4 mg eq/kg) in fodder, 25.6 percent TRR (0.022 mg eq/kg) in kernel, and 28.8 percent TRR (0.021 mg eq/kg) in cobs. The metabolites 3-PBAlc (free and conjugated) and 3-PBA (free) were identified in sweet corn forage at 9.9 percent TRR (0.19 mg eq/kg) and 3.5 percent TRR (0.067 mg eq/kg),

respectively, as well as in sweet corn fodder at 3.4 percent TRR (1.01 mg eq/kg) and 1.6 percent TRR (0.47 mg eq/kg), respectively. Conjugated metabolite 4'-OH-3-PBA was a minor metabolite identified in sweet corn forage and fodder at 0.6 percent TRR (0.011 mg eq/kg) and 0.5 percent TRR (0.16 mg eq/kg), respectively. Conjugated metabolite 4'-OH-3-PBAlc was a minor metabolite identified only in sweet corn fodder at 0.4 percent TRR (0.11 mg eq/kg). No metabolites were identified in kernel or cobs in the phenyl label study. All metabolites identified in this study were unique to this label.

Two unknown components with TRRs greater than 0.05 mg eq/kg were found in the partitioned acetonitrile/water extracts of forage from both labels. These components were analysed again by TLC using a different solvent system and were found to be comprised of several compounds (determined to contain both rings) but none which exceeded 10 percent TRR.

Snap beans

In a published journal article, snap bean seedlings (Phaseolus vulgaris L.), grown in greenhouse conditions, were treated with [^{14}C-acid] or [^{14}C-alcohol] labelled cis-permethrin or trans-permethrin (Ohkawa, 1977, Journal of Pesticide Science). Each radiolabelled chemical was evenly applied to the upper surface of one primary leaf of 14-day old seedlings by microsyringe. At intervals of 1, 2, 4, 8 and 14 DAT, leaves were harvested and rinse 3x with methanol to remove surface residues. The rinsed leaves were frozen, ground into a powder, and then extracted 3x with methanol. Characterization and identification was carried out by TLC. Following TLC analyses, various derivatization and hydrolysis procedures were carried out (i.e. methylation with diazometane, hydrolysis with β-glucosidase, hydrolysis with 6N HCl for 6 hours at 80^{o}C).

After application of radiolabelled cis- and trans-permethrin to the leaf surface of one primary leaf of snap bean plants, the distribution of the radioactivity was mostly located in/on the leaf treated with each isomer 10 DAT. Quantitation of the radiocarbon showed that more than 99 percent of the recovered radioactivity was found in the treated leaf 14 DAT while < 1 percent was in the other parts of the bean plants, indicating limited translocation of permethrin and/or its metabolites within the plant.

In the acid label study, approximately 80-88 percent of the AR was recovered from snap bean leaves at 8 DAT and 14 DAT. At 8 DAT, approximately 52-54 percent of the radioactive residue recovered was found in the surface wash, 42-45 percent of the recovered radioactivity was found in the methanol extract, and only 3.2-3.5 percent of the recovered radioactivity remained in the PES. At 14 DAT, approximately 18-20 percent of the recovered radioactivity was found in the surface wash, 67-72 percent of the recovered radioactivity was found in the in the methanol extract, and 10-13 percent of the recovered radioactivity remained in the PES. The parent, permethrin (sum of cis and trans isomers), was the predominant residue in snap bean leaves at 8 DAT and 14 DAT, accounting for 60-73 percent of the radioactive residues at 8 DAT and decreasing to 22-30 percent of the radioactive residues at 14 DAT. Conjugated DCVA (sum of cis and trans isomers) was a major metabolite (exclusive to the acid label study) identified in snap bean leaves at 8 DAT and 60 DAT at 10-12 percent and 18-38 percent of the recovered radioactivity, respectively. No other compounds were identified in the acid label study.

In the alcohol label study, approximately 72-93 percent of the AR was recovered from snap bean leaves at 8 DAT and 14 DAT. At 8 DAT, approximately 52-54 percent of the radioactive residue recovered was found in the surface wash, 42-44 percent of the recovered radioactivity was found in the methanol extract, and only 4.6-4.8 percent of the recovered radioactivity

remained in the PES. At 14 DAT, approximately 18-21 percent of the recovered radioactivity was found in the surface wash, 63-66 percent of the recovered radioactivity was found in the in the methanol extract, and 13-19 percent of the recovered radioactivity remained in the PES. The parent, permethrin (sum of cis and trans isomers), was the predominant residue in snap bean leaves at 8 DAT and 14 DAT, accounting for 55-65 percent of the radioactive residues at 8 DAT and decreasing to 21-25 percent of the radioactive residues at 14 DAT. The metabolite 3-PBAlc was found in both free and conjugated forms at 6.9-7.8 percent of the recovered radioactivity (8 DAT) and 11-18 percent of the recovered radioactivity (14 DAT).

The metabolite 2'-OH-3-PBAlc (free and conjugated) was found at 1.4-8.8 percent of the recovered radioactivity (8 DAT) and 4.2-15.0 percent of the recovered radioactivity (14 DAT). The metabolites 3-PBA (free), 4'-OH-3-PBAlc (free and conjugated), 2'-OH-permethrin (free), and 4'-OH-permethrin (free) were all minor metabolites that did not exceed 8.2 percent of the recovered radioactivity. It is noted that the levels of conjugated metabolites in snap bean leaves increased over time.

When applied to the leaf surface of snap bean plats, both trans-permethrin and cis-permethrin were readily metabolized in and/or on the leaf of the plants. Levels of trans-permethrin appeared to degrade somewhat faster than levels of cis-permethrin in snap bean plants.

Conclusions

In summary, the unchanged parent (sum of cis and trans isomers) is the predominant residue in permethrin-treated plants, notably in soya bean leaves, cotton seeds, head cabbage, sweet corn forage and fodder, and snap bean leaves. Residues of permethrin (sum of cis and trans isomers) were highest just after application and then decreased over time. The trans isomer of permethrin appears to degrade more quickly than the cis-isomer of permethrin in some matrices (soya bean leaves and cabbage) but remained constant in cotton seeds. Permethrin also appears to have limited translocation within plants.

In sweet corn kernel and cobs, the unchanged parent is present at very low levels and no metabolites were identified in these matrices or in cotton seeds. The metabolism of permethrin in plants involves the hydrolysis of the ester bond to form DCVA and 3-PBAlc, the latter which is further oxidized to form 3-PBA and was similar in all crops investigated. Other major metabolites observed after foliar application were DCVA (sum of cis and trans isomers, in soya bean leaves, cabbage, sweet corn forage, and snap bean leaves), 3-PBAlc (soya bean leaves, head cabbage, sweet corn forage, and snap bean leaves), 2'-OH-3-PBAlc (soya bean leaves and snap bean leaves), and 4'-OH-3-PBAlc (head cabbage). The metabolism of permethrin in plants is similar to other pyrethroid compounds.

Animal metabolism

The Meeting received animal metabolism studies with permethrin in lactating goats, laying hens, and rats.

Lactating goats

The metabolism of [^{14}C-cyclopropyl]-permethrin and [^{14}C-phenyl]-permethrin was investigated in two lactating goats following repeated oral administration by gelatine capsule. The animals were dosed once daily in the afternoon for 4 consecutive days (cyclopropyl label =102 mg permethrin/day, phenyl label = 122 mg permethrin/day). Feed consumption during the

dosing period was assumed to be 2 kg/day. The nominal daily doses were equivalent to 51 ppm in the diet for the goat fed [^{14}C-cyclopropyl-^{14}C]-permethrin and 61 ppm in the diet for the goat fed [^{14}C-phenyl]-permethrin. During the dosing period, urine and faeces were sampled once daily, while milk was collected twice daily. Liver, kidney, muscle, fat, and gastro-intestinal content samples were collected after animal sacrifice, approximately 16 hours after administration of the last dose.

Most of the radioactivity was recovered in the excreta with urine containing 33-48 percent of the administered dose (AD) and faeces containing 29-32 percent of the AD. The gastro-intestinal contents accounted for 9.4 percent of the AD (cyclopropyl label only). The radioactivity recovered in milk and remaining tissues (fat and muscle not reported) was low, each accounting for ≤0.9 percent of the AD. Residues in milk did not reach a plateau by the end of the study.

The calculated TRR in the pooled whole milk samples was 0.14 mg eq/kg (0-24 h) and 0.17 mg eq/kg (72-88 h) for the cyclopropyl label, and was 0.24 mg eq/kg (0-24 h) and 0.41 mg eq/kg (72-88 h) for the phenyl label. TRRs in buttermilk and skimmed milk were 0.07 – 0.17 mg eq/kg (52 – 57 percent TRR in milk) and 0.06 – 0.13 mg eq/kg 43 – 48 percent TRR in milk), respectively. For tissues, TRR were highest in liver (0.91 – 1.18 mg eq/kg), followed by kidney (0.78 – 1.04 mg eq/kg), perirenal fat (0.10 – 0.24 mg eq/kg), omental fat (0.07 – 0.17 mg eq/kg), subcutaneous fat (0.06 – 0.15 mg eq/kg), and muscle (0.02 – 0.04 mg eq/kg, for each – leg and rump).

Whole milk samples were extracted with diethyl ether:ethanol and subsequently partitioned with hexane and acetonitrile (ACN). The PES from the diethyl ether:ethanol (containing the milk proteins) were hydrolysed by boiling with 6 mol/L HCl for 4 hours and partitioning with dichloromethane. Characterization and identification was carried out by TLC and HPLC.

For the cyclopropyl label-treated goats, solvent extraction of whole milk released the majority of the radioactivity in the ACN fraction (64.3 percent TRR) and 20.1 percent TRR in the hexane:ether fraction. The PES contained 13.4 percent TRR and following acid hydrolysis 10.7 percent TRR remained unextracted. Permethrin was the major residue in whole milk, accounting for 46.5 percent TRR (0.060 mg eq/kg). Hydroxypermethrin (free) was a minor metabolite identified in whole milk accounting for 8.1 percent TRR (0.011 mg eq/kg).

For the phenyl label-treated goats, solvent extraction of whole milk released the majority of the radioactivity in the ACN fraction (60.1 percent TRR) and 25.3 percent TRR in the hexane:ether fraction. The PES contained 7.6 percent TRR and following acid hydrolysis 2.8 percent TRR remained unextracted. Permethrin was the major residue in whole milk, accounting for 55.5 percent TRR (0.166 mg eq/kg). Hydroxypermethrin (free) was a minor metabolite identified in whole milk accounting for 2.6 percent TRR (0.008 mg eq/kg).

Liver and kidney samples were extracted by incubation with protease enzyme followed by extraction with methanol. Characterization and identification was carried out by TLC and HPLC.

For the cyclopropyl label-treated goats, protease incubation and methanol extraction of liver and kidney samples released the majority of the radioactivity (93.4 percent TRR and 95.4 percent TRR, respectively). The PES remaining in liver and kidney were 6.6 percent and 4.9 percent, respectively. Permethrin was not observed in the liver or kidney from the cyclopropyl label study. The predominant residue identified was DCVA (sum of cis and trans isomers) at 16.1 percent TRR (0.193 mg eq/kg) in the liver and at 26.3 percent TRR (0.271 mg eq/kg) in kidney.

Trans-DCVA-glucoronide was a major metabolite identified in kidney (22.0 percent TRR, 0.23 mg eq/kg). DCVA-lactone was a minor metabolite in liver and kidney at 1.0 percent TRR (0.012 mg eq/kg) and 0.6 percent TRR (0.006 mg eq/kg), respectively. An unknown component in the liver co-chromatographed with the reference standard for OH-DCVA, however the level of radioactivity was not reported (but would be <11 percent TRR, 0.13 mg eq/kg). Hydroxy-DCVA (level of radioactivity not reported) was found as a component of two unknown radioactive regions. All metabolites identified in this study are unique to the cyclopropyl label.

For the phenyl label-treated goats, protease incubation and methanol extraction of liver and kidney samples released the majority of the radioactivity (91.0 percent TRR and 95.5 percent TRR, respectively). The PES remaining in liver and kidney were 9.0 percent and 4.5 percent, respectively. Permethrin was identified in the liver at only 2.0 percent TRR (0.018 mg eq/kg) but was not seen in the kidney in the phenyl label study. The predominant residue identified was 3-PBA at 12.5 percent TRR (0.11 mg eq/kg) in the liver and at 56.7 percent TRR (0.44 mg eq/kg) in the kidney. The metabolite 4'-OH-3-PBA was a major metabolite identified in liver (10.7 percent TRR, 0.097 mg eq/kg) but was not observed in kidney. Metabolite 4'-OH-permethrin was a minor metabolite identified in liver (2.0 percent TRR, 0.018 mg eq/kg) but not seen in kidney.

An unknown region of radioactivity in the liver was further investigated by improved TLC resolution and base hydrolysis of the liver extract (refluxed for 1.5 hours with 5.6 percent w/v of KOH) which identified the free and conjugated metabolites 3-PBAlc (up to 28.5 percent TRR, ~0.26 mg eq/kg) and 4'-OH-3-PBAlc (5.5 percent TRR, ~0.05 mg eq/kg). Another unknown component in the liver co-chromatographed with the reference standard for hydroxy-DCVA, however the level of radioactivity not reported.

Incubation with protease enzyme and extraction with methanol released 89.1 percent TRR, 0.035 mg eq/kg (cyclopropyl label) and 75.5 percent TRR, 0.015 mg eq/kg (phenyl label) in muscle. The PES represented 10.9 percent TRR, 0.004 mg eq/kg (cyclopropyl label) and 24.5 percent TRR, 0.005 mg eq/kg (phenyl label), and were not further analysed. Although no residues were identified in muscle, one component from phenyl label extracts had a similar retention time to that of permethrin (level of radioactivity not reported).

Solvent extraction of each type of fat released the majority of the radioactivity, with 79.6-90.6 percent TRR (0.05-0.08 mg eq/kg) extracted in the cyclopropyl label study and 84.3-92.9 percent TRR (0.14-0.20 mg eq/kg) extracted in the phenyl label study. The PES represented 9.4-20.4 percent TRR (0.01-0.02 mg eq/kg, cyclopropyl label) and 7.1-15.7 percent TRR (0.01-0.04 mg eq/kg, phenyl label). The pooled extracts from the phenyl label were found to contain a single component that was identified as permethrin (level of radioactivity not reported). The radioactivity from the combined extracts of the chlorophenyl label were too low for analysis.

All samples were stored at ≤-15°C and were analysed within 2 – 9 months after sample collection. The storage stability of the extracts (both labels) from milk, liver, and kidney from the goat metabolism study (stored at ≤-15°C) was investigated. Comparison of the chromatographic profiles between liver and kidney samples extracted in the original study and re-extracted over 2 years later (no specific dates for initial and follow-up extractions were provided) showed no significant changes to the composition radioactivity. Samples of milk extracts (both labels) taken for analysis 2 and 7 months after collection also displayed similar chromatographic profiles.

Laying hen

The metabolism of [^{14}C-cyclopropyl-^{14}C]-permethrin and [^{14}C-phenyl]-permethrin was investigated in laying hens following repeated oral administration by gelatine capsule. The animals were dosed once daily in the afternoon for 7 consecutive days (cyclopropyl label =1.27 mg permethrin/day, phenyl label = 1.27 mg permethrin/day). Feed consumption during the dosing period was ranged from 630 to 964 g/day. The daily doses were equivalent to 11 ppm in the diet for both labels. During the dosing period, excreta was collected once daily, while eggs were collected at least once daily after which they were separated into egg whites and egg yolks. Liver, muscle and fat samples were collected after animal sacrifice, 16 hours after administration of the last dose.

The radioactive residues in excreta accounted for 90—92 percent AD for both labels.

The radioactivity recovered in eggs and liver was low, each accounting for ≤0.2 percent of the AD. The radioactivity recovered in fat and muscle was not reported for either label. Residues in egg yolk did not reach a plateau by the end of the study in hens dosed with either label. In egg white, residues did not reach a plateau by the end of the study in hens dosed with ^{14}C-cyclopropyl-permethrin, however they appear to plateau around 120-144 hours after dosing in hens fed ^{14}C-phenyl-permethrin.

For tissues, cyclopropyl label, TRR were highest in peritoneal fat (0.37 mg eq/kg), followed by skin and subcutaneous fat (0.18 mg eq/kg), liver (0.17 mg eq/kg), leg muscle (0.03 mg eq/kg), and breast muscle (0.01 mg eq/kg). For the phenyl label, TRR were highest in peritoneal fat (0.31 mg eq/kg), followed by liver (0.29 mg eq/kg), skin and subcutaneous fat (0.16 mg eq/kg), leg muscle (0.02 mg eq/kg), and breast muscle (0.01 mg eq/kg).

For the cyclopropyl label treated hens, sequential extractions of egg yolks with acetonitrile, hexane, and water, released 78.4 percent TRR, 11.8 percent TRR, and 2.6 percent TRR, respectively. The PES contained 7.1 percent TRR. The PES were hydrolysed with 6 g/mol HCl by boiling for 2 hours which released an additional 2.3 percent TRR with 4.8 percent TRR remaining unextracted. The parent compound was the major residue in egg yolk, accounting for 57.6 percent TRR (0.159 mg eq/kg). DCVA (sum of cis and trans isomers) was a minor metabolite accounting for 1.2 percent TRR (0.003 mg eq/kg).

For the phenyl label treated hens, sequential extractions of egg yolks with acetonitrile, hexane, and water, released 67.8 percent TRR, 9.2 percent TRR, and 4.1 percent TRR, respectively. The PES contained 18.9 percent TRR. The PES were hydrolysed with 6 g/mol HCl by boiling for 2 hours which released an additional 9.0 percent TRR with 9.9 percent TRR remaining unextracted. The parent compound was the major residue in egg yolk, accounting for 56.7 percent TRR (0.172 mg eq/kg). No metabolites were identified in egg yolk in the phenyl label study.

Only egg whites from the chlorophenyl label contained sufficient radioactivity for analysis. Pooled egg white samples were extracted 2x with acetonitrile. Solvent extraction of the egg whites released 69.6 percent TRR (0.013 mg eq/kg). The PES was 27.8 percent TRR (0.005 mg eq/kg) and was not further analysed. The parent compound was the major residue in egg white, accounting for 52.2 percent TRR (0.010 mg eq/kg). Trans-DCVA was also observed in egg white, accounting for 10.6 percent TRR (0.002 mg eq/kg).

For the cyclopropyl label treated hens, incubation with protease enzyme and extraction with methanol released 89.6 percent TRR (0.143 mg eq/kg) in liver. The PES was 10.4 percent TRR (0.017 mg eq/kg) and was not analysed further. The parent was not found in poultry liver.

The only compound identified was DCVA (sum of cis and trans isomers), accounting for 13.8 percent TRR (0.022 mg eq/kg). For the phenyl label treated hens, incubation with protease enzyme and extraction with methanol released 90.5 percent TRR (0.253 mg eq/kg) in liver. The PES was 9.4 percent TRR (0.026 mg eq/kg). The liver extracts from both labels contained large amounts of unidentified highly polar radioactive material. Acid hydrolysis was not successful in releasing any substantial quantity of radioactivity and were not further analysed. Additional samples of homogenized liver were subjected to an exhaustive extraction and the study report concluded that these unextracted residues represent radioactivity that is covalently bound to insoluble cellular protein and that these results corroborate the presence of the large amounts of polar material observed in the protease/methanol extracts.

Hexane extraction of peritoneal fat samples released 94.6 percent TRR (035 mg eq/kg) from the cyclopropyl label study and 90.3 percent TRR (0.28 mg eq/kg) from the phenyl label study. The PES remaining was 2.7 percent TRR (0.01 mg eq/kg, cyclopropyl label) and 3.2 percent (0.01 mg eq/kg, phenyl label). The parent compound was the major residue in peritoneal fat, accounting for 78.4 percent TRR (0.29 mg eq/kg) for the cyclopropyl label study, and 77.4 percent TRR (0.24 mg eq/kg) for the phenyl label study. The metabolite OH-permethrin was a minor metabolite in fat, accounting for 5.4 percent TRR (0.02 mg eq/kg) for the cyclopropyl label study, and 6.5 percent TRR (0.02 mg eq/kg) for the phenyl label study.

Acetone/water extraction of the leg muscle samples released 62.6 percent TRR (0.016 mg eq/kg) from the cyclopropyl label study and 54.1 percent TRR (0.014 mg eq/kg) from the phenyl label study. The PES remaining was 37.4 percent TRR (0.010 mg eq/kg, cyclopropyl label) and 45.9 percent (0.011 mg eq/kg, phenyl label) and were not further analysed. The parent compound was the predominant residue in leg muscle, accounting for 30.7-33.7 percent TRR (0.008 mg eq/kg for both labels). All other unidentified components were present at ≤ 0.006 mg eq/kg.

Based on the dates of dosing of the hens and the completion of the experimental work, samples/extracts from this study were stored frozen for up to 4 months prior to analyses. As per OECD Test Guideline No. 503 (Metabolism in Livestock), storage stability data are not normally necessary for samples analysed within 6 months of collection, provided evidence is given that attempts were made to limit degradation of residues by appropriate storage of matrices and extracts during the analytical portion of the study.

Conclusions

In summary, the metabolism of permethrin in animals was qualitatively similar, based on hydrolysis of the ester linkage, hydroxylation of a geminal dimethyl group attached to the cyclopropane ring, and hydroxylation at the 4'-position of the phenoxybenzyl moiety. Some metabolites were further conjugated with glucuronic acid. Most of the radioactivity was eliminated via excreta. In goat and poultry matrices, permethrin was the predominant residue in milk, egg (yolk and whites), poultry fat, and poultry muscle. The chlorophenyl label specific metabolite DCVA (sum of cis and trans isomers) was the predominant component of the residue in goat liver, goat kidney, egg white, and poultry liver. The phenyl label specific metabolites 3-PBA (free and conjugated), 4'-OH-3-PBA, and 3-PBAlc were also a major components in goat liver and/or kidney.

Environmental fate

The Meeting received information on soil aerobic metabolism, terrestrial field dissipation, hydrolysis and photolysis properties of permethrin. Studies were also received on the nature of

[^{14}C]-permethrin in confined rotational crops and the magnitude of permethrin in field rotational crops.

Aerobic soil metabolism (laboratory studies)

Permethrin is moderately persistent in aerobic soil from the United States with DT_{50} values ranging from 4 to 263 days. Cis-permethrin (DT_{50} = 7 to 464 days) was more persistent than trans-permethrin (DT_{50} = 3 to 171 days). However, the Meeting noted that the predicted DT_{50} values were extrapolated beyond the study duration (182 days) and should be treated with caution.

The metabolites trans-DCVA, cis-DCVA, 3-PBA, trans-4'OH-permethrin, and cis-4'OH-permethrin were detected, reaching maximum amounts of 6.9 percent of the total applied radioactivity (TAR), 2.6 percent TAR, 5.2 percent TAR, 3.2 percent TAR, and 5.8 percent TAR, respectively.

Additional aerobic soil metabolism studies were conducted using sandy loam soil from the United Kingdom of Great Britain and Northern Ireland. The results of these studies found the half-life of permethrin in sandy loam soil to be 12—113 days, and was greatly affected by application rate (i.e. more rapid degradation of permethrin at lower rates), and moderately influenced by soil moisture (i.e. the rate of degradation being faster in moister soil). The half-life of permethrin in non-sterile soil was 37 days versus sterile soil at 330 days. An additional metabolite (diacid) was observed in one of the studies, reaching a maximum amount of 7.6 percent TAR. These additional studies also confirmed that trans-permethrin degraded more rapidly than cis-permethrin under aerobic conditions.

Field dissipation

The DT_{50} values for permethrin degradation ranged from 17 to 43 days indicating that permethrin is non-persistent.

All residues of permethrin and its metabolites were found only in the upper portion of the soil (0-31cm). Permethrin showed a consistent decline with the trans-isomer dissipating more rapidly than the cis-isomer.

Therefore, the Meeting decided that permethrin shows no potential to accumulate in soil following application in consecutive years.

Hydrolysis

Permethrin is stable to aqueous hydrolysis at pH 3 and pH 6, but under basic conditions it hydrolyses rapidly at higher temperatures. The half-life of the pH 9 samples maintained at 45ºC was calculated to be only 3 days. The cis-isomer was significantly more stable to hydrolysis than the trans isomer (i.e. the trans isomer hydrolyzes about twice as fast as the cis-isomer). The average half-life of the cis and trans isomers at pH 9.6 was ~56 days and 42 days, respectively, at a temperature of 25ºC which decreased to ~9 days and 5.5 days, respectively, when the temperature was increased to 45ºC.

Major degradation products identified were trans-DCVA, cis-DCVA, and 3-PBAlc found only in pH 9 samples (all temperatures) at maximum levels of 44 percent TAR (45ºC, acid label, 7 days), 17 percent TAR (45ºC, acid label, 7 days), and 80 percent TAR (45ºC, alcohol label, 7 days), respectively.

Photolysis

Limited degradation of the parent compound was observed in both irradiated and dark control soil samples (incubation temperature of 25 ± 5ºC), hence soil photolysis was not an important route of dissipation. Degradation products identified include 3-phenoxybenzyl alcohol (4.8 percent TAR) and 3-phenoxybenzoic acid (1.5 percent TAR). None of the other products formed represented more than 4.9 percent TAR.

The DT_{50} for permethrin for aquatic photolysis ranged from 19 to 72 days (pH 5, 25 ± 1ºC). The results also indicated that the rate of degradation of cis-permethrin was greater than that of trans-permethrin during irradiation. Degradation products identified included trans-DCVA (maximum of 26.7 percent TAR), cis-DCVA (maximum of 14.1 percent TAR), as well as 3-PBAlc, 3-PBA, and 3-phenoxybenzaldehyde (3-PBAld) of which none exceeded 4.4 percent TAR.

Confined rotational crops

[^{14}C-cyclopropyl]-Permethrin and [^{14}C-phenyl]-permethrin, formulated as emulsifiable concentrate (EC) formulations, were applied to bare sandy loam soil, in plastic containers maintained in a growth chamber, at an application rate of 3.66 kg ai/ha. Summer wheat (variety Frisal), lettuce (variety Pia), and beetroot (variety Red ace F-1) were sown 33/34, 127/128 and 364/365 days after soil treatment. All crops were harvested at maturity and immature wheat (forage) samples were collected 27–73 days after planting (DAP).

TRR were determined by combustion and were also calculated by summing the extracted and unextracted residues. Results between the two methods were comparable. Results summarized below represent the TRR determined by combustion. Significant uptake and translocation of radioactive residues from soil into the secondary crops was observed, particularly in the case of the cyclopropyl label over all plant-back intervals (PBI) and matrices (particularly wheat straw).

In the **cyclopropyl** label study, in lettuce TRR were 0.53 mg eq/kg at the 30-day PBI and declined to 0.18 mg eq/kg and 0.03 mg eq/kg at the 120-day PBI and 365-day PBI, respectively. A similar trend was observed in beetroot root (2.28 mg eq/kg, 0.38 mg eq/kg, 0.07 mg eq/kg at 30, 125, and 365-day PBI, respectively) and beetroot top (1.37 mg eq/kg, 1.10 mg eq/kg, 0.08 mg eq/kg at 30, 120, and 365-day PBI, respectively). In wheat matrices, TRR also declined over time. In wheat forage, TRR were 1.77 mg eq/kg, 0.16 mg eq/kg, and 0.05 mg eq/kg at 30, 120, and 365-day PBI, respectively. In wheat straw, TRR were 4.37 mg eq/kg, 2.79 mg eq/kg, and 0.56 mg eq/kg at 30, 120, and 365-day PBI, respectively. And in wheat grain, TRR were 1.28 mg eq/kg, 0.87 mg eq/kg, and 0.21 mg eq/kg at 30, 120, and 365-day PBI, respectively.

In the **phenyl** label study, in lettuce TRR were 0.18 mg eq/kg at the 30-day PBI and declined to 0.06 mg eq/kg and 0.02 mg eq/kg at the 120-day PBI and 365-day PBI, respectively. A similar trend was observed in beetroot root (0.21 mg eq/kg, 0.10 mg eq/kg, 0.05 mg eq/kg at 30, 125, and 365-day PBI, respectively). In beetroot top TRR were 0.09 mg eq/kg at the 30-day PBI, increased to 0.16 mg eq/kg at the 120-day PBI, but then declined to 0.04 mg eq/kg at the 365-day PBI. In wheat matrices, TRR also declined over time. In wheat forage, TRR were 0.42 mg eq/kg, 0.14 mg eq/kg, and 0.03 mg eq/kg at 30, 120, and 365-day PBI, respectively. In wheat straw, TRR were 0.97 mg eq/kg, 0.73 mg eq/kg, and 0.15 mg eq/kg at 30, 125, and 365-day PBI,

respectively. And in wheat grain, TRR were 0.80 mg eq/kg, 0.50 mg eq/kg, and 0.13 mg eq/kg at 30, 125, and 365-day PBI, respectively.

Plant samples were extracted sequentially with acetonitrile, acetonitrile:water, and water. Hydrolyses (acid hydrolysis by refluxing with 2 g/mol HCl for one hour, and for wheat forage/straw base hydrolysis by refluxing 1 g/mol NaOH for one hour) were performed to release conjugated metabolites from both the aqueous phases after partitioning of extracted plant residues and from the PES if residues exceeded 0.010 mg eq/kg or 10 percent TRR. Identification of the radioactivity was conducted using TLC and HPLC.

In the **cyclopropyl** label study, the solvent extracted radioactivity ranged from 44.8 percent TRR (wheat grain) to 92.8 percent TRR (beetroot top) at the 30-day PBI, from 50.1 percent TRR (wheat grain) to 83.8 percent TRR (beetroot top) at the 120-day PBI, and from 38.4 percent TRR (wheat grain) to 71.4 percent TRR (beetroot root) at the 365-day PBI. In the **phenyl** label study, the solvent extracted radioactivity ranged from 19.5 percent TRR (wheat grain) to 48.4 percent TRR (lettuce) at the 30-day PBI, from 15.0 percent TRR (wheat straw) to 57.5 percent TRR (beetroot root) at the 120-day PBI, and from 15.4 percent TRR (wheat straw) to 60.3 percent TRR (beetroot root) at the 365-day PBI. In general, extracted residues were lower at the longest PBI compared to the 30-day PBIs, with the exception of beet matrices from the phenyl label where extractability remained the same or increased at the longest PBI.

In the **cyclopropyl** label study, the parent permethrin was not detected or present at very low levels (0.3-0.7 percent TRR, 0.002—0.031 mg eq/kg) in all matrices at all plantback intervals (none detected in any matrix at the 365-day PBI). No parent or metabolites were detected in wheat grain at any plantback interval. At all PBIs, DCVA (sum of cis and trans isomers, free and conjugated) was the major metabolite identified in lettuce (26—32 percent TRR), beetroot roots (21—32 percent TRR), beetroot tops (5.0—27 percent TRR), wheat forage (4.1—25 percent TRR), and wheat straw (2.1—17 percent TRR). Minor metabolites identified were the diacid, DCVA-lactone, and DCVA-OH (sum of cis and trans isomers), none of which exceeded 10 percent TRR in any matrix at any PBI.

In the **phenyl** label study, permethrin, was not detected or present at low levels (3.0—10.8 percent TRR, 0.013—0.046 mg eq/kg) in all matrices at all plantback intervals (none detected in any matrix at the 365-day PBI), with the highest levels found in beetroot root at the 30-day PBI. No residues of permethrin or any of its metabolites were found in wheat grain at any plantback interval or in any matrix at the 365-day PBI as there was not enough radioactivity in samples from this PBI for analysis. There were no major metabolites identified in the phenyl label study. The metabolites 3-PBA, 4'-OH-3-PBAlc, and 2'-OH-3-PBAlc were all minor metabolites that did not exceed 3.9 percent TRR.

Isolation of starch was conducted in control wheat grain samples from the 120-day and 365-day PBI from both labels. The results were compared against those from the fractionation of radioactive residues in treated wheat grain and provided sufficient evidence to conclude that the water-soluble radioactivity and the unextractable radioactivity consists of plant constituents containing incorporated radioactive residues.

In summary, in rotational crops cultivated on permethrin-treated soil, the residues included mainly DCVA (sum of cis and trans isomers). Permethrin was either not present or present at very low levels in all matrices analysed (up to 0.031 mg eq/kg). The principal metabolic pathway of permethrin involves cleavage of the ester to form cis/trans-DCVA and 3-PBAlc, which is oxidated to 3-PBA or hydroxylated to form 4'-OH-3-PBAcid and 4'-OH-3-PBAlc. A

significant amount of $^{14}CO_2$ was naturally incorporated in treated crops as a result of soil degradation of ^{14}C-permethrin.

Field rotational crops

Field rotational crop studies were conducted in the United States during the 1996 growing season.

At the trials in Arizona, Texas, and Florida, the primary crop (field corn) received ten foliar broadcast spray applications of an EC formulation, at a rates of 0.224 kg ai/ha/application, with a 3 to 4-day retreatment interval, for a total rate of 2.24 kg ai/ha/season. Field corn plants were cleared from the plots 30-45 DALA. At 54–60 days following the last application to the primary crop, radish, and leaf lettuce were planted. At the trials in Indiana, Kansas, and Washington, treated plots of the primary crop (winter wheat) received five foliar broadcast spray applications of an EC formulation, at a rate of 0.448 kg ai/ha/application, with a 3 to 6-day retreatment interval, for a total rate of 2.24 kg ai/ha/season. Winter wheat was cleared from the plots 31-32 DALA. At 43-68 days following the last application to the primary crop, spring wheat was planted.

No quantifiable residues (i.e. ≤ 0.05 mg/kg for each isomer) of permethrin or DCVA (free and conjugated) were observed in radish (roots and tops), leaf lettuce, or spring wheat (forage, hay, grain, straw) planted in rotation 43–68 days after the last application to primary crops treated with an EC formulation of permethrin at total rates of 2.24 kg ai/ha/season.

Conclusions

In summary, the environmental fate data demonstrated that permethrin is not persistent in soil. Permethrin is stable in aqueous solutions at environmentally relevant pHs and photolysis of permethrin on the soil surface is not anticipated to be an important dissipation process. The metabolism in rotational crops was shown to be similar to that in primary crops. The parent, permethrin, was either not present or present at very low levels in rotational crops. The predominant residue in rotational crops was DCVA (sum of cis and trans isomers, free and conjugated). The principal metabolic pathway of permethrin involves cleavage of the ester to form cis/trans-DCVA and 3-PBAlc, which is oxidated to 3-PBA or hydroxylated to form 4'-OH-3-PBA and 4'-OH-3-PBAlc.

Methods of analysis

The Meeting received analytical method descriptions and validation data for permethin and its metabolites (DCVA, 3-PBAlc, and 3-PBA) in plant and animal matrices.

Plants

Permethrin: Older methods developed prior to twenty-first century involved extraction of residues of permethrin with hexane:isopropanol or acetone:hexane, partitioning and column clean-up, with residues measured by gas chromatography with electron capture detection (GC-ECD) or gas chromatography with mass spectrometry detection (GC-MSD). A newer QuEChERs

method for permethrin involved extraction with acetonitrile, SPE column clean-up, and LC-MS/MS analysis.

Metabolites: Most of the methods for the analysis of DCVA and 3-PBAlc in plant matrices were developed prior to the twenty-first century and involved extraction of residues with methanol:water, partitioning with organic solvents and/or NaOH, acid hydrolysis, derivatization, followed by column clean-up, and analysis by GC-ECD or GC-MSD. One analytical method (RAN-0001) used for the analysis of DCVA and 3-PBAlc in the submitted potato supervised residue trials deviated slightly from the other methods as the derivatization of DCVA was carried out using a different chemical reagent. The recovery and repeatability of method RAN-0001 for the analysis of residues of DCVA in potatoes were unacceptable.

An unnamed method for the analysis of DCVA and 3-PBAlc in the submitted potato and broccoli supervised residue trials, as well as in various plant matrices (high water content, high oil content, high starch, and dry matrices) from the submitted freezer storage stability study, deviated significantly from the other methods as it involved oxidation of 3-PBAlc to form 3-PBA. Residues of 3-PBA were determined after derivatization, and the results were reported as 3-PBAlc residues.

Most of the methods for the analysis of permethrin, DCVA, and 3-PBAlc in plant matrices (high water, high starch, high oil, and dry commodities), did not have a sufficient number of samples to assess repeatability. However, as most of the methods followed very similar extraction, clean-up, derivatization, and analyses steps, an overall conclusion can be made that these methods (with the exception of RAN-0001 for residues of DCVA) are fit for the purpose of analysing residues of permethrin, DCVA, and 3-PBAlc in the submitted supervised residue trial studies.

The reported LOQs for these methods in plant matrices (RAC and processed commodities) ranged from 0.005 to 0.50 mg/kg for each isomer/analyte.

Animals

Permethrin: The analytical method for the determination of residues of permethrin in animal matrices involved extraction with acetone:hexane, dimethylformamide partitioning, hexane extraction, and column clean-up, with residues measured by GC-ECD. A newer QuEChERs method for permethrin involved extraction with acetonitrile or acetonitrile:water, dispersive SPE clean-up, and LC-MS/MS analysis.

Metabolites: The analytical method for the determination of residues of DCVA, 3-PBAlc, and 3-PBA in animal matrices involved extraction with aqueous methanol, solvent partitioning, acid hydrolysis, derivatization, with residues measured by GC-MSD.

Suitable analytical methods were submitted for the analysis of residues of permethrin (cis and trans isomers) in milk, liver, kidney, muscle, and fat. However, the GC-ECD method is not acceptable for the analysis of residues of permethrin in eggs due to the poor repeatability of the method (i.e. percent relative standard deviations, percentRSD, ranged from 21 to 30 percent).

For the analysis of the metabolites DCVA, 3-PBAlc, and 3-PBA, in milk, eggs, muscle, and fat: the method was unacceptable for all metabolites in milk (n=1 for each analyte at each fortification level, recoveries ranged from 51 to 66 percent), unacceptable for DCVA and 3-PBA in muscle (23 percent RSD at a fortification level of 0.1 mg/kg and recoveries ranging from 54-65 percent, respectively), unacceptable for DCVA in eggs (25-32 percent RSD at fortification levels of 0.05 mg/kg and 0.1 mg/kg), and no validation of any metabolites was conducted in fat.

However, as residues of DCVA, 3-PBAlc, and 3-PBA are not expected or expected to be insignificant in milk, eggs, muscle, and fat, an analytical method for DCVA, 3-PBAlc, and 3-PBA in these matrices is not required.

A suitable analytical method was submitted for the analysis of residues of DCVA and 3-PBAlc in liver and kidney, but this method was unacceptable for the analysis of 3-PBA in these matrices (mean recovery of 66 percent and 28 percentRSD at a fortification level of 0.1 mg/kg).

The validated LOQs for these methods in animal matrices ranged from 0.01 to 0.1 mg/kg for each isomer/analyte.

Stability of residues in stored analytical samples

Plants

Residues of permethrin in incurred samples were determined to be stable at ≤-18ºC for at least 19 months in high water content commodities (lettuce, Brussel sprouts), and high oil content commodities (soya bean). Residues of permethrin in samples fortified at 0.5 mg/kg were determined to be stable at ≤-18ºC for at least 24 months in high starch content commodities (maize starch) and high oil content commodities (soya bean meal).

Residues of DCVA and 3-PBAlc were determined to be stable at approximately -20°C for at least 36 months in high water content commodities (apple, cabbage, maize forage, maize fodder, lettuce, and tomato), high oil content commodities (cotton seed, peanut hulls and nutmeat, soya bean), and high starch content commodities (sorghum grain, sugar beet). Residues of 3-PBA were stable for at least 36 months in all matrices listed above under frozen condition, except for in apples and peanut nutmeat where residues of 3-PBA were only stable for up to 24 months and 3 months of frozen storage, respectively. The stability of residues of 3-PBA in tomatoes is unclear as residues recovered at day 0 and 3 months were < 70 percent (even if procedural recoveries are taken into consideration) and remained low until the 36 month storage period.

The demonstrated storage stability intervals for plant commodities cover the storage durations of the crop field trials, processing studies, and field rotational study, except for samples from one of the potato residue trial studies which were stored frozen for up to 31 months.

Animals

Residues of permethrin were determined to be stable at < 0°C for at least 12 months in milk, bovine fat, eggs, and poultry liver.

Residues of 3-PBA were determined to be stable under frozen conditions (temperature not specified) for at least 36 months in muscle, 36 months) in milk, 38 months in kidney, 40 months in liver, and 41 months) in fat.

No information on the storage stability of residues of DCVA or 3-PBAlc in animal matrices, or any of the metabolites in eggs were received.

The demonstrated storage stability intervals for animal commodities cover the storage durations of samples analysed for residues of permethrin and 3-PBA from the lactating goat feeding study. But there are no storage stability data to support the storage duration of samples analysed for residues of DCVA or 3-PBAlc.

The demonstrated storage stability intervals for animal commodities does not cover the storage durations of samples analysed for residues of permethrin in any sample from the laying hen feeding study. The demonstrated storage stability intervals for 3-PBA cover the storage durations of samples analysed for these residues in poultry liver/kidney and fat, however they do not cover the storage durations for poultry muscle from the laying hen feeding study. There are no storage stability information for any of the metabolites in eggs or for residues of DCVA or 3-PBAlc in any animal commodity.

Because no storage stability data were provided for some analytes in animal matrices, the submitted storage stability data do not cover storage intervals of some samples from the laying hen feeding study, and the recovery data for the analytical method were unacceptable for some analytes in animal matrices, the Meeting decided that the dairy cattle and laying hen feeding studies could not be used to estimate residues in animal commodities.

Definition of the residue

Plant commodities

The nature of the permethrin residues in plant commodities was investigated in soya bean leaves, head cabbage, sweet corn (forage, fodder, kernel, cobs), and snap bean leaves following foliar treatment and in cotton seeds following direct application to the seed.

In plant metabolism studies, permethrin (sum of cis and trans isomers) was the major component of the radioactivity in all tested plant matrices (9.9-97 percent of the recovered radioactivity or 1.0-28.8 percent TRR). In the field trials, permethrin was the major residue in all crops where residues were found. Permethrin was either not present or present at very low levels in all matrices analysed (up to 0.031 mg eq/kg). In the confined rotational study, residues of permethrin were either not present or present at very low levels and are not expected in rotational crops.

Other main components of the ^{14}C residues found in the plant metabolism studies were free and conjugated DCVA, 3-PBAlc, 4'OH-3-PBAlc, and 2'OH-3-PBAlc.

In the acid and cyclopropyl label plant metabolism studies, DCVA (free and conjugated) ranged from 10 to 38 percent of the recovered radioactivity (soya bean leaves, cabbage, and snap bean leaves) or 4.6–18 percent TRR (0.3 – 1.7 mg/kg in sweet corn forage and fodder, respectively), but was not identified in cotton seeds, sweet corn kernel, or sweet corn cobs.

In the alcohol and phenyl label studies, 3-PBAlc (free and conjugated) ranged from 5.5 percent to 23 percent of the recovered radioactivity (soya bean leaves, cabbage, and snap bean leaves) or 3.4–9.9 percent TRR (0.19-1.0 mg eq/kg in sweet corn forage and fodder), but was not found in cotton seeds, sweet corn kernel, or sweet corn cobs.

In the alcohol and phenyl label studies, 4'-OH-3-PBAlc (free and conjugated) ranged from 4.1 to 11 percent of the recovered radioactivity (soya bean leaves, cabbage, and snap bean leaves) or 0.4 percent TRR (0.11 mg eq/kg in sweet corn fodder), but was not identified in cotton seeds, sweet corn kernel, or sweet corn cobs.

In the alcohol and phenyl label studies, 2'-OH-3-PBAlc (free and conjugated) ranged from 1.1 to 15 percent of the recovered radioactivity (soya bean leaves, cabbage, and snap bean leaves), but was not found cotton seeds or sweet corn (forage, fodder, kernel, cobs).

Supervised field trials analysed for permethrin as well as DCVA and 3-PBAlc, with quantifiable residues of DCVA and 3-PBAlc observed in spinach, maize (stover/fodder, silage, forage), and sweet corn (husks and stalks). DCVA was the predominant residue in rotational crops.

The Meeting noted that the main compounds observed for permethrin in plant matrices were also found in other pyrethroid compounds (e.g. cypermethrin/alpha-cypermethrin/zeta-cypermethrin, JMPR 2008) in a variety of plant matrices (leafy crops, cereal grains, root crops, oilseeds, and fruit) following foliar application. The metabolites DCVA and/or 3-PBAlc (both free and conjugated) were major metabolites of cypermethrin in lettuce, sugar beets (roots and tops), maize (grain, ears), and cotton forage. While 3-PBA, 2'-OH-3-PBAlc, and 4'-OH-3-PBAlc were identified in many matrices they were considered minor metabolites.

As suitable analytical methods are available to analyse the parent compound in a variety of plant matrices, the Meeting considered that permethrin (sum of isomers) was a suitable marker for monitoring compliance.

From a dietary risk perspective, as the WHO core assessment group could not conclude on toxicological reference values for permethrin, the Meeting was unable to consider a residue definition for risk assessment.

Animal commodities

The nature of the residue in animal commodities was investigated in lactating goats and laying hens that were orally dosed with permethrin.

In goat and poultry metabolism studies, permethrin was the predominant residue in milk, egg (yolk and whites), poultry fat, and poultry muscle (30.7-78.4 percent TRR, 0.008-0.29 mg eq/kg), however the parent was not identified or identified at low levels in goat liver, goat kidney, goat muscle, goat fat, and poultry liver.

The free and conjugated residues of DCVA, 3-PBA, and/or 3-PBAlc were the predominant residues in liver and kidney (12.5–48.3 percent TRR, 0.11–0.501 mg eq/kg) and exceeded those of the parent. Other significant residues identified only in bovine liver were 4'-OH-3-PBA (10.7 percent TRR, 0.097 mg eq/kg) and 4'-OH-3-PBAlc (5.5 percent TRR, 0.05 mg eq/kg).

Given that metabolites identified in the animal metabolism studies are common to other pyrethroid compounds, they are not suitable for monitoring compliance. As there is a suitable analytical method available to analyse the parent compound in animal matrices, the Meeting considered that permethrin (sum of isomers) was a suitable marker for monitoring compliance.

From a dietary risk perspective, as the WHO core assessment group could not conclude on toxicological reference values for permethrin, the Meeting was unable to consider a residue definition for risk assessment.

Conclusions

The Meeting recommended the following residue definitions:

Definition of the residue for plant and animal commodities (for compliance with the MRL): *permethrin (sum of cis and trans isomers)*

Results of supervised residue trials on crops, fate of residues in processing, & residues in animal commodities.

Due to the submission of key studies late into the review process (plant metabolism, environmental fate data, feeding study), including a number of studies received well into the Meeting, the Meeting did not have time to discuss the results of the supervised residue trials on crops, fate of residues in processing, and residues in animal commodities. In addition, as the WHO core assessment group could not conclude on toxicological reference values for permethrin, the Meeting was unable to consider a residue definition for risk assessment which is needed to continue the assessment. Therefore, the Meeting decided to continue the residue periodic review of permethrin when this compound is next scheduled for toxicological re-evaluation.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that

Definition of the residue for plant and animal commodities (for compliance with the MRL): *permethrin (sum of cis and trans isomers)*.

Definition of the residue for plants and animals for dietary risk assessment:

The Meeting was unable to conclude on a residue definition for risk assessment.

DIETARY RISK ASSESSMENT

No Maximum Residue Levels are recommended, nor are levels estimated for use in long-term and acute dietary exposure assessments as the Meeting could not reach a conclusion on the residue definition for risk assessment for plants and animals.

5.26 Piperonyl butoxide (062) (R)

RESIDUE AND ANALYTICAL ASPECTS

Piperonyl butoxide (PBO) was first evaluated by the JMPR in 1965 and has been evaluated numerous times since. It was last subject to periodic review in 2001, when an acceptable daily intake (ADI) of 0-0.2 mg/kg bw established by the 1995 JMPR was reaffirmed and it was concluded that an ARfD was unnecessary. At the 2002 JMPR, some clarifications were made that enabled refinement of the 2001 evaluation. MRLs were recommended in 2002 for a number of plant and animal commodities. It has not been considered since by the JMPR.

Piperonyl butoxide is a synergist used to prolong the effects of insecticides. The definition of the residue for compliance with MRLs and for dietary risk assessment is piperonyl butoxide. The residue is fat-soluble.

At the Fifty-first Session of the CCPR (2019), piperonyl butoxide was scheduled for evaluation of additional uses by the 2021 JMPR Extra Meeting and was rescheduled to the 2023 Meeting. The current Meeting received information on analytical methods, storage stability, residue field trials for a range of foliar uses and post-harvest uses (on citrus and tree nuts), and processing studies to support new MRLs in raw and processed plant commodities.

Methods of analysis

The Meeting received details of a new LC-MS/MS method of analysis ((GPL-MTH-074 or GPL-MTH-074 with small modifications according to crops) together with method validation and concurrent recovery data to analyse residues of piperonyl butoxide (simultaneously with pyrethrins I) in the full range of commodities and processed commodities for which trials were submitted.

The meeting considered the number of recovery determinations acceptable, when taking account of the method validation (n=3) and concurrent recovery data taken together (n= 1-6 aside from dried plums where concurrent recoveries were not available) and the range of commodity types with acceptable recovery data across a large range of fortification levels (%RSDs were mostly below 7%). In fennel seeds some individual recoveries were high (125 and 127%), though mean recovery was acceptable. Fennel seeds and dill seeds did have more variable recoveries at the LOQ than for other commodities, although the %RSDs remained within the usually acceptable range. In these commodities only, residues of piperonyl butoxide were found in controls, and these fortified samples did require correction for recovery in the control samples. Overall, the meeting considered that the method was demonstrated to have adequate performance for recovery of piperonyl butoxide, with an LOQ of 0.01 mg/kg for piperonyl butoxide residues in all commodities considered by the Meeting (oranges, lemon, grapefruit, sweet and tart cherries, peaches, dried and fresh plums, blackberries, strawberries, cabbages, mustard greens, spinach, lettuce, tomatoes, almonds, pecans, coffee and processed fractions of coffee, dried and fresh herbs of basil and chives, and fennel and dill seeds).

Freezer storage stability of residues in stored samples

The current Meeting received storage stability data obtained concurrently with the supervised residue trials submitted to the Meeting. Samples for assessing storage stability were taken on Day 0 and at termination of the study (except for oranges, for which an intermediate sample was taken). Most commodities showed similar residues at Day 0 and at study termination. Exceptions were almond nutmeat and dried basil.

The Meeting agreed that residues of PBO were stable in frozen storage for at least the duration of the period tested in the following matrices:

Basil (fresh)	174 days
Blackberry	156 days
Cabbage	63 days
Cherries	225 days
Coffee (freeze dried)	39 days
Coffee (green beans)	117 days
Coffee (roasted beans)	47 days
Dill seed	161 days
Orange	102 days
Plum	153 days
Spinach	67 days
Strawberry	230 days
Tomato	63 days

Except for the processed coffee commodities, the demonstrated duration of residue stability covered the storage times for the analytical samples for the commodities listed above. For roasted and freeze-dried coffee, samples were stored for up to 65 days. This is approximately 47% longer than the period of demonstrated stability and extrapolation for that duration is not supported.

Dissipation in storage exceeded 30% (<70% remaining) for almonds (61% remaining at 102 days of storage) and dried basil (59% remaining at 201 days of storage). Residues were analysed only at Day 0 and at study termination; therefore, dissipation kinetics could not be determined for those commodities. For tree nuts, analytical samples of almonds and pecans were stored for up to 69 days. For dried basil, storage times were 145, 172, and 199 days. The Meeting agreed that tree nut and dried basil samples are not suitable for making residue recommendations.

Results of supervised residue trials on crops

The Meeting received data from supervised residue trials and GAP information on citrus (post-harvest use), stone fruits, blackberries, strawberries, brassica vegetables (cabbage), leafy vegetables, tomato (glasshouse use), tree-nuts (post-harvest use), coffee, herbs and spices (seeds). All GAPs considered by the 2023 JMPR were from the United States of America.

Citrus fruits

Registered GAPs for citrus include foliar sprays, soil drenches, and high-volume post-harvest sprays. Supervised trials were conducted using ultra-low volume surface sprays and fogger applications. The meeting agreed that these trials do not match any of the registered GAPs and are not suitable for making residue recommendations.

The Meeting confirmed its previous recommendations.

Stone fruits

The critical GAP for stone fruits consists of ten foliar applications, each at 562 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.25-1.29X critical GAP).

The Meeting did not make a recommendation for stone fruits.

Blackberries

The critical GAP for blackberry (covered under “small fruits and berries”) consists of ten foliar applications, each at 562 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.0-1.45X critical GAP).

The Meeting did not make a recommendation for blackberry.

Strawberries

The critical GAP for strawberry (covered under “small fruits and berries”) consists of ten foliar applications, each at 562 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.0-1.30X critical GAP).

The Meeting did not make a recommendation for strawberry.

Cabbage

The critical GAP for uses on Brassica vegetables including head cabbage consists of ten foliar applications, each at 562 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

Three trials in head cabbage with application rates approximating the cGAP were evaluated by the 2000 JMPR; however, retreatment intervals were not specified. The Meeting agreed that without information on retreatment intervals, these trials could not be used to make residue recommendations.

One new trial was provided to the current Meeting. The trial was conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trial does not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trial was conducted at an exaggerate rate (1.27X critical GAP).

The Meeting did not make a recommendation for cabbage.

Leafy vegetables

The critical GAP for uses on leafy vegetables, including commodities in the Subgroup of Leafy greens and the Subgroup of Brassica leafy vegetables, consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

Trials in lettuce, spinach, mustard greens, and radish leaves with application rates approximating the cGAP were evaluated by the 2000 JMPR; however, retreatment intervals for those trials were not specified. The Meeting agreed that without information on retreatment intervals, these trials could not be used to make residue recommendations.

One new trial for each of head lettuce, spinach, mustard greens, and radish leaves was provided to the current Meeting. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.26-1.27X critical GAP).

The Meeting did not make a recommendation for leafy vegetables.

Tomato

A Codex MRL of 2 mg/kg is established for residues of PBO on tomato.

Two GAPS were provided for tomato: (1) a glasshouse foliar preharvest use consisting of ten foliar applications, each at 562 g ai/ha, on a 3-day interval (1-day interval under extreme pest pressure), with harvest 0 DALA and (2) a post-harvest spray at 0.797 g pyrethrins per tonne fruit on a 7-day interval (1-day interval under extreme pest pressure); the maximum number of applications was not specified. Based on comparison of results from field trials with foliar preharvest applications with the post-harvest spray rate, the Meeting agreed that the foliar preharvest GAP is the critical GAP. The Meeting noted, however, that tomatoes could undergo both pre- and post-harvest treatments.

Trials were conducted with retreatment intervals ranging from 2 to 4 days. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4

days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.27-1.34X critical GAP).

The Meeting confirmed its previous recommendation.

Tree nuts

Two GAPs were provided for nuts: (1) a use on tree nuts consisting of ten foliar applications, each at 562 g ai/ha, on a 3-day interval (1-day interval under extreme pest pressure), with harvest 0 DALA and (2) post-harvest sprays. Neither the maximum number of post-harvest sprays nor the PHI were specified for the post-harvest uses. Depending on the end-use product, surface sprays are conducted as (1) two applications each at 1.17 g/m^2 followed by additional applications at 0.58 g/m^2, done at an initial interval of 7 days for the first 6 weeks followed by a retreatment interval of 15 days or (2) a combination of surface and space sprays at 0.02 g/m^2 and 0.087 g/m^3, respectively, on a 7-day interval. The Meeting agreed that the surface spray use pattern (1.17 g/m^2 + 0.58 g/m^2) is the critical GAP.

The provided trials in almond and pecan reflect only the space spray treatments as 6 sprays, each at 0.52 g ai/m^3 on a 7-day interval. The Meeting agreed that the per volume application could not be converted to a per area rate for comparison to the critical GAP; furthermore, the storage durations for tree nut samples are not supported by the available storage stability data. The Meeting agreed that the trials could not be used to make recommendations for tree nuts.

The Meeting confirmed its previous recommendation.

Coffee

The critical GAP for coffee consists of ten foliar applications, each at 562 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted with retreatment intervals ranging from 2 to 4 days. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.31-2.08X critical GAP) and that three trials are not sufficient to make a recommendation for residues in coffee.

The Meeting did not make a recommendation for coffee.

Herbs

The critical GAP for herbs and spices, which include chive and basil, consists of ten foliar applications, each at 562 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted with retreatment intervals ranging from 2 to 4 days. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also

noted that the trials were conducted at exaggerated rates (1.26-1.28X critical GAP) and that four trials each are needed for chive and basil.

The Meeting did not make a recommendation for herbs.

Spices (seed)

The critical GAP for herbs and spices, which includes dill seed, fennel seed, and mustard seed, consists of ten foliar applications, each at 562 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted with retreatment intervals ranging from 3 to 4 days (3-7 days in study reviewed by 2000 JMPR) and with 14 or 20 applications in the case of the fennel seed trials. In addition to those deviations from the critical GAP, the Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that too few trials were provided to make a recommendation for spices (seed).

The Meeting did not make a recommendation for spices (seed).

Residues in processed commodities

The Meeting did not make any recommendations for processed commodities.

Residues in animal commodities

Farm animal dietary burden

The Meeting did not make any recommendations for animal feed items. The Meeting noted the conclusion of the 2003 JMPR that although uses on animal feed items have been reviewed by the Meeting, adequate animal feeding studies have not been made available, and that the JMPR will re-examine recommendations for residues in animal commodities if/when data from feeding studies become available.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting did not make any recommendations for establishing maximum residue limits and for IEDI assessments.

The definition of the residue for compliance with MRLs and for dietary risk assessment for plant and animal commodities is piperonyl butoxide.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for piperonyl butoxide is 0—0.2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for permethrins were last estimated by the 2002 JMPR. The IEDIs ranged from 20 to 40 percent of the maximum ADI.

Although newer consumption data are available compared to those used by the 2002 Meeting, the current meeting noted the risk estimates and concluded that long-term dietary exposure to residues of piperonyl butoxide from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

An acute reference dose was considered unnecessary for piperonyl butoxide.

5.27 Prochloraz (142) (T,R)**

TOXICOLOGY

Prochloraz is the ISO-approved common name for *N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]-*1H*-imidazole-1-carboxamide (IUPAC), which has the Chemical Abstracts Service number 67747-09-5. Prochloraz is a broad-spectrum fungicide which acts by inhibiting ergosterol biosynthesis.

Prochloraz was previously evaluated by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) in 1983 and 2001, when an ADI of 0–0.01 mg/kg body weight (bw) and an ARfD of 0.1 mg/kg bw were established. Prochloraz was reviewed by the present Meeting as part of the periodic review programme of the Codex Committee on Pesticide Residues (CCPR).

All critical studies contained statements of compliance with good laboratory practice (GLP) and were conducted in accordance with the relevant national or international test guidelines unless otherwise specified. A literature search was conducted and the toxicological information obtained in this search was submitted for the current assessment. Some studies were performed by the Laboratory of Pharmacology and Toxicology in Hamburg. The Meeting is aware of the current debate about allegations of fraud that have been made and investigated concerning this laboratory. As no formal conclusion about these allegations has been reached as yet, the Meeting has decided to include the results from such studies. The Meeting noted that these studies have no impact on the overall evaluation of prochloraz.

Biochemical aspects

Following oral administration, prochloraz was rapidly absorbed, with peak plasma levels of radiolabel reached on average two hours after a low dose (5 mg/kg bw) and about 10 hours following a high dose of 100 mg/kg bw. Half-lives in blood and plasma ranged between 11 and 17 hours. Excretion was rapid, with virtually complete elimination of radioactivity within 96 hours. Small sex differences in plasma levels, blood and plasma half-lives and excretion patterns were observed. Excretion of radioactivity through expiration was negligible at both low and high doses Studies with bile duct-cannulated rats administered a single oral dose of 5 mg/kg bw showed that 48–49 percent of the radioactivity was excreted in bile in both males and females. Based on the biliary and urinary excretion, an average of 74 percent of the administered dose (AD) was absorbed. Tissue distribution was widespread, but levels in tissues were low. The highest levels of radioactivity were found in liver and kidney. Repeated administration of prochloraz (daily oral doses of unlabelled prochloraz at 10 mg/kg bw, followed by a single oral dose of 10 mg/kg bw of labelled prochloraz) had no appreciable influence on the rates of absorption, elimination, nor on the distribution, as judged on the basis of radioactivity levels in excreta and tissues compared to those resulting from a single dose of radiolabelled prochloraz.

Studies in mice and dogs showed the kinetics of prochloraz to be similar in these species.

Prochloraz is metabolized by modification of the phenyl ring moiety through oxidative hydroxylation (sometimes accompanied by substitution of chlorine) and sulfation, and through stepwise degradation of the imidazole ring and the resulting N-alkyl chains. The latter step is

often followed by oxidative deamination to eliminate the nitrogen atoms, and conjugation of the resultant oxyacyl hydroxyl group. The main metabolite in the urine of rats was BTS 9608 (2,4,6-trichlorophenoxyacetic acid). Unchanged prochloraz was not found in urine. In faeces unchanged prochloraz, BTS 44596 (*N*-formyl-*N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]urea) and BTS 3037 (2-(2,4,6-trichlorophenoxy)ethanol) were found.

Toxicological data

The acute oral median lethal doses (LD_{50}) for prochloraz in rats ranged in different studies between 300 mg/kg bw and greater than 4000 mg/kg bw. The acute dermal LD_{50} was greater than 2000 mg/kg bw and the acute inhalation median lethal concentration (LC_{50}) was greater than 2.1 mg/L. Prochloraz was not irritating or, in another study, mildly irritating to the skin of rabbits. Prochloraz was not irritating to the eyes of rabbits. Prochloraz was not a skin sensitizer in two Magnusson & Kligman tests and a Buehler test.

Acute toxicity studies with prochloraz-zinc complex and prochloraz-copper showed similar results to those with prochloraz. Acute oral LD_{50} values for prochloraz-copper complex in rats ranged between 800 mg/kg bw and greater than 2000 mg/kg bw; the dermal LD_{50} was greater than 2000 mg/kg bw. Prochloraz-copper complex was not irritating to the skin of rabbits and was moderately irritating to the eyes of rabbits. Prochloraz-zinc complex was not a skin sensitizer in a Magnusson & Kligman test.

In repeat-dose oral toxicity studies with prochloraz in mice and rats the main target for toxicity was the liver, whereas in dogs the main target for toxicity was the prostate.

In a 13-week study in mice using dietary prochloraz concentrations of 0, 6, 25, 100 or 400 mg/kg bw per day, the NOAEL was 25 mg/kg bw per day, based on reduced body weight gain and effects on the liver at 100 mg/kg bw per day.

In a 90-day study in rats using dietary prochloraz concentrations of 0, 50, 500 or 1500 ppm (equal to 0, 4.4, 43.3 and 137.2 mg/kg bw per day for males, 0, 4.7, 46.6 and 144.9 mg/kg bw per day for females), the no-observed-adverse-effect level (NOAEL) was 50 ppm (equal to 4.4 mg/kg bw per day), based on effects on the thyroid, kidney and liver weights and on histopathological changes in the liver at 500 ppm (equal to 43.3 mg/kg bw per day).

In a 13-week study in dogs using gavage doses of prochloraz at 0, 1 2.5, 7 or 20 mg/kg bw per day, the NOAEL was 2.5 mg/kg bw per day, based on reduced prostate weight at 7 mg/kg bw per day.

In a 1-year study in dogs using gelatin capsules delivering prochloraz doses of 0, 1, 5 or 25 mg/kg bw per day, the NOAEL was 1 mg/kg bw per day, based on reduced prostate weights and histopathological changes in prostate and adrenals at 5 mg/kg bw per day.

The overall NOAEL for the 13-week and the one-year studies in dogs using gavage or gelatine capsule administration was 2.5 mg/kg bw per day, and the overall lowest-observed-adverse-effect level (LOAEL) was 5 mg/kg bw per day.

In a 104-week study in dogs using dietary prochloraz concentrations of 0, 30, 135 or 600 ppm (equal to 0, 0.94, 4.5 and 18 mg/kg bw per day for males, 0, 0.90, 4.1 and

18 mg/kg bw per day for females), the highest dose was increased at week 57 to 1000 ppm (equal to 29 and 28 mg/kg bw per day for males and females respectively). The NOAEL was 135 ppm (equal to 4.1 mg/kg bw per day), on the basis of decreased prostate weight, increased liver weight, changes in alkaline phosphatase (ALP) activity, and histopathological changes in the prostate and liver, all at 600/1000 ppm (equal to 18 mg/kg bw per day).

In a 106- or 121-week (for males and females respectively) study in mice using dietary prochloraz concentrations of 0, 78, 325 or 1300 ppm (equal to 0, 7.5, 33 and 134 mg/kg bw per day for males, 0, 8.8, 36 and 149 mg/kg bw for females), the NOAEL was 78 ppm (equal to 7.5 mg/kg bw per day), based on increased liver weights and liver tumours (unspecified) at 325 ppm (equal to 33 mg/kg bw per day).

In a 78-week study in mice using dietary prochloraz concentrations of 0, 40, 220 or 1200 ppm (equal to 0.0, 4.7, 26.3 and 151.2 mg/kg bw per day for males, 0.0, 6.0, 31.5 and 182.5 mg/kg bw per day for females), the NOAEL was 40 ppm (equal to 4.7 mg/kg bw per day), based on the increased incidence of liver tumours (adenomas and carcinomas) at 220 ppm (equal to 26.3 mg/kg bw per day).

The overall NOAEL for the two chronic toxicity studies in mice was 78 ppm (equal to 7.5 mg/kg bw per day), and the overall LOAEL was 220 ppm (equal to 26.3 mg/kg bw per day).

In a 111- or 115-week (for males and females respectively) study in rats using dietary prochloraz concentrations of 0, 37.5, 150 or 625 ppm (equal to 0, 1.3, 5.1 and 21.5 mg/kg bw per day for males, 0, 1.6, 6.4 and 28.1 mg/kg bw per day for females), the NOAEL was 37.5 ppm (equal to 1.3 mg/kg bw per day), based on macroscopic and microscopic signs of liver toxicity at 150 ppm (equal to 5.1 mg/kg bw per day). No effect on tumour incidence due to prochloraz was observed.

In a 2-year study in rats using dietary prochloraz concentrations of 0, 40, 220 or 1200 ppm (equal to 0, 1.7, 9.4 and 50.3 mg/kg bw per day for males, 0, 2.1, 11.8 and 64.1 mg/kg bw per day for females) the NOAEL was 40 ppm (equal to 1.7 mg/kg bw per day), based on histopathological changes in the liver at 220 ppm (equal to 9.4 mg/kg bw per day). No effect of prochloraz on tumour incidence was observed.

The overall NOAEL for the two chronic toxicity studies in rats was 40 ppm (equal to 1.7 mg/kg bw per day), and the overall LOAEL was 150 ppm (equal to 5.1 mg/kg bw per day).

The Meeting concluded that prochloraz is carcinogenic in mice, but not in rats.

Mechanistic studies indicated that the mode of action (MOA) for tumour formation by prochloraz in mice is through activation of CAR and possibly PXR, a MOA that is not relevant to humans. However, a full investigation of the MOA was not performed.

Prochloraz was tested in an extensive range of in vitro and in vivo assays for genotoxicity. These studies gave consistently negative results.

The Meeting concluded that prochloraz is unlikely to be genotoxic.

In view of the lack of genotoxicity, the absence of carcinogenicity in rats, and the induction of liver tumours in mice through a CAR-mediated MOA, the Meeting concluded that prochloraz is unlikely to pose a carcinogenic risk to humans from the diet.

In a multigeneration study in rats using dietary prochloraz concentrations of 0, 37.5, 150 or 625 ppm (equal to 0, 3.1, 13 and 57 mg/kg bw per day for F0 males, 0, 3.5, 14 and 58 mg/kg bw per day for F0 females, 0, 3.7, 16 and 70 mg/kg bw per day for F1 males, and 0, 4.5, 18 and 81 mg/kg bw per day for F1 females), the NOAEL for parental toxicity was 150 ppm (equal to 13 mg/kg bw per day) based on clinical signs and decreased body weight gain at 625 ppm (equal to 57 mg/kg bw per day). The NOAEL for offspring toxicity was 150 ppm (equal to 13 mg/kg bw per day) based on reduced body weight gain, and effects on liver, brain and thymus weights at 625 ppm (equal to 57 mg/kg bw per day). The NOAEL for reproductive toxicity was 150 ppm (equal to 14 mg/kg bw per day) based on the effects on gestation index, gestation length and dystocia at 625 ppm (equal to 58 mg/kg bw per day).

In another multigeneration study in rats using dietary prochloraz concentrations of 0, 50, 150 or 450 ppm (equal to premating intake levels of 0, 3.8, 10.9 and 34.0 mg/kg bw per day for males, 0, 4.5, 13.7 and 43.0 mg/kg bw per day for females), the NOAEL for parental toxicity was 50 ppm (equal to 3.8 mg/kg bw per day) based on decreased body weight gain at 150 ppm (equal to 10.9 mg/kg bw per day). The NOAEL for offspring toxicity was 150 ppm (equal to 10.9 mg/kg bw per day) based on reduced body weight gain at 450 ppm (equal to 34 mg/kg bw per day). The NOAEL for reproductive toxicity was 50 ppm (equal to 4.5 mg/kg bw per day) based on the effects on gestation index, gestation length and dystocia at 150 ppm (equal to 13.7 mg/kg bw per day).

In a developmental toxicity study in rats using oral doses of prochloraz at 0, 6, 25 or 100 mg/kg bw per day on days 1 to 20 after mating, the NOAEL for maternal toxicity was 25 mg/kg bw per day, based on clinical signs, decreased body weight gain, reduced food consumption and increased liver weight at 100 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 25 mg/kg bw per day, based on reductions in litter size, implantation index and viability index, an increased incidence of dead fetuses and retarded ossification at 100 mg/kg bw per day.

In another developmental toxicity study in rats using gavage doses of prochloraz at 0, 30, 60 or 120 mg/kg bw per day from gestation days (GDs) 6 to 15, the NOAELs for both maternal and embryo/fetal toxicity were 120 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits using gavage doses of prochloraz of 0, 10, 40 or 160 mg/kg bw per day from GD 6 to GD 18, the NOAEL for maternal toxicity was 40 mg/kg bw per day, based on reduced body weight gain, increased liver weights, increased incidences of animals with total litter loss, and increased incidence of fetal resorptions, at 160 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 40 mg/kg bw per day based on the increased incidence of fetal resorptions at 160 mg/kg bw per day.

In another developmental toxicity study in rabbits using gavage doses of prochloraz at 0, 10, 40 or 160 mg/kg bw per day from GDs 7 to 19, the NOAEL for maternal toxicity was 40 mg/kg bw per day, based on decreased feed consumption and a single case of occult faecal

blood observed at 160 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 40 mg/kg bw per day, based on a slight reduction in fetal crown–rump length at 160 mg/kg bw per day.

In a third developmental toxicity study in rabbits using gavage doses from GD 1 to GD 28 of prochloraz at 0, 3, 12 or 48 mg/kg bw per day, the maternal NOAEL was 12 mg/kg bw per day based on increased liver weight and liver discolouration at 48 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 48 mg/kg bw per day, the highest dose tested.

In a study from published literature, pregnant rats were treated by gavage with prochloraz from GD 14 until GD 18 at doses of 0, 31, 62, 125 or 250 mg/kg bw per day. Hypospadias and vaginal pouches were noted in males at 125 mg/kg bw per day and above, indicating that prochloraz alters sexual differentiation in an anti-androgenic manner.

Various studies from public literature investigated the effect of prochloraz on endocrine systems. In vitro, prochloraz antagonized estrogen and/or androgen receptors, inhibited aromatase and interfered with steroidogenesis at the level of CYP17. In vivo studies in rats showed that prochloraz induces signs that are indicative of anti-androgenic activity, such as retained nipples in males (at 5 mg/kg bw and above), reduced plasma and testicular testosterone at 30 mg/kg bw per day and above, increased progesterone levels at 7.8 mg/kg bw per day and above, and delayed entry into male puberty at 125 mg/kg bw per day. In addition, reduced androgen-sensitive gene expression and effects on anogenital distance were observed at 30 mg/kg bw per day and above. In pregnant rats prochloraz delayed parturition and caused dystocia (at 14 mg/kg bw per day and above) effects which are likely to have been secondary to aromatase inhibition. In dogs prochloraz at 2.5 mg/kg bw per day and above led to reduced male reproductive organ weights.

The Meeting concluded that prochloraz is teratogenic, probably through an anti-androgenic mode of action.

In an acute neurotoxicity study in rats using gavage doses of prochloraz at 0, 20, 90 or 405 mg/kg bw, rats were observed for 14 days. The NOAEL for acute neurotoxicity was 405 mg/kg bw, the highest dose tested. The NOAEL for general toxicity was 20 mg/kg bw based on clinical signs, effects on motor activity and rearing counts, righting reflex and approach response, and reduced body temperature, observed at 90 mg/kg bw. No repeat-dose neurotoxicity studies were available, but no evidence of neurotoxicity was observed in other routine repeat-dose studies.

The Meeting concluded that prochloraz is unlikely to be neurotoxic.

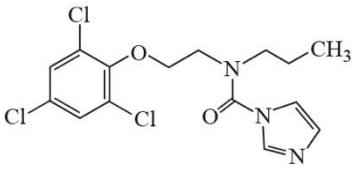
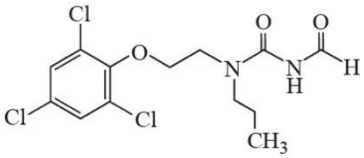
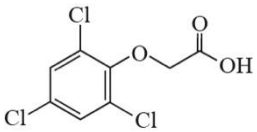
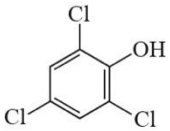
No studies on immunotoxicity were available. In the available toxicity studies on prochloraz no indication of immunotoxic potential was seen.

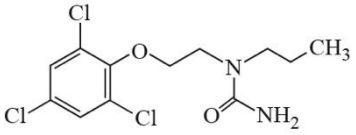
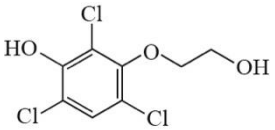
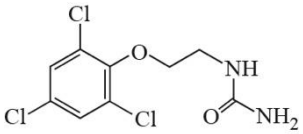
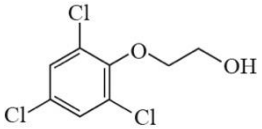
The Meeting concluded that prochloraz is unlikely to be immunotoxic.

Toxicological data on metabolites and/or degradates

Pending the periodic review of the residue definition, a number of potentially relevant major metabolites of prochloraz in crops and livestock were identified. The toxicological characteristics of these metabolites are listed in the table below.

Summary of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	Major rat metabolite (>10% AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Toxicological reference values
Prochloraz 	Parent	Unlikely to be genotoxic in humans (data)	Full dataset	ADI: 0–0.02 mg/kg bw ARfD: 0.2 mg/kg bw
BTS 44596 (*N*-formyl-*N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]urea; M201-03) 	This is an intermediate formed early in rat metabolism; its downstream metabolites BTS 3037, BTS 9608, BTS 45186, M18 found in urine, at a combined level of ≥28%	Not genotoxic in Ames test No genotoxic alert in QSAR analysis	Oral LD_{50}: >3200 mg/kg bw After oral dose of BTS 44596 to rats excretion of radiolabel virtually complete within 72 hours, with 53%–63% of the total dose excreted in urine and the remainder in faeces	Covered by parent
BTS 9608 (2,4,6-trichlorophenoxyacetic acid; M201-13) 	Yes BTS 9608 and its glucuronide, 13–35% in urine	No genotoxic alert from QSAR	No data	Covered by parent
BTS 45186 (2,4,6-trichlorophenol; 2,4,6-TCP; M201-15; M3; Phenachlor) 	Yes Up to 12% in urine (taking the partial absorption of parent into account)	No genotoxic alert in QSAR analysis	Oral LD_{50}: >3200 mg/kg bw. WHO drinking water guideline value of 0.2 mg/L for 2,4,6-TCP 2,4,6-TCP is also a metabolite of pydiflumetofen, for which JMPR 2018 concluded that the toxicity of 2,4,6-TCP and its conjugates is covered by parent	Covered by parent

BTS 44595 (*N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]urea; M201-04) 	No	Not genotoxic in Ames test. No genotoxic alert in QSAR analysis	Oral LD_{50}: >3200 mg/kg bw	TTC Cramer class III: 1.5 µg/kg bw per day
BTS 54906 (3-hydroxy-2,4,6-trichlorophenoxyethanol; M15a) 	No	No genotoxic alert in QSAR analysis		TTC Cramer class III: 1.5 µg/kg bw per day
BTS 44770 (*N*-2-(2,4,6-trichlorophenoxy)ethylurea; M201-05) 	No	No genotoxic alert in QSAR analysis		TTC Cramer class III: 1.5 µg/kg bw per day
BTS 3037 (2-(2,4,6-trichlorophenoxy)ethanol) 	Yes BTS 3037 is an intermediate in rat metabolism; its downstream metabolites BTS 9608 and BTS 45186 found in urine at a combined level of at least 17%.	Not genotoxic in Ames test	Oral LD_{50} 800–1600 mg/kg bw	Covered by parent

ADI: Acceptable daily intake; RA: read across; AD: Administered dose;TTC: Threshold of toxicological concern;

QSAR: Quantitative structure–activity relationship

Microbiological aspects

There is not sufficient information available in the public domain, and no experimental data were submitted that address the possible impact of prochloraz residues on the human intestinal microbiome.

Human data

No health effects of prochloraz were detected during medical surveillance of manufacturing plant personnel.

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

Toxicological evaluation

The Meeting established an ADI of 0–0.02 mg/kg bw for prochloraz on the basis of an overall NOAEL of 1.7 mg/kg bw per day in two 2-year studies in rats. A safety factor of 100 was used. This ADI is supported by an overall NOAEL of 2.5 mg/kg bw per day from a 90-day and a one-year study in dogs. The upper bound of the ADI gives a margin of 1300 relative to the LOAEL for the observed hepatocellular adenomas and carcinomas in mice. The previous ADI of 0–0.01 mg/kg bw, based on increased ALP levels and minimal histopathological effects in one dog in a two-year study, was withdrawn because it is now established that isolated ALP changes in dogs are not adverse.

The Meeting established an ARfD of 0.2 mg/kg bw for prochloraz from a NOAEL of 20 mg/kg bw, based on an acute neurotoxicity study in rats. A safety factor of 100 was used. The Meeting withdrew a previous ARfD of 0.1 mg/kg bw, which had been based on a NOAEL of 10 mg/kg bw per day in a 14-day study in dogs, because it is now established that isolated ALP changes in dogs are not adverse.

A toxicological monograph was prepared.

Levels relevant to risk assessment of prochloraz

Species	Study	Effect	NOAEL	LOAEL
Mouse	Eighteen-month studies of carcinogenicity[a,e]	Toxicity	78 ppm, equal to 7.5 mg/kg bw per day	220 ppm, equal to 26.3 mg/kg bw per day
		Carcinogenicity	78 ppm, equal to 7.5 mg/kg bw per day	220 ppm, equal to 26.3 mg/kg bw per day
Rat	Acute neurotoxicity study[b]	Neurotoxicity	405 mg/kg bw[c]	-
		General toxicity	20 mg/kg bw	90 mg/kg bw
	Two-year studies of toxicity and carcinogenicity[a,e]	Toxicity	40 ppm, equal to 1.7 mg/kg bw per day	150 ppm, equal to 5.1 mg/kg bw per day
		Carcinogenicity	1200 ppm, equal to 50.3 mg/kg bw per day[c]	-
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	50 ppm, equal to 4.5 mg/kg bw per day	150 ppm, equal to 13.7 mg/kg bw per day
		Parental toxicity	50 ppm, equal to 3.8 mg/kg bw per day	150 ppm, equal to 10.9 mg/kg bw per day
		Offspring toxicity	150 ppm, equal to 10.9 mg/kg bw per day	450 ppm, equal to 34 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	25 mg/kg bw per day	100 mg/kg bw per day
		Embryo/fetal toxicity	25 mg/kg bw per day	100 mg/kg bw per day
Rabbit	Developmental toxicity study[b]	Maternal toxicity	40 mg/kg bw per day	160 mg/kg bw per day
		Embryo/fetal toxicity	40 mg/kg bw per day	160 mg/kg bw per day
Dog	Thirteen-week| and one-year study of toxicity[b,e,f]	Toxicity	2.5 mg/kg bw per day	5 mg/kg bw per day

[a] Dietary administration;

[b] Gavage administration;

[c] Highest dose tested;

[d] Lowest dose tested;

[e] Two or more studies combined;

[f] Capsule administration

Acceptable daily intake (ADI) applies to prochloraz

0–0.02 mg/kg bw

Acute reference dose (ARfD) applies to prochloraz

0.2 mg/kg bw

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

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

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

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid; T_{max}: 2 hours at 5 mg/kg bw, 10 hours at 100 mg/kg bw; Absorption 74% in rats
Dermal absorption	No data
Distribution	Widely distributed, highest concentrations found in liver and kidneys
Potential for accumulation	Low
Rate and extent of excretion	Relatively rapid; virtually complete in 96 hours
Metabolism in animals	Extensively metabolized, major metabolites are: BTS 44596, BTS 9608 and BTS 3037, (see Table 1 for systematic and other names)
Toxicologically significant compounds in animals and plants	Prochloraz
Acute toxicity	
Rat, LD_{50}, oral	300 to >4000 mg/kg bw
Rat, LD_{50}, dermal	>2000 mg/kg bw
Rat, LC_{50}, inhalation	>2.1 mg/L
Rabbit, dermal irritation	Not irritating to mildly irritating
Rabbit, ocular irritation	Not irritating to moderately irritating
Guinea-pig, dermal sensitization	Not sensitizing (Magnusson & Kligman, Buehler)
Short-term studies of toxicity	
Target/critical effect	Prostate (dog), liver (rat)
Lowest relevant oral NOAEL	2.5 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day, highest dose tested (rat)

Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver
Lowest relevant NOAEL	1.7 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in mice, but not in ratsa Mode of action for tumour formation by prochloraz in mice is probably through activation of CAR and possibly PXR
Genotoxicity	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Clinical signs, body weight gain, gestation index, gestation length and dystocia
Lowest relevant parental NOAEL	3.8 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	10.9 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	4.5 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	Clinical signs, body weight gain, food consumption, liver, litter size, implantation index, viability index, incidence of dead fetuses and retarded ossification
Lowest relevant maternal NOAEL	25 mg/kg bw per day (rat/rabbit)
Lowest relevant embryo/fetal NOAEL	25 mg/kg bw per day (rat/rabbit)
Neurotoxicity	
Acute neurotoxicity NOAEL	405 mg/kg bw
Subchronic neurotoxicity NOAEL	No data
Developmental neurotoxicity NOAEL	No data
Other toxicological studies	
Immunotoxicity	No data
Studies on toxicologically relevant metabolites	
BTS 45595	Acute oral LD_{50}: >3200 mg/kg bw (rat)
BTS 44596	Acute oral LD_{50}: >3200 mg/kg bw (rat) Not genotoxic (Ames)
BTS 45595	Acute oral LD_{50}: >3200 mg/kg bw (rat)
BTS 45186	Acute oral LD_{50}: >3200 mg/kg bw (rat)
BTS 3037	Acute oral LD_{50}: 800–1600 mg/kg bw (rat) Not genotoxic (Ames)
Microbiological aspects	Insufficient information
Human data	No health effects detected during medical surveillance of manufacturing plant personnel.

[a] Unlikely to pose a carcinogenic risk to humans via exposure from the diet

Summary

	Value	Study	Safety factor
ADI	0– 0.02 mg/kg bw	Two-year study of toxicity and carcinogenicity (rat)	100
ARfD	0.2 mg/kg bw	Acute neurotoxicity study (rat)	100

5.28 Propiconazole (160) (R)

RESIDUE AND ANALYTICAL ASPECTS

Propiconazole is a broad spectrum fungicide used for control of various plant diseases.

Propiconazole underwent periodic review by JMPR in 2004 where an ADI of 0–0.07 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. Propiconazole was re-evaluated for residues by the 2007 JMPR where the residue was defined for plant and animal commodities as propiconazole for compliance with the MRL and propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid (2,4-DCBA), expressed as propiconazole for the estimation of the dietary intakes. The 2007 Meeting further concluded that the residue is fat soluble. Since the periodic review, propiconazole has been reviewed for residues in 2013, 2014, 2015 and 2017.

This compound was scheduled at the Fifty-third Session of the CCPR (2022) for the evaluation of additional MRLs at the 2023 JMPR. The Meeting received information on field rotational crop, freezer storage stability, supervised residue trials and processing.

Environmental fate

Field rotational crop

Four field rotational crop studies were conducted in Europe. Spring barley (small grain crop), carrots (root crop) and lettuce (leafy vegetable crop) were planted at nominal intervals of 30, 60 and 365 days following application to bare soil at rates of 250-254 g ai/ha. No quantifiable (>0.01 mg/kg) uptake of propiconazole residues (parent) was observed in any of the tested commodities at all plant-back intervals.

Methods of analysis

All methods used in the supervised field trials received for the current Meeting were reviewed by the 2007 and 2017 JMPR Meetings and considered valid. These methods include REM 130.11 (LOQ, 0.01 mg/kg), for analysis of parent propiconazole in avocado, peanuts and rice, REM 130.02 (LOQ, 0.02 mg/kg for all commodities except straw; LOQ, 0.04 mg/kg straw) for analysis of parent propiconazole in processed rice commodities and method AG 626 (LOQ, 0.05 mg/kg) for analysis of total residues, convertible to 2,4-DCBA, in avocado and rice grain.

Stability of residues in stored analytical samples

New storage stability data on sugar beet roots and tops, barley grain and apples demonstrated that the propiconazole (parent) residues were stable for at least 751 days, while in dry soya beans propiconazole residues were stable for at least 916 days, when stored at -20 °C.

Stability of total propiconazole residues was previously assessed by the 2007 JMPR where stability was demonstrated in high starch (maize meal, wheat grain, carrots), high oil (peanut nutmeat and maize oil) and high water (peaches, bananas, celery) content commodities for 1095 days, when stored at -20 °C.

The sample storage intervals reported in the supervised residue trials and processing studies were within the demonstrated periods of frozen storage.

Results of supervised residue trials on crops

Avocado

The critical GAP for avocado is from the United States which allows two tree injection or root infusion treatments per year at 1.26 g ai/cm of tree diameter, a 90-day re-treatment interval and a 7-day PHI. Six independent trials from the United States approximating the critical GAP were submitted, where each trial consisted of one plot in which trees received root infusion treatments and a second plot in which trees received trunk injections.

All residues originate from systemic treatments to avocado trees, however, these residues were reported as a function of pitted fruits, with no information on residues in pits. Furthermore, according to the Codex classification and the FAO Manual, the commodity to be analysed is the whole avocado after removal of pit where the residue is calculated and expressed on a whole fruit basis. As the pits account for an average of 15% of the whole fruit weight, all residues for pitted avocadoes were adjusted by a factor of 1.15 for MRL calculation. For dietary risk assessment, no residues were reported for pulp, *per se*, therefore, the total propiconazole residues reported for pitted avocadoes (peel and pulp) were considered.

Following root infusion applications, residues of parent propiconazole in pitted avocadoes were (n=6): <0.01 (5) and 0.01 mg/kg. In whole fruit, residues of parent propiconazole were <0.012 (5) and 0.013 mg/kg.

Total propiconazole residues in pitted avocadoes were (n=6): <0.05, 0.06, 0.07, 0.10 (2) and 0.11 mg eq/kg.

Following trunk injections, residues of parent propiconazole in pitted avocadoes were (n=6): <0.01 (6) mg/kg. In whole fruit, residues of parent propiconazole were <0.012 (6) mg/kg.

Total propiconazole residues in pitted avocadoes were (n=6): <0.05, 0.06 (2), 0.07, 0.09 and 0.12 mg eq/kg.

The Meeting noted that root infusion treatment resulted in overall higher residues among the two treatments, therefore these residues were used to estimate a maximum residue level of 0.02 mg/kg, an STMR of 0.085 mg/kg and an HR of 0.12 mg/kg (based on the highest reported residue) for avocado.

Rice

The critical GAP for paddy rice is from South Korea which allows 4 spray applications of an EC formulation (140 g ai/L), a 2000× dilution, a maximum spray volume of

1600L/ha (resulting in a calculated application rate of 7 g ai/hL), a 7-day re-treatment interval and a PHI of 21 days. The Meeting received ten independent trials from Thailand, India and China conducted at 2.2-3.3 g ai/hL, 7-day re-treatment intervals and a PHI of 21-days.

Residues of parent propiconazole in paddy rice grain were (n=10): 0.49, 0.78, 2.0, 2.3 (2), 2.6, 3.4 (2), 3.7 and 3.8 mg/kg. Using scaling factors of 2.1-3.1, residues of parent propiconazole in paddy rice grain were (n=10): 1.0, 1.6, 6.3, 7.0, 7.2, 8.2, 9.7, 10 and 11 (2) mg/kg.

Total propiconazole residues in paddy rice grain were (n=10): 1.6, 2.2, 3.4, 3.8, 4.7, 5.8, 7.3, 7.9, 8.7 and 8.7 mg/kg. Using scaling factors of 2.1-3.1, residues of total propiconazole in paddy rice grain were (n=10): 3.5, 4.5, 11, 12, 15, 18, 21, 23 and 25 (2) mg eq/kg.

The Meeting estimated a maximum residue level of 30 mg/kg and an STMR of 16.5 mg eq/kg for rice grain.

Peanuts

The critical GAP for peanuts is from the United States which allows 4 foliar spray applications at 123 g ai/ha, a 10-day re-treatment interval and a 14-day PHI. Twelve independent trials from the United States approximating the critical GAP were submitted.

Residues of parent propiconazole in nutmeats were (n=12): <0.01 (6), 0.010, 0.011, 0.014, 0.015 and 0.017 (2) mg/kg.

Consistent with the 2007 JMPR, the current Meeting decided to apply a conservative default factor of 3 to convert parent-only residues to total residues convertible to 2,4-DCBA.

Using this factor, total propiconazole residues in nutmeats were (n=12): <0.03 (6), 0.03 (2), 0.04 (2) and 0.05 (2) mg eq/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg, an STMR of 0.03 mg eq/kg and an HR of 0.05 mg eq/kg for peanuts.

Residues in animal feeds

Peanut, Hay and/or Straw

The critical GAP for peanuts is from the United States which allows 4 foliar spray applications at 123 g ai/ha, a 14-day re-treatment interval and a 14-day PHI. Twelve independent trials from the United States approximating the critical GAP were submitted.

Residues of parent propiconazole in peanut hay were (n=12): 1.22, 5.49, 6.55, 7.54, 7.82, 9.48, 9.55, 9.75, 15, 18, 20, 29 mg/kg, as received.

Applying a 3-fold conversion factor, total propiconazole residues in hay were (n=12): 3.66, 16, 20, 23 (2), 28, 29 (2), 44, 53, 61 and 86 mg eq/kg, as received.

The Meeting estimated a maximum residue level of 50 mg/kg (dw), a median residue of 36.5 mg/kg and highest residue of 91 mg eq/kg (based on the highest reported residue) for peanut hay and/or straw, as received.

Fate of residues during processing

Residues in processed commodities

The Meeting received new information on the fate of propiconazole residues during processing of peanuts and rice.

The 2007 JMPR reviewed rice processing studies where processing factors for total propiconazole residues were determined. However, no MRLs were recommended for the raw commodities, as supervised residue trials did not report residues of the parent propiconazole.

Estimated processing factors for determination of STMR-Ps and HR-Ps

Raw Commodity	Residues in RAC			Processed Commodity	Propiconazole (parent) Processing Factors [Best estimate]	Total Propiconazole (2007 JMPR)		Residues in Processed Commodity	
	MRL mg/kg	STMR mg eq/kg	HR mg eq/kg			Individual Processing Factors	Best estimate	MRL mg/kg	STMR-P mg eq/kg
Rice	30	16.5	Not applicable	Rice grain (clean)	0.78				
				Parboiled rice grain (clean)	0.86				
				Husks	2.5	4.1, 4.0, 4.1, 3.0	4.05	80	67
				Parboiled husks	1.5				
				Husked rice (brown rice)	0.13			4	
				Parboiled husked rice (brown rice)	0.60				
				Bran	0.70	3.5, 3.9, 2.3, 1.7	2.9		48
				Parboiled bran	2.39			80	
				Polished rice	0.07	0.16, 0.19, <0.06, 0.076	0.12		1.95
				Parboiled polished rice	0.33			10	
Peanuts	0.03	0.03	0.05	Meal	0.4, 0.5 [0.5]				
				Butter	0.9, 1.0 [1.0]				
				Oil	0.5, 0.7 [0.6]				

Using the estimated maximum residue level of 30 mg/kg for rice grain and applying the highest processing factor of 2.39 for parboiled bran, the Meeting estimated a maximum residue level of 80 mg/kg for rice bran, processed. Using the STMR of 16.5 ppm and the processing factor of 2.9 for total propiconazole residues, the STMR-P for rice bran, unprocessed was estimated to be 48 mg eq/kg.

Similarly, when applying the highest processing factor of 2.5 for husks, the Meeting estimated a maximum residue level of 80 mg/kg for rice husks. Using the STMR of 16.5 ppm and

the processing factor of 4.05 for total propiconazole residues, the STMR-P for rice husks was estimated to be 67 mg eq/kg.

For husked rice and polished rice, the Meeting estimated maximum residue levels of 4 mg/kg (30 × 0.13 = 3.9 mg/kg) and 10 mg/kg (30 × 0.33 = 9.9 mg/kg), respectively. Using the STMR of 16.5 ppm and the processing factor of 0.118 for total propiconazole residues, the STMR-P was estimated to be 1.95 mg eq/kg for polished rice.

As processing factors for propiconazole in peanut meal, peanut butter and peanut oil were ≤ 1, no maximum residue level was estimated for peanut processed commodities.

Residues in animal commodities

One cow and one poultry study were evaluated by the 2007 JMPR, and only the relevant information from these studies are summarized herein.

Overview of mean and highest residues (mg/kg) observed in the dairy cattle feeding study (JMPR 2007)

Feeding Levels	15 ppm		75 ppm		150 ppm	
	Parent	Total	Parent	Total	Parent	Total
Milk	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)	0.044 (0.08)	<0.01 (<0.01)	0.10 (0.11)
Muscle	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	0.08 (0.11)	<0.05 (<0.05)	0.14 (0.18)
Kidney	<0.05 (<0.05)	0.60 (0.63)	<0.05 (<0.05)	3.8 (4.7)	<0.05 (<0.05)	5.7 (6.5)
Liver	0.08 (0.14)	0.63 (0.81)	0.22 (0.34)	3.7 (4.3)	0.42 (0.66)	5.2 (5.6)
Fat	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	0.15 (0.23)	0.06 (0.08)	0.21 (0.26)

Overview of mean and highest residues (mg/kg) observed in the laying hen feeding study (JMPR 2007)

Feeding Levels	7.5 ppm		37.5 ppm		75 ppm	
	Parent	Total	Parent	Total	Parent	Total
Eggs	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	0.11 (0.18)	<0.05 (<0.05)	0.27 (0.37)
Muscle	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	0.06 (0.07)
Fat	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	0.07 (0.11)
Liver	<0.05 (<0.05)	<0.1 (<0.1)	<0.05 (<0.05)	0.12 (0.16)	<0.05 (<0.05)	0.37 (0.47)
Skin + fat	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	<0.05 (<0.05)	0.06 (0.07)

Farm animal dietary burden

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the current JMPR. Calculations have improved since the last dietary burden calculations were conducted by the 2014 JMPR, where the dietary burdens were estimated using propiconazole (parent) for maximum residue level estimation and using total propiconazole residues for dietary risk assessment. These dietary burdens were calculated using the most recent version of the OECD livestock dietary burden calculator diets and are presented in Annex 6 and summarized below.

Dietary Burden for MRL Calculation

	Maximum Animal Dietary Burden: Propiconazole, ppm			
	USA-Canada	**European Union**	**Australia**	**Japan**
Beef cattle	6.4	3.0	29[a]	4.0
Dairy cattle	13	7.1	29[b]	2.6
Broilers	3.8	2.0	8.4[c]	1.0
Layers	3.8	2.6	8.4	4.0

a. Highest maximum beef cattle dietary burden suitable for MRL estimates for mammalian tissues

b. Highest maximum dairy cattle dietary burden suitable for MRL estimates for milk

c. Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs and tissues

Propiconazole Feeding Study	**Feeding level (ppm) for milk/egg residues**	**Residues (mg/kg) in milk and eggs**	**Feeding level (ppm) for tissue residues**	**Propiconazole Residues (mg/kg)**			
				Muscle	**Liver**	**Kidney**	**Fat**
MRL beef and dairy cattle							
Feeding study	15	<0.01	15	<0.05	0.14	<0.05	<0.05
	75	<0.01	75	<0.05	0.34	<0.05	<0.05
Dietary burden	29	<0.01	29	<0.05	0.18	<0.05	<0.05
MRL broilers and layers							
Feeding study	7.5	<0.05	7.5	<0.05	<0.05	NA	<0.05
	37.5	<0.05	37.5	<0.05	<0.05	NA	<0.05
Dietary burden	8.4	<0.05	8.4	<0.05	<0.05	NA	<0.05

Cattle

Even at the highest feeding level, no measurable residues of propiconazole were observed in milk and muscle. Therefore, since residues above the LOQ of the enforcement method (0.01 mg/kg) are not likely to be reached, the Meeting confirms its previous recommendations for maximum residue levels of 0.01(*) mg/kg in milks and muscle.

In fat and edible offal, measurable residues of propiconazole were observed at the highest feeding levels tested. Therefore, the Meeting estimated maximum residue levels of 0.05 mg/kg for fat and 0.2 mg/kg for edible offal to replace its previous recommendations of 0.01 (*) mg/kg and 0.5 mg/kg, respectively.

Poultry

Similar to cattle, even at the highest feeding level, no measurable residues of propiconazole were observed in eggs and poultry tissues. Therefore, since residues above the LOQ of the enforcement method (0.01 mg/kg) are not likely to be reached, the Meeting confirms its previous recommendations for maximum residue levels of 0.01(*) mg/kg in eggs and muscle.

The Meeting estimated maximum residue levels of 0.01(*) mg/kg in poultry fat and edible offal.

Dietary burden calculation for dietary risk assessment

	Animal Dietary Burden: Total Propiconazole, ppm							
	USA-Canada		European Union		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	16	14	18	4.6	87	48	21	12
Dairy cattle	41	24	26	15	88[a]	49[b]	16	11
Broilers	9.3	9.3	5.6	5.6	20	20	2.7	2.7
Layers	9.3	9.3	7.8	4.6	20[c]	20[d]	11	11

a. Highest maximum dairy cattle dietary burden suitable for HR estimates for mammalian tissues

b. Highest mean dairy cattle dietary burden suitable for STMR estimates for milk and mammalian tissues

c. Highest maximum poultry dietary burden suitable for HR estimates for eggs and poultry tissues

d. Highest mean poultry dietary burden suitable for STMR estimates for eggs and poultry tissues

The calculations used to estimate the STMR and HR values for cattle and poultry matrices are shown below.

Estimated residues for STMR and HR for total propiconazole in cattle commodities

Propiconazole Feeding Study	Feeding level (ppm) for milk residues	Residues (mg/kg) in milk	Feeding level (ppm) for tissue residues	Total Propiconazole Residues (mg eq/kg)			
				Muscle	Liver	Kidney	Fat
HR beef or dairy cattle							
Feeding study			75	0.11	4.3	4.7	0.23
			150	0.18	5.6	6.5	0.26
Dietary burden			88	0.12	4.5	5.0	0.24
STMR beef or dairy cattle							
Feeding study	15	<0.01	15	<0.05	0.63	0.60	<0.05
	75	0.044	75	0.08	3.7	3.8	0.15
Dietary burden	49	0.03	49	0.07	2.4	2.4	0.11

Based on the highest total residues of propiconazole (propiconazole plus all metabolites convertible to 2,4-DCBA, expressed as propiconazole) in cattle tissues, the Meeting estimated

HR values of 0.12 mg eq/kg in muscle, 0.24 mg eq/kg in fats and 5.0 mg eq/kg in edible offal (based on kidney).

Based on the mean total residues of propiconazole (propiconazole plus all metabolites convertible to 2,4-DCBA, expressed as propiconazole) in milk and cattle tissues, the Meeting estimated STMR values of 0.03 mg eq/kg in milks, 0.07 mg eq/kg in muscle, 0.11 mg eq/kg in fats and 2.4 mg eq/kg in edible offal.

Estimated residues for STMR and HR for total propiconazole in poultry commodities

Propiconazole Feeding Study	**Feeding level (ppm) for egg residues**	**Residues (mg/kg) in egg**	**Feeding level (ppm) for tissue residues**	**Total Propiconazole Residues (mg eq/kg)**		
				Muscle	**Liver**	**Fat**
HR broilers and layers						
Feeding study	7.5	<0.05	7.5	<0.05	<0.1	<0.05
	37.5	0.18	37.5	<0.05	0.16	<0.05
Dietary burden	20	0.10	20	<0.05	0.12	<0.05
STMR broilers and layers						
Feeding study	7.5	<0.05	7.5	<0.05	<0.1	<0.05
	37.5	0.11	37.5	<0.05	0.12	<0.05
Dietary burden	20	0.08	20	<0.05	0.11	<0.05

Based on the highest total residues of propiconazole (propiconazole plus all metabolites convertible to 2,4-DCBA, expressed as propiconazole) in eggs and poultry tissues, the Meeting estimated HR values of 0.10 mg eq/kg in eggs, 0.05 mg eq/kg in muscle and fat and 0.12 mg eq/kg in edible offal.

Based on the mean total residues of propiconazole (propiconazole plus all metabolites convertible to 2,4-DCBA, expressed as propiconazole) in eggs and poultry tissues, the Meeting estimated STMR values of 0.08 mg eq/kg in eggs, 0.05 mg eq/kg in muscle and fat and 0.11 mg eq/kg in edible offal.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and international estimate of short-term intakes assessment.

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

Definition of the residue for dietary risk assessment for plant and animal commodities: propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for propiconazole is 0–0.07 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for propiconazole were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 2 to 20 percent of the maximum ADI.

Acute dietary exposure

The ARfD for propiconazole is 0.3 mg/kg bw. The International Estimate of Short-Term Intakes (international estimate of short-term intakes) for propiconazole were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs ranged from 70 to 100 percent of the ARfD.

5.29 Pyrethrins (063) (R)

RESIDUES AND ANALYTICAL ASPECTS

Pyrethrins were first evaluated by the JMPR in 1965 and has been evaluated numerous times since. It was last subject to periodic review in 2000 (residues) following toxicological assessment in 1999, when an acceptable daily intake (ADI) of 0-0.04 mg/kg bw established by the 1972 JMPR was reaffirmed and an ARfD of 0.2 mg/kg bw was established. MRLs were recommended for a number of plant commodities by the 2000 JMPR, and for additional uses in 2003 (cereal grains) and 2005 (tree nuts) by these later JMPR meetings.

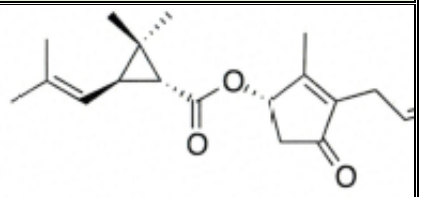
Pyrethrins are a naturally occurring insecticide containing six biologically active, chemically related esters. The esters of chrysanthemic acid (Pyrethrins I) are pyrethrin 1, cinerin 1, and jasmolin 1, and the esters of pyrethric acid (Pyrethrins II) are pyrethrin 2, cinerin 2, and jasmolin 2. Ratios of Pyrethins I to Pyrethrins II is typically 0.2:2.8, with the ratio of pyrethrins:cinerins:jasmolins being 71:21:7[18] The definition of the residue for compliance with MRLs and for dietary risk assessment is total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract. The residue is fat-soluble.

At the Fifty-first Session of the CCPR (2019), pyrethrins were scheduled for evaluation of additional uses by the 2021 JMPR Extra Meeting and rescheduled to the 2023 Meeting. The current Meeting received information on analytical methods, storage stability, residue field trials for a range of foliar uses and post-harvest uses (on citrus and tree nuts), and processing studies to support new MRLs in raw and processed plant commodities. In addition, the meeting received a metabolism study in tomato, which identified a metabolite not previously considered by the Meeting.

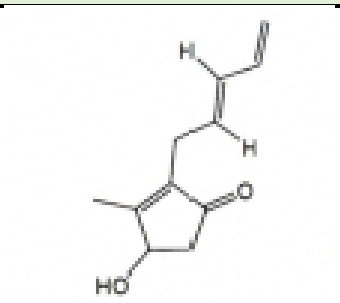
Plant metabolism

Tomato (foliar application)

The following compounds are discussed:

Common or code name	Chemical name molecular formula molar mass, g/mol	Structure
Pyrethrin 1	Pyrethrin 1 $C_{21}H_{28}O_3$ 328.45	

[18] See https://www.atsdr.cdc.gov/ToxProfiles/tp155-c4.pdf (cited 22 September 2023)

Common or code name	Chemical name molecular formula molar mass, g/mol	Structure
Pyrethrolone	Pyrethrolone $C_{11}H_{14}O_2$ 178.23	

Following treatment of greenhouse-grown tomato plants with thee applications of [cyclopentenone-2-^{14}C]-pyrethrin 1 at either 33 g ai/ha or 165 g ai/ha 14, 9, and 5 days before harvest, total radioactive residues (TRR) in tomato fruit ranged from 0.023 to 0.035 mg eq/kg (low rate) and from 0.110 to 0.219 mg eq/kg (high rate). Extraction with acetonitrile and acetonitrile + water (1+1, v/v) resulted in 82—85 percent TRR being extracted. Post-extraction solids (PES) contained the balance of the radioactivity (15—18 percent TRR; 0.005 mg eq/kg low rate, 0.023 mg eq/kg high rate). In total, approximately 10 percent of the non-extracted residue (0.004 mg eq/kg low rate, 0.014 mg eq/kg high rate) was released with pectinase, cellulase, and protease treatments, with protease releasing the most radioactivity (~ 4.9 percent TRR; 0.002 mg eq/kg low rate, 0.008 mg eq/kg high rate).

Pyrethrin 1 was identified in tomato fruit at ≤19 percent TRR (0.004 mg/kg in low rate samples; 0.029 mg/kg in high rate samples). After multiple analyses, pyrethrolone was the only other identified compound in tomato fruit and occurred at levels of approximately ½ those of pyrethrin 1 (0.002 mg/kg in low rate samples; 0.012 mg/kg in high rate samples). Other components of the HPLC peak were more hydrophilic, each accounting for ≤14.7 percent TRR (≤0.004 mg/kg in low rate samples; ≤ 0.021 mg/kg in high rate samples).

The Meeting noted that standards of chrysanthemic acid derivative, which were observed in metabolism studies reviewed by the 2000 JMPR, were not included in the current tomato study, and no metabolites related to this metabolic pathway were identified in the study. Investigation of unidentified compound by in silico methods suggests that all of the compounds contained at least two nitrogen atoms. A possible explanation might be that the structures represent metabolites that are numerous steps away from the parent compound and possibly already near natural compounds i.e. (poly-)peptides.

The Meeting noted that the new tomato metabolism study provided only limited additional data on the nature of residues in crops beyond that considered during periodic review by the 2000 JMPR.

On the basis of the data obtained from supervised trials, the Meeting did not make any recommendations for establishing MRLs and for IEDI assessments. This was due to the fact that no trial matched the GAP and / or insufficient data.

The definition of the residue for compliance with MRLs and for dietary risk assessment for plant and animal commodities: total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract.

The residue is fat-soluble.

Methods of analysis

The Meeting received details of a new LC-MS/MS method of analysis (GPL-MTH-074 or GPL-MTH-074 with small modifications according to crops) together with method validation and concurrent recovery data to analyse residues of pyrethrins (simultaneously with piperonyl butoxide) in the full range of commodities and processed commodities for which trials were submitted.

Residues of pyrethrins were determined as pyrethrin I (sum of pyrethrin 1, cinerin 1 and jasmolin 1) The validation data covered the recovery of pyrethrin I the relevant method (with or without modification) in the respective crops.

Average recoveries and relative standard deviations were within the range generally considered acceptable for all tested fortification levels (0.02 to 10 mg/kg) and matrices (citrus fruits, stone fruits, blackberry, strawberry, leafy vegetables, fruiting vegetables, tree nuts, coffee, herbs (fresh and dried), and spices) and fortification levels, with the exception of concurrent recoveries from fresh chives for which the average recovery at the 0.01 mg/kg fortification was 67 percent. When concurrent and method validation recoveries are considered together, the average recovery (±RSD) for fresh chives is 74±12 percent. On that basis and the acceptable method performance for other high-water matrices, the meeting concluded that the method was adequate for analysis of pyrethrin I in the tested commodities. The validated LOQ for pyrethrin 1 was 0.02 mg/kg. The ratio of pyrethrin 1 to total pyrethrins in the test substance used in the field trials was reported to be 1:1.8; therefore the LOQ of 0.02 mg pyrethrin 1/kg translates to a total pyrethrin LOQ of approximately 0.04 mg/kg (see Results of supervised residue trials, below).

Freezer storage stability of residues in stored samples

The JMPR Meeting in 2000 previously assessed storage stability data for a range of representative commodities. Whilst in most commodities, pyrethrin was concluded to be stable (with > 80% remaining after storage). The 2000 Meeting noted that in samples of broccoli, bean pods, vines, and hay, dry orange pulp, dry and wet tomato pomace, liver, and kidney, only 35-70% of the concentration of pyrethrins remained after 12-27 months of storage.

The current Meeting received storage stability data obtained concurrently with the supervised residue trials submitted to the Meeting. Although most samples showed dissipation of residues in storage, the loss was considered minimal (at least 70% of the Day 0 level remaining), and the Meeting agreed that residues of pyrethrin I were stable in frozen storage for at least the duration of the period tested in the following matrices:

Orange	102 days
Cherries	225 days
Plum	153 days
Blackberry	156 days
Strawberry	230 days
Cabbage	63 days
Spinach	67 days
Tomato	63 days
Coffee (green beans)	117 days

Coffee (roasted beans)	47 days
Coffee (freeze dried)	39 days
Basil (fresh)	174 days
Dill seed	161 days

Except for the processed coffee commodities, the demonstrated duration of residue stability covers the storage times for the analytical samples for the commodities listed above. For roasted and freeze-dried coffee, samples were stored for up to 63 days. This is approximately 47 percent longer than the period of demonstrated stability and extrapolation for that duration is not supported.

Dissipation in storage exceeded 30 percent (<70 percent remaining) for almonds (66 percent remaining at 102 days of storage) and dried basil (60 percent remaining at 201 days of storage). Residues were analysed only at Day 0 and at study termination; therefore, dissipation kinetics could not be determined for those commodities. For tree nuts, analytical samples of almonds and pecans were stored for up to 69 days. For dried basil, storage times were 153, 180, and 207 days. The Meeting agreed that tree nut and dried basil samples are not suitable for making residue recommendations.

Results of supervised residue trials on crops

The Meeting received data from supervised residue trials and GAP information on citrus (post-harvest use), stone fruits, blackberries, strawberries, brassica vegetables (cabbage), leafy vegetables, tomato (glasshouse use), tree-nuts (post-harvest use), coffee, herbs and spices (seeds). All GAPs considered by the 2023 JMPR were from the United States.

As noted by the 2000 JMPR, pyrethrins II are degraded during analysis; total pyrethrin levels can be estimated from the proportion of pyrethrins I and pyrethrins II in the formulation by multiplying the measured pyrethrin 1 concentration by the ratio of total pyrethrins to pyrethrin 1 in the test substance. Residues values reported in the field trials were in terms of total pyrethrins using a ratio of ca. 1.8.

Citrus

Registered GAPs for citrus include foliar sprays, soil drenches, and high-volume post-harvest sprays. Supervised trials were conducted using ultra-low volume surface sprays and fogger applications. The meeting agreed that these trials do not match any of the registered GAPs and are not suitable for making residue recommendations.

The Meeting confirmed its previous recommendations.

Stone fruits

The critical GAP for stone fruits consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The

Meeting also noted that the trials were conducted at exaggerated rates (1.25—1.29X critical GAP).

The Meeting did not make a recommendation for stone fruits.

Blackberries

The critical GAP for blackberry (covered under "small fruits and berries") consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.0–1.45X critical GAP).

The Meeting did not make a recommendation for blackberry.

Strawberries

The critical GAP for strawberry (covered under "small fruits and berries") consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.0–1.30X critical GAP).

The Meeting did not make a recommendation for strawberry.

Cabbage

The critical GAP for uses on *Brassica* vegetables including head cabbage consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

Three trials in head cabbage with application rates approximating the cGAP were evaluated by the 2000 JMPR; however, retreatment intervals were not specified. The Meeting agreed that without information on retreatment intervals, these trials could not be used to make residue recommendations.

One new trial was provided to the current Meeting. The trial was conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trial does not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trial was conducted at an exaggerate rate (1.27X critical GAP).

The Meeting did not make a recommendation for cabbage.

Leafy vegetables

The critical GAP for uses on leafy vegetables, including commodities in the Subgroup of Leafy greens and the Subgroup of Brassica leafy vegetables, consists of ten foliar applications,

each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

Trials in lettuce, spinach, mustard greens, and radish leaves with application rates approximating the cGAP were evaluated by the 2000 JMPR; however, retreatment intervals for those trials were not specified. The Meeting agreed that without information on retreatment intervals, these trials could not be used to make residue recommendations.

One new trial for each of head lettuce, spinach, mustard greens, and radish leaves was provided to the current Meeting. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.26-1.27X critical GAP).

The Meeting did not make a recommendation for leafy vegetables.

Tomato

A Codex MRL of 0.05 mg/kg is established for residues of pyrethrins on tomato.

Two GAPS were provided for tomato: (1) a glasshouse foliar preharvest use consisting of ten foliar applications, each at 56 g ai/ha, on a 3-day interval (1-day interval under extreme pest pressure), with harvest 0 DALA and (2) a post-harvest spray at 0.0797 g pyrethrins per tonne fruit on a 7-day interval (1-day interval under extreme pest pressure); the maximum number of applications was not specified. Based on comparison of results from field trials with foliar preharvest applications with the post-harvest spray rate, the Meeting agreed that the foliar preharvest GAP is the critical GAP. The Meeting noted, however, that tomatoes could undergo both pre-and post-harvest treatments.

Trials were conducted with retreatment intervals ranging from 2 to 4 days. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.27-1.34X critical GAP).

The Meeting confirmed its previous recommendation.

Tree nuts

A Codex MRL of 0.5 mg/kg is established for residues of pyrethrins on tree nuts.

Two GAPs were provided for nuts: (1) a use on tree nuts consisting of ten foliar applications, each at 56 g ai/ha, on a 3-day interval (1-day interval under extreme pest pressure), with harvest 0 DALA and (2) post-harvest sprays. Neither the maximum number of post-harvest sprays nor the PHI were specified for the post-harvest uses. Depending on the end-use product, surface sprays are conducted as (1) two applications each at 0.117 g/m^2 followed by additional applications at 0.058 g/m^2, done at an initial interval of 7 days for the first 6 weeks followed by a retreatment interval of 15 days or (2) a combination of surface and space sprays at 0.004 g/m^2 and 0.0174 g/m^3, respectively, on a 7-day interval. The Meeting agreed that the surface spray use pattern (0.117 g/m^2 + 0.058 g/m^2) is the critical GAP.

The provided trials in almond and pecan reflect only the space spray treatments as 6 sprays, each at 0.052 g ai/m^3 on a 7-day interval. The Meeting agreed that the per volume

application could not be converted to a per area rate for comparison to the critical GAP; furthermore, the storage durations for tree nuts samples are not supported by the available storage stability data. The Meeting agreed that the trials could not be used to make recommendations for tree nuts.

The Meeting confirmed its previous recommendation.

Coffee

The critical GAP for coffee consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted with retreatment intervals ranging from 2 to 4 days. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.31-2.08X critical GAP) and that three trials are not sufficient to make a recommendation for residues in coffee.

The Meeting did not make a recommendation for coffee.

Herbs

The critical GAP for herbs and spices, which include chive and basil, consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted with retreatment intervals ranging from 2 to 4 days. The trials were conducted using 10 applications made with retreatment intervals ranging from 2 to 4 days. The Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that the trials were conducted at exaggerated rates (1.26—1.28X critical GAP) and that four trials each are needed for chive and basil.

The Meeting did not make a recommendation for herbs.

Spices (seed)

The critical GAP for herbs and spices, which includes dill seed, fennel seed, and mustard seed, consists of ten foliar applications, each at 56 g ai/ha, with harvest 0 DALA. The retreatment interval specified is 3 days except under extreme pest pressure, in which case a 24-hour interval is allowed.

The trials were conducted with retreatment intervals ranging from 3 to 4 days (3-7 days in study reviewed by 2000 JMPR) and with 14 or 20 applications in the case of the fennel seed trials. In addition to those deviations from the critical GAP, the Meeting agreed that since the label gave no restrictions on the number or frequency of 24-hour retreatment intervals that may be used on a crop, the trials do not match the critical GAP and are not suitable for making residue recommendations. The Meeting also noted that too few trials were provided to make a recommendation for spices (seed).

The Meeting did not make a recommendation for spices (seed).

Residues in processed commodities

The Meeting did not make any recommendations for processed commodities.

Residues in animal commodities

Farm animal dietary burden

The Meeting did not make any recommendations for animal feed items. The Meeting noted the conclusion of the 2003 JMPR that although uses on animal feed items have been reviewed by the Meeting, adequate animal feeding studies have not been made available, and that the JMPR will reexamine recommendations for residues in animal commodities if/when data from feeding studies become available.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting did not make any recommendations for establishing maximum residue limits and for IEDI assessments.

The definition of the residue for compliance with MRLs and for dietary risk assessment for plant and animal commodities is *total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract*.

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for permethrins is 0—0.04 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for permethrins were last estimated by the 2005 JMPR. The IEDIs ranged from 0 to 1 percent of the maximum ADI.

Although newer consumption data are available compared to those used by the 2005 Meeting, the current meeting noted the very low risk estimates and concluded that long-term dietary exposure to residues of permethrins from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for permethrins is 0.2 mg/kg bw. The International Estimate of Short-Term Intakes (IESTIs) for permethrins were last calculated by the 2005 JMPR. The IESTIs were <1 percent of the ARfD for children and <1 percent of the ARfD for the general population.

Although newer consumption data are available compared to those used by the 2005 Meeting, the current meeting noted the very low risk estimates and concluded that long-term dietary exposure to residues of permethrins from uses considered by the JMPR is unlikely to present a public health concern.

5.30 Tetraniliprole (324) (R)

The critical GAP for mandarins and lemons is the same (citrus fruit). As such the residues from both crops can be assessed against the critical GAP in the United States for citrus fruit of three foliar applications at 60 g ai/ha, with a retreatment interval of 5 days and a PHI of 1 day. • Residues of tetraniliprole in mandarins both for maximum residue estimation and risk assessment in ranked order were (n=4): 0.17, 0.18, 0.19 and 0.54 mg/kg in whole fruit. • Residues of tetraniliprole in lemons both for maximum residue estimation and risk assessment in ranked order were (n=5): 0.062, 0.13, 0.19, 0.20 and 0.77 mg/kg in whole fruit.

The combined dataset for residues in mandarins and lemons both for MRL and risk assessment in ranked order were (n=9): 0.062, 0.13, 0.17, 0.18, 0.19, 0.19, 0.20, 0.54 and 0.77 mg/kg in whole fruit. Mandarins are a major crop and as such at least 6 trials should be available. Considering the request of the EU, noting that the median residues for mandarins and lemons are similar and the datasets are of a similar population (MannWhitney) the 2023 Meeting agreed to combine the datasets. The 2023 Meeting estimated a maximum residue level of 1.5 mg/kg, and an STMR of 0.19 mg/kg for Subgroup of Mandarins (including mandarin-like hybrids), based on the combined dataset of mandarins and lemons. Thereby replacing its previous recommendation (JMPR 2022) of a maximum residue level of 1.0 mg/kg and an STMR of 0.185 mg/kg for tetraniliprole in the subgroup of mandarins (including mandarin-like hybrids).

5.31 Thiamethoxam (245) (see also Chothianidin, 238) (R)

RESIDUE AND ANALYTICAL ASPECTS

Thiamethoxam (ISO common name) is a broad-spectrum, neonicotinoid insecticide with registered uses on multiple crops. It was evaluated for the first time by JMPR 2010, which established an ADI of 0–0.08 mg/kg bw and an ARfD of 1 mg/kg bw. Thiamethoxam underwent subsequent evaluations by the JMPR in 2011, 2012, 2014 and 2021.

The definition of the residue for compliance with MRLs for animal and plant commodities is thiamethoxam. For dietary risk assessment, the residue definitions are thiamethoxam and clothianidin (a.k.a. CGA322704), assessed separately, for plant and animal commodities except poultry and the sum of thiamethoxam, CGA 265307 (N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine), and MU3 (amino-([(2-chlorothiazol-5-ylmethyl)-amino]-methylene)-hydrazide), expressed as thiamethoxam, along with clothianidin (assessed separately) for poultry commodities. The residue is not fat-soluble.

Thiamethoxam was scheduled at the Fifty-second Session of the CCPR for the evaluation of additional MRLs in 2022 and rescheduled to the 2023 JMPR. The current Meeting received additional information on analytical methods, storage stability, field trials and processing studies to support new MRLs in commodities of tree nuts, bulb vegetables, goji berry and stems and petioles. The Meeting also received monitoring data from India for cumin seeds from 2018 to 2023.

Clothianidin (238) is a metabolite of thiamethoxam and a registered active ingredient. In addition to considering residues of thiamethoxam, the Meeting also considered residues of clothianidin arising from the uses of thiamethoxam (see section 5.7 Clothianidin (238))

Methods of analysis

The Meeting received new recovery data for the use of Method AG-765 (reviewed by the 2010 JMPR) and validation data for method R20013B, used for goji berry, and the method used for cumin seeds. Method AG-765 and R20013B were demonstrated to have adequate performance for recovery of thiamethoxam, with an LOQ of 0.01 mg/kg. The method for cumin seeds was validated with an LOQ of 0.1 mg/kg for thiamethoxam.

Storage stability

The 2010 JMPR determined that residues of thiamethoxam are stable for 1-2 years under frozen (-18°C) conditions for a large range of commodities, including the high-water and high-oil commodities considered by the current Meeting. New storage stability data were submitted to the Meeting for fresh and dried goji berries. The 2023 JMPR concluded that thiamethoxam is stable in fresh and dried goji berries for at least 13 months. The stability of residues in crops under consideration by the present Meeting is considered to be adequately demonstrated for the periods that field trials samples had been stored prior to analysis.

Results of supervised residue trials on crops

The Meeting received data from supervised residue trials and GAP information on bulb onions, goji berry, celery and almonds. Monitoring data were also provided to the Meeting for cumin seeds.

Bulb onion

The critical GAP for bulb onions is from the United States and is a seed treatment consisting of one application of 0.2 mg ai/seed.
Residues of thiamethoxam in independent trials provided to the current Meeting approximating the critical GAP were (n=7): <u>≤0.01</u> (6) and 0.014 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR of 0.01 mg/kg and an HR of 0.014 mg/kg for bulb onion.

Residues of clothianidin in bulb onion in independent trials approximating the critical GAP for thiamethoxam were (n=7): <0.01 (7) mg/kg.

Goji berry

Goji berries are in the CODEX crop group of fruiting vegetables, other than cucurbits. The 2010 JMPR recommended a maximum residue level of 0.7 mg/kg for fruiting vegetables, other than cucurbits, for a critical GAP of two applications of 0.1 kg ai/ha, a RTI of 7 days and a PHI of 3 days.

The critical GAP from China for goji berry is different from the GAP considered by the 2010 JMPR for fruiting vegetables other that cucurbits and consists of one application of 0.01 kg ai/hL with a PHI of 5 days.

Residues of thiamethoxam in independent trials provided to the current Meeting approximating the critical GAP were (n=5): 0.021, 0.071, <u>0.21</u> 0.36 and 0.62 mg/kg. The highest single analytical result was 0.65 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, an STMR of 0.21 mg/kg and an HR of 0.65 mg/kg for goji berry.

The Meeting withdrew its previous recommendation of a maximum residue level of 0.7 mg/kg for fruiting vegetables other that cucurbits and recommended a new maximum residue level of 0.7 mg/kg, an STMR of 0.08 mg/kg and a HR of 0.47 mg/kg for fruiting vegetables other than cucurbits except goji berry. #

Residues of clothianidin in goji berry in independent trials approximating the critical GAP for thiamethoxam were (n=5): <0.01 (3), 0.019, 0.032 mg/kg. The highest single analytical result was 0.034 mg/kg.

Stems and petioles

Celery is in the CODEX subgroup of stems and petioles. The 2010 JMPR estimated a maximum residue level of 1 mg/kg for celery using the NAFTA calculator and based on the same critical GAP for stems of petioles considered by the current Meeting. The critical GAP is for the United States and consists of two applications of 96.25 g ai/ha with a RTI of 7 days and a PHI of 5 days.

Residues of thiamethoxam in celery in independent trials provided to the 2010 JMPR approximating the critical GAP were (n=4): 0.09, 0.13, 0.30 and 0.37 mg/kg. The highest single analytical result was 0.4 mg/kg.

The Meeting estimated a maximum residue level of 0.8 mg/kg, using the OECD MRL calculator, a STMR of 0.215 mg/kg and a HR of 0.4 mg/kg for stems and petioles. The Meeting withdrew its previous recommendation of a maximum residue level of 1 mg/kg for celery.

Residues of clothianidin in celery in independent trials approximating the critical GAP for thiamethoxam were (n=4): <0.01 (2), 0.01 and 0.02 mg/kg.

Tree nuts

The critical GAP for tree nuts is from the United States and consists of two applications of 70 g ai/ha with a RTI of 7 days and a PHI of 14 days.

Residues of thiamethoxam in pecan in independent trials from the 2010 JMPR approximating the critical GAP were (n=5): <0.01(5) mg/kg.

Residues of thiamethoxam in almonds in independent trials provided to the current Meeting approximating the critical GAP were (n=5): <0.01 (5) mg/kg.

Based on the data for pecan and almond the Meeting estimated a maximum residue level, STMR and HR of 0.01* mg/kg for tree nuts. The Meeting decided to withdraw the maximum residue level for pecan of 0.01* mg/kg and to recommend a maximum residue level of 0.01* mg/kg for the group of tree nuts.

Residues of clothianidin in pecan in independent trials approximating the critical GAP for thiamethoxam were (n=5): <0.01 (5) mg/kg.

Residues of clothianidin in almonds in independent trials approximating the critical GAP for thiamethoxam were (n=5): <0.01(5) mg/kg.

Cumin seed

No GAP information or residue trials for the use of thiamethoxam on cumin seed was provided to the Meeting. The Meeting received monitoring data from India and of the 1089 samples analysed, 356 samples contained quantified residues. The residues of thiamethoxam were:
0.11, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.12, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.13, 0.14, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.15, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.17, 0.18, 0.18, 0.18, 0.18, 0.18, 0.18, 0.18, 0.18, 0.19, 0.19, 0.19, 0.19, 0.19, 0.19, 0.20, 0.20, 0.20, 0.20, 0.20, 0.20, 0.20, 0.20, 0.20, 0.20, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.22, 0.23, 0.23, 0.23, 0.23, 0.23, 0.23, 0.24, 0.24, 0.24, 0.24, 0.24, 0.24, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, 0.25, **0.26**, 0.26, 0.26, 0.26, 0.27, 0.27, 0.27, 0.27, 0.28, 0.28, 0.28, 0.28, 0.28, 0.29, 0.29, 0.29, 0.30, 0.30, 0.30, 0.31, 0.31, 0.31, 0.31, 0.31, 0.31, 0.31, 0.32, 0.32, 0.32, 0.32, 0.32, 0.32, 0.33, 0.33, 0.33, 0.33, 0.33, 0.33, 0.34, 0.34, 0.34, 0.34, 0.34, 0.35, 0.35, 0.35, 0.35, 0.35, 0.35, 0.36, 0.36, 0.36, 0.37, 0.37, 0.37, 0.38, 0.38, 0.38, 0.39, 0.39, 0.40, 0.40, 0.40, 0.40, 0.40, 0.40, 0.40, 0.40, 0.40, 0.40, 0.40, 0.40, 0.41, 0.41, 0.41, 0.41, 0.41, 0.41, 0.42, 0.42, 0.42, 0.42, 0.42, 0.42, 0.42, 0.42, 0.42, 0.42, 0.43, 0.43, 0.43, 0.43, 0.43, 0.44, 0.44, 0.44, 0.45, 0.46, 0.46, 0.46, 0.46, 0.46, 0.47, 0.47, 0.47, 0.48, 0.48, 0.48, 0.48, 0.49, 0.49, 0.49, 0.50, 0.50, 0.51, 0.51, 0.51, 0.52, 0.52, 0.52, 0.52, 0.52, 0.53, 0.53, 0.54, 0.54, 0.54, 0.55, 0.55, 0.55, 0.55, 0.56, 0.56, 0.57, 0.57, 0.57, 0.57, 0.58, 0.60, 0.60, 0.60, 0.61, 0.61, 0.61, 0.61, 0.62, 0.64, 0.64, 0.64, 0.65, 0.67, 0.67, 0.67, 0.69, 0.70, 0.71, 0.72, 0.72, 0.74, 0.75, 0.77, 0.77, 0.78, 0.80, 0.80, 0.81, 0.82, 0.84, 0.86, 0.87, 0.87, 0.91, 0.92, 0.94, 0.96, 1.04, 1.11, 1.17, 1.19, 1.21, 1.28, 1.52 and 4.58 mg/kg

According to the current procedure (2015 JMPR) sufficient data of detected residues are available to estimate a maximum residue level. The upper 95 percent one tailed confidence limit of the ninety-fifth percentile of the detected residues is 0.92 mg/kg.
The Meeting estimated a maximum residue level of 1 mg/kg and a median residue of 0.26 mg/kg.

Animal feeds

Almond hulls

The critical GAP for tree nuts is from the United States and consists of two applications of 70 g ai/ha with a RTI of 7 days and a PHI of 14 days.
Residues of thiamethoxam in independent trials provided to the current Meeting approximating the critical GAP were (n=5): 0.16, 0.18, 0.32, 0.55 and 0.62 mg/kg on an as received basis.

The Meeting estimated a maximum residue level of 2 mg/kg (on a dry weight basis, using a DM content of 90 percent), a median residue of 0.32 mg/kg for almond hulls.

Residues of clothianidin in independent trials approximating the critical GAP for thiamethoxam were (n=5): <0.01, 0.01, 0.02, 2 x 0.04 mg/kg on an as received basis.

Fate of residues during processing

The nature of the residue for thiamethoxam on processing was considered by the JMPR in 2010. Thiamethoxam is stable under conditions simulating pasteurization, baking/boiling/brewing and sterilization.

The Meeting received data showing the effect of drying on the magnitude of the residue in goji berry. Residues of thiamethoxam in dried goji berry from independent trials approximating the GAP were:

Sun-dried goji berries (n=5): 0.0465, 0.096, 0.145, 0.705 and 1.4 mg/kg

Hot air-dried goji berries (n=5): 0.0535, 0.215, 0.235, 1.45 and 1.7 mg/kg.

The Meeting noted that residues in sun-dried and hot air-dried goji berries were similar. The Meeting estimated a maximum residue level of 5 mg/kg, a STMR of 0.225 mg/kg and a HR of 1.7 mg/kg for dry goji berry based on the combined dataset.

Processing factors for dried goji berry were estimated by the Meeting and are summarised in the table below. The Meeting noted that the individual Pf for sun-dried and hot air-dried goji berries were similar and decided to estimate a Pf on the basis of all the data.

Processing factors and residue estimates for thiamethoxam in goji berry

		Processing factors	
Raw commodity	**Processed commodity**	**Individual levels**	**Best estimate (combined dataset)**
Goji berry	Sun-dried goji berry	1.1, 1.5, 2.3, 2.4, 4.6	2.53
	Hot air-dried goji berry	1.6, 2.65, 2.85, 3.75, 10.4	

Residues in animal commodities

The Meeting added the residue levels for almond hulls to the dietary burden calculation used by the 2021 JMPR Meeting. Dietary burden calculations are provided in Annex 6. The dietary burden estimates remain unchanged from the JMPR 2021, and the Meeting confirmed the previous recommendations of maximum residue levels in animal products.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and IESTIs assessments.

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

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities (except poultry): *thiamethoxam and clothianidin* (clothianidin considered separately).

Definition of the residue for dietary risk assessment for poultry: *sum of thiamethoxam, CGA 265307, and MU3, expressed as thiamethoxam and clothianidin* (clothianidin considered separately).

The residue is not fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for thiamethoxam is 0–0.08 mg/kg bw. The IEDIs for thiamethoxam were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2023 JMPR Report.

The IEDIs ranged from 1 to 7 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of thiamethoxam from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for thiamethoxam is 1.0 mg/kg bw. The IESTIs for thiamethoxam were calculated for the food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMR-Ps were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2023 JMPR Report.

The IESTIs ranged from 0 to 1 percent of the ARfD for children and from 0 to 1 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of thiamethoxam from uses considered by the present Meeting is unlikely to present a public health concern.

5.32 Thiophanate-methyl (077) (T,R)**

TOXICOLOGY

Thiophanate-methyl is the ISO-approved common name for dimethyl 4,4′-(O-phenylene)-*bis*(3-thioallophanate) (IUPAC), which has the Chemical Abstracts Service number 23564-05-8. Thiophanate-methyl is a systemically active fungicide that inhibits the synthesis of β-tubulin. Thiophanate-methyl was previously evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1973, 1975, 1977, 1995, 1998, 2006 and 2017. At JMPR 1998 an ADI of 0–0.08 mg/kg body weight (bw) was established and this was maintained until JMPR 2017 when a new ADI of 0–0.09 mg/kg bw was established. In addition, in 2017 an ARfD of 1 mg/kg bw was established. The 2017 Meeting did not receive any information on the toxicology of carbendazim, a significant plant and livestock metabolite of thiophanate-methyl and for this reason the Meeting was unable to determine the residue definition of the substance and complete its evaluation.

As a consequence of the submission of new data, the present Meeting re-evaluated thiophanate-methyl. A literature search performed by the monographers identified two potentially relevant publications.

A summary of the information from the JMPR 2017 evaluation is presented below; the text taken from that monograph is shown in italics.

Biochemical aspects

The absorption, distribution, metabolism and excretion (ADME) of thiophanate-methyl, as well as its toxicokinetics, were described in the 2017 monograph.

> *Thiophanate-methyl is rapidly and almost completely absorbed (88–89 percent) after oral administration of a dose of 14 mg/kg bw in mice (Noguchi, 1970; Noguchi & Kosaka, 1971). Thiophanate-methyl is rapidly excreted (approximately 47 percent in urine and approximately 40 percent in bile) within 48 hours of administration in rats (Bernard, 2011b). Plasma half-lives were 1.6–2.8 hours after a dose of 13 mg/kg bw and 2.4–7.8 hours after a dose of 140–170 mg/kg bw in rats (Tanoue et al, 1992a, b). Absorption and excretion patterns were similar in male and female rats (Bernard, 2011b). There is no potential for accumulation (Kosaka et al., 1975). Thiophanate-methyl is widely distributed in rats, with highest levels in liver and thyroid (Tanoue et al., 1992a, b). The major urinary metabolite in rats was 5-hydroxycarbendazim sulphate (5-OH-MBC-S at 8.7 percent of the administered dose). Minor metabolites were 5- and 4-hydroxythiophanate-methyl, each representing approximately 2 percent of the administered radiolabel. The major faecal metabolites were 4-hydroxythiophanate-methyl (6–10 percent), 5-OH-MBC-S (2–5 percent) and carbendazim (2–3 percent). Unchanged thiophanate-methyl accounted for*

approximately 20–24 percent and 50 percent of the administered radiolabel after repeated low and high doses, respectively, (Nabetani & Mori, 1993).

Two oral, single-dose kinetic studies (one in ICR mice and one in B6D2F1 mice) performed with unlabelled thiophanate-methyl and administered by gavage at 2000 mg/kg bw, showed systemic exposure and distribution to the testis of thiophanate-methyl and its major metabolites. These studies also demonstrated that carbendazim is a major plasma metabolite in the mouse, but levels were lower in the testes.

An in vitro comparative human/rat metabolism study showed that the metabolic pathways in both species were identical and no unique metabolite was detected in human microsome samples.

Toxicological data

The acute toxicity of thiophanate-methyl was described in the JMPR 2017 monograph. No new acute toxicity studies were submitted for the purposes of this evaluation.

In rats, the oral LD_{50} was greater than 5000 mg/kg bw (Nishibe, 1990b); in rabbits the dermal LD_{50} was greater than 2000 mg/kg bw (Nishibe, 1990c); and in rats, the inhalation LC_{50} was 1.7–1.98 mg/L (Nishibe, 1987). Thiophanate-methyl was not irritating to the skin or eyes of rabbits (Nishibe, 1987, 1986). Thiophanate-methyl was a skin sensitizer in a Magnusson and Kligman test in guinea pigs (Nishibe, 1989), but not in a Buehler test (Nishibe & Mochizuiki, 1993).

The short-term toxicity of thiophanate-methyl was described in the JMPR 2017 monograph. No new studies were submitted for the purposes of this evaluation.

In repeated-dose oral toxicity studies with thiophanate-methyl in mice, rats and dogs, the most sensitive organs were the liver, thyroid and the haematological system.

In a pre-guideline 6-month dietary toxicity study (with limited investigations) in mice administered dietary thiophanate-methyl concentrations of 0, 12.8, 64, 320, 1600 or 8000 ppm (equal to 0, 2, 10, 50, 250 and 1240 mg/kg bw per day for males and 0, 2, 11, 52, 231 and 1630 mg/kg bw per day for females, respectively), the NOAEL was 1600 ppm (equal to 231 mg/kg bw per day) based on decreased body weight gain and haematological changes indicative of slight anaemia in males and females at 8000 ppm (equal to 1240 mg/kg bw per day) (Hashimoto, 1970b).

In a 13-week dietary toxicity study in rats administered dietary thiophanate-methyl concentrations of 0, 200, 2200, 4200, 6200 or 8200 ppm (equal to 0, 13.9, 155, 293, 427 and 565 mg/ kg bw per day for males and 0, 15.7, 173, 323, 479 and 647 mg/kg bw per day for females, respectively), the NOAEL was 200 ppm (equal to 13.9 mg/kg bw per day) based on haematological changes indicative of slight anaemia, increased thyroid and liver weights, follicular hyperplasia and hypertrophy of the thyroid and hepatocellular hypertrophy and increased lipofuscin pigment in both sexes and increased severity of glomerulonephrosis in males observed at 2200 ppm (equal to 155 mg/kg bw per day) (Nishibe & Takaori, 1990).

In a pre-guideline 6-month dietary toxicity study (with limited investigations) in rats administered dietary thiophanate-methyl concentrations of 0, 12.8, 64, 320, 1600 or 8000 ppm (equal to 0, 1, 4, 20, 95 and 500 mg/kg bw per day for males and 0, 1, 5, 22, 110

and 660 mg/kg bw per day for females, respectively), the NOAEL was 1600 ppm (equal to 95 mg/kg bw per day) based on decreased body weight gain, haematological changes indicative of slight anaemia, decreased glucose levels and increased cholesterol levels, increased thyroid weights and histological changes in the thyroid in males and females at 8000 ppm (equal to 500 mg/kg bw per day) (Noguchi & Hashimoto, 1970c).

In a 3-month toxicity study in dogs, administering thiophanate-methyl by gelatine capsule at doses of 0, 50, 200 and 800/400 mg/kg bw per day, the LOAEL was 50 mg/kg bw per day based on the hypertrophy of the follicular epithelial cells of the thyroid at this dose level (Auletta, 1991).

In a pre-guideline 2-year toxicity study (with limited investigations) in dogs administered thiophanate-methyl by gelatine capsule at doses of 0, 2, 10, 50 or 250 mg/kg bw per day, the NOAEL was 10 mg/kg bw per day based on effects on thyroid weight and histopathology of the thyroid in both sexes at 50 mg/kg bw per day (Hashimoto et al., 1972).

The overall NOAEL for the studies in dogs was 10 mg/kg bw per day, and the overall LOAEL was 50 mg/kg bw per day.

The long-term toxicity and carcinogenicity of thiophanate-methyl were described in the JMPR 2017 monograph. No new studies were submitted for the purposes of this evaluation.

In a 18-month carcinogenicity study in CD-1 mice, thiophanate-methyl was administered at dietary concentrations of 0, 150, 640, 3000 or 7000 ppm (equal to 0, 24, 99, 468 and 1079 mg/kg bw per day for males and 0, 29, 123, 558 and 1329 mg/kg bw per day for females, respectively). The NOAEL for chronic toxicity and carcinogenicity was 150 ppm (equal to 29 mg/kg bw per day) based on the hepatocellular centrilobular hypertrophy at nine months and hepatocellular adenomas in females observed at 640 ppm (equal to 123 mg/kg bw per day) (Tompkins, 1992).

In a 2-year combined chronic toxicity/carcinogenicity study in Fisher 344 rats administered dietary thiophanate-methyl concentrations of 0, 75, 200, 1200 or 6000 ppm (equal to 0, 3.3, 8.8, 54 and 281 mg/kg bw per day for males and 0, 3.8, 10.2, 64 and 335 mg/kg bw per day for females, respectively), the NOAEL for chronic toxicity and carcinogenicity was 200 ppm (equal to 8.8 mg/kg bw per day) based on reduced body weight gain in both sexes; increased total cholesterol and total protein in both sexes; decreased albumin to globulin ratio in both sexes at 12 and/or 18 months; decreased levels of chloride and potassium; decreased T4 and T3 and increased TSH in males at 24 months; increased urinary protein and granular kidneys in males; follicular cell hyperplasia and hypertrophy in the thyroid in both sexes at 12 and 24 months; a possible increase in the incidence of thyroid follicular cell adenoma in males; centrilobular hepatocellular hypertrophy and occurrence of lipofuscin pigment in both sexes at 12 and 24 months; lipidosis of the adrenal cortex in females at 12 months; and increased severity of nephropathy in both sexes at 24 months observed at 1200 ppm (equal to 54 mg/kg bw per day). In males, the incidence of thyroid follicular cell adenoma was increased at 1200 ppm and above, but reached statistical significance only at 6000 ppm (Takaori, 1993).

A mechanistic study in rats showed that thiophanate-methyl induced cytochromes CYP450 (not further specified) and cytochrome b5 as well as uridine diphosphate

[Erratum from 2017 report item] glucuronosyltransferase (UDPGT), an enzyme that plays an important role in the clearance of T4 in the liver. Thiophanate-methyl also inhibited porcine thyroid microsomal peroxidase, an enzyme involved in thyroid hormone synthesis. However, this was not confirmed in more recent studies. Four in vitro TPO (thyroperoxidase) activity inhibition assays of thiophanate methyl in different species (rat, dog, pig, human) (Haines, 2018a, b, c and d) were submitted to explore further the potential underlying mechanism of the thyroid effects seen with thiophanate-methyl in rats. These studies showed that thiophanate-methyl does not inhibit TPO.

T4 supplementation counteracted the hypertrophy of the thyroid and the TSH response, indicating that thiophanate-methyl caused the hypertrophy by negative feedback mechanism. The mechanistic study demonstrates that the thyroid effects resulting from thiophanate-methyl are likely to be the result of a reduction in thyroid hormones. In another study, thiophanate-methyl induced increases in CYP3A and CYP2B1 in the liver of rats (Takaori, 1993; Paolini et al., 1999).

The 2017 Meeting concluded that thiophanate-methyl was carcinogenic in mice and rats. That Meeting considered the different modes of action that might underlie the tumour induction observed. The effects on the thyroid, including the induction of thyroid follicular cell adenoma in rats, may be secondary effects resulting from liver enzyme induction that enhances thyroid hormone excretion and leads to perturbations in systemic thyroid hormone levels and an increase in TSH concentration. The continuous stimulation of the thyroid gland by TSH is known to cause follicular cell hypertrophy/hyperplasia and, depending on dose and time, to result in follicular cell adenomas/adenocarcinomas. Rodents are particularly sensitive to any decreases in T4 and T3 levels that might result from liver enzyme induction. This is a well-established adverse outcome pathway without relevance for humans. Another possible mode of action for the carcinogenic effect may be the interference of the thiophanate-methyl metabolite carbendazim with mitotic spindle proteins leading to aneuploidy (see below).

The genotoxicity of thiophanate-methyl was described in the JMPR 2017 monograph.

Thiophanate-methyl was tested in an adequate range of in vitro and in vivo assays for genotoxicity. Thiophanate-methyl did not cause gene mutations or structural chromosomal aberrations; however, it caused changes in chromosome number (aneuploidy) both in vitro and in vivo. Induction of micronucleus formation in B6D2F1 mice was seen after single doses (500 mg/kg bw and above), but the response was about six times lower when compared with that for the metabolite of thiophanate-methyl, carbendazim (Myhr & Brusick, 1981; McSheehy et al., 1984; Murli, 1988; Nishibe, 1990; Barale et al., 1993; Marshall, 1996a, b; Proudlock, 1999).

Carbendazim caused changes in chromosome number (aneuploidy) both in vitro and in vivo (in somatic cells and germ cells) as a result of its interference with mitotic spindle proteins. The nature of the mechanism is thus consistent with the identification of a threshold dose below which no toxicological effect would occur. Like thiophanate-methyl, carbendazim did not cause gene mutations or structural chromosomal aberrations.

In 2017, the Meeting concluded that the genotoxic effect of thiophanate-methyl was a threshold phenomenon and was probably related to the production of carbendazim.

Two new micronucleus tests, one in bone marrow and one in spermatids were provided but were not considered useful for the assessment of aneuploidy.

The present Meeting confirmed that thiophanate-methyl causes aneuploidy, a threshold phenomenon.

The present Meeting also confirmed that thiophanate-methyl is unlikely to pose a carcinogenic risk to humans at dietary dose levels.

The reproductive and developmental toxicity of thiophanate-methyl was described in the JMPR 2017 monograph. No new studies were submitted for the purposes of this evaluation.

In a two-generation dietary reproductive toxicity study in rats administered thiophanate-methyl at dietary doses of 0, 200, 630 or 2000 ppm (equal to pre-mating doses of 0, 14.6, 46.0 and 147.1 mg/kg bw per day for males and 16.8, 52.2 and 164.3 mg/kg bw per day for females, respectively), the NOAEL for parental toxicity was 200 ppm (equal to 14.6 mg/kg bw per day) based on thyroid hyperplasia in males and increased TSH levels in females at 630 ppm (equal to 46 mg/kg bw per day). The NOAEL for offspring toxicity was 200 ppm (equal to 16.8 mg/kg bw per day) based on decreased body weights (in F2b) during lactation, at 630 ppm (equal to 52.2 mg/kg bw per day). The NOAEL for reproductive toxicity was 2000 ppm (equal to 147 mg/kg bw per day), the highest dose tested (Müller, 1993; Müller & Singer, 1995).

In a developmental toxicity study in rats administered gavage doses of thiophanate-methyl of 0, 100, 300 or 1000 mg/kg bw per day, the NOAEL for maternal toxicity was 300 mg/kg bw per day based on a reduced body weight gain at 1000 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 1000 mg/kg bw per day, the highest dose tested (Rodwell, 1981a, b).

In a developmental toxicity study in rabbits administered gavage doses of thiophanate-methyl of 0, 5, 10, 20 and 40 mg/kg bw per day, the NOAEL for maternal toxicity was 10 mg/kg bw per day based on a reduced body weight gain at 20 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 20 mg/kg bw per day based on supernumerary thoracic ribs at 40 mg/kg bw per day. This effect was considered unlikely to be an effect of a single dose (York, 1997a,b).

The 2017 Meeting concluded that thiophanate-methyl was not teratogenic. In the absence of any new information, the present Meeting re-affirmed the same conclusion.

The neurotoxic and immunotoxic potentials of thiophanate-methyl were described in the JMPR 2017 monograph. No new studies were submitted for the purposes of this evaluation.

In a study of acute neurotoxicity in rats administered gavage doses of thiophanate-methyl of 0, 50, 125, 500, 1000 or 2000 mg/kg bw, the NOAEL for general toxicity was 125 mg/kg bw based on transient reductions in body weight gains (including

body weight losses) and feed consumption at 500 mg/kg bw. The NOAEL for neurotoxicity was 2000 mg/kg bw, the highest dose tested (Foss, 2005).

In a 13-week study of neurotoxicity in rats administered thiophanate-methyl at dietary doses of 0, 100, 500 or 2500 ppm (equal to 0, 6.2, 30 and 150 mg/kg bw per day for males and 0, 6.8, 35 and 166 mg/kg bw per day for females, respectively), the NOAEL for general toxicity was 500 ppm (equal to 30 mg/kg bw per day) based on decreased body weights and feed consumption in females and increased liver and thyroid weights in both sexes at 2500 ppm (equal to 150 mg/kg bw per day). The NOAEL for neurotoxicity was 2500 ppm (equal to 150 mg/kg bw per day), the highest dose tested (Foss, 2007).

The 2017 Meeting concluded that thiophanate-methyl was not neurotoxic. In the absence of any new information the present Meeting re-affirmed the same conclusion.

No immunotoxicity tests with thiophanate-methyl were available. However, the data from the available toxicity studies did not indicate an immunotoxic potential for thiophanate-methyl.

The 2017 Meeting concluded that thiophanate-methyl was unlikely to be immunotoxic. In the absence of any new information, the present Meeting re-affirmed the same conclusion.

Toxicological data on metabolites and/or degradates

The toxicological characterization of some plant/livestock metabolites of thiophanate-methyl was addressed in the JMPR 2017 monograph. It is stated there that the main residues in crops and livestock were thiophanate-methyl, carbendazim, 5-OH-MBC and 5-OH-MBC-S.

As major rat metabolites of the parent, the toxicities of 5-OH-MBC and 5-OH-MBC-S were considered in the 2017 evaluation to be covered by that of thiophanate-methyl.

New data on metabolites 4-OH-TM and 5-OH-MBC

Two new in vivo bone marrow micronucleus studies, one with 4-OH-TM, and one with 5-OH-MBC were negative, however both studies had limitations and were considered to be potentially false negatives. Therefore, it cannot be excluded that both 4-OH-TM and 5-OH-MBC are aneugenic like their precursors (thiophanate-methyl and carbendazim, respectively).

Assessment of metabolite carbendazim

Carbendazim itself is used as a pesticide. The JMPR 1995 Meeting established an ADI of 0–0.03 mg/kg bw per day, and the 2005 Meeting added ARfDs of 0.1 mg/kg bw for women of child-bearing age and 0.5 mg/kg bw for the general population.

For the present Meeting insufficient toxicological information was submitted on carbendazim to allow a re-evaluation of this metabolite and thus confirm or amend the reference values established in 1995 (ADI) and 2005 (ARfD). The newly submitted mouse kinetic studies with thiophanate-methyl indicate that carbendazim is a major plasma metabolite of thiophanate-methyl. However, it is well established that carbendazim is significantly more toxic than thiophanate-methyl. In view of this, and in line with the established practice of adopting the threshold of toxicological concern (TTC) approach for metabolites with no (or limited) test data,

the present Meeting agreed to use the TTC Cramer class III value of 1.5 µg/kg bw per day for both the chronic and acute dietary risk assessment of carbendazim as a metabolite of thiophanate methyl as a conservative value. The genotoxicity (direct DNA reactivity) TTC value was considered inappropriate in this case because in the period since the last JMPR evaluation of carbendazim in 2005, no significant new information has emerged to challenge the conclusion reached then, that carbendazim is an aneugen with a threshold mechanism.

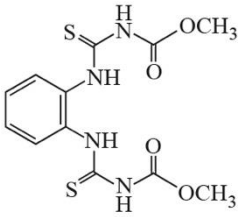
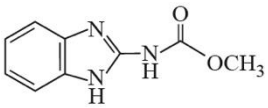
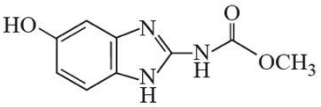
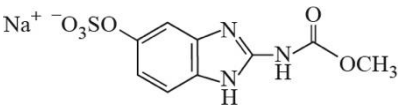
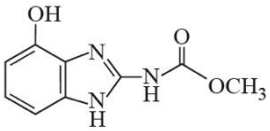
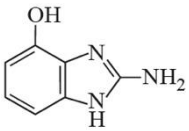
New information on metabolites 5-OH-MBC and 5-OH-MBC-S

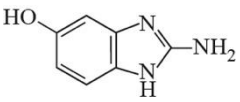
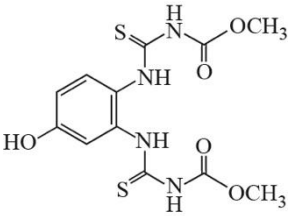
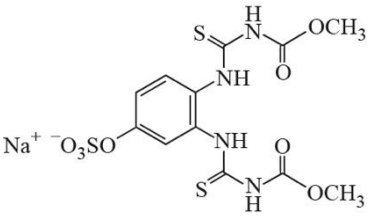
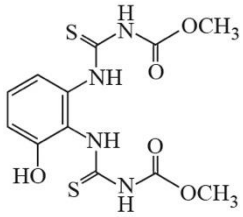
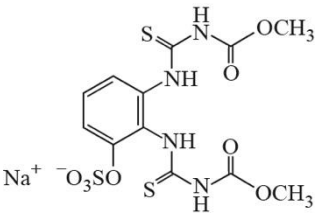
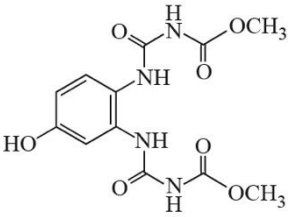
The present Meeting reconsidered the conclusion, previously reached, that the metabolites 5-OH-MBC and 5-OH-MBC-S, as major rat metabolites of thiophanate-methyl, are covered by the parent. Given their close structural similarity to carbendazim and an in silico analysis submitted for the purpose of this evaluation showing the same mutagenic (aneugenic) alerts as carbendazim, the Meeting agreed that both metabolites should be treated as for carbendazim. Therefore the TTC Cramer class III value of 1.5 µg/kg bw per day should be used in the dietary risk assessment of these metabolites if required.

The current evaluation has also identified additional plant/livestock metabolites (4-OH-MBC, 4-OH-TM, 4-OH-TM-S, 3-OH-TM, 3-OH-TM-S, 5-OH-2-AB, 4-OH-2-AB and 4-OH-FH-432). A toxicological characterization of these metabolites was performed using genotoxicity in silico analyses and structural similarity considerations.

The table below summarizes the available toxicological information on all the plant and livestock metabolites of interest and the associated toxicological reference values (TRVs).

Summary of toxicological characterization of plant/livestock metabolites

Compound, codes and structure	Major rat metabolite (>10% AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Toxicological reference values
Thiophanate-methyl (TM) 	Parent	Aneugenic (data)	Full dataset	ADI: 0–0.09 mg/kg bw per day ARfD: 1 mg/kg bw
Carbendazim (MBC) 	Yes, but not covered by parent, as well-established MBC more potent than TM	Aneugenic (data)	Insufficient data to establish specific TRVs	TTC Cramer class III: 1.5 µg/kg bw per day
5-OH-MBC 	Yes, but not covered by parent as similar to MBC, which is more potent than TM	Aneugenic (QSAR and RA from MBC); Negative in vivo micronucleus study (considered potential false negative)	No data but close structural similarity to MBC, hence MBC TRVs	TTC Cramer class III: 1.5 µg/kg bw per day
5-OH-MBC-S 	Yes, but not covered by parent as similar to MBC, which is more potent than TM	Aneugenic (QSAR and RA from MBC)	No data but close structural similarity to MBC, hence MBC TRVs	TTC Cramer class III: 1.5 µg/kg bw per day
4-OH-MBC 	No	No data but close structural similarity to MBC, so considered aneugenic	No data but close structural similarity to MBC, hence MBC TRVs	TTC Cramer class III: 1.5 µg/kg bw per day
4-OH-2-AB 	No	Aneugenic (QSAR and RA from MBC)	No data but close structural similarity to MBC, hence MBC TRVs	TTC Cramer class III: 1.5 µg/kg bw per day

5-OH-2-AB 	No	No data but close structural similarity to MBC, so considered aneugenic	No data but close structural similarity to MBC, hence MBC TRVs	TTC Cramer class III: 1.5 µg/kg bw per day
4-OH-TM 	No	Aneugenic (QSAR and RA from TM) Negative in vivo micro-nucleus (considered potential false negative)	No data but close structural similarity to TM, hence TM TRVs	ADI: Covered by parent ARfD: Covered by parent
4-OH-TM-S 	No	Aneugenic (QSAR and RA from TM)	No data but close structural similarity to TM, hence TM TRVs	ADI: Covered by parent, ARfD: Covered by parent
3-OH-TM 	No	No data but close structural similarity to TM, so aneugenic	No data but close structural similarity to TM, hence TM TRVs	ADI: Covered by parent ARfD: Covered by parent
3-OH-TM-S 	No	No data but close structural similarity to TM, so aneugenic	No data but close structural similarity to TM; hence TM TRVs	ADI: Covered by parent ARfD: Covered by parent
4-OH-FH-432 	No	Aneugenic (QSAR and RA from TM)	No data	TTC Cramer class III: 1.5 µg/kg bw per day

RA: Read-across; TM: Thiophanate-methyl; MBC: Carbendazim; TTC: Threshold of toxicological concern; QSAR: Quantitative structure–activity relationship; ADI: Acceptable daily intake; ARfD: Acute reference dose

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of thiophanate-methyl residues on the human intestinal microbiome.

Human data

Thiophanate-methyl has been commercially produced since 1969. No health effects related to thiophanate-methyl have been reported in manufacturing plant personnel or from agricultural use.

The present Meeting concluded that the existing database on thiophanate-methyl was adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

Toxicological evaluation

The Meeting re-affirmed the ADI of 0–0.09 mg/kg bw for thiophanate-methyl established by the 2017 Meeting.

The Meeting re-affirmed the ARfD of 1 mg/kg bw for thiophanate-methyl established by the 2017 Meeting.

An addendum to the toxicological monograph was prepared.

Levels relevant to risk assessment of thiophanate-methyl

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity[a]	Toxicity	150 ppm, equal to 29 mg/kg bw per day	640 ppm, equal to 123 mg/kg bw per day
		Carcinogenicity	150 ppm, equal to 29 mg/kg bw per day	640 ppm, equal to 123 mg/kg bw per day
Rat	Acute neurotoxicity study[b]	Neurotoxicity	2000 mg/kg bw[c]	-
	Two-year studies of toxicity and carcinogenicity[a]	Toxicity	200 ppm, equal to 8.8 mg/kg bw per day	1200 ppm, equal to 54 mg/kg bw per day
		Carcinogenicity	200 ppm, equal to 8.8 mg/kg bw per day	1200 ppm, equal to 54 mg/kg bw per day
	Two-generation study of reproductive toxicity[a]	Reproductive toxicity	2000 ppm, equal to 147 mg/kg bw per day[c]	-
		Parental toxicity	200 ppm, equal to 14.6 mg/kg bw per day	630 ppm, equal to 46 mg/kg bw per day
		Offspring toxicity	200 ppm, equal to 16.8 mg/kg bw per day	630 ppm, equal to 52.2 mg/kg bw per day
	Developmental toxicity study[b]	Maternal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
		Embryo/fetal toxicity	1000 mg/kg bw per day[c]	-
Rabbit	Developmental toxicity study[b]	Maternal toxicity	10 mg/kg bw per day	20 mg/kg bw per day
		Embryo/fetal toxicity	20 mg/kg bw per day	40 mg/kg bw per day
Dog	13-week and 1-year studies of toxicity[d, f]	Toxicity	10 mg/kg bw per day	50 mg/kg bw per day

[a] *Dietary administration;* [b] *Gavage administration;* [c] *Highest dose tested;*
[d] *Two or more studies combined;* [f] *Capsule administration*

*Acceptable daily intake (ADI)**

0–0.09 mg/kg bw

*Acute reference dose (ARfD)**

1 mg/kg bw

* Applies to thiophanate-methyl, and the following metabolites: 3-OH-TM, 3-OH-TM-S, 4-OH-TM and 4-OH-TM-S, expressed as thiophanate-methyl.

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 thiophanate-methyl
(All re-affirmed information is italicised)

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	*Rapid and almost complete (up to 89% in rats)*
Dermal absorption	*≥ 53% at 0.3 mg/rat; ≥ 23% at 32 mg/rat*
Distribution	*Widespread distribution, highest concentrations found in liver and thyroid*
Potential for accumulation	*Low*
Rate and extent of excretion	*Rapid; 87% of AD in 48 hours*
Metabolism in animals	*Extensively metabolized* *Major metabolites are 5-OH-MBC-S, 5-OH-MBC and MBC*
Toxicologically significant compounds in animals and plants	Thiophanate-methyl, carbendazim, 3-OH-TM, 3-OH-TM-S, 4-OH-TM and 4-OH-TM-S
Acute toxicity	
Rat, LD_{50}, oral	*>5000 mg/kg bw*
Rat, LD_{50}, dermal	*>2000 mg/kg bw*
Rat, LC_{50}, inhalation	*>1.7 mg/L*
Rabbit, dermal irritation	*Not irritating*
Rabbit, ocular irritation	*Not irritating*
Guinea pig, dermal sensitization	*Sensitizing (Magnussen & Kligmann)*
Short-term studies of toxicity	
Target/critical effect	*Liver, thyroid, haematological effects*
Lowest relevant oral NOAEL	*10 mg/kg bw per day (dog)*
Lowest relevant dermal NOAEL	*No data*
Lowest relevant inhalation NOAEC	*No data*
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	*Body weight, clinical chemistry, urine analysis, histopathology of liver, thyroid, kidney, adrenal*
Lowest relevant NOAEL	*8.8 mg/kg bw per day (rat)*
Carcinogenicity	*Carcinogenic in mice (liver) and rats (thyroid)*[a] *Tumours are not relevant for humans due to differences in thyroid homeostasis between rodents and humans*
Genotoxicity	Genotoxic in vivo, threshold phenomenon (aneuploidy) confirmed; new, but inadequate, negative in vivo studies
Reproductive toxicity	

Target/critical effect	*No reproductive effects*
Lowest relevant parental NOAEL	*14.6 mg/kg bw per day (rat)*
Lowest relevant offspring NOAEL	*16.8 mg/kg bw per day (rat)*
Lowest relevant reproductive NOAEL	*147 mg/kg bw per day (rat)*
Developmental toxicity	
Target/critical effect	*Supernumerary ribs*
Lowest relevant maternal NOAEL	*10 mg/kg bw per day (rabbit)*
Lowest relevant embryo/fetal NOAEL	*20 mg/kg bw per day (rabbit)*
Neurotoxicity	*Not neurotoxic*
Acute neurotoxicity NOAEL	*2000 mg/kg bw, highest dose tested (rat)*
Subchronic neurotoxicity NOAEL	*150 mg/kg bw per day, highest dose tested (rat)*
Developmental neurotoxicity NOAEL	*No data*
Other toxicological studies	
Immunotoxicity	*No evidence from routine studies*
Mechanistic studies	Negative in vitro thyroid peroxidase assays in different species
Studies on toxicologically relevant metabolites	
Carbendazim	No new information
4-OH-TM	Negative bone marrow micronucleus study, but potentially false
5-OH-MBC	Negative bone marrow micronucleus study, but potentially false
5-OH-MBC, 5-OH-MBC-S, 4-OH-2-AB, 4-OH-TM, 4-OH-TM-S, 4-OH-FH-432	Aneugenic based on genotoxicity in silico analysis and read-across from carbendazim and thiophanate-methyl
Microbiological aspects	No data was submitted
Human data	No clinical cases or poisoning incidents have been recorded

[a] Unlikely to pose a carcinogenic risk to humans via exposure from the diet

Summary

	Value	Study	Safety factor
ADI	0–0.09 mg/kg bw [a]	Two-year study of toxicity and carcinogenicity (rat)	100
ARfD	1 mg/kg bw [a]	Acute neurotoxicity study (rat)	100

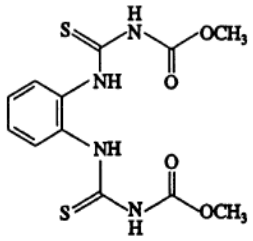
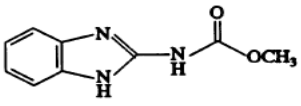
[a] Applies to thiophanate-methyl and metabolites 3-OH-TM, 3-OH-TM-S, 4-OH-TM and 4-OH-TM-S expressed as thiophanate-methyl

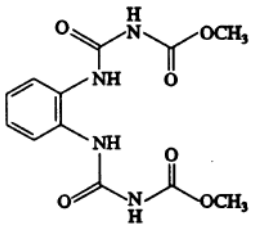
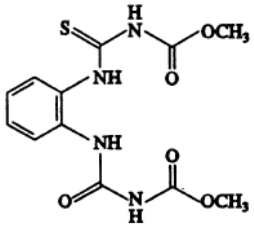
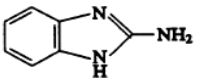
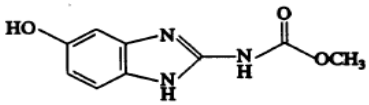
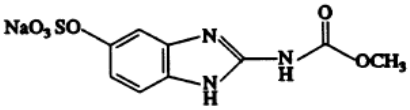
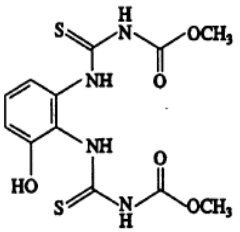
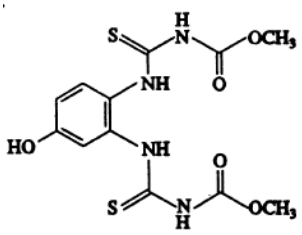
Thiophanate-methyl (77) and its related compounds carbendazim (72) and benomyl (69) are systemic benzimidazole fungicides with protective and curative action against a wide range of disease on cereals, fruits and vegetables. Those three compounds were first evaluated in 1973 (T,R) by JMPR and re-evaluated within the periodic review programme of CCPR in 1995 (T) and in 1998 (R). Since then, thiophanate-methyl was further evaluated in 2006 for toxicology and in 2003 for residues. Carbendazim was also further evaluated in 2003 (R), 2005 (T) and 2010 (residues in spices). Benomyl was not further evaluated since the 1998 periodic review because the data were not submitted to the JMPR. Currently the CXLs for thiophanate-methyl, carbendazim and benomyl are listed only under carbendazim (expressed as carbendazim), indicating the source of the data (B or C or Th) on which the MRL is based.

Under the periodic programme, the 2017 Meeting was requested to evaluate for toxicology and residues for thiophanate-methyl (77) and carbendazim (72). However, the review was unable to be completed due to lack of toxicology data. At the Fifty-fourth Session of the CCPR (2023), thiophanate-methyl was rescheduled for the periodic evaluation of both toxicology and residues. The 2017 Meeting received data on physical and chemical properties, metabolism and environmental fate, residue analysis, use patterns, supervised trials, processing and animal feeding studies for thiophanate-methyl. No additional residue data were submitted to the present Meetings.

The Meeting noted that carbendazim is an important metabolite of thiophanate-methyl. Carbendazim is also formed from benomyl. Therefore, the Meeting agreed that studies conducted with carbendazim or benomyl are relevant to the interpretation of the metabolism and environmental fate of thiophanate-methyl.

Chemical name, abbreviation, and structure of thiophanate-methyl and its metabolites discussed below

Chemical name	Abbreviation	Structure
Thiophanate-methyl; Dimethyl 4,4'-(o-phenylene)bis(3-thioallophanate) MW: 342.39 g/mol	TM	 Radio-labelled in the phenyl ring for metabolism and environmental fate studies
Carbendazim; Methyl (1H-benzimidazol-2-yl)carbamate MW: 191.21 g/mol	MBC	

Chemical name	Abbreviation	Structure
Dimethyl[(1,2-phenylene) bis(iminocarbonyl)]bis(carbamate); Dimethyl 4,4'-(o-phenylene)bis(allophanate)	FH-432	
Methyl N-[2-(N'-methoxycarbonylthioureido)phenyl aminocarbonyl]-carbamate; Methyl 4-[2-(methoxycarbonyl-2-thioureido)phenyl]-allophanate	DX-105	
2-Amino-1H-benzimidazole	2-AB	
Methyl (5-hydroxy-1H-benzimidazol-2-yl)carbamate	5-OH-MBC	
Sodium 2-(methoxycarbonylamino)-1H-benzimidazol-5-yl sulfate	5-OH-MBC-S	
Dimethyl 4,4'-(3-hydroxy-o-phenylene)bis(3-thioallophanate)	3-OH-TM	
Dimethyl 4,4'-(4-hydroxy-o-phenylene)bis(3-thioallophanate)	4-OH-TM	

Thiophanate-methyl is not volatile (vapour pressure, <8.8 x 10^{-6} Pa at 20°C) Thiophanate-methyl is hydrolytically stable at environmental pH (5-7) and ambient temperature (22°C) but hydrolytically degraded at higher pH and in the processing study. Aqueous photolysis (half-life, 2.17 days in sterilized aqueous solution at pH 5) is likely to be one of major degradation pathways in the environment.

Plant metabolism

The metabolism of thiophanate-methyl was studied in apple, grape, tomato, green bean, lima bean, soya bean, sugar beet, and wheat. Those plants were treated with foliar application, except tomato with soil treatment.

Apple

^{14}C-TM (phenyl ring label) formulated as a 64 percent WP was applied to outdoor apple trees. Three foliar applications were made at a rate of 3.9 kg ai/ha and samples were harvested one day and 7 days after the final application. Apples were rinsed twice with 50 percent aqueous methanol.

Total radioactive residues in whole apple decreased over time from 5.2 mg eq/kg (1 DALA) to 2.2 mg eq/kg (7 DALA). Of the total radioactivity, 93—97 percent TRR was present in rinsate. After washing, total residues were 2.6—7.0 percent TRR (0.71—0.76 mg eq/kg) in peel and 0.1—0.4 percent TRR (0.007—0.011 mg eq/kg) in pulp.

In extraction of residues in peel and pulp with a mixture solvent of methanol:Tris buffer:$CHCl_3$ (11:5:5, v/v/v), 53–70 percent TRR, 16–37 percent TRR and 5.0–15 percent TRR were counted in chloroform fraction, aqueous fraction and PES, respectively.

In whole apple (1 and 7 DALA), the parent TM was most major component, accounting for 45–65 percent TRR (0.96–3.3 mg/kg) and MBC compound was found at 22–33 percent TRR (0.72–1.2 mg eq/kg). FH-432 and DX-105 were found, but at much lesser extents of 3.5–5.1 percent TRR (0.11—0.18 mg eq/kg) and 1.3—2.1 percent TRR (0.046—0.068 mg eq/kg), respectively.

In this apple study, nearly all residues (>99 percent TRR) were present at the surface. TM and MBC were major components, accounting for up to 65 percent TRR or 3.3 mg eq/kg and 33 percent TRR or 1.2 mg eq/kg, respectively. FH-432 and DX-105 metabolites were found at up to 4.9 percent TRR or 0.18 mg eq/kg and 2.1 percent TRR or 0.068 mg eq/kg, respectively. Other various metabolites were detected, but at very minor levels.

Grape

^{14}C-TM (phenyl ring label) was applied to grape vines potted in a sandy loam soil. A single foliar application of ^{14}C-TM formulated as SC 500 g/L was made at a rate of 1.1 kg ai/ha. Mature grapes were harvested 35 days after the application. Grape berries attached to the stem was rinsed with aqueous acetonitrile. The rinsed grape was homogenized and grape juice was separated from the pomace. Pomace and grape leaves were extracted with aqueous acetonitrile and then acetone.

Total residues were 1.3 mg eq/kg in grape berries and 20 mg eq/kg in leaves. The TRR in grape berries comprised 22 percent TRR in rinsate, 37 percent TRR in juice and 41 percent TRR in pomace. Solvent extraction recovered 26 percent TRR from the pomace and 87 percent TRR from the leaves.

In grape berries, parent was found only in rinsate at 3.7 percent TRR. MBC was found at 54 percent TRR (0.68 mg eq/kg), distributed in rinsate (17 percent TRR), juice (16 percent TRR) and pomace (20 percent TRR). 5-OH-MBC was found at 13 percent TRR (0.16 mg eq/kg), distributed in juice (7.5 percent TRR) and pomace (5.4 percent TRR). FH-432, DX-105 and eight unknown metabolites were found, but at each below 4.1 percent TRR (less than 0.052 mg eq/kg).

In grape leaves, parent was not present. MBC was found at 72 percent TRR (14 mg eq/kg). FH-432 and 5-OH-MBC were found at 7.6 percent TRR (1.5 mg eq/kg) and 5.7 percent TRR (1.1 mg eq/kg), respectively.

Tomato

^{14}C-TM (phenyl ring label) was applied to tomato planted in a sandy loam soil and kept outdoors under a plastic roof. A SC formulation of ^{14}C-TM (500 g/L) was applied three times on the soil simulating drip irrigation. Three drip applications were made at rates of 0.70–2.31 kg ai/ha at 15–75 days after planting. Mature tomatoes were harvested 7 days after the last application. Harvest fresh tomato was rinsed with aqueous acetonitrile. The rinsed tomato was homogenized and tomato juice was separated from the pomace. Pomace was extracted with aqueous acetonitrile and then acetonitrile.

Total residue in mature tomato was 0.012 mg eq/kg, representing 0.5 percent TRR in rinsate, 61 percent TRR in juice and 39 percent TRR in pomace. Solvent extraction recovered 15 percent TRR from the pomace.

In juice and pomace, parent was not present. 2-AB and three unknown metabolites were detected, but below 0.01 mg eq/kg.

In application of TM by drip irrigation, TM did not lead to significant radioactive residues in tomato plant.

Green bean

Snap beans (3-4 cm long pods) were planted in pots in greenhouse and a single foliar application of ^{14}C-TM (label position not given) in 50 percent aqueous acetone at 5 g ai/hL was made. Samples were collected 14 days after treatment. Pods and leaves each was rinsed with methanol and then water.

Total radioactive residues were 0.47 mg eq/kg in pods, 23.4 mg eq/kg in leaves and 0.96 mg eq/kg in stem. Methanol extraction recovered about 93 percent of the total radioactivity, for pods and leaves, 70-80 percent of the extraction were counted in the rinsate.

Parent TM and DX-105 was present at 18 percent TRR (0.086 mg eq/kg) in pods (parent 16 percent and DX-105 2.7 percent). In leaves and stems, TM and DX-105 was present at 10 percent TRR (2.34 mg eq/kg; parent 9.9 percent and DX-105 0.05 percent) and 18 percent TRR (0.174 mg eq/kg; parent 18 percent and DX-105 0.37 percent), respectively. MBC was a major component, found at 48 percent TRR (0.226 mg eq/kg) in pods, 57 percent TRR (13.3 mg eq/kg) in leaves, and 45 percent TRR (0.435 mg eq/kg) in stems. FH-432 was detected at levels of 6.7-9.2 percent TRRs in the three parts of green beans.

In an additional experiment (greenhouse), conducted with non-labelled TM 70 percent WP

(168 g ai/hL), TM, MBC, were analysed by HPLC-UV. In the pods, leaves and stems, parent and MBC were major components, accounting for 58–91 percent and 8.1–32 percent, respectively. DX-105 (0.5–10 percent) and FH-432 (0.2–0.5 percent) were detected at minor levels in the three parts of beans.

Lima bean (with pods)

^{14}C-TM (phenyl ring label) formulated as 70 percent WP was applied to lima bean plants in a field plot. Twice foliar applications were made at a rate of 1.18 kg ai/ha, the first at 30 percent bloom and the second at 7 days after first application. The pods were harvested 28 DALA and the foliage were taken 35 DALA. Lima bean pods were rinsed with 50 percent aqueous acetone and foliage was not rinsed.

Total radioactive residues were 0.047 mg eq/kg in pods (28 DALA) and 1.4 mg eq/kg in foliage (35 DALA). TRR in pods rinsate was 0.001 mg eq/kg.

In extraction with a mixture of methanol:Tris buffer:chloroform (11:5:5, v/v/v), 57 percent TRR in pods (11 percent in chloroform fraction and 46 percent in aqueous methanol) and 64 percent TRR in foliage (28 percent in chloroform fraction and 36 percent in aqueous methanol) were extracted. 43 percent TRR and 35 percent TRR were remained in the PES of pods and foliage, respectively.

In the pods, parent and MBC were not found. As major components, two unknowns (metabolite C and D) were present in aqueous methanol fraction containing 46 percent TRR. In foliage, parent was not present but MBC was found at 26 percent TRR (0.35 mg eq/kg). Major unknown component A (hydrolysis to 2-AB and it is likely to be conjugate of MBC) found in foliage at 50 percent TRR (0.68 mg eq/kg; 36 percent TRR in aqueous methanol fraction), was very unstable and easily converted into 2-AB.

In this study, parent compound was not present in both pods and foliage of lima bean. MBC was found only in foliage as a major metabolite. Major polar metabolites A, C and D were present, however, they were not identified.

Soya bean (with pods)

Soya bean plants (3.5–4.5 cm pods) were sprayed once with ^{14}C-TM (label position not given) suspension of 70 g ai/hL and kept outdoors. Samples were collected 7 days (leaves) and 14 days (pods and leaves) after treatment. Methanol was used for dipping for ten minutes and extraction of residues from the pods and leaves.

Total radioactive residue was 60 mg eq/kg in pods (14 DAT). TRR in leaves decreased 341 mg eq/kg (7 DAT) to 181 mg eq/kg (14 DAT) over time. Methanol extraction recovered about 92 percent of the total radioactivity in pods and leaves, of which 90–95 percent was counted in the methanol dipping solution.

In pods (14 DAT), parent compound was present at 86 percent TRR (52 mg/kg). MBC was found at 9.4 percent TRR (5.6 mg eq/kg). In leaves (14 DAT), parent and MBC were found at 73 percent TRR (132 mg/kg) and 15 percent TRR (27 mg eq/kg), respectively. At 7 DAT, parent and MBC in the leaves were present at 82 percent TRR (279 mg/kg) and 11 percent TRR (38 mg eq/kg),

respectively. Minor components, FH-432 and DX-105 were detected only in leaves at less than 4.4 percent TRR. In both pods and leaves of soya bean, parent TM was predominant, accounting for 73–86 percent TRR and MBC was found as a major, accounting for 9.4–15 percent TRR.

Additionally, pods and leaves, sprayed with non-labelled TM solution of 5 g ai/hL or 70 g ai/hL of 50 percent aqueous acetone and kept under indoor and outdoor, were analysed by HPLC-UV. The results showed that TM and MBC were major components and FH-432 and DX-105 very minor in pods and leaves indoor and outdoor. Fraction of parent was higher in indoor pods than outdoor pods, indicating a faster degradation of the parent compound under outdoor conditions.

The Meeting noted that the metabolism of benomyl in soya bean evaluated by the 1998 JMPR is relevant to the interpretation of the metabolism of TM.

Soya bean plants were sprayed with [U-phenyl-^{14}C] benomyl at 2x0.11 kg ai/ha with 14 day intervals at early pod stage. In soya bean plants harvested after the first and second application and at 35 DALA, TRR was 22, 8 and 0.7 mg/kg as benomyl. The main residues in mature beans (dry) were benomyl (0.05 mg/kg; 7.1 percent TRR) and carbendazim (0.14 mg/kg benomyl eq; 20 percent TRR) and 2-AB (2-aminobenzimidazole, 0.42 mg/kg benomyl eq; 60 percent TRR). Significant loss of the methoxycarbonyl moiety to form 2-AB occurred only in soya bean seeds.

Sugar beet

^{14}C-TM (phenyl ring label) was applied to sugar beets as a 70 percent WP formulation with three foliar sprays (21-days intervals) at a rate of 0.39 kg ai/ha. The root, foliage and stem samples were collected separately on 21 days after final application. Total radioactive residues were 0.12 mg eq/kg in root, 0.026 mg eq/kg in root rinse (water wash), 2.8 mg eq/kg in stem and 3.3 mg eq/kg in foliage. In extraction using a solvent mixture of methanol:Tris buffer:chloroform (11:5:5, v/v/v), 43–67 percent TRR and 4.1–11 percent TRR were contained in chloroform fraction and aqueous methanol fraction, respectively. For root (51 percent TRR in the PES), 22 percent TRR was not released by cellulase and acid hydrolyses.

The parent compound was present at levels of 27 percent TRR (0.031 mg/kg) in root, 41 percent TRR (1.4 mg/kg) in foliage and 21 percent TRR (0.59 mg/kg) in stem. MBC was a major metabolite found, representing 15 percent TRR (0.018 mg eq/kg) in root, 26 percent TRR (0.84 mg eq/kg) in foliage and 24 percent TRR (0.67 mg eq/kg) in stem. FH-432 metabolite was found in foliage (13 percent TRR, 0.43 mg eq/kg) and stem (11 percent TRR, 0.30 mg eq/kg). 2-AB was detected in the PES subjected to hydrolyses of acid and base.

The Meeting noted that the metabolism of benomyl in sugar beet evaluated by the 1998 JMPR is relevant to the interpretation of the metabolism of TM.

Sugar beet plants were treated three times with [U-phenyl-^{14}C]benomyl at 0.55 kg ai/ha. Mature plants were harvested 3 weeks after the final treatment. Carbendazim represented 41 percent TRR and 19 percent TRR in the tops and roots respectively and 2-AB accounted for 1.9 percent and 0.36 percent TRR. In another study with sugar beets with five applications of benomyl at the same rate, the main residues in the tops were carbendazim (63 percent TRR), benomyl (3.7 percent TRR) and 2-AB (0.7 percent TRR). In the roots, only carbendazim (4.4 percent TRR) and 2-AB (trace, 4.4 percent TRR) were found.

Wheat

A single-spray application of ^{14}C-TM (phenyl ring label) formulated as 70 percent WP was made to spring wheat plants growing in a field plot. A rate of 0.75 kg ai/ha was applied to wheat plants just before the stem elongation stage and wheat samples were taken after 0 day, 28 days (foliage) and 69 days (straw, grain) of application of test substance.

Total radioactive residues were 9.9 mg eq/kg in 0 DAT plant, 0.36 mg eq/kg in foliage and 1.2 mg eq/kg in straw. TRR in grain was <0.01 mg eq/kg. 1.9 percent TRR and 0.5 percent TRR were present in rinsate of foliage and straw, respectively.

In extraction with a mixture of methanol: Tris buffer (pH 6.0) (11:5, v/v) and chloroform (grain and rinsates, excepted), 5.7 percent and 17 percent of the total radioactivity in foliage were contained in chloroform fraction and aqueous methanol fraction, respectively. In straw, 8 percent TRR and 12 percent TRR were contained in chloroform fraction and aqueous methanol fraction, respectively. Extractability of radioactivity in wheat samples was only 20–23 percent of the total radioactivity.

Radioactivity in unextracted residues was 78 percent TRR in foliage and 86 percent TRR in straw. Most of the radioactivity was lignin and cellulose materials, accounting for 61 percent TRR (0.22 mg eq/kg) in foliage and 65 percent TRR (0.74 mg eq/kg) in straw. This indicated that considerable residues were intrinsically incorporated into cellulosic and lignin type components of the cell wall.

In wheat foliage and straw, parent compound was not detected. MBC was found at 3.3 percent TRR (0.012 mg eq/kg; 0.8 percent in chloroform fraction; 2.5 percent in PES) in foliage and 4 percent TRR (0.043 mg eq/kg; 3.8 percent in chloroform fraction and 0.2 percent in PES) in straw. The amounts of parent and MBC in wheat grain was considered negligible with the low level of total radioactivity (<0.01 mg eq/kg).

In metabolism studies for TM, TM and the metabolite MBC were principal residues. TM accounted for up to 65 percent TRR (3.3 mg/kg in apple) and 86 percent TRR (0.20 mg/kg in green bean pods). MBC accounted for up to 48 percent TRR (0.23 mg eq/kg in green bean pods) and 54 percent TRR (0.68 mg eq/kg in grape). Amount of TM was 2–9 times greater than that of MBC in apple, sugar beet root and soya bean pods. On the contrary, amount of MBC was 2.6–15 times greater than that of TM in grape and green bean pods. Metabolites DX-105 and FH-432 (FH-432, up to 6.7 percent TRR, 0.031 mg eq/kg in green bean pods) were also found but very minor. For wheat grain, lima bean pods and tomato (soil treatment), both TM and MBC were not found. Metabolism of TM forming MBC might be a direct process involving cyclization resulting in side chain elimination. MBC might be also formed by cyclization via DX-105 or FH-432. MBC and other metabolites can be present in crop as conjugate forms with plant materials.

The Meeting noted that the metabolism of benomyl evaluated by the 1998 JMPR is relevant to the interpretation of the metabolism of TM.

In metabolism studies for benomyl, benomyl is metabolized in plants mainly to carbendazim. The postulated metabolic pathway of benomyl in plants includes loss of the butylcarbamoyl group to form carbendazim. To determine the amount of benomyl remaining in or on plant tissues, the sample was subjected to reflux under caustic conditions, in which

carbendazim is converted to 2-AB. In aquatic systems at pH 5 to 9, the hydrolytic, photochemical and biological degradation of carbendazim showed that 2-AB was the main degradation product. Based on these observations, it is likely that presence of 2-AB found in some plants may be due to caustic conditions.

In conclusion, thiophanate-methyl, carbendazim or benomyl treated in plants leads to presence of carbendazim in crops, accounting for significant portion.

Environmental fate in soil

The Meeting received information on soil aerobic metabolism, soil photolysis and aqueous hydrolysis properties.

Hydrolysis

The hydrolysis of TM in buffer solutions was studied at pH 5, 7, and 9 at 22—65°C. Half-life of TM, interpolated at 25°C, was 867, 36 and 0.7 days and at pH 5, 7 and 9, respectively. The major hydrolysis products were MBC (up to 16 percent on molar basis at 33 days, pH 7 and 22°C) and AV-1951.

Photolysis

In aqueous and soil photolysis, DT_{50} of TM in water was 2.17 days at pH 5 and DT_{50} of TM by soil photolysis was 0.75 days. TM degraded significantly to MBC by photolysis.

Aerobic degradation in soil

TM degraded rapidly. The major metabolite was MBC. Minor metabolites, DX-105, FH-432, CM-0237, CM-0238, 2-AB and AV-1951 were found in soil. The main degradation pathway of TM in soil proceeded through formation of MBC and various minor metabolites with ultimate formation of bound residues and carbon dioxide.

Half-life of TM in soil is 0.29, 0.5, 0.6, 0.7, 1, 1, 4 and 7 days (geometric mean: 1 days).

Half-life of MBC in soil is 39, 40, 50 and 58 days (geometric mean: 46 days).

TM is not persistent in soil with half-life of 1 day while MBC is moderately persistent with half-life of 46 days.

Rotational crop studies

For interpreting rotational crop studies, the use rates for primary crops submitted to the current Meeting ranged up to 4.2 kg ai/ha.

Confined rotational crop study

^{14}C-TM 70 percent WP formulation was applied once to bare soil (sandy loam) at a rate of 1.6 kg ai/ha. After 30, 120 and 365 days after treatment, lettuce, carrot and wheat were seeded and the plants were grown outdoor. TRR levels in rotational crops, carrot and lettuce, were generally decreased with prolonged PBIs. For wheat samples, consistent decrease was not shown with

longer PBI.

Parent was not detected in food commodities from rotational crops. Metabolites MBC and FH-432 were below 0.01 mg eq/kg in carrot roots and wheat grain and MBC in lettuce decreased 0.024 mg eq/kg (30-day PBI) to 0.003 mg eq/kg (365-day PBI).

In feed, parent was not detected. MBC and FH-432 could be detected in most feed crops at below approximately 0.1 mg eq/kg. 2-AB and 5-OH-2-AB could be detected in wheat matrices, but at below 0.1 mg eq/kg.

The 1998 JMPR report contained some additional confined rotational crop studies with carbendazim or benomyl relevant to TM.

A crop rotation study with lettuce and radishes grown on soil containing aged residues of carbendazim was conducted in Germany. Lettuce and radishes were sown in soil treated with 3 mg/kg carbendazim and aged for 224 days. On the day of planting the soil contained residues of 0.23 mg/kg carbendazim and a total ^{14}C residue of 2 mg/kg as carbendazim. Over a period of 84 days, the plants absorbed only a negligible amount of the radioactivity present in the soil (0.02 to 0.04 mg/kg in radishes and 0.03 to 0.06 mg/kg in lettuce).

In the United States two trials were conducted with loamy sand soil in a greenhouse treated with [2-^{14}C] carbendazim at the rate of 1.1 kg ai/ha and aged for 30 days or with 3.4 kg ai/ha and aged for 120 or 145 days. The soils were then planted with beet, cabbage and barley crops. In the first study, at the final harvest of the mature crop cabbage plants had total ^{14}C residues of about 0.03 mg/kg carbendazim equivalents, intact carbendazim representing <0.005 mg/kg. Barley straw had total ^{14}C residues of 0.05 mg/kg, with about 0.01 mg/kg intact carbendazim. Barley grain, beets and beet foliage contained total residue of <0.01 mg/kg at harvest. In the second study beets, beet foliage, cabbage, barley grain and barley straw at final harvest contained total residues of 0.012, 0.013, 0.053, 0.025 and 0.129 mg/kg respectively. The carbendazim concentration was about 0.03 mg/kg in cabbage and 0.005 mg/kg in barley straw.

Snap beans, sweet corn, carrots and tomatoes were planted in soil which had been treated with [2-^{14}C]benomyl at a rate of 2.2 kg/ha about one year before planting. No detectable levels of ^{14}C (<0.01 mg/kg as benomyl) were found in the edible portions. Leaves and stems from the plants showed trace residues (<0.1 mg/kg benomyl equivalents).

In rotational crop studies treated to soil with MBC or benomyl ^{14}C-labelled, MBC was present up to 0.03 mg/kg in food crop (cabbage) and up to 0.005 mg/kg in feed (barley straw).

Field rotational crop study

A single application of TM (500 g/L SC) was done to bare soil at a rate of 4.2 kg ai/ha during 2011—2012 in the United Kingdom of Great Britain and Northern Ireland and Spain. At nominal intervals of 30, 70, 120 and 365 days after the application, both carrot and spinach were planted in the United Kingdom of Great Britain and Northern Ireland and Spain, and spring barley was planted in the United Kingdom of Great Britain and Northern Ireland and spring wheat in Spain. In this study, no residues of TM and MBC were detected above 0.01 mg/kg for any rotational crop samples.

Carryover of TM and MBC residues into rotational crops is unlikely to occur.

Animal metabolism

Lactating goats

^{14}C-TM was administered to lactating goats for 5 consecutive days. Two goats were dosed orally in capsules twice daily at 52.4 and 57.3 ppm in the feed, corresponding to 1.15 mg/kg bw and 1.19 mg/kg bw, respectively. Milk, urine and faeces were collected during the dosing period. Approximately 14 hours after the last dose, goat was sacrificed with subsequent collection of organs and tissues.

Excretion in urine, faeces and milk was 56 percent, 14 percent and 1.5 percent (0.92 mg eq/kg) of the administered dose, respectively.

The mean residue concentration in milk was 0.92 mg eq/kg (max., 1.6 mg eq/kg). The radioactive residues in edible tissues were 0.12 mg eq/kg in muscle, 0.19 mg eq/kg in fat, 4.6 mg eq/kg in liver and 1.3 mg eq/kg in kidney.

Extraction of radioactivity in the milk and tissue by using different solvent systems was in the range of 58–84 percent of the total radioactivity. Acid and base hydrolyses on the liver PES further released 43 percent TRR.

Residues in milk appeared to reach plateau levels by day two of dosing. Parent was present at a very low level of 0.3 percent TRR (<0.01 mg/kg). 5-OH-MBC-S was a major component, accounting for 73 percent TRR (0.62 mg eq/kg). MBC was found at 10 percent TRR (0.085 mg eq/kg). Metabolites 5-OH-MBC (2.7 percent TRR), 4-OH-TM (1 percent TRR), 3-OH-TM-S (1.2 percent TRR) were found but at low levels.

In muscle, parent and MBC were present at 24 percent TRR (0.02 mg/kg) and 26 percent TRR (0.03 mg /kg), respectively. Metabolites 5-OH-MBC-S (7 percent TRR) and 3-OH-TM (3.5 percent TRR) were found but at low levels.

In fat, parent was present at 6.2 percent TRR (0.011 mg/kg). MBC was a predominant component, accounting for 45 percent TRR (0.083 mg eq/kg). Metabolite 3-OH-TM (3.5 percent TRR) was found but at low level.

In kidney, parent was present at 1.6 percent TRR (0.01 mg/kg). 5-OH-MBC-S was also a major component, accounting for 35 percent TRR (0.45 mg eq/kg). MBC and 4-OH-MBC were found at 21 percent TRR (0.27 mg eq/kg) and 17 percent TRR (0.23 mg eq/kg), respectively. Metabolites 5-OH-MBC (1.8 percent TRR) and 4-OH-TM (3.1 percent TRR) were found but at low levels.

In liver, parent was present at 0.8 percent TRR (0.04 mg/kg). MBC was found at 9.4 percent TRR (0.43 mg eq/kg). Metabolites, 4-OH-MBC and 5-OH-MBC were present at 5.8 percent TRR (0.27 mg eq/kg) and 7.2 percent TRR (0.32 mg eq/kg), respectively. Another major component (53 percent TRR, 2.4 mg eq/kg) present in liver was a found as an unknown fraction, comprising

32 percent TRR in aqueous methanol fraction and 21 percent TRR released from the post-extraction solids by protease enzyme treatment. The residues were characterized as di-hydroxy analogues of unknown TM metabolites, indicating that residues may exist as glucose conjugates in ionic association with various proteins. One metabolite was identified tentatively as a glucose conjugate of dihydroxy-2-AB with m/z 327.

The 1998 JMPR Report contained some additional metabolism studies on cows and goats with carbendazim or benomyl relevant to TM.

In the liver of the carbendazim-dosed cows, 4,5-DHHBC-G (S-[4,5-dihydro-5-hydroxy-2-(methoxycarbonylamino)-1H-benzimidazol-4-yl]glutathione) and other sulfur-linked dihydrohydroxy-carbendazim conjugates (15.2 percent) predominated, with smaller amounts of 4,5-DDBC (methyl 4,5-dihydro-4,5-dihydroxybenzimidazol-2-ylcarbamate) and ADDB (2-amino-4,5-dihydro-4,5-dihydroxybenzimidazole; 0.8 percent), and 5-OH-MBC (2.7 percent).

Major components found in goat were as follow: TM and MBC in muscle; MBC in fat; MBC, 5-OH-MBC and 4-OH-MBC in liver; MBC, 5-OH-MBC-S and 4-OH-MBC in kidney; MBC and 5-OH-MBC-S in milk.

Laying hens

^{14}C-TM (phenyl ring label) was administered to a total of 30 laying hens (2 groups of 15 hens). Hens were fed in capsules orally once daily for 10 days at a dose level of 48 ppm in the feed. Within 25 hours of the last dose, hens were sacrificed.

Most (93 percent) of administered dose was excreted. Total residues were 0.069 mg eq/kg in muscle, 0.061 mg eq/kg in fat, 0.15 mg eq/kg in skin, 1.7 mg eq/kg in liver, 1.2 mg eq/kg in kidney and 0.54 mg eq/kg in egg yolk and 0.13 mg eq/kg in egg white.

Extraction using different solvent systems recovered 36–95 percent of the administered dose. Further treatments on post extraction solids of low extractability sample released more residues, namely 26 percent TRR in muscle, 31 percent TRR in skin, 64 percent TRR in liver and 55 percent TRR in kidney.

In breast muscle, parent was present at 8.9 percent TRR (0.006 mg/kg). 5-OH-MBC was a major component, accounting for 38 percent TRR (0.026 mg eq/kg). MBC was found at 12 percent TRR (0.008 mg eq/kg). Metabolites 5-OH-MBC-S (1.4 percent TRR), 5-OH-2-AB (2.6 percent TRR) and 4-OH-FH-432 (4.6 percent TRR) were found but at low levels.

In fat of hens, parent was present at 7.1 percent TRR (0.005 mg/kg). MBC was a major metabolite found at 24 percent TRR (0.014 mg eq/kg). 5-OH-MBC was found at a low level of 5.9 percent TRR (0.003 mg eq/kg). Metabolites 5-OH-MBC-S (0.8 percent TRR) and 4-OH-TM-conjugate (2.5 percent TRR) were found but at low levels.

In skin, parent was present at 4.8 percent TRR (0.007 mg/kg). 5-OH-MBC was a major component, accounting for 22 percent TRR (0.033 mg eq/kg). MBC was found at a low level of 2.3 percent TRR. Metabolite 4-OH-TM (27 percent TRR; free, 4.2 percent TRR and conjugate, 17

percent TRR) and 4-OH-2-AB (3.9 percent TRR) were found at a high or low level.

In liver, parent was present at 6.4 percent TRR (0.11 mg/kg). 5-OH-MBC was found at 6.3 percent TRR (0.11 mg eq/kg). MBC was found at a low level of 1.7 percent TRR (0.028 mg eq/kg). Metabolite 4-OH-TM (4.8 percent TRR; free 1.6 percent TRR and conjugate 3.2 percent TRR) was found but at a low level.

In kidney, parent was present at 3.7 percent TRR (0.045 mg/kg). The major metabolites were found as 5-OH-MBC (15 percent TRR, 0.18 mg eq/kg) and 5-OH-MBC-S (12 percent TRR, 0.14 mg eq/kg). MBC was found at 5.9 percent TRR (0.073 mg eq/kg). Metabolites 4-OH-TM-conjugate (2.1 percent TRR; 4-OH-TM -S, 1.0 percent TRR) and 5-OH-2-AB (4.6 percent TRR) were found but low levels.

In liver and kidney, significant portions of the radioactive PES were shown to be conjugated 5-OH-MBC.

In egg yolk, parent was a major component, accounting for 45 percent TRR (0.24 mg/kg). 5-OH-MBC and MBC were found at 10 percent TRR (0.056 mg eq/kg) and 10 percent TRR (0.054 mg eq/kg), respectively.

In egg white, parent was a major component, accounting for 45 percent TRR (0.058 mg/kg). MBC and 5-OH-MBC were found at 21 percent TRR (0.027 mg eq/kg) and 17 percent TRR (0.022 mg eq/kg), respectively. 5-OH-MBC-S was also present at 5.8 percent TRR (0.007 mg eq/kg).

Major metabolites found in hens tissue and eggs dosed with TM were as follows: 5-OH-MBC in muscle, MBC in fat, 5-OH-MBC in skin, TM, MBC and 5-OH-MBC in liver, TM, MBC, 5-OH-MBC and 5-OH-MBC-S in kidney, TM, MBC and 5-OH-MBC in eggs.

In summary, in lactating goats, TM was rapidly metabolized to MBC, which was then hydroylated at various positions and subsequently conjugated. In laying hens, TM was hydroxylated on the phenyl moiety to form 3- or 4-OH-TM, followed by cleavage to 4- or 5-OH-MBC and conjugation with a sulfate moiety. Another degradative pathway involves hydrolysis and cyclization of TM to MBC followed by formation of 5-OH-MBC.

From the 1998 JMPR Report, MBC and benomyl relevant to TM, are metabolized in a similar manner in both ruminant (cows and goats) and laying hens. Carbendazim is oxidized to an epoxide, which can undergo a number of transformations to the identified compounds. These include hydrolysis to a dihydrodiol, reduction to 4-OH-MBC and 5-OH-MBC, and sulfate conjugation.

In livestock dosed with TM, major metabolites appeared as MBC, 5-OH-MBC and 5-OH-MBC-S. In livestock dosed with MBC or benomyl, major metabolite is 5-OH-MBC.

The metabolism of thiophanate-methyl was evaluated by the WHO Core Assessment Group of the 2023 JMPR. The metabolism of thiophanate-methyl is similar between livestock, rats, and mice.

Methods of analysis

All methods involve extraction with organic solvents, typically methanol, clean-up by liquid-liquid partition or solid phase extraction and determination by HPLC or LC-MS or LC-MS/MS. TM and MBC are main analytes determined in plant and animal commodities with LOQs of 0.01 or 0.05 mg/kg.

Multi-residue methods are currently available for TM and MBC in plant commodities and TM, MBC and 5-OH-MBC in animal commodities.

Stability of pesticide residues in stored analytical samples

In studies on storage stability of TM in non-homogenized commodities frozen at -10 to -20℃, TM was stable at least for 36 months in apple, 60 months in cucumber, 70 months in snap beans and 12 months in grapes, strawberries, dry peas, wheat grain and rape seed. It was noted that TM in homogenized grape stored at -18℃ was greatly degraded at a storage period of 7 or 10 days. In the homogenized samples of rape seed, dry peas, and wheat grain, stored at -18℃, TM was stable up to one month.

MBC was stable at least for 24 months in chopped commodities (apple, tomato, spinach, sugar beet, snap bean) and ground wheat grain, stored frozen at -10 to -20℃. A separate study showed that MBC was stable at least for 12 months in non-homogenized commodities (strawberry, grape, dry peas, rape seed and wheat grain), stored frozen at -10 to -20°C.

In a cattle feeding study, storage stability of TM, MBC, 5-OH-MBC, and 5-OH-MBC-S were tested. TM in muscle was stable at least for 265 days. MBC was stable at least for 229 days in muscle, 264 days in liver, and 258 days in whole milk. 5-OH-MBC was stable at least for 229 days in liver. 5-OH-MBC-S was stable at least for 258 days.

Definition of the residue

In plants, thiophanate-methyl and the metabolite carbendazim were principal residues. Thiophanate-methyl accounted for up to 65 percent TRR in apple and 86 percent TRR in green bean pods. Carbendazim accounted for up to 48 percent TRR in green bean pods and 54 percent TRR in grape. Amount of thiophanate-methyl was 2-9 times greater than that of carbendazim in apple, sugar beet root and soya bean pods. On the contrary, amount of carbendazim was 2.6-15 times greater than that of thiophanate-methyl in grape and green bean pods.

In rotational crops, parent was not detected and metabolites carbendazim and FH-432 were below 0.01 mg eq/kg in carrot roots and wheat grain and carbendazim in lettuce decreased over time (0.003 mg eq/kg at 365-day PBI).The Meeting agreed that it is not expected that residue levels of parent and the metabolites can affect significantly on residues in rotational crops.

The Meeting noted that parent thiophanate-methyl and the metabolite carbendazim were found in most plants investigated and that suitable methods are available for their analysis. Further, thiophanate-methyl is vulnerable to conversion to carbendazim in storage condition of homogenized sample, analysis procedure, and processing condition.

The Meeting agreed that the residue definition for compliance with the MRL for plant commodities should be the sum of thiophanate-methyl and carbendazim, expressed as thiophanate-methyl.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties.

Metabolite 4-OH-TM was considered to be covered by the HBGV of thiophanate-methyl. It was only found in apple fruits and at levels of 0.2 percentTRR representing <1 percent compared to thiophanate-methyl residues. The Meeting concluded that 4-OH-TM does not significantly contribute to the dietary risk and decided not to include it in the residue definition for risk assessment.

Carbendazim, a metabolite of thiophanate-methyl in plants, accounting for a high proportion (up to 54 percent TRR) should be included in the residue definition for dietary risk assessment. The Meeting agreed that for carbendazim, the threshold of toxicological concern approach (Cramer Class III 1.5 µg/kg bw/day) can be applied for both the chronic and acute exposure estimates.

For metabolites (DX-105, FH-432, 5-OH-MBC, 4-OH-MBC, 4-OH-2-AB, 5-OH-2-AB, AV-1951, and 2-AB) found in plants, residues of carbendazim were at least 4-fold greater than these metabolites (individually). Metabolites 5-OH-MBC, 4-OH-MBC, 4-OH-2-AB, and 5-OH-2-AB can be assessed using the threshold of toxicological concern approach (Cramer Class III 1.5 µg/kg bw/day). Therefore, the exposure estimates for carbendazim address the risk for these metabolites in the context of the TTC assessment indirectly.

Therefore, the Meeting concluded that the residue definition for dietary risk assessment for plant commodities should be thiophanate-methyl. In addition, carbendazim needs to be assessed against the TTC Cramer Class III threshold.

In goats, parent compound accounted for 24 percent TRR in muscle, 6.2 percent TRR in fat, 0.8 percent TRR in liver, 1.6 percent TRR in kidney, and 0.3 percent TRR in milk. Carbendazim was found at 26 percent TRR in muscle, 45 percent TRR in fat, 9.4 percent TRR in liver, 21 percent TRR in kidney, and 10 percent TRR in milk. In milk and kidney, 5-OH-MBC (free and sulfate conjugated, i.e., 5-OH-MBC-S) was found at higher proportions than parent and carbendazim: goat milk (76 percent TRR: 73 percent TRR as 5-OH-MBC-S) and goat kidney (37 percent TRR; 35 percent TRR as 5-OH-MBC-S).

In hen, parent compound accounted for 8.9 percent TRR in muscle, 7.1 percent TRR in fat, 6.4 percent TRR in liver, 3.7 percent TRR in kidney, 4.8 percent TRR in skin, 45 percent TRR in egg yolk and white. Carbendazim was found at 12 percent TRR in muscle, 24 percent TRR in fat, 1.7 percent TRR in liver, 5.9 percent TRR in kidney, 2.3 percent TRR in skin, 10 percent TRR in egg yolk, and 21 percent TRR in egg white. 5-OH-MBC (free and sulfate conjugated) accounted for higher proportions than parent and carbendazim: hen muscle (40 percent TRR), hen liver (6.3 percent TRR), hen kidney (26 percent TRR), hen skin (22 percent TRR), egg yolk (10 percent TRR) and egg white (23 percent TRR).

Therefore, the Meeting agreed that the residue definition for compliance with the MRL for livestock commodities should be the sum of thiophanate-methyl, carbendazim and 5-OH-MBC (free and conjugated), expressed as thiophanate-methyl, noting that there is a method available for analysis of TM, MBC and 5-OH-MBC (free and conjugated).

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and the toxicological properties.

Metabolites, 4-OH-TM, 4-OH-TM-S, 3-OH-TM and 3-OH-TM-S, they can be covered by the HBGVs of thiophanate-methyl. In goat and hen, residue levels of these metabolites were very low (4-OH-TM, up to 4.2 percent; 4-OH-TM-S, 1.0 percent TRR; 3-OH-TM, 2.8–3.5 percent TRR; 3-OH-TM-S, 1.2 percent TRR; for 4-OH-TM conjugate, 23 percent TRR in hen skin, which is only a minor contributor to daily consumption), therefore, the metabolites would not contribute significantly on the dietary intake relative to thiophanate-methyl. The Meeting agreed not to include the metabolites in the residue definition for the dietary risk assessment.

Carbendazim and 5-OH-MBC (free and conjugated) accounted for high proportions (up to 76 percent TRR) of the residue in goat and hen commodities. The Meeting agreed that these compounds can be assessed separately using the threshold of toxicological concern approach (Cramer Class III), applying the 1.5 µg/kg bw/day threshold for both the chronic and acute exposure estimates.

Metabolites, 4-OH-MBC, 4-OH-2-AB, 5-OH-2-AB, and 4-OH-FH-432, were found in goat and hen, where their proportions were much lower (4-OH-2-AB, 3.9 percent TRR; 5-OH-2-AB, 2.6–4.6 percent TRR; 4-OH-FH-432, 4.6 percent TRR; for 4-OH-MBC, 5.8-17 percent TRR, 17 percent TRR in goat kidney which is only a minor contributor to daily consumption) than those of carbendazim or 5-OH-MBC (free and conjugated). As noted above, TTC assessments for both carbendazim or 5-OH-MBC (free and conjugated) address the risk for these metabolites in the context of the TTC assessment indirectly.

For dietary risk assessment for livestock commodities, the Meeting concluded that the residue definition should be thiophanate-methyl. In addition, carbendazim and 5-OH-MBC (free and conjugated) need to be assessed, separately, against the TTC Cramer Class III threshold.

In goat, thiophanate-methyl concentrations in muscle tissues were higher to those in fat tissues. The log P_{ow} of thiophanate-methyl and carbendazim is 1.4 and 1.5, respectively. The sum of MBC and 5-OH-MBC-S was 1.3–2.3 times higher in cream than in skim milk. The Meeting decided that the residues are not fat-soluble.

The Meeting recommended the following residue definitions for thiophanate-methyl:

Definition of the residue for compliance with the MRL for plant commodities: *the sum of thiophanate-methyl and carbendazim, expressed as thiophanate-methyl*

Definition of the residue for compliance with the MRL for animal commodities: *the sum of thiophanate-methyl, carbendazim, and 5-OH-MBC (free and conjugated), expressed as thiophanate-methyl*

Definition of the residue for dietary risk assessment for plant and animal commodities: *thiophanate-methyl*.

The residue is not fat-soluble.

Note: Carbendazim and 5-OH-MBC (free and conjugated) need to be assessed, separately, against the TTC Cramer Class III threshold. The threshold applies to both chronic and acute exposure estimates.

Results of supervised residue trials on crops

The Meeting received supervised residue trial data arising from use of thiophanate-methyl for post-harvest treated citrus fruits (orange, mandarin), pome fruits (apple, pear), stone fruits (cherry, plum, apricot, nectarine, peach), berries and other small fruits (grape, strawberry), bulb vegetables (spring onion), fruiting vegetables (cucumber, summer squash, melon, watermelon, tomato), legume vegetables (common bean), pulses (soya bean, dry beans), root and tuber vegetables (sugar beet), cereal grains (barley, oat, wheat), tree nuts (almond, hazelnut, pecan, pistachio) and oil seeds (peanut, rape seed).

In the absence of GAP information, the Meeting withdrew its previous recommendations for maximum residue levels for TM, carbendazim, and/or benomyl forasparagus, banana, barley, barley, hay and/or straw, beans (dry), brussels sprouts, carrot, cattle meat, chicken fat, coffee beans, common bean (pods and/or immature seeds), edible offal (mammalian), eggs, garden pea, shelled (succulent seeds),, lettuce, head, milks, oranges, sweet, sour (including orange-like hybrids, subgroup, mango, peanut fodder, peppers, chilli, peppers, chilli, dried, pineapple,, poultry meat, rice, hay and/or straw,, rice, husked, rye, soya bean (dry), soya bean, hay and/or straw, spices, fruits and berries, spices, roots and rhizomes, spices, seeds, tomato, wheat, wheat, hay and/or straw.

To estimate a maximum residue level, the sum of TM and MBC (total residue), expressed as TM, was calculated by adjustment of molecular weight (a factor of 1.79 for MBC to TM; a factor of 0.558 for TM to MBC). Calculation of total residue at below LOQ is shown in the table below.

Calculation of total residue (sum of TM and MBC) in case of residue below LOQ

TM (mg/kg)	MBC (mg/kg)	Total, expressed as TM (mg/kg)
<0.01	<0.01	<0.03
<0.01	0.02	0.05
0.01	<0.01	0.03

For residue trials on apple, pear, cherry, plum, apricot, nectarine, peach, grape, strawberry, spring onion, cucumber, summer squash, melon, water melon, sugar beet, almond, pecan, pistachio, peanut, and rape seed, the US GAPs were submitted. This Meeting considered on these crops for an estimation of a maximum residue as below.

Pome fruits

Apple, pear

Independent residue trials on apple and pear were conducted in 1992 in the United States. In these trials, concurrent recoveries were not satisfactory and sample storage period was not covered by the period considered as stable.

Therefore, the Meeting did not estimate a maximum residue level for apple and pear and withdrew its previous recommendation of 3 mg/kg for pome fruits (group).

Stone fruits

Cherry, nectarine, peach

Independent residue trials on cherry, nectarine and peach were conducted in 1990 or 1991 in the United States. The trials did not match the US GAP for stone fruits. In these trials, concurrent recoveries were not satisfactory and sample storage period was not covered by the period considered as stable.

Therefore, the Meeting did not estimate a maximum residue level for cherry, nectarine and peach.

Plum, apricot

Independent residue trials on plum were conducted in 2000 and 2001 in northern France and Germany. Independent residue trials on apricot were conducted in 2006 in the United States. However, the trials did not match the US GAP for stone fruits.

Therefore, the Meeting did not estimate maximum residue levels for plum and apricot.

The Meeting withdrew its previous recommendations of 2 mg/kg for apricot, 10 mg/kg for cherries (subgroup), 2 mg/kg for nectarine, 2 mg/kg for peach, and 0.5 mg/kg for plums (including fresh prunes (subgroup).

Berries and other small fruits

Grape, strawberry

Independent residue trials on grape were conducted in 2001-2002 and 2013 in northern France and Germany. However the trials did not match the US GAP. Further, analytical method was not sufficiently validated.

Independent residue trials on strawberry were conducted in 1991 in the United States, approximating the US GAP. In these trials, sample storage period was not covered by the period considered as stable.

The Meeting did not estimate a maximum residue level for grape and strawberry and withdrew its previous recommendation of 1 mg/kg for berries and other small fruits.

Bulb vegetables

Spring onion

Two independent trials using TM were conducted in 2005 in the United States, matching the US GAP.

The Meeting did not estimate a maximum residue level for spring onion as a number of trials was not sufficient.

Fruiting vegetables, cucurbits

Cucumber, summer squash, melon, watermelon

Independent residue trials on cucumber were conducted in 1991 and 1992 in the United States. The trials did not match the US GAP. In these trials, sample storage period was not covered by the period considered as stable.

Residue trials on summer squash and watermelon were conducted in 1991 in the United States. The trials did not match the US GAP. In these trials, concurrent recoveries were not satisfactory and sample storage period was not covered by the period considered as stable.

Residue trials on melon were conducted in Spain between 2000 and 2002. The trials did not match the US GAP.

The Meeting did not estimate a maximum residue level for cucumber, summer squash, watermelon, and melon and withdrew its previous recommendation of 0.05* mg/kg for cucumber and gherkin and 0.5 mg/kg for summer squash.

Root and tuber vegetables

Sugar beet

A total of 12 independent residue trials were conducted in 1997 (11 trials) and 2005 (1 trial) in the United States. In eleven trials, concurrent recoveries were not satisfactory.

The Meeting did not estimate a maximum residue level for sugar beet and withdrew its previous recommendation of 0.1* mg/kg for sugar beet.

Tree nuts

Almond

The US critical GAP is a per-application rate of 1.18 kg ai/ha (2.35 kg ai/ha/year) with application between pink bud and petal fall.

Independent residue trials were conducted in 1998 in the United States at exaggerated rates of 4 x 1.14–1.27 kg ai/ha (4.66-4.96 kg ai/ha/year), with retreatment intervals ranging from 27 to 122 days, with the final application at the hull split stage.

The TM residue values in almond were (n=5): <0.05 (5) mg/kg

The MBC residue values in almond were (n=5): <0.05 (5) mg/kg.

The total residue values in almond were (n=5, as TM): <0.14 (5) mg/kg TM eq.

The Meeting agreed that the applications were close to harvest, no residue (below LOQ) in the trials was expected. Therefore, the Meeting decided to estimate a maximum residue level for almond.

For TM residues, the Meeting estimated an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg for almond.

For MBC residues, the Meeting estimated an STMR of 0.05 mg/kg and an HR of 0.05 mg/kg for almond.

Pecan

Independent residue trials were conducted in 1991 in the United States, matching the US GAP. In these trials, concurrent recoveries were not satisfactory and sample storage period was not covered by the period considered as stable.

The Meeting did not estimate a maximum residue level for pecan.

Pistachio

Three independent trials using TM were conducted in 2002 in the United States. The Meeting did not estimate a maximum residue level for pistachio as the trials did not match the US GAP and the number of trials was not sufficient.

For almond (TN 0660), the Meeting estimated a maximum residue level of 0.15* mg/kg, expressed as TM. The Meeting withdrew its previous recommendation of 0.1* mg/kg for tree nuts (group).

Oil seeds

Peanut

Independent residue trials were conducted in 1991 (eight trials) and 2005 (one trial) in the United States, matching the US GAP. In the eight trials conducted in 1991, sample storage period was not covered by the period considered as stable.

The Meeting did not estimate a maximum residue level for peanut and withdrew its previous recommendation of 0.1* mg/kg for peanut.

Rape seed

Four independent residue trials were conducted in 2001 in the United States, matching the US GAP. However, the number of trials was not sufficient.

The Meeting could not estimate a maximum residue level and withdrew its previous recommendation of 0.05* mg/kg for rape seed.

Feed commodities

Almond hulls

The US critical GAP for almond is a per-application rate of 1.18 kg ai/ha (2.35 kg ai/ha/year) with application between pink bud and petal fall.

Independent residue trials were conducted in 1998 in the United States at rates of 4 x 1.14–1.27 kg ai/ha (4.66-4.96 kg ai/ha/year) with retreatment intervals ranging from 27 to 122 days, with the final application at the hull split stage.

The trials did not match the GAP. The Meeting did not estimate a maximum residue level for almond hulls.

Fate of residues during processing

High-temperature hydrolysis

Using ^{14}C-TM (phenyl ring label), typical processing conditions were simulated: 20 min at pH 4 and 90°C for pasteurization, 60 min at pH 5 and 100°C for baking, brewing and boiling, 20 min at pH 6 and 120°C sterilization.

TM was stable at pasteurization condition. However, at higher pH condition and elevated temperature, TM was not stable. TM was hydrolysed mainly to MBC and at much less extent to 2-AB. Under baking, brewing, and boiling conditions, TM and MBC were found at levels of 85 percent and 14 percent of the applied radioactivity, respectively (AV-1951, also found at 1.4 percent of the AR). Under the sterilization condition, TM and AV-1951 were not detected, while MBC accounted for 92 percent the applied radioactivity and 2-AB was found at a level of 10 percent of the applied radioactivity.

Residues in animal commodities

Farm animal dietary burden

No feed commodities are relevant for an estimation of dietary burden.

Farm animal feeding studies

Lactating ruminants

Holstein cows were orally dosed with capsules containing TM of 67.1, 205, and 839 ppm. Three cows per dose level (2.6, 7.3 and 24.0 mg/kg bw/day) were fed daily for 28 days. Analysed compounds were different by part: MBC and 5-OH-MBC (free and conjugated) for milk, TM and MBC for muscle, MBC for fat, MBC and 5-OH-MBC (free) for liver and MBC, 4-OH-MBC and 5-OH-MBC (free and conjugated) for kidney. The plateau of TM-related residues in milk was reached after 14 days of dosing.

The sum of all relevant metabolites in the dose levels were as follows, as TM eq.: <0.05–0.95 mg eq/kg in muscle, <0.05–0.42 mg eq/kg in fat, 0.20–2.7 mg eq/kg in liver, 0.38–4.6 mg eq/kg in kidney and 0.23–2.4 mg eq/kg in whole milk.

For tissues, TM residue was analysed only for muscle and detected at <0.05 mg/kg, 0.08 mg/kg, and 0.64 mg/kg at dose levels of 67.1 ppm, 205 ppm, and 839 ppm, respectively.

MBC residue was analysed in all tissues and detected at <0.05 mg/kg, 0.06 mg/kg, and 0.23 mg/kg for fat, 0.07 mg/kg, 0.15 mg/kg, and 1.2 mg/kg for liver, and 0.06 mg/kg, 0.16 mg/kg, 0.92 mg/kg for kidney at the dose levels, respectively.

4-OH-MBC was analysed only for kidney and detected at <0.05 mg/kg at the lower two doses and 0.06 mg/kg at the highest dose.

5-OH-MBC (free) was analysed only for liver and detected at <0.05 mg/kg at all dose levels.

5-OH-MBC (free and conjugated) was analysed only for kidney and detected at 0.17 mg/kg, 0.30 mg/kg, and 2.0 mg/kg at the dose levels, respectively.

For whole milk, MBC and 5-OH-MBC (free and conjugated) residues were analysed. MBC was detected at 0.05 mg/kg, 0.10 mg/kg, and 0.53 mg/kg at the dose levels, respectively. 5-OH-MBC (free and conjugated) was detected at 0.07 mg/kg, 0.17 mg/kg, and 0.94 mg/kg at the dose levels, respectively. In the whole milk, the sum of MBC plus 5-OH-MBC (free and conjugated) was 0.10 mg/kg TM eq., 0.37 mg/kg TM eq., and 1.99 mg/kg TM eq. The sum residue level was 1.3-2.3 times higher in cream than in skim milk.

Laying hens

Laying hens were orally dosed with capsules containing TM at 0.40, 1.3 and 4.3 ppm. Four hens per dose level (0.033, 0.11, 0.36 mg/kg bw) were fed daily at for 28 days. Analysed compounds were different by part: TM, MBC and 5-OH-MBC for egg, MBC and 5-OH-MBC for muscle, MBC for fat and TM and 5-OH-MBC for liver. No residues were detected in any tissue from the treated hens (<0.05 mg/kg).

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for International Estimated Daily Intakes (IEDIs) and International Estimate of Short-Term Intake (IESTI) assessment.

Definition of the residue for compliance with the MRL for plant commodities: *the sum of thiophanate-methyl and carbendazim, expressed as thiophanate-methyl*

Definition of the residue for compliance with the MRL for animal commodities: *the sum of thiophanate-methyl, carbendazim, and sodium 2-(methoxycarbonylamino)-1H-benzimidazol-5-yl (5-OH-MBC) (free and conjugated), expressed as thiophanate-methyl*

Definition of the residue for dietary risk assessment for plant and animal commodities: *thiophanate-methyl.*

The residue is not fat-soluble.

Note: Carbendazim and sodium 2-(methoxycarbonylamino)-1H-benzimidazol-5-yl (5-OH-

MBC) (free and conjugated) need to be assessed, separately, against the TTC Cramer Class III threshold. The threshold applies to both chronic and acute exposure estimates.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for thiophanate-methyl is 0-0.09 mg/kg bw. The IEDIs of thiophanate-methyl were calculated for the 17 GEMS/Food cluster diets using the STMR value estimated by the current JMPR. The results are shown in Annex 3 to of the 2023 JMPR Report.

The IEDIs of thiophanate-methyl were <1 percent of the maximum ADI.

The Meeting concluded that the long-term dietary exposure to residues of thiophanate-methyl from the use considered by the current Meeting is unlikely to present a public health concern.

Acute dietary exposure

The ARfD for thiophanate-methyl is 1 mg/kg bw. The IESTIs of thiophanate-methyl were calculated for the food commodity for which HR was estimated by the current Meeting. The results are shown in Annex 4 to the 2023 JMPR Report.

The IESTIs were <1 percent of the ARfD for children and the general population.

The Meeting concluded that the acute dietary exposure to residues of thiophanate-methyl from the use considered by the current Meeting is unlikely to present a public health concern.

Consideration of metabolites using TTC approach

The Meeting agreed that the following compounds could be individually assessed using the threshold of toxicological concern for Cramer Class III compounds of 1.5 µg/kg bw/day, applying the threshold for both the chronic and acute exposure estimates: carbendazim, 5-OH-MBC (free and conjugated), 4-OH-MBC, 4-OH-2-AB, 5-OH-2-AB, and 4-OH-FH-432. Based on the relative amounts of those metabolites in food and feed commodities, the Meeting noted that assessments for carbendazim and 5-OH-MBC (free and conjugated) will address exposures for the remaining metabolites listed above.

The estimated long-term and acute exposures of carbendazim were 0.00167 µg/kg bw/day and 0.2 µg/kg bw/day, respectively. 5-OH-MBC (free and conjugated) is only present in animal commodities. Since the Meeting estimated a livestock dietary burden of 0 ppm, no dietary exposure to 5-OH-MBC (free and conjugated) is expected.

The estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds. The Meeting concluded that based on the exposures to carbendazim and 5-OH-MBC (free and conjugated), exposures to carbendazim, 5-OH-MBC (free and conjugated), 4-OH-MBC, 4-OH-2-AB, 5-OH-2-AB, and 4-OH-FH-432 are unlikely to present a dietary exposure concern from the use evaluated by the current Meeting.

Should further uses be considered in the future, this conclusion may need to be re-evaluated.

5.33 Tricyclazole (337) (T,R)**

TOXICOLOGY

Tricyclazole is the ISO-approved common name for 5-methyl[1,2,4]triazolo[3,4-b][1,3]benzothiazole (IUPAC), Chemical Abstracts Service number 41814-78-2. Tricyclazole is a systemic fungicide from the benzothiazole chemical group that is recommended for the control of the fungus *Pyricularia grisea*, popularly known as rice blast. As an antifungal agrochemical it acts by inhibiting melanin synthesis. It is a conjugate base of a 5-methyl[1,2,4]triazolo[3,4-b][1,3]benzothiazol-1-ium.

Tricyclazole has not previously been evaluated by the Joint FAO/WHO Meeting on Pesticides Residues (JMPR) and was reviewed by the present meeting at the request of the Codex Committee on Pesticides Residues (CCPR).

Some of the studies discussed for this evaluation do not comply with good laboratory practice (GLP) as the data were generated before the implementation of GLP guidelines. However, the critical studies were conducted in a similar manner to current test guidelines, unless otherwise specified. A limited amount of additional information from a literature search was identified that complemented the toxicological information submitted for the current assessment. Overall, the Meeting considered that the database was adequate for the risk assessment.

Biochemical aspects

Following administration of ^{14}C-labelled tricyclazole as a single oral gavage dose to rats at 2 or 40 mg/kg bw, tricyclazole was readily and rapidly absorbed, and this was followed by rapid and extensive biphasic elimination. Following dosing at 2, 7, 28 or 50 mg/kg bw, the maximum plasma concentration (C_{max}) was achieved between five minutes (at 7 mg/kg bw) and one hour (at 50 mg/kg bw) post dose, with the plasma concentration curves and area under the concentration–time curve (AUC) indicating that absorption starts to saturate from 28 mg/kg bw upwards.

Following oral and intravenous dosing at 2 mg/kg bw, the AUCs for 0–96 hours for the two methods of delivery were 11.7 µg.hour/mL and 12.5 µg.hour/mL, respectively. The total absorption of the orally administered dose was at least 90 percent at 2 mg/kg bw. Only between 0.85 percent and 2.0 percent of the orally administered [^{14}C]tricyclazole, whether administered at 2 or 40 mg/kg bw, remained in the tissues after 168 hours, with some affinity for red blood cells (RBCs) being apparent. Absorbed tricyclazole was extensively metabolized with 29 metabolites found in faeces and urine. Tricyclazole alcohol was the most significant metabolite identified in animal studies, along with derivatives of tricyclazole acid, however each of these were present individually at less than 5 percent of the administered radioactivity. In combination, tricyclazole alcohol and its three derivatives were present as metabolites totalling 13 percent of administered dose (AD). The terminal elimination phase was 34–51 hours.

Between 31 and 61 percent of orally administered radiolabel was excreted in the urine, with slightly higher recoveries in females; faecal elimination of radiolabel was 39–65 percent

Following intravenous dosing, 35 percent to 47 percent of the dose was excreted in urine, with up to 58 percent excreted in faeces, indicating extensive biliary elimination.

No potential for accumulation was demonstrated in the available studies.

Toxicological data

The acute oral median lethal dose (LD_{50}) of tricyclazole was 237 mg/kg bw and the dermal LD_{50} was greater than 5000 mg/kg bw. The inhalation median lethal concentration (LC_{50}) of tricyclazole was greater than 2.58 mg/L. Tricyclazole was not irritating to the skin or eyes of rabbits, and was not skin sensitizing in the Guinea pig maximization or mouse local lymph node assay (LLNA).

In repeat-dose toxicity studies with tricyclazole, effects on body weight, body weight gain and on food consumption were commonly seen in rats, mice and dogs. The liver was the target organ in rats, mice and dogs, with changes in clinical chemistry and increases in liver weight.

In a preGLP, 90-day dietary toxicity study in mice, tricyclazole was administered at concentrations of 0, 400, 1000, 2500 or 3600 ppm (equivalent to 0, 60, 150, 375 and 540 mg/kg bw per day). The NOAEL was 400 ppm (equivalent to 60 mg/kg bw per day), based on mortality at 1000 ppm (equivalent to 150 mg/kg bw per day).

In a 6-month preGLP toxicity study, tricyclazole was administered via the diet to mice at concentrations of 0, 310, 800, 1900 or 3000 ppm (equivalent to 0, 47. 120, 285 and 450 mg/kg bw per day). A NOAEL of 310 ppm (equivalent to 47 mg/kg bw per day) was identified based on increased absolute and relative liver weights and proliferation of small bile ducts at 800 ppm (equivalent to 120 mg/kg bw per day) and above.

In a 90-day preGLP dietary toxicity study in rats, tricyclazole was administered at dietary concentrations of 0, 282, 635 or 1,640 ppm (equal to 0, 21, 47 and 180 mg/kg bw per day for males, 0, 23, 54 and 190 mg/kg bw per day for females). The NOAEL was 282 ppm (equal to 21 mg/kg bw per day) based on decreased body weight at 635 ppm (equal to 47 mg/kg bw per day).

In a 1-year oral toxicity study in dogs, tricyclazole was administered in gelatine capsules at dose levels of 0, 5, 15 and 45 mg/kg bw per day. The NOAEL was 15 mg/kg bw per day, based on decreased body weight and increased liver and kidney weights, at 45 mg/kg bw per day.

In a 12-month preGLP oral study in mice, tricyclazole was administered at dietary concentrations of 50, 140, 400 or 620 ppm (equivalent to 0, 7.5, 21, 60 and 93 mg/kg bw per day). The NOAEL was 620 ppm (equivalent to approximately 93 mg/kg bw per day), the highest dose tested.

In a 2-year preGLP dietary study, mice were treated at dietary concentrations of 0, 50, 140 or 400 ppm (equivalent to approximately 0, 3.5, 10 and 29 mg/kg bw per day for males, 0, 3.6, 10.4, and 30 mg/kg bw per day for females). The NOAEL was 400 ppm (equivalent to approximately 29 mg/kg bw per day), the highest dose tested.

In a 95-week study, mice were administered tricyclazole in the diet at 0, 25, 75, 250 or 1000 ppm (equal to 0, 2.59, 7.98, 24.9 and 101 mg/kg bw per day for males, 0, 2.2, 6.67, 21.8 and 91 mg/kg bw per day for females). The NOAEL was 75 ppm (equal to 6.67 mg/kg bw per day) based on increased liver weight and periportal hepatocellular fatty change and hepatocyte degeneration, observed at 250 ppm (equal to 21.8 mg/kg bw per day). The NOAEL for carcinogenic effects was 1000 ppm (equal to 91 mg/kg bw per day), the highest dose tested.

In a 2-year dietary study, carried out before internationally agreed GLP or guidelines, rats were administered tricyclazole at 0, 100, 275 or 620 ppm (equal to 0, 4.1, 11 and 26 mg/kg per day for males, 0, 5.3, 16, and 40 mg/kg per day for females). The NOAEL was 275 ppm (equal to 11 mg/kg bw per day) based on body weight decreases at 620 ppm (equal to 26 mg/kg bw per day). There were no treatment-related increases in neoplasms in any treated group.

In a 2-year dietary study, rats were administered tricyclazole at 0, 40, 126 or 400 ppm (equal to 0, 1.8, 5.9 and 18 mg/kg bw per day for males, 0, 2.3, 7.1 and 22 mg/kg bw per day for females). The NOAEL was 126 ppm (equal to 5.9 mg/kg bw per day), based on suppression of body weight gain and reduced food consumption in females, and suppression of body weight gain in males, at 400 ppm (equal to 18 mg/kg bw per day). There was no increase in treatment-related neoplasms in any treated group.

The overall NOAEL for chronic toxicity in rats was 275 ppm (equal to 11 mg/kg bw per day) based on body weight decreases at 400 ppm (equal to 18 mg/kg bw day). The overall NOAEL for carcinogenicity was 620 ppm (equal to 26 mg/kg bw), the highest dose tested.

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

Tricyclazole was tested for genotoxicity in an adequate range of in vitro and in vivo assays. It was positive in two in vitro mouse lymphoma assays, however no mutagenicity was observed in the in vivo mutagenicity test (lacZ bacteriophage mouse transgenic rodent assay), and tricyclazole was negative in an in vivo mouse micronucleus assay.

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

In view of the lack of genotoxicity in vivo and the absence of carcinogenicity in mice and rats, the Meeting concluded that tricyclazole is unlikely to pose a carcinogenic risk to humans at levels occurring in the diet.

In a two-generation reproductive toxicity study in rats administered tricyclazole at 0, 30, 100 or 400 ppm in the diet (equivalent to 0, 2.1, 7.0 and 27.7 mg/kg bw per day for males, 0, 2.3, 7.0 and 30.6 mg/kg bw per day for females) the NOAEL for parental toxicity was 100 ppm (equivalent to 7.0 mg/kg bw per day) based on decreased mean body weight in males and females in the F0 and F1 generations, along with decreased mean body weight gain, decreased food consumption and increased liver weight (absolute and relative) in F0 and F1 parental animals at 400 ppm (equivalent to 27.7 mg/kg bw per day). The NOAEL for reproductive toxicity was 400 ppm (equivalent to 28 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 100 ppm (equivalent to 7.0 mg/kg bw per day), as decreases in body weight gain and delayed sexual maturity in the pups were observed at 400 ppm (equivalent to 28 mg/kg bw per day).

In a developmental toxicity study, rats were dosed daily with tricyclazole by gavage at 0, 5, 20 or 50 mg/kg bw per day from gestation day (GD) 0 to GD 20. The NOAEL for maternal toxicity was 5 mg/kg bw per day based on suppressed body weight gain and food consumption at 20 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 20 mg/kg bw per day due to incomplete ossifications at 20 mg/kg bw per day.

In a developmental toxicity study, rabbits were dosed daily by oral gavage with tricyclazole at 0, 7.5, 25 or 75 mg/kg bw per day from GD 7 to GD 28. The maternal NOAEL was 25 mg/kg bw per day based on lower mean body weight gains and reduced food consumption at 75 mg/kg bw per day. The embryo/fetal NOAEL was 25 mg/kg bw per day based on lower mean fetal weight at 75 mg/kg bw per day.

The Meeting concluded that tricyclazole is not teratogenic.

No specific neurotoxicity studies were conducted, however no signs of neurotoxicity were observed in other acute or repeat-dose studies.

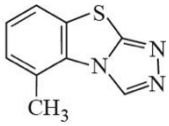
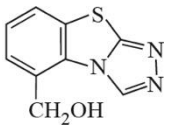
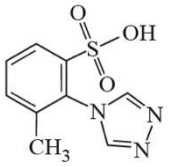
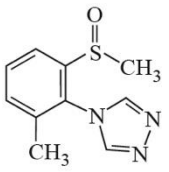
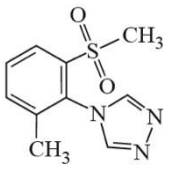
The Meeting concluded that tricyclazole is unlikely to be neurotoxic.

No specific data were submitted regarding immunotoxicity, but no evidence of immunotoxicity was reported in routine toxicological studies with tricyclazole.

The Meeting concluded that tricyclazole is unlikely to be immunotoxic.

Toxicological data on metabolites and/or degradates

Summary of toxicological characterization of plant/livestock metabolites

cCompound, codes and structure	Major rat metabolite (>10% AD)	Genotoxicity assessment (data, QSAR, read-across)	General toxicity	Toxicological reference values
Tricyclazole 	Parent	Data Not genotoxic in vivo	Full dataset	ADI: 0–0.05 mg/kg bw ARfD: 0.05 mg/kg bw
Tricyclazole alcohol, X355227 	While tricyclazole alcohol and derivative made up more than 13% of AD, additional toxicity tests were also conducted	Not genotoxic in in vitro tests	Oral LD_{50} between 200 and 300 mg/kg bw Combined repeat-dose oral toxicity with screening for reproductive/developmental toxicity indicated NOAEL of 22 mg/kg bw per day, compared with parent at 5 mg/kg bw per day in the same study	Covered by parent based on lower toxicity of metabolite
X12691895 (M3) 	No	Not genotoxic in in vitro tests		Limit to Cramer class III TTC: 1.5 µg/kg bw per day
X484574 (M1) 	No	Not genotoxic in in vitro tests		Limit to Cramer class III TTC: 1.5 µg/kg bw per day
X11967410 (Metabolite D) 	No	Not genotoxic in in vitro tests		Limit to Cramer class III TTC: 1.5 µg/kg bw per day

QSAR: Quantitative structure–activity relationship; TTC: Threshold of toxicological concern; AD: Administered dose; ADI: Acceptable daily intake; ARfD: Acute reference dose

Finally, some of the common triazole metabolites, including triazole-alanine, triazole-acetic acid and triazole-lactic acid were observed at variable levels in crops but not in rat absorption, distribution, metabolism and excretion (ADME) studies with tricyclazole. No further data on these metabolites was presented in the dossier. However, as reference doses have been previously

established for these triazole metabolites by JMPR in 2008, additional toxicological consideration was not thought necessary at this time.

The Meeting concluded that metabolite triazole alcohol (X355227) is toxicologically relevant and not of greater potency than the parent The Meeting concluded that metabolites X484574, X12691895 and X11967410 were not genotoxic, but could not conclude on the toxicological relevance of these metabolites. On this basis, they are considered to fall within Cramer class III for toxicity.

Microbiological aspects

There was no information available in the public domain and no experimental data were submitted that addressed the possible impact of tricyclazole residues on the human intestinal microbiome.

Human data

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

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

Toxicological evaluation

The Meeting established an ADI of 0–0.05 mg/kg bw based on the NOAEL of 5 mg/kg bw per day in the rat development study and using a safety factor of 100. This was supported by the NOAEL of 6.7 mg/kg bw per day observed in a 95-week study in mice. This ADI also applies to tricyclazole alcohol.

The Meeting established an ARfD of 0.05 mg/kg bw based on the NOAEL of 5 mg/kg bw per day in the rat development study that showed suppressed maternal body weight gain, seen in the first three days of the study. A safety factor of 100 was used. This ARfD also applies to tricyclazole alcohol.

A toxicological monograph was prepared.

Levels relevant to risk assessment of tricyclazole

Species	Study	Effect	NOAEL	LOAEL
Mouse	95-week study of toxicity and carcinogenicity [a]	Toxicity	75 ppm, equal to 6.67 mg/kg bw per day	250 ppm, equal to 21.8 mg/kg bw per day
		Carcinogenicity	1000 ppm, equal to 91 mg/kg bw per day [c]	-
Rat	Two-year studies of toxicity and carcinogenicity [a,d]	Toxicity	275 ppm, equal to 11 mg/kg bw per day	400 ppm, equal to 18 mg/kg bw per day
		Carcinogenicity	620 ppm, equal to 26 mg/kg bw per day [c]	-
	Two-generation study of reproductive toxicity [a]	Reproductive toxicity	400 ppm, equivalent to 27.7 mg/kg bw per day [c]	-
		Parental toxicity	100 ppm, equivalent to 7.0 mg/kg bw per day	400 ppm, equivalent to 27.7 mg/kg bw per day
		Offspring toxicity	100 ppm, equivalent to 7.0 mg/kg bw per day	400 ppm, equivalent to 27.7 mg/kg bw per day
	Developmental toxicity study [b]	Maternal toxicity	5 mg/kg bw per day [e]	20 mg/kg bw per day
		Embryo/fetal toxicity	20 mg/kg bw per day	50 mg/kg bw per day
Rabbit	Developmental toxicity study [b]	Maternal toxicity	25 mg/kg bw per day	75 mg/kg bw per day
		Embryo/fetal toxicity	25 mg/kg bw per day	75 mg/kg bw per day
Dog	One-year studies of toxicity [f]	Toxicity	15 mg/kg bw per day	45 mg/kg bw per day
Tricyclazole alcohol				
Rat	Combined repeat oral dosing with reproduction/ development toxicity screening[a]	Parental, reproduction and developmental toxicity	22 mg/kg bw per day[c]	

[a] Dietary administration; [b] Gavage administration; [c] Highest dose tested
[d] Two or more studies combined; [e] Lowest dose tested [f] Capsule administration

Acceptable daily intake (ADI) applies to tricyclazole and tricyclazole alcohol, expressed as tricyclazole

0–0.05 mg/kg bw

Acute reference dose (ArfD) applies to tricyclazole and tricyclazole alcohol, expressed as tricyclazole

0.05 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 tricyclazole

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Fast absorption (T_{max} ca 10–30 minutes) Almost completely absorbed (ca 89% in males, 96% females)
Dermal absorption	No data
Distribution	Distributed according to relative organ blood flow; highest amounts in liver and kidney, with lower amounts in plasma, stomach and bone marrow
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Urinary and faecal elimination, via the bile were the primary routes of elimination (ca 97%); urinary excretion (ca 27–48%), biliary excretion (58%)
Metabolism in animals	Primary metabolite is tricyclazole alcohol
Toxicologically significant compounds in animals and plants	Tricyclazole, tricyclazole alcohol, X11967410 (metabolite D)
Acute toxicity	
Rat, LD_{50}, oral	237 mg/kg bw
Rat, LD_{50}, dermal	>2000 mg/kg bw
Rat, LC_{50}, inhalation	>2.58 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea pig, dermal sensitization	Not sensitizing (Magnussen & Kligmann/Buehler)
Short-term studies of toxicity	
Target/critical effect	Decreased body weight (mouse, rat, dog) Liver; increased organ weight and proliferation of small bile ducts (mouse)
Lowest relevant oral NOAEL	15 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	300 mg/kg bw per day (rat)
Long-term studies of toxicity and carcinogenicity	

Target/critical effect	Mouse: liver (increased organ weights, periportal hepatocellular fatty change, peripheral acidophilic degeneration of hepatocytes) Rat: reduced body weights, and feed consumption Liver (slight increase in bile duct hyperplasia)
Lowest relevant NOAEL	6.67 mg/kg bw per day (mouse)
Carcinogenicity	Not carcinogenic
Genotoxicity	Unlikely to be genotoxic
Reproductive toxicity	
Target/critical effect	Parental effects: decreased body weight, body weight gain, and food consumption (both sexes, rat), increased liver weight (both sexes, rat) Reproductive effects: none Developmental effects: reduced pup weights, delayed maturity
Lowest relevant parental NOAEL	100 ppm, equal to 7.0 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	100 ppm, equal to 7.0 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	400 ppm, equal to 28 mg/kg bw per day (rat)
Developmental toxicity	
Target/critical effect	Rat: Maternal effects: decreased body weight, body weight gain, feed consumption and adjusted body weight Developmental effects: decreased body weight, delayed ossification Rabbit: Maternal effects: effects on body weight gain and feed consumption Developmental effects: lower mean fetal weight No teratogenic effects
Lowest relevant maternal NOAEL	5 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	20 mg/kg bw per day (rat)
Neurotoxicity	No specific neurotoxicity studies were conducted, however no signs of neurotoxicity were observed in other routine studies
Other toxicological studies	
Immunotoxicity	No data
Studies on toxicologically relevant metabolites	
Tricyclazole alcohol	Acute oral LD_{50}: between 200 and 300 mg/kg bw (rat) Combined dietary and reproduction study basis for a NOAEL: 22 mg/kg bw per day (rat) Not genotoxic (Ames, micronucleus in vitro)
X484574 (M1), X12691895 (M3)	Not genotoxic (Ames, micronucleus in vitro)
X11967410 (Metabolite D)	Not genotoxic (Ames, micronucleus in vitro)

Microbiological data	No data submitted
Human data	No clinical cases or poisoning incidents have been recorded

Summary

	Value	Study	Safety factor
ADI	0–0.05 mg/kg bw [a]	Rat developmental study	100
ARfD	0–0.05 mg/kg bw [a]	Rat developmental study	100

[a] Applies to tricyclazole and tricyclazole alcohol, expressed as tricyclazole

RESIDUE AND ANALYTICAL ASPECTS

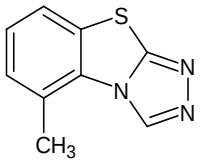
Tricyclazole, 5-methyl-1,2,4-triazolo[3,4-*b*]benzothiazole (IUPAC name), is a benzothiazole systemic fungicide for protecting rice plant from rice blast by preventing the fungus (*Pyricularia oryzae*) from penetrating the rice plant. Tricyclazole is a melanin biosynthesis inhibitor and is registered for use on rice in various countries.

(a) No specification has been established for tricyclazole by the Joint FAO/WHO Meeting on Pesticide Specifications.

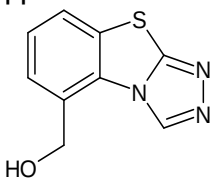
At the Fifty-first Session of the CCPR, tricyclazole was scheduled for the evaluation as a new compound by the Meeting in 2021. It was rescheduled to the current Meeting. The Meeting received information on identity, chemical and physical properties, plant and animal metabolism, rotational crops, environmental fate, residue analysis and storage stability, use pattern, supervised trials on rice, processing and livestock feeding.

The following abbreviated names were used for the metabolites commonly found in plants and animals in the appraisal of tricyclazole.

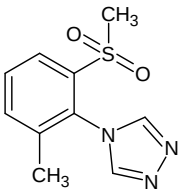
List of metabolites described in this appraisal



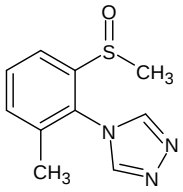
Tricyclazole



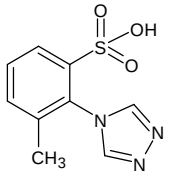
Tricyclazole-OH
1,3,4-triazolo[3,4-b][1,3]benzo-thiazol-5-methanol



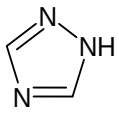
Met D
4-[(2-methyl-6-methylsulfonyl) phenyl]-4*H*-1,2,4-triazole



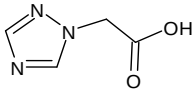
M1
4-[2-methyl-6-(methylsulfinyl) phenyl]-4*H*-1,2,4-triazole



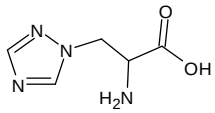
M3
3-methyl-2-(4*H*-1,2,4-triazol-4-yl)benzenesulfonic acid



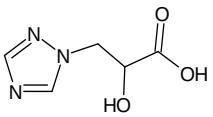
1,24-Triazole



TR acetic acid
Triazole acetic acid



TR alanine
Triazole alanine



TR lactic acid
Triazole lactic acid

Based on the information on physical and chemical properties, tricyclazole is not volatile and more soluble in organic solvents (except in n-heptane) than in water with a Log Pow of 1.41–1.42 at 20°C. Tricyclazole is hydrolytically stable at pH 4–7. It is stable against aqueous photolysis with a DT_{50} of 145 days. It is unlikely that either hydrolysis or aqueous photolysis can be a major degradation pathway of tricyclazole in the environment.

Plant metabolism

The Meeting received information on the metabolism of tricyclazole applications to rice grown under the flooded conditions. Tricyclazole was registered for use on rice and the residue trial data were submitted to the Meeting on rice only. Either tricyclazole uniformly labelled with ^{14}C in the phenyl ring (hereafter described as [PH]-label) or on position three of the triazole ring (hereafter described as [TR]-label) was used in the plant and animal metabolism studies and environmental fate studies.

Rice

In all the submitted studies, the last application was made between BBCH 45–52. Radioactive residues in collected rice matrices were measured and expressed in mg tricyclazole-equivalents/kg.

In the first study in 2020, rice was sown and grown to maturity on sandy loam soil in a greenhouse. The soil was flooded shortly after emergence of rice to a depth of 5 cm above the soil surface and maintained. Water was drained before each application and re-flooded 1 day later, and 2.4-days before sample collection. Either label of tricyclazole was applied as foliar spray at a target rate of 0.225 kg ai/ha at BBCH 34 and 0.450 kg ai/ha at BBCH 49. Forage samples were taken 7 days after the first application (7 DAFA) corresponding to BBCH 34 and grain and straw samples 49 days and 93 days after the last application (DALA) corresponding to BBCH 83–89 and BBCH 89 (mature).

From applications of either of the two labels, TRR from were highest in straw (6.01–13.8 mg eq/kg at 49 and 93 DALA) followed by forage (3.66–5.58 mg eq/kg at 7 DAFA), and hulls (1.15–2.59 mg eq/kg at 49 and 93 DALA). TRR in husked rice were lower at 0.15–0.26 mg eq/kg at 49 and 93 DALA.

Following applications with either labels, neutral solvents (acetonitrile/water) extracted >60 percent TRR from all samples and the neutral extraction followed by acid extractions (1 mol/L HCl/acetonitrile, and then reflux in 1 mol/L HCl) recovered 83–103 percent TRR: 100–103 percent TRR from forage; 83–97 percent TRR from husked rice; 83–90 percent TRR from hulls; and 91–96 percent TRR from straw.

In the post-extraction solids (PES) of husked rice after only neutral extraction or after sequential extraction by neutral and acid were subjected to starch isolation. Starch accounted for 1.5–5.4 percent TRR. In the PES of hulls after neutral and acidic extractions, more than half of radioactivity was isolated as lignin (8.5—11 percent TRR). About 1 percent TRR remained unextracted.

Parent tricyclazole was the most predominant residue, most of which were extracted by neutral organic solvents. Acid extractions recovered up to 11 percent TRR. This indicates that the majority of tricyclazole residue was present in a free form. In total, neutral organic solvents and acid extracted tricyclazole: 95–95 percent TRR (3.6–5.3 mg/kg) from forage; 21–69 percent TRR from husked rice (55–68 percent TRR for [PH]-label and 44 percent TRR for [TR]-label) (0.082–0.179 mg/kg); 67–76 percent TRR (1.16–1.74 mg) from hulls; and 81–88 percent TRR (7.46–10.8

mg/kg) from straw.

Tricyclazole-OH was found at much lower concentrations and ratios compared to tricyclazole (in most cases lower than 1/10 of those of parent). In total, neutral organic solvents and acid extracted tricyclazole-OH: 0.9–1.4 percent TRR (0.048–0.049 mg eq/kg) from forage; 0.4–2.9 percent TRR (0.001–0.008 mg eq/kg) from husked rice, 4.3–5.8 percent TRR (0.089–0.11 mg eq/kg) from hulls, and 2.0–2.5percent TRR (0.22–0.24 mg eq/kg) from straw.

Met D was tentatively identified in these commodities at very low levels, lower than tricyclazole. In total, neutral organic solvents and acid extracted Met D: 0.6 percent TRR from forage (0.023–0.031 mg eq/kg); 0.6 percent TRR (0.001 mg eq/kg) from husked rice, 0.6–0.9 percent TRR (0.014–0.015 mg eq/kg) from hulls, and 2.0–2.5 percent TRR (0.086–0.18 mg eq/kg) from straw.

Another metabolite, M3, was found only in the neutral extract of 93 DALA [PH]-label straw at 1.6 percent TRR (0.099 mg eq/kg).

In the samples collected following applications of [TR]-labelled tricyclazole, TR alanine, TR acetic acid and TR lactic acid were identified in forage, husked rice and hulls but not in straw. 1,2,4-Triazole was not found in any of the samples tested. In husked rice, TR alanine accounted for 24–27 percent TRR, comparable to the levels of parent tricyclazole, with TR acetic acid at 6.7–11 percent TRR and TR lactic acid at 0.5–0.9 percent TRR. These triazole-derived compounds can also arise from the uses of pesticides containing triazole moiety.

In another study conducted in 2003, the metabolism of tricyclazole was investigated following foliar applications with [TR]-label tricyclazole to rice. Germinated rice seeds were sown and grown in greenhouse, and then transplanted and grown to maturity outdoor under the flooded condition. The application of [TR]-labelled tricyclazole was made in two separate plots: (1) plot 1 received early (BBCH 23–24) and late (BBCH 50–52) application at 0.496 and 0.979 kg ai/ha (total, 1.476 kg ai/ha); and (2) plot 2 was treated with only the late application at a rate of 0.927 kg ai/ha. The plots were maintained flooded to a water depth of 9–18 cm above the soil.

From only plot 1, forage samples were collected 0, 14 and 30 DAFA. From both plots, immature rice samples were collected 0 and 14 DALA, and mature panicles and straw were collected 82 DALA. After storage in refrigeration for a long time (*ca.* 3 years), grains were processed into husked rice and hulls.

Following applications of [TR]-label, TRR in comparative samples were higher after two applications than one application. TRR in forage decreased significantly over time after either one or two applications However, there was no significant decrease of radioactivity after 3 years of frozen storage. In mature samples after two applications, TRR was highest in straw (22 mg eq/kg) followed by hulls (4.2 mg eq/kg) and much lower in husked rice (0.33 mg eq/kg).

The percentage of radioactive residues extracted by acetone/water followed by acetonitrile/1 mol/L HCl reflux, or acetonitrile/water followed by 1 mol/L HCl reflux was comparable for all matrices. The extractability in neutral solvents from forage decreased according to the time between the application and sampling. After acid hydrolysis, radioactive residues remained unextracted were: 0.5–21 percent TRR in forage, 7.7–7.9 percent TRR in

husked rice, 33 percent TRR in hulls, and 28 percent TRR in straw. Without acid hydrolysis, radioactive residues remain unextracted were much higher, up to 70 percent TRR. In the unextracted radioactive residues in husked rice, about 60 percent (46 percent TRR) was recovered as starch indicating that tricyclazole was extensively metabolized and incorporated in glucose units. In the unextracted radioactive residues in forage, hulls and straw, major radioactivity was associated with lignin.

Following the applications with [TR]-label, only tricyclazole and tricyclazole-OH were identified in any extracts. Tricyclazole was the predominant residue and mostly extracted by neutral organic solvents. At longer time between the application and sampling, percentage of tricyclazole in TRR decreased with increase of tricyclazole extracted by acid hydrolysis. Tricyclazole accounted for 6.0–11 percent TRR in husked rice (0.013–0.030 mg eq/kg), 25–30 percent TRR (1.1–1.2 mg eq/kg) in hulls, and 27–34 percent TRR (4.6–16 mg eq/kg) from straw.

Tricyclazole-OH accounted for far lower concentrations and ratios with less amounts extracted by acid hydrolysis. Tricyclazole-OH in neutral organic solvent extracts and acid hydrolysates accounted for 1.4–4.1 percent TRR (0.005–0.01 mg eq/kg) in husked rice, 6.7–8.1 percent TRR (0.23–0.33 mg eq/kg) in hulls, and 8.0–17 percent TRR (1.1–7.7 mg eq/kg) in straw.

No other metabolites (including triazole-derived metabolites) were found.

In an older study, the metabolism of [PH]-tricyclazole in rice was investigated. After transplanting of three-week old seedlings into a plot, the plot was flooded and maintained flooded until harvest. Foliar applications of tricyclazole were made at late tillering stage and at late boot stage, each at a rate equivalent to 0.28 kg ai/ha. The rice grain was harvested at 79 DALA. The harvested rice grain was separated into hulls and husked rice.

Extractability was at 68–76 percent TRR. In the ethyl acetate extracts, only tricyclazole and tricyclazole-OH were identified. Tricyclazole accounted for 15 percent TRR (0.004 mg/kg) in husked rice and 22 percent TRR (0.086 mg/kg) in hulls. Tricyclazole-OH accounted for 4.1 percent TRR (0.001 mg eq/kg) in husked rice and 32 percent TRR (0.12 mg eq/kg) in hulls.

Summary of plant metabolism

Metabolism of tricyclazole in rice after foliar applications was studied on rice under the flooded conditions in greenhouse or outdoor. In these studies [PH]-labelled and/or [TR]-labelled tricyclazole was used. In most of the studies, labelled tricyclazole was applied two times as foliar application.

In all of the studies, tricyclazole was the predominant radioactive residue in husked rice, hulls, straw and forage. Most of tricyclazole was found in neutral organic solvent extracts. Far less amount of tricyclazole-OH was found in the extracts of these commodities (mostly about 1/10 to 1/4 of tricyclazole). Tricyclazole and tricyclazole-OH were also identified in rats, ruminants and poultry metabolism studies.

Met D and M3 were identified at even lower levels than tricyclazole-OH.

TR alanine, TR acetic acid and TR lactic acid were found in forage, husked rice and hulls

following the treatment with [TR]-labelled tricyclazole. In husked rice, TR alanine accounted for at comparative levels as tricyclazole.

Some of the unextracted radioactivity after organic solvents/acid extractions in husked rice associated with starch with inconclusive levels. In forage, hulls and straw, unextracted radioactivities were associated mostly with lignin.

The Meeting considered that the metabolism of tricyclazole in flooded rice occurs through: (1) oxidation to tricyclazole-OH; (2) opening of the ring connecting the phenyl and triazole rings to produce Met D and M3; (3) through 1,2,4-triazole to triazole-derived metabolites; (4) ultimately bound to or incorporated into natural components.

Environmental fate

The Meeting received information on a number of studies on degradation/dissipation of tricyclazole under aerobic and anaerobic conditions, photodegradation on the soil surface, and confined and field rotational crop trials.

Aerobic and anaerobic degradation in soils

After incubation of tricyclazole in soils under aerobic and anaerobic conditions for various length (90, 120 and 356 d), parent tricyclazole was the predominant residue. Tricyclazole was shown to be stable and persistent in soil with DT_{50} from 240–>1000 d. As the high-temperature/pressure extraction method resulted in faster degradation of tricyclazole and higher occurrence of degradate than the low temperature/pressure extraction, it may be concluded that real degradation product is only Met D but occurring at a very low level. Tricyclazole was moderately immobile to immobile in soils.

Tricyclazole partitioned rapidly from the paddy water phase with DT_{50} of <2 d. However, it did not appear to decrease in the soil in the drained paddy. Met D was not detected in the drained paddy soil cores. After 5 years of annual application of tricyclazole to bare soil did not result in significant accumulation of tricyclazole in soils. DT_{50} was estimated to be 199 d in soil.

Photodegradation in soil

After irradiating tricyclazole on the soil surface, tricyclazole remained the predominant component of the extracted residue. Tricyclazole is stable to soil photolysis. In the natural environments, soil photolysis is unlikely to be a significant route of degradation of tricyclazole.

Rotational crops studies

The Meeting received information on confined rotational crop and field rotational crop studies.

Confined rotational crop studies

In the confined rotational crop studies, consistent metabolic profile was demonstrated across all succeeding crops (wheat, lettuce and radish) and PBIs. Tricyclazole accounted for up to 18

percent TRR (radish root), tricyclazole-OH 4.6 percent TRR (radish leaves). Met D and M3 accounted for higher ratios of up to 40 percent TRR (mature lettuce) and 51 percent TRR (radish root). M1 accounted for up to 16 percent TRR (radish leaves). They were found in food commodities mostly <LOQ or slightly higher. The residues above 0.05 mg eq/kg were found only in crop commodities used as feedstuff and one sample of radish leaf. The degradation of tricyclazole in soils and following uptake by rotational crops proceed through similar pathway as in the plant metabolism.

Field rotational crop studies

In the field rotational crop studies, residues of tricyclazole in harvested crops were mostly below 0.01 mg/kg, with some sporadic cases above it in leaves. The Meeting concluded that it was unlikely that detectable residues of tricyclazole and its metabolites would be found in succeeding crops from the use of tricyclazole on rice according to GAP.

Animal metabolism

The Meeting received information on metabolism of [PH]-labelled tricyclazole in beef cattle, lactating cow and laying hens. No metabolism studies were conducted with [TR]-label.

Beef cattle

The oral administration of tricyclazole at a dose level of 1 ppm for 3 days to a steer resulted in low levels of radioactive residues in liver (0.69 mg eq/kg) and kidney (0.011 mg eq/kg) and no detectable residues in muscle, back fat and kidney fat. In the liver sample after methanol extraction and acid and base hydrolysis, only tricyclazole and tricyclazole-OH were found. They occurred in similar amounts (31 percent TRR) and together accounted for 61 percent TRR. They were released more by acid hydrolysis than methanol extraction and base hydrolysis. Both tricyclazole and tricyclazole-OH were identified in rat metabolism studies. Other identified metabolites in rat urine were not found in this study on a steer liver.

Dairy cattle

The oral administration of [PH]-labelled tricyclazole twice daily at a dose level of 0.99 ppm for 5 days to a lactating cow resulted in low levels of radioactivity in milk, at the highest 0.0042 mg eq/kg in day 2 afternoon milk and day 5 afternoon milk. The plateau was reached on day 2. After the final dose, radioactivity in milk declined rapidly. Characterization of radioactivity was not attempted due to the low radioactivity.

Laying hens

The oral administration of [PH]-labelled tricyclazole to laying hens twice daily at 0.6 or 6 ppm for 10 days resulted in relatively low levels of radioactivity in eggs with the mean maximum TRR of 0.033 (day 6) and 0.019 mg eq/kg (day 11) in egg white and egg yolk, respectively from the higher dose. The mean TRR in egg white from the high dose appeared to reach a peak on day 5–6. The mean TRR in egg yolk from the high dose appeared to reach a plateau on day 6–8. The overall mean TRR in egg white and yolk from high dose were 0.019 and 0.012mg eq/kg, respectively. After the last dose, the TRR in egg white declined faster than in egg yolk.

Broiler chickens

The oral administration of [PH]-labelled tricyclazole to broiler chickens twice daily at 0.6 or 6 ppm for 5 days resulted in radioactive residues in liver (0.23 and 0.028 mg eq/kg from the high and low dose) and kidney (0.067 and 0.008 mg eq/kg from the high and low dose). No or low radioactivity was found in muscle, skin or fat (≤ 0.006 and ≤ 0.001 mg eq/kg from the high and low dose, respectively). In the extracts of the liver, following methanol extraction, and acid and base hydrolysis, only tricyclazole and tricyclazole-OH were found, in total, at 23 percent TRR and 1.2 percent respectively. Tricyclazole was extracted more by acid reflux than methanol extraction.

Summary of animal metabolism

In the metabolism studies using [PH]-labelled tricyclazole in beef cattle, lactating cows and laying hens, tricyclazole residues were not detected above the LOQ in bovine milk, muscle or fat, or poultry eggs, muscle or fat. Liver and kidney contained higher radioactive residues than the LOQ in cattle and poultry. From cattle and poultry liver, which contained the highest level of radioactivity, only parent or tricyclazole and tricyclazole-OH were found. They were extracted more by acid hydrolysis than methanol extraction.

Although there was only limited evidence of characterization of radioactive residues in bovine liver and chicken liver, the metabolism of tricyclazole in ruminants and poultry are qualitatively similar and also similar to that in rat. Tricyclazole-OH was the main metabolite in these studies. The major metabolic pathway in animals may involve: (1) hydroxylation of the methyl group attached to the benzene ring, and (2) further metabolism, including potential incorporation to natural components.

Residue analytical methods

Analytical methods

Information was available on analytical methods for tricyclazole and tricyclazole-OH, and a number of triazole-derived metabolites, and metabolites M1, M3 and Met D in rice grain and husked rice, various crop commodities (high acid, high water, high protein/starch, and high oil), ruminant and poultry tissues, milk and eggs, for data generation and for enforcement. The methods generally employ extraction of samples with acetone/water, methanol/water, acetonitrile/water, or 2 mol/L sulfuric acid (with or without reflux), with or without acid hydrolysis, with or without partition, clean-up using various types of SPE column, and separation and quantification with GC–MS or HPLC–MS/MS. The LOQ in most methods was 0.01 mg/kg for tricyclazole, tricyclazole-OH, triazole-derived metabolites, M1, M3 and Met D. Some methods have the LOQ of 0.05 mg/kg for tricyclazole in rice, and tricyclazole and tricyclazole-OH in rice straw and green plant.

The results of recovery tests for analytical methods for rice matrices resulted in recoveries and RSD within the acceptable range. The Meeting concluded that the methods were sufficiently validated and are suitable to measure tricyclazole and its metabolites in rice commodities and animal commodities. The recovery tests for other plant commodities mostly showed acceptable recoveries and RSD, except that for Method 01062/004, the RSD values of TR

alanine were slightly higher than 20 percent at 0.01 mg/kg fortification in melon pulp and peel, sweet pepper and sunflower seed; and for Method DAS 120581, the RSD for tricyclazole was 21 percent at 1.0 mg/kg fortification in lemon.

An analytical method for enforcement using the QuEChERS extraction, clean-up with SPE column, and separation/quantification by HPLC-MS/MS was tested for high acid, high water, high protein/starch and high oil crops, egg, milk, kidney and fat, resulting in recoveries and RSD in the acceptable range. In a cross-validation study, the extraction efficiency of this QuEChERS based method was low compared to the extraction in the plant metabolism study. Another method using acidic acetonitrile extraction was available for monitoring, but this method was not subjected to efficiency test.

Storage stability

The Meeting received information on storage stability of tricyclazole and tricyclazole-OH fortified at 0.1 mg/kg in rice grain, rice straw, rice whole plant as well as various commodities of high acid content (whole orange), high water content (lettuce), high protein content (dried haricot bean), high starch content (carrot), high oil content (soya beans), bovine (muscle, liver, kidney fat and milk) and poultry (egg), when stored frozen at -18°C or below, except that whole bovine milk was stored at 2–8°C. Summary of frozen storage stability of is shown below.

Category	Commodity	Stable period (months) [a]	
		Tricyclazole	Tricyclazole-OH
	Plant matrices		
High acid content	Whole orange	33	33
High water content	Lettuce	33	33
	Rice whole plant	12	12
High protein content	Dried haricot bean	33	33
High starch content	Carrot	33	33
	Rice grain	12	12
High oil content	Soya bean	33	33
Dry sample	Rice straw	12	12
	Animal matrices		
Bovine	Muscle	2	2
	Liver	2	2
	Kidney	2	2
	Fat	2	2
	Whole milk (stored at 2–8°C)	2	2
Poultry	Egg	2	2

a Stable for at least the longest periods tested.

The stable periods in the storage stability studies on plant and animal commodities cover the sample storage intervals in the residue trials on rice and animal feeding study.

Definition of residue

Plant commodities

The plant metabolism of tricyclazole was studied in rice plant. Tricyclazole has been registered for use only on rice. The most predominant residue was consistently parent tricyclazole. Residues of tricyclazole were not expected to occur in succeeding crops after uses of tricyclazole on rice following GAP. Analytical methods were available to determine tricyclazole in plant commodities. Therefore, tricyclazole is considered a suitable marker for MRL compliance for rice.

In considering what compounds should be included in the residue definition for dietary risk assessment, the Meeting considered likely occurrence and toxicological relevance. A number of metabolites were identified at low levels in rice commodities: tricyclazole-OH, Met D, M1, M3 and triazole-derived metabolites. Triazole-derived metabolites occur also from uses of triazole-containing pesticides and for these compounds there has been a separate ADI established by JMPR. Tricyclazole was evaluated by this Meeting for toxicology.

The Meeting concluded that metabolite tricyclazole-OH is toxicologically relevant and not of greater potency to the parent. Its toxicity is covered by the HBGVs of the parent.

Tricyclazole-OH occurred less than one tenth of tricyclazole in most metabolism studies. Tricyclazole-OH was also found in rat metabolism studies. However, when tricyclazole-OH is quantified above 0.01 mg/kg in residue trials, the level of tricyclazole-OH at 30 DALA (corresponding to PHI in the cGAP) was 0.071–0.42 time (6 values with the mean of 0.17) compared to tricyclazole in rice grain and 0.18–0.51 time (4 values with the mean of 0.45) in rice hay and straw. As tricyclazole-OH is not of greater toxicity to tricyclazole, and its contribution to exposure would on average more than 10 percent (if included in the residue definition for dietary risk assessment), the Meeting decided to include tricyclazole-OH in the residue definition for risk assessment, after conversion to tricyclazole by molecular weights. While tricyclazole-OH was analysed in all rice straw and hull samples, it was not analysed in rice grain samples in some trials. In such a case, a conversion factor of 0.16 (0.17x189.49/205.24) is used to estimate tricyclazole-OH from the value of tricyclazole.

Met D, M1 and M3 occurred at very low concentrations (mostly <0.01 mg/kg) in rotational crops, plant metabolism, and soil degradation but not in rat metabolism. The Meeting concluded that metabolites Met D, M1 and M3 were not genotoxic but could not conclude on the toxicological relevance of these metabolites. On this basis, the Meeting agreed to apply the TTC approach within Cramer Class III (1.5 µg/kg bw/d) for toxicity.

Animal commodities

In the animal metabolism studies, tricyclazole is predominant residue in both ruminants and poultry. Analytical methods were available to determine tricyclazole in animal commodities. Therefore, tricyclazole was considered a suitable marker for MRL compliance for animal commodities.

In considering which metabolites should be included in the residue definition for dietary risk assessment, the Meeting considered likely occurrence and toxicological relevance. The

metabolic profiles were qualitatively similar among rat, ruminant and poultry. In the animal commodities, residues were expected to be very low and detectable residues may occur only in liver and kidney among tissues, milk and eggs. In ruminant and poultry metabolism studies, only liver was subjected to residue characterization. Tricyclazole and tricyclazole-OH were the only identified radioactive residues and no other metabolites were identified.

In the metabolism studies and feeding studies on cattle, tricyclazole-OH was found at similar levels as parent tricyclazole. In poultry metabolism studies and feeding studies, tricyclazole-OH was much lower than tricyclazole. This may be partly because of unacceptably low recoveries of analytical method for tricyclazole-OH used in poultry feeding studies, which might result in underestimation of tricyclazole-OH. The Meeting considered it appropriate to include tricyclazole-OH in the residue definition for risk assessment after conversion to tricyclazole by molecular weights.

As only liver was subjected to residue characterization, based on the value of octanol/water partition coefficient of 1.4, the Meeting concluded that the residue is not fat-soluble.

Conclusion

Based on the above, the Meeting recommended the following residue definition.

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

Definition of the residue for risk assessment for plant and animal commodities: s*um of tricyclazole and 1,3,4-triazolo[3,4-b][1,3]benzo-thiazol-5-methanol, expressed as tricyclazole.*

The residue is not fat-soluble.

Results of supervised residue trials on crops

The Meeting received supervised trial data for tricyclazole residues on rice conducted in Brazil. Within the framework of residue trials, residues in rice grain, husked rice, rice hay and/or straw and rice hulls were also determined and reported in each trial.

For summing tricyclazole and tricyclazole-OH, tricyclazole-OH concentration was converted to that of tricyclazole equivalents using the ratio of their molecular weights. Residues reported as <LOQ or <LOD were regarded as being at LOQ or LOD. When tricyclazole-OH was not analysed in rice grain, a conversion factor of 0.16 was used to estimate tricyclazole-OH concentrations from tricyclazole concentrations.

Rice and husked rice

The critical GAP for rice is from Uruguay which allows two foliar applications each at 0.300 kg ai/ha with a PHI of 30 days. There is a description about application timing which is, “first application, at the end of the booting; and second application, approximately 14 days after the

previous one. In case one application is to be made, the best time is the late booting."

A total of 14 supervised residue trials were conducted on rice in Brazil during the growing seasons 2003, 2006, 2011 and 2014/2015. In these trials, tricyclazole (WP or SC formulation) was applied twice as foliar applications at a nominal rate of either 0.225, 0.25 or 0.300 kg ai/ha with application intervals of 14–15 days. Last application was made mostly at growth stage BBCH 61–73 but in two trials, the last application was made during BBCH macro-stage 8 (ripening). The Meeting considered that these two trials were not conducted according to GAP and did not use the results of these trials in estimating maximum residue level or STMR.

In the 2006 trials, seed treatment was conducted prior to two later foliar applications. Comparing the residue results with the residues of trials without seed treatment but with two foliar applications at similar timing, there was no significant effect of additional seed treatment on residue levels in rice, and therefore these trials were considered together with those trials conducted with only two foliar applications.

Rice

Residues in rice from trials matching or approximating cGAP in Uruguay were (n=12): <0.01(4), 0.01, 0.42, 0.73, 1.04, 1.32, 1.44, 2.28 and 3.17 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg for rice.

The sum of tricyclazole and tricyclazole-OH, expressed as tricyclazole (hereafter described as "total residues") was calculated by either summing the concentrations of tricyclazole and tricyclazole-OH after molecular weight adjustment or by using conversion factor of 0.16 from tricyclazole to tricyclazole-OH.

Total residues in rice from trials matching or approximating cGAP in Uruguay were (n=12): <0.01 (4), 0.01, 0.45, 1.02, 1.11, 1.53, 1.68, 2.87 and 3.68 mg/kg.

The Meeting estimated an STMR of 0.735 mg/kg for rice.

Husked rice

Residues in husked rice from trials matching or approximating cGAP in Uruguay were (n=12): <0.01 (5), 0.01 (2), 0.02, 0.03 (2), 0.08, and 0.186 mg/kg.

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

The total residues in husked rice from trials matching or approximating cGAP in Uruguay were (n=12): <0.01 (5), 0.01, 0.01, 0.03, 0.03, 0.04, 0.09 and 0.22 mg/kg.

The Meeting estimated an STMR of 0.01 mg/kg for husked rice.

Rice, hay and/or straw

In the trials on rice, straw samples were obtained and analysed in five trials. The residues of tricyclazole in straw from trials matching or approximating the cGAP in Uruguay were (n=5): <0.01 (3), 0.343 and 2.18 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg (dw) for rice (based on the dry matter of 90 percent), hay and/or straw on a basis of straw data.

The total residues in rice straw were calculated by summing up the triazole and triazole-OH concentrations. Total residues in rice straw from trials matching or approximating GAP in Uruguay were: <0.01 (3), 0.50 and 3.47 mg/kg.

The Meeting estimated a median residue of 0.01 mg/kg and highest residue of 3.47 mg/kg (as received) for rice, hay and/or straw.

Rice hulls

In the trials on rice, hull samples were prepared and analysed in five trials. The residues of tricyclazole in hulls from trials matching or approximating the cGAP in Uruguay were (n=5): 0.02, 0.02, 0.024, 1.81 and 5.25 mg/kg.

The Meeting estimated a maximum residue level of 15 mg/kg (dw) (based on the dry matter of 90 percent) for rice hulls.

The total residues in rice hulls from trials matching or approximating cGAP in Uruguay were: 0.02 (2), 0.03, 2.59 and 6.23 mg/kg.

The Meeting estimated a median residue of 0.03 mg/kg (as received) for rice hulls.

Fate of residues during processing

High-temperature hydrolysis

High-temperature hydrolysis studies were conducted with [TR]-labelled tricyclazole and tricyclazole-OH under three conditions simulating processing. Both tricyclazole and tricyclazole-OH were hydrolytically stable under the conditions simulating pasteurization, baking/brewing/boiling, and sterilization. No degradation products were detected under any of these conditions.

Processing of rice

A study was conducted to determine processing factors from rice grain (RAC) to processed products, husked rice, polished rice, by-products (bran and germ), and hulls. In the residue trials, concentrations of tricyclazole and tricyclazole-OH were determined in rice grain, husked rice and hulls. Using these data, maximum residue levels and STMR were estimated.

Processing factors of tricyclazole and the sum of tricyclazole and tricyclazole-OH were

estimated for processed commodities and they are shown below. Residues of tricyclazole and tricyclazole-OH in rice grain, husked rice and hulls indicate that the residues are located mostly in hulls. This implies that residues in polished rice would be as low as or lower than those in husked rice. Therefore, despite the guidance in the FAO Manual to select the lowest individual processing factor value as the best estimate where all individual processing factors are not finite values, the Meeting decided to use the median as the best estimate of processing factor for husked rice.

Processing factor from rice grain to hull is higher than one but the maximum level and STMR were estimated using the residue trials.

Although the processing factor of polished rice is lower than 1, since polished rice contributes to *ca.* 80 percent of all traded rice (rice grain, husked rice and polished rice), the Meeting decided to establish a maximum residue level and STMR for polished rice. The Meeting estimated the maximum residue level and STMR of 0.03 mg/kg and 0.02 mg/kg for polished rice (the same levels as husked rice).

For the purpose of calculating animal dietary burden, the median residue for rice by-products was calculated by multiplying the STMR for rice of 0.735 by the processing factor of 0.15 to be 0.11 mg/kg (as received).

Processed commodity	**Processing factor for tricyclazole**	
	Individual values	**Best estimate**
Husked rice	<0.038, <0.17, <0.22, <0.33	0.20
Polished rice	<0.038, <0.17, <0.22, 0.5	0.20
By-products (bran and germ)	<0.096, <0.42, <0.56, <0.83	0.096
Hulls	<0.096, 1.2, 1.7, 2.0	1.4

Processed commodity	**Processing factor for total residue**	
	Individual values	**Best estimate**
Husked rice	<0.062, <0.30, <0.30, <0.49	0.30
Polished rice	<0.062, <0.30, <0.30, 0.55	0.30
By-products (bran and germ)	<0.15, <0.72, <0.76, <1.2	0.15
Hulls	<0.15, 2.0, 2.6, 2.7	2.3

a/ ordered by trials.

Residues in animal commodities

Livestock feeding studies on beef cattle, lactating cows, and laying hens were provided.

Cattle

Four groups of four beef cattle were fed tricyclazole at nominal level of 0.5, 1.5, 5.0 or 15 ppm in the diet for 30 days. It should be noted that the procedural recovery for tricyclazole-OH was 36–80 percent indicating underestimation of tricyclazole-OH. No residue was detected in the muscle or fat from any of the four dose groups. Also in the metabolism study, at 1 ppm in the diet, no radioactive residue was detected in muscle or fat. In liver of the 0.5 ppm group, tricyclazole and tricyclazole-OH were detected at the LOD of 0.002 mg/kg. In the 1.5 ppm group, the maximum

levels of tricyclazole and tricyclazole-OH were 0.05 and 0.07 mg/kg; in the 5 ppm group, 0.16 and 0.33 mg/kg; in the 15 ppm group, 0.35 and 0.55 mg/kg, respectively.

In kidney, tricyclazole was detected only in 5 ppm and 15 ppm groups at maximum 0.02 and 0.04 mg/kg, respectively. Tricyclazole-OH was detected in kidney in all dose groups: in 0.5 and 1.5 ppm groups at the LOD level, in 5 ppm group at maximum 0.03 mg/kg and in 15 ppm at maximum 0.13 mg/kg.

When three groups of three lactating cows were fed tricyclazole at a nominal rate of 1.5, 5.0 or 15 ppm in the diet for 30 consecutive days, neither tricyclazole nor tricyclazole-OH residues were detected in any milk samples from any of the dose level. In this study, the procedural recovery of tricyclazole-OH was 22–54 percent, unacceptably low. In the metabolism study, TRR were very low (maximum at 0.0042 mg eq/kg) at the dose level of 0.99 ppm in the diet.

Poultry

Three groups of six laying hens were given tricyclazole at 14 ppm in the diet for 14 consecutive days. In eggs collected day 10, 12 and 14 were low: ≤0.03 mg/kg on average with the maximum individual residue level of 0.04 mg/kg on day 14. The level of tricyclazole-OH in eggs was also low: ≤0.03 mg/kg on average with the maximum individual residue level of 0.03 mg/kg on day 10. Procedural recovery of tricyclazole-OH was low on 2 days of the above dates.

Levels of tricyclazole in tissues were also low. In muscle and fat and skin, tricyclazole was at the maximum 0.02 mg/kg and tricyclazole-OH not detected. The highest tricyclazole levels were found in liver with a mean of 0.22 mg/kg and a maximum of 0.26 mg/kg, and tricyclazole-OH 0.05 and 0.07 mg/kg respectively. This is consistent with the metabolism study.

Animal dietary burden

Animal dietary burden calculations for cattle and poultry are provided below. The dietary burdens were estimated using the OECD diets listed in Appendix IX of the 2016 edition of the FAO Manual. For the calculation, total residue values were used. Since tricyclazole is not registered in Australia and rice straw is not imported in Australia, the Meeting calculated animal dietary burdens for Australian ration without rice straw.

Estimated maximum and mean dietary burdens of total tricyclazole (ppm diet)

	US-Canada		EU		Australia [g]		Japan	
	max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.185	0.185	0.386	0.001	0.383	0.383 [b]	2.15 [a]	0.031
Dairy cattle	0.185	0.185	0.217	0.025	0.216	0.216 [d]	0.976 [c]	0.015
Poultry broiler	0.179	0.179	0.012	0.012	0.442 [e]	0.442 [f]	0.006	0.006
Poultry layer	0.179	0.179	0.006	0.006	0.442 [e]	0.442 [f]	0.024	0.024

a Highest maximum dietary burden for beef cattle suitable for estimation of maximum residue levels for mammalian meat, fat and offal

b Highest mean dietary burden for beef cattle suitable for estimation of STMRs for mammalian meat, fat and offal

c Highest maximum dietary burden for dairy cattle suitable for estimation of maximum residue level for milks

d Highest mean dietary burden for dairy cattle suitable for estimation of STMRs for milks

e Highest maximum dietary burden for broiler and layer suitable for estimation of maximum residue levels for poultry meat, fat, offal, and eggs
f Highest mean dietary burden for broiler and layer suitable for estimation of STMRs for poultry meat, fat, offal and eggs
g Dietary burdens calculated without rice straw

Animal commodity maximum residue levels

Mammals

For dairy cattle, the highest maximum dietary burden of total tricyclazole residue was 0.976 ppm and the highest mean dietary burden was 0.216 ppm.

In the feeding study on lactating cows, even at the highest dose level of 15 ppm, neither tricyclazole nor tricyclazole-OH was detected in milk. In the metabolism study using the dose level of 0.99 ppm, the TRR was at the maximum 0.042 mg eq/kg.

For beef cattle, the highest maximum dietary burden of tricyclazole/tricyclazole OH was 2.15 ppm and the highest mean dietary burden was 0.383 ppm. In the feeding study on beef cattle, even at the highest dose level of 15 ppm, no residues were detected in muscle and fat. At 1 ppm in the metabolism study, the TRR in muscle and fat were below the LOQ. In liver and kidney, low-level residues were observed in the 1.5 ppm and 5.0 ppm.

	Feed level (ppm)	**Residues (mg/kg)**	
		Liver	**Kidney**
MRL		(tricyclazole)	
Feeding study	1.5	0.05	<0.02
	5.0	0.16	0.02
Dietary burden	2.15	0.07	0.008 a/
STMR		(Total residue)	
Feeding study	0.5	0.038	0.018
Dietary burden, STMR	0.216	0.016	0.008
HR			
Feeding study	1.5	0.11	0.018
	5.0	0.46	0.057
Dietary burden, HR	2.13	0.18	0.025

a/ calculated using the residue value of 0.02 mg/kg at 5.0 ppm.

The Meeting estimated maximum residue levels of 0.01 mg/kg (*) for meat (mammalian other than marine mammals), mammalian fats (except milk fats) and milks; and, based on the residue levels in liver, 0.1 mg/kg for edible offal (mammalian).

The Meeting also estimated STMRs and HRs of 0 mg/kg for muscle (mammalian other than marine mammals), and mammalian fats (except milk fats); 0.016 and 0.18 mg/kg for edible offal (mammalian), respectively. An STMR for milks was estimated to be 0 mg/kg.

Poultry

For poultry broiler and layer, the highest maximum and mean dietary burden of tricyclazole/tricyclazole OH was 0.289 ppm. In the feeding study, at the dose level of 14 ppm, the

maximum individual residue levels for tricyclazole and tricyclazole-OH were 0.04 and 0.03 mg/kg. In the metabolism studies, at the dose level of 0.6 ppm, the maximum TRR in egg white was 0.008 mg eq/kg and in egg yolk was 0.003 mg/kg. At the dose level of 0.289 ppm, residues of tricyclazole or tricyclazole-OH was not expected.

As for tissues, in the feeding study, at the dose level of 14 ppm, tricyclazole and tricyclazole-OH were at the maximum 0.02 mg/kg in muscles and skin/fat. In the metabolism study, at a dose level of 6 ppm, TRR in muscle, skin and fat were at the maximum 0.006 mg eq/kg. Therefore, the residue levels at 0.289 were expected to be much lower than 0.01 mg/kg.

Liver and kidney contained finite residues although the levels of tricyclazole-OH might be underestimated due to low procedural recoveries of the analytical method used.

	Feed level (ppm)	**Residues (mg/kg)**
		Liver
MRL		(tricyclazole)
Feeding study	14	0.26
Dietary burden, HR	0.442	0.008
STMR		(Total residue)
Feeding study	14	0.27
Dietary burden, STMR	0.442	0.009
HR		
Feeding study	14	0.325
Dietary burden, HR	0.442	0.010

The Meeting estimated maximum residue levels of 0.01 mg/kg (*) for poultry meat, fat, and eggs and 0.01 mg/kg for poultry, edible offal. The Meeting also estimated STMRs and HRs of 0 mg/kg for poultry meat, fat and eggs, and 0.008 and 0.010 mg/kg for poultry edible offal.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 below are suitable for establishing maximum residue limits and for IEDI and International Estimate of Short-Term Intakes (international estimate of short-term intakes) assessment.

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

Definition of the residue for risk assessment for plant and animal commodities: *Sum of tricyclazole and 1,3,4-triazolo[3,4-b][1,3]benzo-thiazol-5-methanol, expressed as tricyclazole.*

The residue is not fat-soluble.

Long-term dietary exposure

The ADI of 0–0.05 mg/kg bw was established for tricyclazole by the current JMPR. The IEDIs for tricyclazole were calculated for the 17 GEMS/Food consumption Cluster Diets using the STMR or STMR-P values estimated by the current JMPR. The results are shown in Annex 3 to the 2023 JMPR Report.

The IEDIs were <1 percent of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of tricyclazole from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The ARfD of 0.05 mg/kg bw was established for tricyclazole by the current JMPR. The International Estimate of Short-Term Intakes for tricyclazole were calculated for rice and its processed foods for which STMR and STMR-P were estimated by the current Meeting. The results are shown in Annex 4 of the 2023 JMPR Report.

The International Estimate of Short-Term Intakes ranged from 0 to 40 percent of the ARfD for children and from 0 to 20 percent of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of tricyclazole from uses considered by the present Meeting is unlikely to present a public health concern.

Threshold of toxicological concern (TTC) consideration for metabolites

The Meeting noted that metabolites, Met D, M1 and M3 were not considered to be genotoxic. As no further information was available, the Meeting areed to apply the TTC approach (Cramer Class III, 1.5 µg/kg bw/d) for toxicity.

In the rice metabolism study, Met D was detected in husked rice at 0.001 mg/kg from the application rate of 1.5 time the cGAP rate. In the field rotational crop study, while in most of the samples M1, M2 or Met D were below the LOQ of 0.01 mg/kg or below the LOD of 0.003 mg/kg, in some samples they were detected above the LOQ. The application rate to a bare soil was higher than the individual application rate of cGAP but lower than the total annual rate. Adjusting the highest reported residue levels for each edible commodity by applying the proportionality concept to the cGAP rate (by multiplying by a factor of 1.33), assuming that the level below the LOQ or LOD was to be at the LOQ or LOD, and utilizing the value between the LOQ and LOD, the levels of M1, M3 and Met D were 0.016, 0.08 and 0.009 mg/kg respectively in radish leaf, 0.004, 0.008 and 0.004 mg/kg in radish root, 0.004, 0.011 and 0.004 mg/kg in lettuce, and 0.004, 0.004, and 0.004 mg/kg in wheat grain. Among these three metabolites, M3 showed the highest levels. Using the level in radish leaf rather than in lettuce leaf as a representative for leafy vegetables, the dietary exposure to M3 calculated using the 17 cluster diets were 0.06–0.24 µg/kg bw/d, significantly lower than the TTC for Cramer Class III.

For the other two metabolites, M1 and Met D, the calculated dietary exposure was lower than that of M3.

The Meeting concluded that the chronic dietary exposure of metabolites M1, M3 and Met D arising from uses of tricyclazole considered by the Meeting is unlikely to present a public health concern.

5.34 Triflumeron

Consideration of this compound resulted in a toxicological evaluation only, and this was included in the FAO/WHO publication Pesticide residues in food 2022: Part II –toxicological, ISBN 978-92-4-008598-5.

5.35 Zeta-cypermethrin (118) (R)

RESIDUES AND ANALYTICAL ASPECTS

Zeta-cypermethrin is a synthetic pyrethroid used as an insecticide. It was first evaluated in 1979 JMPR, and the most recent periodic re-evaluation was conducted by the 2006 JMPR for toxicological aspects and the 2008 JMPR for residues. The 2006 JMPR established an ADI and ARfD for cypermethrins (including alpha- and zeta-cypermethrin) of 0-0.02 mg/kg bw and 0.04 mg/kg bw, respectively.

Definition of the residue for both compliance with MRLs and estimation of dietary intake for plant and animal commodities: cypermethrins (sum of isomers).

The residue is fat-soluble.

The compound was evaluated for additional maximum residue levels in 2009, 2011 and 2019.

At the fifty-second CCPR (2021), zeta-cypermethrin was listed for consideration of further additional maximum residue levels by the 2022 JMPR, and it was carried over to the 2023 JMPR.

The current Meeting received new information on methods of analysis, use patterns, and supervised residue trials on blackberry, blueberry, avocado, bulb onions and green onions.

Methods of analysis

The Meeting received four methods of analysis used in the supervised trials (Method P-3559, Method P-3451, Method RAN-231M and Method RAN-0193M). Additional information on a multi-residue method suitable for enforcement which had been evaluated by the 2009 JMPR (Method DFG S19) was also provided. In these methods, zeta-cypermethrin was extracted with mixed solvent containing acetone (e.g. acetone-water, hexane-acetone) and analysed using gas chromatography with an electron-capture detector (GC-ECD), LC-MS/MS or GC-MS.

The Meeting confirmed validation of the following methods for zeta-cypermethrin: Method P-3559 (GC-ECD) in commodities with high acid content including blackberry and blueberry with an LOQ of 0.05 mg/kg; Method P-3451 (GC-ECD) in avocado with an LOQ of 0.035 mg/kg, Method RAN-0193M (GC-ECD) in commodities with high water content including bulb onion and spring onion with an LOQ of 0.05 mg/kg.

Stability of pesticide residues in stored analytical samples

The current JMPR received no new information on stability of the residues.

The 2008 JMPR evaluated the storage stability of cypermethrins in lettuce, green peas, rape seed and wheat grain in the freezer for up to 12 months and concluded that the residue is stable. The JMPR noted that in an alpha-cypermethrin study on apples, residues were apparently stable (110 percent) for 52 weeks (12 months) but had declined to 65 percent by week 84 (19.6 months).

The 2011 JMPR evaluated that the storage stability of zeta-cypermethrin in high water content commodities, crops with high acid content, and high oil content and very low water content for up to 18 months and concluded that the residue is stable for at least 18 months when stored at -18 °C.

The Meeting, taking into account the longest period of storage stability study available (18 months), confirmed that residue of zeta-cypermethrin is stable for up to 20 months (18 months + 10

percent) and decided that the data with a longer storage period than 20 months could not be used for evaluation.

Results of supervised trials on crops

Cane berries

The critical GAP for zeta-cypermethrin on cane berry in the United States is six foliar applications at 56 g ai/ha with minimum intervals between sprays of 7 days and a PHI of 1 day. In independent trials conducted with zeta-cypermethrin in the United States matching the US GAP, residues of cypermethrins (sum of isomers) in blackberry were (n=3): 0.12, 0.17 and 0.20 mg/kg (with the highest individual value of 0.22 mg/kg).

The Meeting could not estimate maximum residue level, STMR and HR for cane berries due to insufficient number of trials.

Bush berries

The critical GAP for zeta-cypermethrin on bushberry in the United States is six foliar applications at 56 g ai/ha with minimum intervals between sprays of 7 days and a PHI of 1 day. In independent trials conducted with zeta-cypermethrin in the United States matching the US GAP, residues of cypermethrins (sum of isomers) in blueberry were (n=6): 0.26, 0.34, 0.35, 0.45, 0.48 and 0.52 mg/kg (with the highest individual value of 0.53 mg/kg).

Since blueberry is a representative commodity for the subgroup of bush berries in the Codex classification and the same GAP covers commodities in the subgroup, the Meeting estimated maximum residue level, STMR and HR for cypermethrins in subgroup of bush berries of 1.5, 0.40 and 0.53 mg/kg, respectively.

Avocado

The critical GAP for zeta-cypermethrin on avocado in the United States is six foliar applications at 56 g ai/ha with minimum intervals between sprays of 7 days and a PHI of one day. In independent trials conducted with zeta-cypermethrin in the United States matching the US GAP, residues of cypermethrins (sum of isomers) in avocado were (n=5): 0.07, 0.08, 0.14, 0.20 and 0.27 mg/kg (with the highest individual value of 0.28 mg/kg).

The Meeting estimated maximum residue level, STMR and HR for cypermethrins in avocado of 0.5, 0.14 and 0.28 mg/kg, respectively.

Bulb onions

The 2008 JMPR estimated a maximum residue level of 0.01* mg/kg on onions based on the critical GAP in Germany (an application of alpha-cypermethrin at 0.013 kg ai/ha with a PHI of 14 days).

The critical GAP of zeta-cypermethrin for bulb vegetables in the United States is five foliar applications at 56 g ai/ha with minimum intervals between sprays of 7 days and a PHI of 7 day. Two trials on onion were conducted with zeta-cypermethrin in the United States matching the US GAP,

but these residue data were not suitable for evaluation because they were derived from unvalidated analytical method (Method RAN-0231M).

In addition, 16 independent trials on onion were conducted in the United States with five foliar applications at 112 g ai/ha (2N US GAP). In three trials, storage periods were longer than 20 months. From the valid trials at 2N US GAP rate, the residue data were (n=12): <0.05 (12) mg/kg.

Onion is the representative commodity for the Codex subgroup of bulb onions and the GAP covers all commodities in this subgroup. The Meeting estimated maximum residue level of 0.05* mg/kg for cypermethrins in subgroup of bulb onions, to replace its previous recommendation of 0.01* mg/kg. Since all residues were <LOQ in exaggerated trials, the Meeting estimated STMR and HR of 0 and 0 mg/kg, respectively.

Spring onion

The critical GAP for zeta-cypermethrin on bulb vegetables in the United States is five foliar applications at 56 g ai/ha with a minimum interval between sprays of 7 days and a PHI of 7 days. Two trials conducted with zeta-cypermethrin in the United States matching the US GAP were available, but these residue data were not suitable for evaluation because they were derived from unvalidated analytical method (Method RAN-0231M).

In addition, five independent trials on spring onion were conducted with zeta-cypermethrin in the United States with five foliar applications at 112 g ai/ha (2N US GAP). In two trials, storage periods were longer than 20 months. From the valid trials at 2N US GAP rate, the residues were (n=3): 0.36, 0.85 and 5.2 mg/kg (with the highest individual value of 5.4 mg/kg).

The Meeting could not estimate maximum residue level, STMR and HR for cypermethrins in spring onion due to insufficient number of trials.

Residues in animal commodities

Since none of the commodities evaluated by the current JMPR are on the OECD feed table, animal dietary burden does not change from the last evaluation.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI and International Estimated Short-Term Intake (IESTI) assessment.

Definition of the residue for both compliance with MRL and estimation of dietary intake for plant and animal commodities: *cypermethrins (sum of alpha and zeta).*

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The International Estimated Daily Intakes for the 17 GEMS/Food cluster diets, based on the recommendations of the current JMPR, were in the range 7–20 percent of the maximum ADI of 0.02 mg/kg bw for cypermethrins. The results are shown in Annex 3 to the report.

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

Acute dietary exposure

The IESTI for cypermethrin was calculated. The results are shown in Annex 4 to the Report.

The IESTIs for cypermethrins from the intake of the residue evaluated by the Meeting were 0–20 percent for general population and 0–30 percent for children of the ARfD (0.04 mg/kg bw). The Meeting concluded that acute dietary exposure from the residues of cypermethrins, from uses that have been considered by the JMPR, is unlikely to present a public health concern.

Annex 1: Acceptable daily intakes, acute reference doses, recommended maximum residue levels, supervised trials median residue values and other values recorded by the 2023 JMPR Meeting

Apart from the abbreviations indicated above, the following qualifications are used in the Table

* (following recommended MRL)	At or about the limit of quantification
ar	The median or highest residue is reported at the moisture content of the feed commodity "as received"
dw	The value is reported in the dry weight of the feed commodity
HR-P	Highest residue in a processed commodity, in mg/kg, calculated by multiplying the HR in the raw commodity by the processing factor
Po	The recommendation accommodates post-harvest treatment of the commodity.
PoP (following recommendation for processed foods) (classes D and E in the Codex classification)	The recommendation accommodates post-harvest treatment of the primary food commodity.
STMR-P	An STMR for a processed commodity calculated by applying the concentration or reduction factor for the process to the STMR calculated for the raw agricultural commodity.
W (in place of a recommended MRL)	The previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended.

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
1,4-Dimethylnaphthalene (331) ADI: 0–0.3 mg/kg bw ARfD: Unnecessary		Baked potato (unpeeled)	-	-	5.1	-
		Boiled potato (peeled)	-	-	0.17	-
		Boiled potato (unpeeled)	-	-	2.3	-
		Canned potatoes (unpeeled)	-	-	2.2	-
	MO 0105	Edible offal (mammalian)	0.5	-	0.22	-
	PE 0112	Eggs	0.03	-	0.017	-
		Fried potato (unpeeled)	-	-	5.2	-
	MF 0100	Mammalian fats	0.03	-	0.018	-
	MM 0095	Meat (from mammals other than marine mammals)	0.03 (fat)	-	0.014 (muscle) 0.018 (fat)	-
		Microwaved potatoes (unpeeled)	-	-	1.5	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	ML 0106	Milks	0.03	-	0.02	-
		Peeled potato	-	-	2.1	-
	VR 0589	Potato	15 (Po)	-	8.65	-
		Potato crisps (peeled)	-	-	1.2	-
		Potato crisps (unpeeled)	-	-	1.6	-
		Potato dried pulp			28	-
	DV 0589	Potato flakes (flour)	-	-	1.3	-
		Potato fries (chips) (peeled)	-	-	0.43	-
		Potato fries (chips) (unpeeled)	-	-	1.6	-
		Potato process waste	-	-	2.5	-
		Potato starch	-	-	3.9	-
	PO 0111	Poultry edible offal	0.2	-	0.12	-
	PF 0111	Poultry fats	0.3	-	0.11	-
	PM 0110	Poultry meat	0.3 (fat)	-	0.043 (muscle) 0.11 (fat)	-
		Sliced potato	-	-	3.9	-
Definition of the residue for compliance with the MRL for plant commodities: *1,4-dimethylnaphthalene.* Definition of the residue for dietary risk assessment for plant commodities: *Sum of 1,4-dimethylnaphthalene and metabolite 1-hydroxymethyl-4-methylnaphthalene (M21), expressed as 1,4-dimethylnaphthalene.* Definition of the residue for compliance with the MRL for animal commodities, except milk: *Sum of 1,4-dimethylnaphthalene and metabolite 4-methyl-1-naphthoic acid (M23), expressed as 1,4-dimethylnaphthalene.* The residue in animal commodities except milk is fat-soluble. Definition of the residue for compliance with the MRL for milk: *Glycine conjugate of 4-methyl-1-naphthoic acid (M02).* The residue definition in milk is not fat-soluble. Definition of the residue for dietary risk assessment for animal commodities: *Sum of 1,4-dimethylnaphthalene, metabolite 4-methyl-1-naphthoic* acid (*M23), and its glycine conjugate 4-methyl-1-naphthoic acid (M02) expressed as 1,4-dimethylnaphthalene.*						
Acetamiprid (246)	VP 0546	Soya bean (dry)	0.01	-	0.01	-
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *acetamiprid.* Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of acetamiprid and desmethyl-acetamiprid, expressed as acetamiprid*. The residue is not fat-soluble.						
Boscalid (221) ADI: 0-0.04 mg/kg bw ARfD: Unnecessary (2006)	FI 0355	Pomegranate	2	-	0.041	-
Definition of the residue for compliance with the MRL for plant commodities and for dietary risk assessment for plant and animal commodities: *Boscalid.* Definition of the residue for dietary risk assessment 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.						
Carbendazim (72)	-	-	-	-	-	-
The present Meeting was asked by the CCPR to re-evaluate carbendazim under the periodic review programme. However, insufficient toxicological information was submitted to allow a re-evaluation of this substance to confirm or amend the reference values established in 1995 (ADI) and 2005 (ARfD). On this basis, the WHO Core Assessment Group withdraws the current ADI and ARfD values. Recommendations for maximum residue levels for carbendazim are reported under thiophanate-methyl.						
Carbofuran (96) ADI: 0–0.001 mg/kg ARfD: 0.001 mg/kg bw	FC 0004	Oranges, Sweet, Sour (subgroup)	W	0.5	-	-
	AL 1020	Alfalfa fodder	W	10	-	-
	AL 1021	*Alfalfa forage (green)*	W	10	-	-
	FI 0237	Banana	W	0.01 (*)	-	-
	VC 4199	Cantaloupe	W	0.2	-	-
	MF 0812	Cattle fat	W	0.05 (*)	-	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	AB 0001	Citrus pulp, Dry [(1)]	W	2.0	-	-
	SB 0716	Coffee beans	W	1.0	-	-
	SO 0691	Cotton seed	W	0.1	-	-
	VC 0424	Cucumber	W	0.3	-	-
	MO 0105	Edible offal of cattle, goats, horses, pigs & sheep	W	0.05 (*)	-	-
	MF 0814	Goat fat	W	0.05 (*)	-	-
	MF 0816	Horse fat	W	0.05 (*)	-	-
	AF 0645	*Maize forage[(1)]*	W	0.5	-	-
	GC 0645	Maize[(1)]	W	0.05 (*)	-	-
	FC 0206	Mandarin[(1)]	W	0.5	-	-
	MM 0096	Meat of cattle, goats, horses, pigs & sheep	W	0.05 (*)	-	-
	ML 0106	Milks	W	0.05 (*)	-	-
	MF 0818	Pig fat	W	0.05 (*)	-	-
	VR 0589	Potato	W	0.2	-	-
	SO 0495	Rape seed	W	0.05 (*)	-	-
	AS 0649	Rice straw and fodder, dry	W	1.0	-	-
	CM 0649	Rice, husked	W	0.1	-	-
	MF 0822	Sheep fat	W	0.05 (*)	-	-
	GC 0651	Sorghum	W	0.1 (*)	-	-
	AF 0651	*Sorghum forage (green)*	W	2	-	-
	AS 0651	Sorghum straw and fodder, dry	W	0.5	-	-
	HS 0193	Spices, roots and rhizomes	W	0.1	-	-
	VC 0431	Squash, summer	W	0.3	-	-
	AV 0596	*Sugar beet leaves or tops[(1)]*	W	0.07	-	-
	VR 0596	Sugar beet[(1)]	W	0.2	-	-
	GS 0659	Sugar cane	W	0.1 (*)	-	-
	SO 0702	Sunflower seed	W	0.1 (*)	-	-
	VO 0447	Sweet corn (corn-on-the-cob)	W	0.1	-	-
[(1)]Arising from the use of carbosulfan						

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		$STMR_{chronic}$ or $STMR\text{-}P_{chronic}$ (mg/kg)	$STMR_{acute}$ or $STMR\text{-}P_{acute}$ (mg/kg)	$HR_{(acute)}$ or $HR\text{-}P_{(acute)}$ (mg/kg)
			New	Previous			
Carbosulfan (145) ADI: 0–0.01 mg/kg bw ARfD: 0.02 mg/kg bw	AB 0001	Citrus pulp, Dry	W	0.1	-	-	-
	SO 0691	Cotton seed	W	0.03 (*)	0.11	0.21	-
	MO 0105	Edible offal (mammalian)	W	0.05 (*)	-	-	-
	VO 0440	Eggplant	0.15		0.36	0.71	0.91
	PE 0112	Eggs	W	0.05 (*)	-	-	-
	GC 0645	Maize	W	0.05 (*)	-	-	-
	AF 0645	Maize forage	W	0.05 (*)	-	-	-

	FC 0206	Mandarin	W	0.1	-	-	-
	FI 0345	Mango	0.1	-	0.265	0.52	1.3
	MM 0095	Meat (from mammals other than marine mammals)	W	0.05 (*) fat	-	-	-
	ML 0106	Milks	W	0.03 (*)	-	-	-
	FC 0004	Oranges, sweet, sour (subgroup)	W	0.1	-	-	-
	VR 0589	Potato	W	0.05	-	-	-
	PM 0110	Poultry meat	W	0.05 (*)	-	-	-
	PO 0111	Poultry, edible offal of	W	0.05 (*)	-	-	-
	GC 0649	Rice	W	0.05 (*)	-	-	-
	AS 0649	Rice straw and fodder, dry	W	0.05 (*)	-	-	-
	HS 0191	Spices, fruits and Berries	W	0.07	-	-	-
	HS 0193	Spices, roots and rhizomes	W	0.1	-	-	-
	VR 0596	Sugar beet	W	0.3	-	-	-
	AV 0596	Sugar beet leaves or tops	W	0.05 (*)	-	-	-

$STMR(-P)_{chronic}$ Expressed as toxic equivalent residues (carbosulfan +10×carbofuran)

$STMR(-P)_{acute}$ Expressed as toxic equivalent residues (carbosulfan + 20×carbofuran)

$HR_{(acute)}$ Expressed as toxic equivalent residues (carbosulfan + 20×carbofuran)

Definition of the residue for compliance with the MRL for plant commodities: *Carbosulfan plus carbofuran (expressed as carbosulfan).*

Definition of the residue for dietary risk assessment for plant commodities: *Carbosulfan plus 10×(sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan* for long-term dietary exposure and *Carbosulfan plus 20×(sum of carbofuran, 3-hydroxy carbofuran (free and conjugated), 3-hydroxy-7-phenol and 3-keto-7-phenol), expressed as carbosulfan* for acute dietary exposure.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *Not established.*

Compound	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Clothianidin (238)	AM 0660	Almond hulls	0.1 (dw) T	-	0.02 (as)	-
	VS 0624	Celery	W	0.04, T	-	-
	HS 0780	Cumin seed	1	-	0.25	-
	VO 0050	Fruiting vegetables other than cucurbits	W	0.05	-	-
	VO 0050	Fruiting vegetables other than cucurbits except goji berry	0.05, T	-	0.02, T	0.03, T
	VO 2704	Goji berry	0.06, T	-	0.01, T	0.034, T
	DV 2704	Goji berry, dried	0.3, T	-	0.051, T	0.18, T
	TN 0085	Group of tree nuts	0.01*, T	-	0.01, T	0.01, T
	VA 0385	Onion, bulb	0.01*, T	-	0.01, T	0.01, T

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	TN 0672	Pecan	W	0.01*	-	-
	VS 2080	Subgroup of stems and petioles	0.04 T	-	0.01 T	0.02 T
T = based on thiamethoxam use only, C = based on clothianidin use only (as) – as received; (dw) – dry weight Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: *clothianidin.* The residue is not fat-soluble.						
Cyantraniliprole (263) ADI: 0–0.03 mg/kg bw ARfD: Unnecessary	FI 0326	Avocado	0.4	-	0.03	-
	VD 0071	Bean (dry)	W	0.3		
	VD 2065	Beans, dry, subgroup of	0.6	-	0.032	-
	FB 2005	Cane berries, subgroup of	4	-	1	-
	PE 0112	Eggs	0.3	0.15	0.048	-
	AB 0269	Grape pomace, dried	15	-	3.4	-
	DF 0269	Grape, dried (=Currants, raisins, and sultanas)	3	-	0.73	-
	FB 0269	Grapes	2	-	0.56	-
	FT 0305	Olives	1	-	0.33	-
	SO 0305	Olives for oil production	1	-	0.33	-
	VD 2066	Peas, dry, subgroup of	0.6		0.032	-
	VD 4521	Soya bean (dry)	W	0.4	-	-
	DT 1114	Tea, green, black (black, fermented and dried)	50	-	4.05	-
	FB 1236	Wine-grapes	W	1	-	-
	For dietary exposure and/or dietary burden estimations					
		Grape	-	-	-	-
		Alcoholic fermentation wine	-	-	1.1	-
		Bottled wine	-	-	0.90	-
		Juice	-	-	0.49	-
		Malolactic fermentation wine	-	-	0.95	-
		Must	-	-	1.4	-
		Wet pomace	-	-	2.6	-
		Olive	-	-		-
		Processed olive	-	-	0.19	-
		Raw oil	-	-	0.40	-
		Refined oil	-	-	0.26	-
		Tea Infusion	-	-	0.055	-
		Poultry fat	-	-	0.009	-
		Poultry meat	-	-	0.004	-
		Poultry offal	-	-	0.036	-
Definition of the residue for compliance with the MRL for plant and animal commodities: *cyantraniliprole*. Definition of residue for estimation of dietary intake for unprocessed plant commodities: *cyantraniliprole*. Definition of residue for estimation of dietary intake for processed plant commodities: *sum of cyantraniliprole and IN-J9Z38, expressed as cyantraniliprole*. Definition of residue for estimation of dietary intake for animal commodities: *sum of cyantraniliprole, 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-3,4-dihydro-3,8-dimethyl-4-oxo-6-quinazolinecarbonitrile [IN-J9Z38], 2-[3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazol-5-yl]-1,4-dihydro-8-methyl-4-oxo-6-quinazolinecarbonitrile [IN-MLA84], 3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1H-pyrazole-5-carboxamide [IN- N7B69] and3-Bromo-1-(3-chloro-2-pyridinyl)-N-[4-cyano-2[[(hydroxymethyl)amino]carbonyl]-6-methylphenyl]-1H-pyrazole-5-carboxamide [IN-MYX98], expressed a cyantraniliprole*.						

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
The residue is not fat-soluble. Note: metabolites IN-K5A78, IN-F6L99, and IN-N5M09 are assessed using Cramer Class III threshold of 1.5 µg/kg per day.						
Cyflumetofen (273)	SB 0716	Coffee bean	0.08	-	0.043	-
		Coffee beans instant powder	-	-	0.010	-
	SM 0716	Coffee beans roasted		-	0.027	-
	VC 0424	Cucumber	0.5	-	0.085	-
		Hops beer	-	-	0.049	-
		Hops extract	-	-	13.9	-
	MU 1100	Hops, dried	15	-	3.6	-
		Nectarine canned	-	-	0.012	-
		Nectarine jam	-	-	0.028	-
	DF 0245	Nectarine, dried	2	-	1.1	-
		Peach canned	-	-	0.012	-
		Peach jam	-	-	0.028	-
	DF 0247	Peach, dried	2	-	1.1	-
	FS 0013	Subgroup of cherries	0.4	-	0.106	-
	FS 2001	Subgroup of peaches	0.3	-	0.125	-
Definition of the residue for plant commodities (for compliance with the MRL): *Cyflumetofen.* Definition of the residue for plant commodities (for estimation of dietary intake): *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen.* Definition of the residue for animal commodities (for compliance with the MRL and estimation of dietary intake): *Sum of cyflumetofen and 2-trifluoromethylbenzoic acid (metabolite B-1), expressed as cyflumetofen.* Residue is not fat-soluble.						
Deltamethrin (135)	FI 0350	Papaya	0.2	-	0.01	0.01
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *sum of the deltamethrin and its trans- and α-R- isomers.* The residue is fat-soluble.						
Difenoconazole (224)	FB 2005	Cane berries	3	-	0.69	1.7
	CF 3516	Maize aspirated grain fractions [a]	-	-	0.5	-
	CF 3517	Maize gluten [a]	0.05	-	0.031	-
	OC 0645	Maize oil, crude	0.02	-	0.012	-
	AS 3569	Maize, bran [a]	-	-	0.032	-
	CF 1255	Maize, flour	0.015	-	0.008	-
	AS 0645	Maize, hay and/or straw [a]	15 (dw)	-	2.4 (as received)	8.5 (as received)
	VL 0485	Mustard greens	8	-	1.6	6.1
	FS 0014	Prunes	4	-	0.94	2.6
	VR 0494	Radish	0.7	-	0.17	0.31
	VL 0494	Radish leaves	8	-	1.6	6.1
	FS 0012	Stone fruits	1.5	-	0.365	1.02
	GC 2091	Subgroup of maize Cereals	0.015	-	0.01	-
	VR 0508	Sweet potato	4	-	1.2	1.9
(a) Value not relevant for IEDI assessment calculations. The definition of the residue for compliance with MRL and for dietary intake for plant commodities is parent *difenoconazole*, while for animal commodities it is defined as sum of difenoconazole and 1-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-(1,2,4-triazol)-1-yl-ethanol (CGA205375), expressed as difenoconazole. The residue is fat-soluble.						
	DT 1114	Black, Green tea infusions	-	-	0.038	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Diflubenzuron (130)		Tea, Black, Green, dried and fermented (subgroup)	40	-	9.4	-
Definition of the residue for compliance with the MRL for plant and animal commodities: *diflubenzuron* Definition of the residue for dietary risk assessment for plant and animal commodities: *diflubenzuron* The residue is fat-soluble.						
Dinotefuran (255)	VO 2704	Goji berry	0.6	-	0.12	0.34
	DV 2704	Goji berry, dried	2	-	0.26	1.1
	VO 0050	Group of fruiting vegetables other than cucurbits (except sweet corn and mushrooms)	W	0.5	-	-
	VO 0050	Group of fruiting vegetables other than cucurbits (except goji berry)	0.5	-	0.15 A)	0.55 A)
A) Residue recommendations were made by the 2012 JMPR. Definition of the residue for compliance with the MRL for plant commodities: *dinotefuran*. Definition of the residue for dietary risk assessment for plant commodities: sum of *dinotefuran, UF, and DN, expressed as dinotefuran*. Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: *sum of dinotefuran and UF, expressed as dinotefuran.* The residue is not fat-soluble.						
Emamectin (247) (addendum) ADI: 0–0.0005 mg/kg bw ARfD: 0.02 mg/kg bw	-	-	-	-	-	-
Emamectin was previously evaluated at JMPR 2011 when an ADI of 0–0.000 5 mg/kg bw and ARfD of 0.03 mg/kg bw were established for emamectin benzoate. Emamectin benzoate was evaluated by JECFA in 2013. The committee confirmed the HBGVs established by JMPR 2011. At JMPR 2014Meeting the ARfD of 0.03 mg/kg bw was withdrawn and an ARfD of 0.02 mg/kg bw established. Emamectin was evaluated by the present Meeting, due to a request for additional information on analytical methodology, storage stability and MRLs. The results of the newly submitted studies did not affect the previously established ADI or ARfD for emamectin benzoate.						
Florylpicoxamid (332) ADI: 0–0.1 mg/kg bw ARfD: Unnecessary	FB 0269	Grapes	3	-	0.375	-
	FB 0275	Strawberry	1.5	-	0.26	-
	FI 0327	Banana	0.4	-	0.021	-
	FI 0345	Mango	0.5	-	0.021	-
	VC 2039	Subgroup of fruiting vegetables, cucurbits - cucumbers and summer squashes	0.3	-	0.063	-
	VC 2040	Subgroup of fruiting vegetables, cucurbits – melons, pumpkins and winter squashes	0.4	-	0.0795	-
	VO 2045	Subgroup of tomatoes	0.9	-	0.12	-
	VO 0444	Peppers, chili	0.8	-	0.15	-
	VO 0445	Peppers, sweet	0.8	-	0.15	-
	HS 0444	Peppers, chili, dried	8	-	1.5	-
	VO 2046	Subgroup of eggplants	0.9	-	0.12	-
	VD 0533	Lentil (dry)	0.02	-	0	-
	VR 0596	Sugar beet	0.05	-	0.021	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	GC 0654	Wheat	0.03	-	0.021	-
	SO 0495	Rape seed	0.15	-	0.021	-
	DF 0269	Grape, dried	7	-	0.8	-
	JF 0269	Grape, juice	-	-	0.1	-
		Grape, jelly	-	-	0.023	-
		Grape, wine (red)	-	-	0.02	-
		Grape, wine (white)	-	-	0.01	-
	DV 0448	Tomato, dried	6	-	0.72	-
	DM 0448	Tomato, paste/ puree	-	-	0.076	-
	JF 0448	Tomato, juice	-	-	0.01	-
		Tomato, canned fruit	-	-	<0.004	-
	DM 3523	Refined sugar	-	-	<0.004	-
	CM 0654	Wheat bran (unprocessed)	0.07	-	0.046	-
		Wheat white flour (550)	-	-	<0.019	-
		Wheat wholemeal flour	-	-	0.025	-
		Wheat wholemeal bread	-	-	0.021	-
	CF 1210	Wheat germ	-	-	<0.019	-
		Wheat starch	-	-	<0.019	-
	CF 3522	Wheat gluten	0.04	-	0.027	-
	MO 0105	Edible offal (Mammalian)	0.09	-	0.023 (liver) 0.022 (kidney)	-
	PE 0269	Eggs	0.02	-	0	-
	MF 0100	Mammalian fats (except milk fats)	0.15	-	0.043	-
	MM 0095	Meat (from mammals other than marine mammals)	0.15	-	0.024 (muscle) 0.043 (fat)	-
	ML 0095	Milks	0.03	-	0.013	-
	PF 0111	Poultry fats	0.02	-	0	-
	PM 0111	Poultry meat	0.02	-	0	-
	PO 0111	Poultry, edible offal of	0.02	-	0	-
	AS 0654	Wheat, hay and/or straw	2 (dw)	-	0.086 (as received)	-
	Additional values used in estimating livestock dietary burdens					
					Median residue (-P) mg/kg	highest residue (-P) mg/kg
	AS 3552	Wheat, forage	-	-	0.22	6
	AS 0654	Wheat, hay and/or straw	-	-	0.086	1.6
	AM 0495	Rape seed, forage	-	-	0.07	0.12
	AM 0596	Sugar beet, leaves or tops	-	-	0.0325	0.2
		Sugar beet pulp, dry	-	-	0.13	-
		Sugar beet, ensiled pulp	-	-	0.02	-
		Sugar beet, molasses	-	-	0.004	-
	CF 3521	Wheat aspirated grain fractions	-	-	0.18	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	CF 3522	Wheat gluten feed meal	-	-	0.02	-
	CF 3515	Wheat milled bypdts (Shorts)	-	-	0.025	-
	DM 3525	Tomato pomace, wet	-	-	1.4	-
	AM 0495	Rapeseed, forage	-	-	0.07	0.12
The residue definition for compliance with the MRL and dietary exposure for plant commodities is *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid.* The residue definition for compliance with the MRL and dietary exposure for animal commodities is *sum of florylpicoxamid and X12485649 expressed as florylpicoxamid.* The residue is fat-soluble.						
Fluazinam (333)	-	-	-	-	-	-
Definition of the residue for plant commodities for enforcement of MRLs: *fluazinam* Definition of the residue for plants for dietary risk assessment: *the Meeting was unable to conclude on a residue definition for risk assessment.*						
Fluopyram (243)	GC0640	Barley	0.4	0.2	0.041	-
	GC0641	Buckwheat	0.4		0.041	-
	MO0105	Edible offal, (mammalian)	8	8	3.8	7.4
	PE0112	Eggs	2	2	0.46	1.5
	MF0100	Mammalian fats (except milk fats)	1.5	1.5	0.67	1.5
	MM0095	Meat (from mammals other than marine mammals)	1.5	1.5	muscle: 0.51 fat: 0.67	muscle: 1.0 fat: 1.5
	ML0106	Milks	0.8	0.8	0.48	-
	GC0647	Oats	0.4	0.2	0.041	-
	PO111	Poultry, edible offal of	4	5	0.88	3.1
	PF0111	Poultry fats	1	1	0.28	0.90
	PM0110	Poultry meat	1.5	1.5	Muscle: 0.19 Fat: 0.28	Muscle: 0.97 Fat: 0.90
	GC0650	Rye	0.2	0.9	0.035	-
	GC0651	Sorghum	0.6		0.18	-
	GC0653	Triticale	0.2	0.9	0.035	-
	GC0654	Wheat	0.2	0.9	0.035	-
	CF0654	Wheat bran	0.6	-	0.081	-
	CF1211	Wheat flour	-	-	0.0036	-
	CF1210	Wheat germ	0.5	-	0.072	-
		(animal feed commodities)			(median)	(highest)
		Aspirated grain fraction of wheat	-	-	2.1	
	AS0640	Barley, hay and/or straw	6 (dw)	-	Straw: 0.67 Hay: 1.2 (ar)	straw: 1.9 hay: 4.1 (ar)
	AS0640	Barley straw and fodder, dry	W	2	-	-
	AS3559	Oat, hay and/or straw	6 (dw)	-	Straw: 0.67 Hay: 1.2 (ar)	straw: 1.9 hay: 4.1 (ar)

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	AS0647	Oat straw and fodder, dry	W	2	-	-
	AS0650	Rye, forage	-	-	0.24 (ar)	1.3 (ar)
	AS3560	Rye, hay and/or straw	6 (dw)		Straw: 0.67 Hay: 1.2 (ar)	straw: 1.9 hay: 4.1 (ar)
	AS0650	Rye straw and fodder, dry	W	23	-	-
	AS0651	Sorghum, forage (green)	-	-	0.43 (ar)	3.2 (ar)
	AS3561	Sorghum, stover	3 (dw)	-	0.45 (ar)	1.5 (ar)
	AS0653	Triticale, forage			0.24 (ar)	1.3 (ar)
	AS0653	Triticale, hay and/or straw	6 (dw)	-	Straw: 0.67 Hay: 1.2 (ar)	straw: 1.9 hay: 4.1 (ar)
	AS0653	Triticale straw and fodder, dry	W	23	-	-
	AS3552	Wheat, forage	-	-	0.24 (ar)	1.3 (ar)
	AS0654	Wheat, hay and/or straw	6 (dw)	-	Straw: 0.67 Hay: 1.2 (ar)	straw: 1.9 hay: 4.1 (ar)
	AS0654	Wheat straw and fodder, dry	W	23	-	-
dw: dry weight basis, ar: as received. Definition of the residue for compliance with MRL and for estimation of dietary risk assessment for plant commodities: *fluopyram.* Definition of the residue for compliance with the MRL for animal commodities: *sum of fluopyram and 2-(trifluoromethyl)benzamide, expressed as fluopyram.* Definition of the residue for dietary risk assessment for animal commodities: *sum of fluopyram, 2-(trifluoromethyl)benzamide and the combined residues of N-(E)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide and N-(Z)-2-[3-chloro-5-(trifluoromethyl)pyridine-2-yl]ethenyl)-2-trifluoromethyl)benzamide, all expressed as fluopyram.* The residue is not fat-soluble.						
Imazapyr (267)	GC 0649	Rice	0.06	-	0.01	-
	CM 1206	Rice bran, unprocessed	0.2	-	0.015	-
	AS 0649	Rice, hay and/or straw	0.015	-	-	-
	CM 0649	Rice, husked	0.07	-	0.01	-
	CM 1205	Rice, polished	0.05	-	0.01	-
	GC 0654	Wheat	0.6	0.05 *	0.079	-
	CM 0654	Wheat bran, unprocessed	1	-	0.116	-
	CF 1210	Wheat germ	1	-	0.11	-
	AS 0654	Wheat straw and fodder, dry	W	0.05 *	-	-
	AS 0654	Wheat, hay and/or straw	1 (dw)	-	-	-
	Dietary exposure					
		Wheat gluten	-	-	0.032	-
		Wheat starch	-	-	0.004	-
	CF 1212	Wheat whole meal (flour)	-	-	0.078	-
		Wheat whole meal bread	-	-	0.062	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	CF 1211	Wheat, flour	-	-	0.050	-
	Animal dietary					
					Median residue mg/kg	**Highest residue mg/kg**
		Rice straw	-	-	0.01 (ar)	0.013 (ar)
	CF 3522	Wheat gluten meal	-	-	0.035	-
		Wheat hay	-	-	0.32 (dw)	0.532 (dw)
	CF 3514	Wheat middlings	-	-	0.057	-
	CF 3514 and 3515	Wheat milled by-products	-	-	0.078	-
	CF 3515	Wheat shorts	-	-	0.063	-
		Wheat straw	-	-	0.005 (dw)	0.012 (dw)
(as) – as received; (dw) – dry weight Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: *Imazapyr*. The residue is not fat-soluble.						
Iprodione (111) ADI: 0–0.06 mg/kg bw ARfD: 0.6 mg/kg bw	TN 0660	Almond	0.3	0.2	0.17	0.0395
	AM 0660	Almond hulls	50 (dw)	2	n.a.	14.85 (ar)
	FP 0226	Apple (in 1994 10 Po was withdrawn)	-	-	-	-
	GC 0640	Barley	W	2	-	-
	AL 0061	Bean, hay and/or straw *(Phaseolus* spp)	20 (dw)	100	highest: 7.72 (ar)	median: 3.7 (ar)
	VD 0071	Beans (*Phaseolus* spp) - dry	W	0.1	-	-
	VP 0061	Beans with pods (*Phaseolus* spp) - immature pods and succulent seeds	1.5	-	0.81	0.31
	FB 0264	Blackberries	W	30	-	-
	VB 0400	Broccoli [a]	40	25	24	9.4
	FB 2005	Cane berries, subgroup of	50	-	22.6	13.5
	VR 0577	Carrot	W	10 (Po)	-	-
	FS 0013	Cherries, subgroup of	0.3	10	0.14	0.042
	VP 2845	Common bean (pods and/or immature seeds)	W	2	-	-
	VC 0424	Cucumber	W	2	-	-
	FB 0269	Grapes	W	10	-	-
	FI 0341	Kiwifruit	W	5	-	-
	VL 0482	Lettuce, head	W	10	-	-
	VL 0483	Lettuce, leaf	W	25	-	-
	VA 0385	Onion, bulb	0.15	0.2	0.11	0.05
	FS 2001	Peaches (including Nectarines and Apricots), Subgroup of	0.05*	-	0.05	0.05
	FS 0247	Peaches	W	10	-	-
	FP 0009	Pome fruits (group)	W	5 (Po)	-	-
	VR 0589	Potato	0.05*	-	0.05	0.05
	VR 0589	Potato culls	0.15	-	n.a.	0.10
	DV 0589	Potato flakes/granules	0.05*	-	-	0.0145
	SO 0495	Rape seed	W	0.5	-	-
	FB 0272	Raspberries, red, black	W	30	-	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	GM 0649	Rice, husked	W	10	-	-
	HS 0193	Spices, roots and rhizomes	W	0.1	-	-
	HS 0190	Spices, seeds	W	0.05 (*)	-	-
	FB 0275	Strawberry	W	10	-	-
	VR 0596	Sugar beet	W	0.1 (*)	-	-
	SO 2091	Sunflower seed	W	0.5	-	-
	VO 0448	Tomato	W	5	-	-
	VL 2832	Witloof chicory (sprouts)	W	1	-	-
		Potato chips	-	-	n.a.	0.023
	Residue level for feed					
	AL 1030	Bean, forage (*Phaseolus* spp)	n.a.	-	12.2 (ar)	7.4 (ar)
	VR 0589	Potato culls	0.15	-	n.a.	0.10
(ar) – as received; (dw) – dry weight; n.a. = not applicable [a] On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of iprodione for the consumption of broccoli may present a public health concern. Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: *iprodione*. Definition of the residue for compliance with the MRL for animal commodities: *not concluded*. Definition of the residue for dietary risk assessment for animal commodities: *iprodione + 3-(3,5-dichlorophenyl)-2,4-dioxoimidazolidine-1-carboxamide (RP302490) + N-(3,5-dichloro-4-hydroxyphenyl)-2-carbamoylacetamide (RP36114).*						
Isocycloseram (334) ADI: 0–0.02 mg/kg bw ARfD: 0.5 mg/kg bw general population 0.08 mg/kg bw females of child-bearing age	AB 1230	Apple pomace, wet	1	-	0.25	-
	VB 0400	Broccoli	0.7	-	0.211	0.46
	VB 0402	Brussels sprouts	2	-	0.072	0.81
	VB 0041	Cabbages, head	4	-	0.0385	1.2
	VB 0404	Cauliflower	0.5	-	0.051	0.32
	OR 0001	Citrus Oil	80	-	13	-
	SB 0716	Coffee bean	0.04	-	0.01	-
	SO 0691	Cotton seed	0.5	-	0.11	-
	VC 0424	Cucumber	0.1	-	0.024	0.063
	MO 0105	Edible offal (Mammalian)	0.3	-	0.013	0.16
	VO 0440	Eggplant	0.3	-	0.07	0.18
	FP 0009	Group of pome fruits	0.4	-	0.105	0.27
	GC 0645	Maize	0.01(*)	-	0.01	-
	AL 3558	Maize, stover	1.5	-	0.46	1
	MF 0100	Mammalian fats (except milk fats)	0.4	-	0.024	0.37
	MM 0095	Meat (from mammals other than marine mammals)	0.02	-	Muscle (0.0022) Fat (0.024)	Muscle (0.011) Fat (0.362)
	VC 0046	Melons, except watermelon	0.15	-	0.024	0.078
	ML 0106	Milks	0.05	-	0.0021	0.043
	VA 0385	Onion, bulb	0.01(*)	-	0.01	0.01
	AB 0004	Oranges, dried pulp	3	-	0.41	
	VO 0444	Peppers, chili	0.6	-	0.15	0.4
	(HS 0444)	Peppers, chili, dried	4.2	-	1.1	2.8
	VO 0445	Peppers, sweet	0.3	-	0.0935	0.18
	VR 0589	Potato	0.01(*)	-	0	0
	DF 0014	Prune, dried	1.5	-	0.22	-
	VD 0541	Soya bean (dry)	0.15	-	0.0225	-
	AL 3533	Soya bean hulls	1	-	0.14	-
	AL 0541	Soya bean, hay and/or straw	20	-	5.3	14
	VC 0431	Squash, summer	0.09	-	0.012	0.063

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	FS 0013	Subgroup of cherries	1	-	0.344	0.62
	FC 0002	Subgroup of lemons and limes (including citron)	0.5	-	0.052	0.25
	FC0003	Subgroup of Mandarins (including mandarin-like hybrids)	0.4	-	0.088	0.25
	FC 0004	Subgroup of oranges, sweet, sour (including orange-like hybrids)	0.4	-	0.064	0.22
	FS 2001	Subgroup of peaches (including nectarine and apricots)	0.3	-	0.0985	0.23
	FS 0014	Subgroup of plums (including fresh Prunes)	0.4	-	0.071	0.32
	FC 0005	Subgroup of pummelo and grapefruits (including shaddock-like hybrids, among others grapefruit)	0.3	-	0.0645	0.15
	VO 0448	Tomato	0.5	-	0.1	0.43
	DV 0448	Tomato, dried	2	-	0.32	1.4
	DM 3525	Tomato, pomace	8	-	1.6	-
Definition of the residue for compliance with the MRL for plant commodities and for dietary risk assessment for plant commodities: *isocycloseram*. Definition of the residue for compliance with the MRL for animal commodities: *isocycloseram*. Definition of the residue for dietary risk assessment for animal commodities: the sum of *isocycloseram and metabolites* N-[2-amino-1-(hydroxymethyl)-2-oxo-ethyl]-4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4H-isoxazol-3-yl]-2-methyl-benzamide and 4-[5-(3,5-dichloro-4-fluoro-phenyl)-5-(trifluoromethyl)-4*H*-isoxazol-3-yl]-2-methyl-*N*-(3-oxoisoxazolidin-4-yl)benzamide (expressed as isocycloseram). The residue is fat-soluble.						
Isoflucypram (330) ADI: 0–0.06 mg/kg bw ARfD: Unnecessary	GC 0640	Barley	0.1	-	0.020	
	GC 0653	Triticale	0.05	-	0.020	
	GC 0654	Wheat	0.05	-	0.020	
	AS 0640	Barley, hay and/or straw	5	-	Median: 0.70 (dw)	
	AS 0653	Triticale, hay and/or straw	5	-	Median: 1.1 (dw)	
	AS 0654	Wheat, hay and/or straw	5	-	Median: 1.1 (dw)	
	ML 0106	Milks	0.005*	-	0.012	
	FM 0183	Milk fats	0.005*	-	-	
	MM 0095	Meat (from mammals other than marine mammals)	0.01*	-	Muscle: 0.034 Fat: 0.034	
	MF 0100	Mammalian fats (except milk fats)	0.01*	-	0.034	
	MO 0105	Edible offal (mammalian)	0.01*	-	0.034	
	PE 0112	Eggs	0.01*	-	0.012	
	PM 0110	Poultry meat	0.01*	-	Muscle: 0.012	

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
					Fat: 0.0012	
	PF 0111	Poultry fats	0.01*	-	0.012	
	PO 0111	Poultry, edible offal of	0.01*	-	0.012	
	-	Barley brewer's grain	-	-	Median: 0.028	
	-	Barley beer	-	-	0.0076	
	-	Pearl barley	-	-	0.0076	
	CF 3511	Barley flour	0.02	-	0.035	
	CM 3510	Barley bran, unprocessed	0.05	-	Median: 0.064	
	CF 1210	Wheat germ	0.015	-	-	
	-	Wheat bran, unprocessed	0.015	-	-	

	Isoflucypram residues in livestock feeds			
	CCN	**Commodity**	**Median/ Median-P (mg/kg)**	**Highest (mg/kg)**
	GC 0640	Barley	0.010	-
	GC 0653	Triticale	0.010	-
	GC 0654	Wheat	0.010	-
	AS 0640	Barley, hay and/or straw	0.28	1.1
	AS 0653	Triticale, hay and/or straw	0.55	3.6
	AS 0654	Wheat, hay and/or straw	0.55	3.6
	-	Barley brewer's grain	0.017	-
	CM 3510	Barley bran, unprocessed	0.043	-
	-	Wheat aspirated grain fractions	1.5	-
	CF 1210	Wheat germ	0.011	-
	-	Wheat gluten	0.0094	-

	Sum of isoflucypram and isoflucypram-desmethyl-propanol (free and conjugated) residues, expressed as isoflucypram, in feeds.			
	CCN	**Commodity**	**Median (mg/kg)**	
	GC 0640	Barley	0.022	
	GC 0653	Triticale	0.020	
	GC 0654	Wheat	0.020	
	AS 0640	Barley, hay and/or straw	0.38	
	AS 0653	Triticale, hay and/or straw	0.57	
	AS 0654	Wheat, hay and/or straw	0.57	
	-	Barley bran, unprocessed	0.079	
	-	Barley brewer's grain	0.037	

	Isoflucypram-desmethyl-propanol (free and conjugated), expressed as isoflucypram, in foods.			
	CCN	**Commodity**	**Median (mg/kg)**	
	GC 0640	Barley	0.012	
	GC 0653	Triticale	0.010	
	GC 0654	Wheat	0.010	
	ML 0106	Milks	0.0013	
	MM 0095	Meat (from mammals other than marine mammals)	0.0035	
	MF 0100	Mammalian fats (except milk fats)	0.0035	
	MO 0105	Edible offal (mammalian)	0.0035	
	PE 0112	Eggs	0.0015	
	PM 0110	Poultry meat	0.0015	
	PF 0111	Poultry fats	0.0015	
	PO 0111	Poultry, edible offal of	0.0015	
	-	Barley beer	0.0072	
	-	Pearl barley	0.0042	
	-	Barley flour	0.025	
	Metabolites of containing the isoflucypram-desfluoro-N-methyl-cyclopropyl-pyrazole-carboxamide-mercapto structure, expressed as isoflucypram, in rotational crops.			
	CCN	**Commodity**	**Median (mg/kg)**	
	VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	0.010	
	VL 2050	Subgroup of leafy greens	0.015	
	VL 0054	Subgroup of leaves of Brassicaceae, raw	0.015	
Definition of the residue for compliance with the MRL for plant and animal commodities: *Isoflucypram*. Definition of the residue for dietary risk assessment for plant commodities: *Sum of isoflucypram and isoflucypram-propanol (free and conjugated), expressed as isoflucypram.* Definition of the residue for dietary risk assessment for animal commodities: *Sum of isoflucypram, isoflucypram-propanol (free and conjugated), isoflucypram-carboxylic acid, isoflucypram-desmethyl-carboxylic acid, and isoflucypram-2-propanol (free and conjugated), expressed as isoflucypram.* The residue is fat-soluble.				

Compound	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Isotianil (335) ADI: 0–0.05 mg/kg bw ARfD: Unnecessary	FI0327	Banana	0.01 (*)	-	0	-
	FC0002	Subgroup of lemons and limes (including citron)	0.5	-	0.012	-
	FC0003	Subgroup of Mandarins (including mandarin-like hybrids)	0.4	-	0.012	-
	FC0004	Subgroup of oranges, sweet, sour (including orange-like hybrids)	0.4	-	0.012	-
	FC0005	Subgroup of Pummelo and grapefruits (including shaddock-like hybrids, among other grapefruit)	0.2	-	0.00715	-

	PO0111	Poultry, Edible offal of	0.02 (*)	-	0	-
	PF0111	Poultry fats	0.02 (*)	-	0	-
	PM 0110	Poultry meat	0.02 (*)	-	0	-
	MO 0105	Edible offal (Mammalian)	0.02 (*)	-	0	-
	MF 0100	Mammalian fats (except milk fats)	0.02 (*)	-	0	-
	MM 0095	Meat (from mammals other than marine mammals)	0.02 (*)	-	0	-
	ML 0106	Milks	0.02 (*)	-	0	-
	OR 0001	Citrus oil, edible	40	-	7.86	-
		Orange juice		-	0.0204	-
		Orange oil		-	7.86	-
		Orange peel processed		-	0.216	-
		Marmalade		-	0.0204	-

	Residue values used for estimation of livestock dietary burdens (isotianil+DCIT-acid)			
			Total residue	
	CCN	**Commodity**	**Median or median-P (mg/kg)**	**Highest or highest-P mg/kg**
	AB0001	Citrus pulp, dried	0.1158	

Compound	**CCN**	**Commodity**	**Recommended Maximum residue level (mg/kg)**		**STMR or STMR-P mg/kg**	**HR or HR-P mg/kg**
			New	**Previous**		
Mepiquat-chloride (336) ADI: 0–0.3 mg/kg bw ARfD: 0.6 mg/kg bw	SO0691	Cotton seed	4	-	1.3	-
	OC0691	Cotton seed oil, crude	-	-	0.056	-
	OR0691	Cotton seed oil, edible	-	-	0.052	-
	MO0105	Edible offal (mammalian)	0.04	-	Liver: 0.047 Kidney: 0.027	Liver: 0.059 Kidney: 0.036
	PE0112	Eggs	0.008(*)	-	0	0
	FB0269	Grapes	4	-	0.705	2.6
	DF0269	Grape, dried (=currants, raisins and sultanas)	20	-	2.7	10
	JF0269	Grape juice		-	0.78	-
	MF0100	Mammalian fat (except milk fats)	0.01	-	0.0092	0.0092
	MM0095	Meat (from mammals other than marine mammals)	0.01	-	Muscle: 0.0092 Fat: 0.0092	Muscle: 0.0092 Fat: 0.0092
	ML0106	Milk	0.008(*)	-	0.018	-
	PO0111	Poultry, edible offal of	0.008(*)	-	0	0
	PF0111	Poultry fats	0.008(*)	-	0	0
	PM0110	Poultry meat	0.008(*)	-	0	0
			-	-		-
		(animal feed commodities)	-	-	Median	-
		Cotton delinted seed	1.6	-		-
	AM3588	Cotton seed hulls		-	0.36	-
	AM3589	Cotton seed meal	8	-	2.5	-
	AB0269	Grape pomace, dried	15	-	1.8	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		Grape pomace, wet		-	0.78	-
All residue estimates above are expressed as mepiquat cation. Definition of the residue for compliance with the MRL for plant and animal commodities: *mepiquat cation* Definition of the residue for dietary exposure assessment for plant commodities: *mepiquat cation* Definition of the residue for dietary exposure assessment for animal commodities: *mepiquat cation and 4-hydroxy-1,1-dimethylpiperidinium cation (4-hydroxymepiquat cation, free and conjugated), expressed as mepiquat cation.* The residue is not fat-soluble.						
Oxathiapiprolin (291)	AM0660	Almond hulls	0.05	-	0.02	-
	FI0326	Avocado	0.09	-	0.0575	-
	TN0085	Group of tree nuts	0.01 (*)	-	0.01	0.01
	MU1100	Hops, dried	5	-	1.55	
	FB2006	Subgroup of bush berries	0.5	-	0.056	-
(as) – as received; (dw) – dry weight Definition of the residue for compliance with the MRL: *oxathiapiprolin.* Definition of the residue for dietary risk assessment for plant and animal commodities: *Sum of oxathiapiprolin, 5-(trifluoromethyl)-1H-pyrazole-3-carboxylic acid and 1-ß-D-glucopyranosyl-3-(-(trifluoromethyl)- H-pyrazole-5-carboxylic acid, expressed as parent equivalents*. The residue is not fat-soluble.						
Permethrin (120)	-	-	-	-	-	-
Definition of the residue for plant and animal commodities (for compliance with the MRL): Permethrin (sum of *cis* and *trans* isomers). Definition of the residue for plants and animals for dietary risk assessment: The Meeting was unable to conclude on a residue definition for risk assessment. No MRLs are recommended, nor are levels estimated for use in long-term and acute dietary exposure assessments as the Meeting could not reach a conclusion on the residue definition for risk assessment for plants and animals, and due to late submission of the relevant key data.						
Piperonyl butoxide (062)	-	-	-	-	-	-
Due to insufficient trials or limited data obtained from supervised trials, the Meeting did not make any recommendations for establishing MRLs and for IEDI assessments. The definition of the residue for compliance with MRLs and for dietary risk assessment for plant and animal commodities: *piperonyl butoxide*. The residue is fat-soluble.						
Prochloraz (142) ADI: 0–0.02 mg/kg bw ARfD: 0.2 mg/kg bw	-	-	-	-	-	-
The Meeting did not finalize the review for residues and will continue the periodic review in 2024.						
Propiconazole (160)	FI 0326	Avocado	0.02	-	0.085	0.12
	MO 0105	Edible offal (mammalian)	0.2	0.5	2.4	4.5 (liver) 5.0 (kidney)
	PE 0112	Eggs			0.08	0.10
	MF 0100	Mammalian fats (except milk fats)	0.05	0.01 (*)	0.11	0.23
	MM 0095	Meat (from mammals other than marine mammals)	-	-	0.07 (muscle) 0.11 (fat)	0.12 (muscle) 0.24 (fat)
	ML 0106	Milks	-	-	0.03	
	SO 0697	Peanut	0.03	-	0.03	0.05
	AL 0697	Peanut, hay and/or straw	50 (dw)	-	36.5 (as received)	91 (as received)
	PF 0111	Poultry fats	0.01 (*)	-	0.05	0.05

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	PM 0110	Poultry meat		-	0.05	0.05
	PO 0111	Poultry, edible offal of	0.01 (*)	-	0.11	0.12
	CM 1206	Rice bran, processed	80	-	48	-
	GC 0649	Rice grain	30[a]	-	16.5	-
	CM 1207	Rice, hulls	80	-	67	-
	CM 0649	Rice, husked	4	-		-
	CM 1205	Rice, polished	10	-	1.95	-
	Input for dietary burden calculations for maximum residue level estimation using parent propiconazole residues					
	CCN	**Commodity**	**Recommended residue level(mg/kg)**			
			Median		**Highest**	
		Peanut meal	0.005 (0.01 x 0.5)			
	AL 0697	Peanut, hay and/or straw	9.515 (as received)		30 (as received)	
	CM 1206	Rice bran, unprocessed	18 (7.7 × 2.39)		-	
	GC 0649	Rice grain	7.7		-	
	CM 1207	Rice hulls	19 (7.7 × 2.5)		-	
	Definition of the residue for compliance with the MRL for plant and animal commodities: *propiconazole.* Definition of the residue for dietary risk assessment for plant and animal commodities: *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole.* The residue is fat-soluble.					
Pyrethrins (063)	-	-	-	-	-	-
On the basis of the data obtained from supervised trials, the Meeting did not make any recommendations for establishing MRLs and for IEDI assessments. This was due to the fact that no trial matched the GAP and / or insufficient data. The definition of the residue for compliance with MRLs and for dietary risk assessment for plant and animal commodities: *total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with World Standard pyrethrum extract*. The residue is fat-soluble						
Tetraniliprole (324)	FC 0003	Subgoup of mandarins (including mandarin-like hybrids)	1.5	1.0	0.19	-
The critical GAP for mandarins and lemons is the same (citrus fruit). As such the residues from both crops can be assessed against the critical GAP in the USA for citrus fruit of three foliar applications at 60 g ai/ha, with a retreatment interval of 5 days and a PHI of 1 day. • Residues of tetraniliprole in mandarins both for maximum residue estimation and risk assessment in ranked order were (n=4): 0.17, 0.18, 0.19 and 0.54 mg/kg in whole fruit. • Residues of tetraniliprole in lemons both for maximum residue estimation and risk assessment in ranked order were (n=5): 0.062, 0.13, 0.19, 0.20 and 0.77 mg/kg in whole fruit. The combined dataset for residues in mandarins and lemons both for MRL and risk assessment in ranked order were (n=9): 0.062, 0.13, 0.17, 0.18, 0.19, 0.19, 0.20, 0.54 and 0.77 mg/kg in whole fruit. Mandarins are a major crop and as such at least 6 trials should be available. Considering the request of the EU, noting that the median residues for mandarins and lemons are similar and the datasets are of a similar population (Mann-Whitney) the 2023 Meeting agreed to combine the datasets. The 2023 Meeting estimated a maximum residue level of 1.5 mg/kg, and an STMR of 0.19 mg/kg for Subgroup of Mandarins (including mandarin-like hybrids), based on the combined dataset of mandarins and lemons. Thereby replacing its previous recommendation (JMPR 2022) of a maximum residue level of 1.0 mg/kg and an STMR of 0.185 mg/kg for tetraniliprole in the Subgroup of Mandarins (including mandarin-like hybrids).						
Thiamethoxam (245)	AM 0660	Almond hulls	2 (dw)	-	0.32 (as)	-
	VS 0624	Celery	W	1	-	-
	HS 0780	Cumin seed	1	-	0.26	-
	VO 0050	Fruiting vegetables other than cucurbits	W	0.7	-	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)			STMR or STMR-P mg/kg		HR or HR-P mg/kg	
			New	Previous					
	VO 0050	Fruiting vegetables other than cucurbits except goji berry	0.7	-		0.08		0.47	
	VO 2704	Goji berry	1.5	-		0.21		0.65	
	DV 2704	Goji berry, dried	5	-		0.225		1.7	
	TN 0085	Group of tree nuts	0.01*	-		0.01		0.01	
	VA 0385	Onion, bulb	0.02	-		0.01		0.014	
	TN 0672	Pecan	W	0.01*		-		-	
	VS 2080	Subgroup of stems and petioles	0.8	-		0.215		0.4	
(as) – as received; (dw) – dry weight Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: *thiamethoxam.* Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities (except poultry): *thiamethoxam and clothianidin* (considered separately). Definition of the residue for dietary risk assessment for poultry: *sum of thiamethoxam, CGA 265307, and MU3, expressed as thiamethoxam and clothianidin* (clothianidin considered separately). The residue is not fat-soluble.									
Thiophanate-methyl (077) ADI: 0–0.09 mg/kg bw ARfD: 1 mg/kg bw	TN 0660	Almond	0.15*	0.1		TM	0.05	TM	0.05
						MBC	0.05	MBC	0.05
	FS 0240	Apricot	W	2	B	-	-	-	-
	VS 0621	Asparagus	W	0.2	C	-	-	-	-
	FI 0327	Banana	W	0.2	B	-	-	-	-
	GC 0640	Barley	W	0.5	C	-	-	-	-
	AS 0640	Barley, hay and/or straw	W	2	C	-	-	-	-
	VD 0071	Beans (dry)	W	0.5	Th	-	-	-	-
	FB 0018	Berries and other small fruits, except grapes	W	1	B, Th	-	-	-	-
	VB 0402	Brussels sprouts	W	0.5	B	-	-	-	-
	VR 0577	Carrot	W	0.2	B	-	-	-	-
	MM 0812	Cattle meat	W	0.05*	B	-	-	-	-
	FS 0013	Cherries (subgroup)	W	10	T	-	-	-	-
	PF 0840	Chicken fat	W	0.05	B	-	-	-	-
	SB 0716	Coffee beans	W	0.1	C	-	-	-	-
	VP 0526	Common bean (pods and/or immature seeds)	W	0.5	T	-	-	-	-
	VC 0424	Cucumber	W	0.05*	B, C	-	-	-	-
	MO 0105	Edible offal (mammalian)	W	0.05*	B	-	-	-	-
	PE 0112	Eggs	W	0.05*	B	-	-	-	-
	VP 0529	Garden pea, shelled (succulent seeds)	W	0.02	T	-	-	-	-
	VC 0425	Gherkin	W	0.05*	B, C	-	-	-	-
	FB 0269	Grapes	W	3	B, T	-	-	-	-
	VL 0482	Lettuce, head	W	5	T	-	-	-	-
	FI 0345	Mango	W	5	C	-	-	-	-
	ML 0106	Milks	W	0.05*	B	-	-	-	-
	FS 0245	Nectarine	W	2	B	-	-	-	-
	FC 0004	Oranges, sweet, sour (including orange-	W	1	B	-	-	-	-

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)			STMR or STMR-P mg/kg		HR or HR-P mg/kg	
			New	Previous					
		like hybrids) (subgroup)							
	FS 0247	Peach	W	2	B	-	-	-	-
	SO 0697	Peanut	W	0.1*	T	-	-	-	-
	AL 0697	Peanut fodder	W	3	T	-	-	-	-
	VO 0444	Peppers chili	W	2	T	-	-	-	-
	HS 0444	Peppers chili, dried	W	20	C	-	-	-	-
	FI 0353	Pineapple	W	5	B	-	-	-	-
	FS 0014	Plums (including fresh prunes) (subgroup)	W	0.5	B	-	-	-	-
	FP 0009	Pome fruits (group)	W	3	B, C, T	-	-	-	-
	PM 0110	Poultry meat	W	0.05*	B	-	-	-	-
	SO 0495	Rape seed	W	0.05*	C	-	-	-	-
	AS 0469	Rice, hay and/or straw	W	15	C	-	-	-	-
	CM 0649	Rice, husked	W	2*	B	-	-	-	-
	GC 0650	Rye	W	0.1	C, T	-	-	-	-
	VD 0541	Soya bean (dry)	W	0.5	T	-	-	-	-
	AL 0541	Soya bean, hay and/or straw	W	0.1	C	-	-	-	-
	HS 0191	Spices, fruits and berries	W	0.1		-	-	-	-
	HS 0193	Spices, roots and rhizomes	W	0.1		-	-	-	-
	HS 0190	Spices, seeds	W	5		-	-	-	-
	VC 0431	Squash, summer	W	0.5	T	-	-	-	-
	VR 0596	Sugar beet	W	0.1*	T	-	-	-	-
	VO 0448	Tomato	W	0.5	B, C	-	-	-	-
	TN 0085	Tree nuts (group)	W	0.1*	B	-	-	-	-
	GC 0654	Wheat	W	0.05*	B, T	-	-	-	-
	AS 0654	Wheat, hay and/or straw	W	1	Risk a	-	-	-	-
Note: Previous MRL was the sum of benomyl, carbendazim, and thiophanate-methyl, expressed as carbendazim. Letters in upper case indicate the source(s) of the data on which the MRL is based. (B: benomyl; C: carbendazim; T: thiophanate-methyl). Definition of the residue for compliance with the MRL for plant commodities: *the sum of thiophanate-methyl and carbendazim, expressed as thiophanate-methyl.* Definition of the residue for compliance with the MRL for animal commodities: *the sum of thiophanate-methyl, carbendazim, and sodium 2-(methoxycarbonylamino)-1H-benzimidazol-5-yl (5-OH-MBC) (free and conjugated), expressed as thiophanate-methyl.* Definition of the residue for dietary risk assessment for plant and animal commodities: *thiophanate-methyl.* Carbendazim and 5-OH-MBC (free and conjugated) need to be assessed, separately, against the TTC Cramer Class III threshold. The threshold applies to both chronic and acute exposure estimates. The residue is not fat-soluble.									
Tricyclazole (337) ADI: 0–0.05 mg/kg bw ARfD: 0.05 mg/kg bw	MO 0105	Edible offal (mammalian)	0.1	-		Liver 0.016 (Kidney 0.008)		Liver 0.18 (Kidney 0.025)	
	PE 0112	Eggs	0.01 (*)	-		0		0	
	CM 0649	Husked rice	0.3	-		0.01		-	
	MF 0100	Mammalian fats (except milk fats)	0.01 (*)	-		0		0	

Compound	CCN	Commodity	Recommended Maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	MM 0095	Meat (from mammals other than marine mammals)	0.01 (*)	-	0	0
	ML 0106	Milks	0.01 (*)	-	0	-
	CM 1205	Polished rice	0.3	-	0.01	-
	PF 0111	Poultry fats	0.01 (*)	-	0	0
	PM 0110	Poultry meat	0.01 (*)	-	0	0
	PO 0111	Poultry, edible offal of	0.01 (*)	-	0.009	0.010
	GC 0649	Rice	5	-	0.735	-
	AS 0649	Rice, hay and/or straw	5 (dw)	-	0.01 (median, ar)	3.47 (highest, ar)
	AS 3570	Rice, hulls	15 (dw)	-	0.02 (median, ar)	-
	For calculating animal dietary burden and dietary risk assessment					
	CM 1206	Rice bran, unprocessed	-	-	0.058 ar	-
		Rice germ	-	-	0.058 ar	-
(as) – as received; (dw) – dry weight Definition of the residue for compliance with the MRL for plant and animal commodities: *Tricyclazole.* Definition of the residue for risk assessment for plant and animal commodities: *Sum of tricyclazole and 1,3,4-triazolo[3,4-b][1,3]benzo-thiazol-5-methanol, expressed as tricyclazole.* The residue is not fat-soluble.						
Zeta-cypermethrin (118) ADI: ARfD:	FI0326	Avocado	0.5	-	0.14	0.28
	VA2031	Subgroup of bulb onions	0.05*	0.01*	0	0
	FB2006	Subgroup of bush berries	1.5	-	0.40	0.53
Definition of the residue for both compliance with MRL and estimation of dietary intake for plant and animal commodities: *cypermethrins (sum of alpha and zeta).* The residue is fat-soluble.						

Annex 2: Index of reports and evaluations of pesticides by the JMPR

Numbers in parentheses after the names of pesticides are Codex classification numbers. The abbreviations used are:

T, evaluation of toxicology
R, evaluation of residue and analytical aspects
E, evaluation of effects on the environment

Abamectin (177)	1992 (T,R), 1994 (T,R), 1995 (T), 1997 (T,R), 2000 (R), 2015 (R), 2017 (T), 2018 (R)
Acephate (095)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T), 1984 (T,R), 1987 (T), 1988 (T), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1996 (R), 2002 (T), 2003 (R), 2004 (corr. to 2003 report), 2005 (T), 2006 (R), 2011 (R)
Acetamiprid (246)	2011 (T, R), 2012 (R), 2015 (R), 2017 (R), 2021 (R), 2023 (R)
Acetochlor (280)	2015 (T, R), 2019 (T, R)
Acibenzolar-S-methyl (288)	2016 (T, R)
Acrylonitrile	1965 (T, R)
Afidopyropen (312)	2019 (T, R), 2021 (R), 2022 (R)
Aldicarb (117)	1979 (T, R), 1982 (T,R), 1985 (R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1994 (R), 1996 (R), 2001 (R), 2002 (R), 2006 (R)
Aldrin (001)	1965 (T), 1966 (T, R), 1967 (R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Allethrin	1965 (T, R)
Ametoctradin (253)	2012 (T, R)
Aminocarb (134)	1978 (T, R), 1979 (T, R)
Aminocyclopyrachlor (272)	2014 (T, R)
Aminomethylphosphonic acid (AMPA, 198)	1997 (T, R)
Aminopyralid (220)	2006 (T, R), 2007 (T,R)
Amitraz (122)	1980 (T, R), 1983 (R), 1984 (T,R), 1985 (R), 1986 (R), 1989 (R), 1990 (T,R), 1991 (R & corr. to 1990 R evaluation), 1998 (T)
Amitrole (079)	1974 (T, R), 1977 (T), 1993 (T, R), 1997 (T), 1998 (R)
Anilazine (163)	1989 (T, R), 1992 (R)
Atrazine	2007 (T)
Azinphos-ethyl (068)	1973 (T, R), 1983 (R)
Azinphos-methyl (002)	1965 (T), 1968 (T, R), 1972 (R), 1973 (T), 1974 (R), 1991 (T, R), 1992 (corr. to 1991 report), 1993 (R), 1995 (R), 2007 (T)

Chlormequat (015)	1970 (T,R), 1972 (T,R), 1976 (R), 1985 (R), 1994 (T,R), 1997 (T), 1999 (ARfD), 2000 (R), 2017 (T, R), 2022 (R)
Chlorobenzilate (016)	1965 (T), 1968 (T,R), 1972 (R), 1975 (R), 1977 (R), 1980 (T)
Chloropicrin	1965 (T,R)
Chloropropylate	1968 (T,R), 1972 (R)
Chlorothalonil (081)	1974 (T,R), 1977 (T,R), 1978 (R), 1979 (T,R), 1981 (T,R), 1983 (T,R), 1984 (corr. to 1983 report and T evaluation), 1985 (T,R), 1987 (T), 1988 (R), 1990 (T,R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1997 (R), 2009 (T), 2010 (R), 2012 (R), 2015 (R), 2019 (T, R)
Chlorpropham (201)	1965 (T), 2000 (T), 2001 (R), 2005 (T), 2008 (R)
Chlorpyrifos (017)	1972 (T,R), 1974 (R), 1975 (R), 1977 (T,R), 1981 (R), 1982 (T,R), 1983 (R), 1989 (R), 1995 (R), 1999 (T), 2000 (R), 2004 (R), 2006 (R), 2021 (R)
Chlorpyrifos-methyl (090)	1975 (T,R), 1976 (R, Annex I only), 1979 (R), 1990 (R), 1991 (T,R), 1992 (T and corr. to 1991 report), 1993 (R), 1994 (R), 2001 (T), 2009 (R)
Chlorthion	1965 (T)
Clethodim (187)	1994 (T,R), 1997 (R), 1999 (R), 2002 (R), 2019 (T, R)
Clofentezine (156)	1986 (T,R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 2005 (T), 2007 (R), 2021 (R)
Clothianidin (238)	2010 (T,R), 2011 (R), 2014 (R), 2021 (R), 2023 (R)
Coumaphos (018)	1968 (T,R), 1972 (R), 1975 (R), 1978 (R), 1980 (T,R), 1983 (R), 1987 (T), 1990 (T,R)
Crufomate (019)	1968 (T,R), 1972 (R)
Cyanophenfos (091)	1975 (T,R), 1978 (T: ADI extended, but no evaluation), 1980 (T), 1982 (R), 1983 (T)
Cyantraniliprole (263)	2013 (T,R), 2015 (R), 2018 (R), 2023 (R)
Cyazofamid (281)	2015 (T, R), 2018 (R)
Cyclaniliprole (296)	2017 (T, R), 2019 (R)
Cycloxydim (179)	1992 (T,R), 1993 (R), 2009 (T), 2012 (R)
Cyflumetofen (273)	2014 (T,R), 2023 (R)
Cyfluthrin (157)	1986 (R), 1987 (T and corr. to 1986 report), 1989 (R), 1990 (R), 1992 (R), 2006 (T), 2007 (R)
Cyhalothrin (including lambda-cyhalothrin(146)	1984 (T,R), 1986 (R), 1988 (R), 2007 (T), 2008 (R), 2015 (R), 2018 (T), 2019 (R)
Cyhexatin (067)	1970 (T,R), 1973 (T,R), 1974 (R), 1975 (R), 1977 (T), 1978 (T,R), 1980 (T), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1988 (T), 1989 (T), 1991 (T,R), 1992 (R), 1994 (T), 2005 (T,R)
Cypermethrin (118)	1979 (T,R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 evaluation), 1988 (R), 1990 (R), 2006 (T), 2008 (R), 2009 (R), 2011 (R), 2019 (R), 2021 (R)

Cyproconazole (239)	2010 (T,R), 2013 (R)
Cyprodinil (207)	2003 (T,R), 2004 (corr. to 2003 report), 2013 (R), 2015 (R), 2017 (R), 2018 (R), 2019 (T, R), 2021 (R)
Cyromazine (169)	1990 (T,R), 1991 (corr. to 1990 R evaluation), 1992 (R), 2006 (T), 2007 (R), 2012 (R)
2,4-D (020)	1970 (T,R), 1971 (T,R), 1974 (T,R), 1975 (T,R), 1980 (R), 1985 (R), 1986 (R), 1987 (corr. to 1986 report, Annex I), 1996 (T), 1997 (E), 1998 (R), 2001 (R), 2017 (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), 2016 (R), 2023 (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), 2016 (T), 2022 (R)
1,2-Dibromoethane (023)	1965 (T,R), 1966 (T,R), 1967 (R), 1968 (R), 1971 (R), 1979 (R), 1985 (R)
Dicamba (240)	2010 (T,R), 2011 (R), 2012 (R), 2013 (R), 2019 (T, R)
Dichlobenil (274)	2014 (T,R)
Dicloran (083)	2003 (R)
Dichlorfluanid (082)	1969 (T,R), 1974 (T,R), 1977 (T,R), 1979 (T,R), 1981 (R), 1982 (R), 1983 (T,R), 1985 (R)
1,2-Dichloroethane (024)	1965 (T,R), 1967 (R), 1971 (R), 1979 (R), 1985 (R)
Dichlorvos (025)	1965 (T,R), 1966 (T,R), 1967 (T,R), 1969 (R), 1970 (T,R), 1974 (R), 1977 (T), 1993 (T,R), 2011 (T), 2012 (R)
Dicloran (083)	1974 (T,R), 1977 (T,R), 1998 (T,R)
Dicofol (026)	1968 (T,R), 1970 (R), 1974 (R), 1992 (T,R), 1994 (R), 2011 (T), 2012 (R)
Dieldrin (001)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (R), 1970 (T,R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Difenoconazole (224)	2007 (T,R), 2010 (R), 2013 (R), 2015 (R), 2017 (R), 2021 (R), 2022 (R), 2023 (R)
Diflubenzuron (130)	1981 (T,R), 1983 (R), 1984 (T,R), 1985 (T,R), 1988 (R), 2001 (T), 2002 (R), 2011 (R), 2023 (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), 2019 (T, R), 2022 (T, R)
Dimethomorph (225)	2007 (T,R), 2014 (R), 2016 (R)
Dimethrin	1965 (T)
1,4- Dimethylnaphthalene (331)	2023 (R)
Dinocap (087)	1969 (T,R), 1974 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (R), 2000 (T), 2001 (R)
Dinotefuran (255)	2012 (T,R), 2023 (R)
Dioxathion (028)	1968 (T,R), 1972 (R)
Diphenyl (029)	1966 (T,R), 1967 (T)
Diphenylamine (030)	1969 (T,R), 1976 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1998 (T), 2001 (R), 2003 (R), 2008 (R)
Diquat (031)	1970 (T,R), 1972 (T,R), 1976 (R), 1977 (T,R), 1978 (R), 1994 (R), 2013 (T,R), 2018 (R)
Disulfoton (074)	1973 (T,R), 1975 (T,R), 1979 (R), 1981 (R), 1984 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1996 (T), 1998 (R), 2006 (R)
Dithianon (180)	1992 (T,R), 1995 (R), 1996 (corr. to 1995 report), 2010 (T), 2013 (T,R)
Dithiocarbamates (105)	1965 (T), 1967 (T,R), 1970 (T,R), 1983 (R propineb, thiram), 1984 (R propineb), 1985 (R), 1987 (T thiram), 1988 (R thiram), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T thiram), 1993 (T,R), 1995 (R), 1996 (T,R ferbam, ziram; R thiram), 2004 (R), 2012 (R), 2014 (R)
4,6-Dinitro-ortho-cresol (DNOC)	1965 (T)
Dodine (084)	1974 (T,R), 1976 (T,R), 1977 (R), 2000 (T), 2003 (R), 2004 (corr. to 2003 report)
Edifenphos (099)	1976 (T,R), 1979 (T,R), 1981 (T,R)
Emamectin benzoate (247)	2011 (T,R), 2014 (R), 2022 (R), 2023 (R)
Endosulfan (032)	1965 (T), 1967 (T,R), 1968 (T,R), 1971 (R), 1974 (R), 1975 (R), 1982 (T), 1985 (T,R), 1989 (T,R), 1993 (R), 1998 (T), 2006 (R), 2010 (R)
Endrin (033)	1965 (T), 1970 (T,R), 1974 (R), 1975 (R), 1990 (R), 1992 (R)
Esfenvalerate (204)	2002 (T,R)
Ethephon (106)	1977 (T,R), 1978 (T,R), 1983 (R), 1985 (R), 1993 (T), 1994 (R), 1995 (T), 1997 (T), 2002 (T), 2015 (T, R)
Ethiofencarb (107)	1977 (T,R), 1978 (R), 1981 (R), 1982 (T,R), 1983 (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), 2018 (T,R), 2021 (R)
Imazamox (276)	2014 (T,R), 2017 (R)
Imazapic (266)	2013 (T,R), 2015 (R)
Imazapyr (267)	2013 (T,R), 2015 (R), 2017 (R), 2023 (R)
Imazethapyr (289)	2016 (T,R)
Imidacloprid (206)	2001 (T), 2002 (R), 2006 (R), 2008 (R), 2012 (R), 2015 (R), 2017 (R)
Indoxacarb (216)	2005 (T,R), 2007 (R), 2009 (R), 2012 (R), 2013 (R), 2022 (R)
Inpyrfluxam(329)	2022 (T, R)
Isocycloseram (334) 2023 (T,R)	
Isoflucypram (330)	2022 (T, R), 2023 (T,R)
Iprodione (111)	1977 (T,R), 1980 (R), 1992 (T), 1994 (R), 1995 (T), 2001 (R), 2023 (T,R)
Isofenphos (131)	1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (T,R), 1988 (R), 1992 (R)
Isofetamid (290)	2016 (T,R), 2018 (R)
Isoprothiolane (299)	2017 (T, R), 2021 (R), 2021 (T)
Isopyrazam (249)	2011 (T,R), 2017 (R)
Isotianil (335) 2023 (T,R)	
Isoxaflutole (268)	2013 (T,R), 2021 (R)
Kresoxim-methyl (199)	1998 (T,R), 2001 (R), 2018 (T,R), 2019 (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), 2015 (R)
Lufenuron (286)	2015 (T, R), 2018 (R)
Malathion (049)	1965 (T), 1966 (T,R), 1967 (corr. to 1966 R evaluation), 1968 (R), 1969 (R), 1970 (R), 1973 (R), 1975 (R), 1977 (R), 1984 (R), 1997 (T), 1999 (R), 2000 (R), 2003 (T), 2004 (R), 2005 (R), 2008 (R), 2013 (R), 2016 (T)

Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (R), 2011 (R), 2012 (R), 2014 (R), 2018 (T, R)
Pyrasulfotole (321)	2021 (T, R)
Pyraziflumid (322)	2021 (T, 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), 2023 (-)
Pyridate (315)	2019 (T), 2022 (R)
Pyrifluquinazon (316)	2019 (T, R)
Pyrimethanil (226)	2007 (T, R), 2013 (R)
Pyriofenone (310)	2018 (T, R), 2019 (R)
Pyriproxyfen (200)	1999 (R, T), 2000 (R), 2001 (T), 2018 (R), 2019 (R)
Quinclorac (287)	2015 (T, R), 2017 (R), 2022 (R)
Quinoxyfen (223)	2006 (T, R), 2021 (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), 2022 (T, R)
Saflufenacil (251)	2011 (T, R), 2016 (R), 2017 (R)
Sedaxane (259)	2012 (T, R), 2014 (R)
Spices	2004 (R), 2005 (R), 2007 (R), 2010 (R), 2015 (R), 2019 (R)
Spinetoram (233)	2008 (T, R), 2012 (R), 2017 (R), 2021 (R)
Spinosad (203)	2001 (T, R), 2004 (R), 2008 (R), 2011 (R)
Spirodiclofen (237)	2009 (T, R)
Spiromesifen (294)	2016 (T, R), 2021 (R), 2022 (R)
Spiropidion (323)	2021 (T, R)
Spirotetramat (234)	2008 (T, R), 2011 (R), 2012 (R), 2013 (R), 2015 (R), 2019 (R)
Sulfoxaflor (252)	2011 (T, R), 2013 (R), 2014 (R), 2016 (R), 2018 (R), 2021 (R)
Sulfuryl fluoride (218)	2005 (T, R)
2,4,5-T (121)	1970 (T,R), 1979 (T,R), 1981 (T)
Tebuconazole (189)	1994 (T, R), 1996 (corr. to Annex II of 1995 report), 1997 (R), 2008 (R), 2010 (T), 2011 (R), 2015 (R), 2017 (R), 2019 (R), 2021 (R)
Tebufenozide (196)	1996 (T, R), 1997 (R), 1999 (R), 2001 (T, R), 2003 (T)
Tecnazine (115)	1974 (T, R), 1978 (T, R), 1981 (R), 1983 (T), 1987 (R), 1989 (R), 1994 (T, R)
Teflubenzuron (190)	1994 (T), 1996 (R), 2016 (T, R)
Temephos	2006 (T)
Terbufos (167)	1989 (T, R), 1990 (T,R), 2003 (T), 2005 (R)
Tetraniliprole (324)	2021 (T), 2022 (T, R), 2023 (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), 2019 (T, R)
Thiacloprid (223)	2006 (T, R)

Annex 3: International Estimated Daily Intakes (IEDIs) of pesticide residues

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.05	4.82	0.24	2.45	0.12	3.93	0.20	25.44	1.27	8.74	0.44	16.23	0.81
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.05	6.18	0.31	3.66	0.18	0.25	0.01	6.82	0.34	3.49	0.17	19.38	0.97
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.05	20.66	1.03	5.23	0.26	11.90	0.60	37.90	1.90	21.16	1.06	56.46	2.82
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0108	1.27	0.01	2.20	0.02	0.09	0.00	11.81	0.13	0.46	0.00	1.69	0.02
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.05	0.66	0.03	0.69	0.03	0.96	0.05	10.20	0.51	1.25	0.06	2.97	0.15
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.35	13.49	4.72	26.63	9.32	15.05	5.27	16.28	5.70	6.47	2.26	47.88	16.76
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.028	0.32	0.01	3.07	0.09	0.07	0.00	5.00	0.14	0.29	0.01	5.57	0.16
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.35	0.59	0.21	0.36	0.13	0.46	0.16	1.88	0.66	NC	-	1.15	0.40
FP 0229	Medlar, raw (incl processed)	RAC	0.35	0.47	0.16	0.29	0.10	0.36	0.13	1.49	0.52	NC	-	0.92	0.32
FP 0230	Pear, raw	RAC	0.35	2.16	0.76	6.24	2.18	0.05	0.02	4.07	1.42	1.16	0.41	5.34	1.87
FP 0307	Persimmon, Japanese, raw (i.e. Kaki fruit)	RAC	0.35	1.91	0.67	0.01	0.00	1.94	0.68	1.96	0.69	NC	-	0.25	0.09
FP 0231	Quince, raw	RAC	0.35	0.73	0.26	0.54	0.19	0.01	0.00	0.07	0.02	0.06	0.02	1.31	0.46
FS 0013	Subgroup of Cherries, raw	RAC	1.5	0.92	1.38	9.15	13.73	0.01	0.02	0.61	0.92	0.06	0.09	6.64	9.96
FS 0014	Subgroup of Plums, raw	RAC	0.25	2.40	0.60	8.60	2.15	0.06	0.02	2.52	0.63	0.58	0.15	4.16	1.04
DF 0014	Plums, dried (prunes)	PP	0.7	0.09	0.06	0.06	0.04	0.01	0.01	0.18	0.13	0.04	0.03	0.06	0.04
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.6	8.01	4.81	5.87	3.52	0.18	0.11	8.19	4.91	1.64	0.98	22.46	13.48

FB 2005	Subgroup of Caneberries, raw	RAC	2.53	0.42	1.06	1.05	2.66	0.01	0.03	0.02	0.05	0.02	0.05	1.24	3.14
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	2.53	0.53	1.34	1.31	3.31	0.40	1.01	1.66	4.20	0.01	0.03	0.99	2.50
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	2.53	0.62	1.57	0.33	0.83	0.34	0.86	1.42	3.59	0.01	0.03	1.51	3.82
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	1.09	13.02	14.19	9.25	10.08	0.03	0.03	16.91	18.43	3.70	4.03	54.44	59.34
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2.6	0.51	1.33	0.51	1.33	0.01	0.03	1.27	3.30	0.12	0.31	2.07	5.38
JF 0269	Grape juice (from wine grapes)	PP	0.46	0.14	0.06	0.29	0.13	0.05	0.02	0.30	0.14	0.24	0.11	0.05	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.38	0.67	0.25	12.53	4.76	2.01	0.76	1.21	0.46	3.53	1.34	4.01	1.52
FB 0275	Strawberry, raw	RAC	0.555	0.70	0.39	2.01	1.12	0.04	0.02	1.36	0.75	0.37	0.21	2.53	1.40
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.05	5.23	0.26	6.94	0.35	99.45	4.97	32.47	1.62	48.30	2.42	24.70	1.24
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.255	10.48	2.67	0.01	0.00	7.24	1.85	6.87	1.75	19.98	5.09	6.25	1.59
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.041	3.40	0.14	2.10	0.09	2.65	0.11	10.89	0.45	NC	-	6.67	0.27
FI 0341	Kiwifruit, raw	RAC	0.0073	0.03	0.00	0.36	0.00	0.01	0.00	1.17	0.01	0.06	0.00	0.69	0.01
VA 0035	Group of Bulb vegetables, raw	RAC	1.02	34.29	34.98	46.37	47.30	4.73	4.82	41.36	42.19	21.08	21.50	52.54	53.59
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	1.52	6.43	9.77	40.26	61.20	0.80	1.22	9.94	15.11	12.07	18.35	17.73	26.95
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.565	53.14	30.02	86.21	48.71	6.28	3.55	92.76	52.41	15.64	8.84	155.30	87.74
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.565	42.04	23.75	76.13	43.01	10.69	6.04	84.59	47.79	24.92	14.08	203.27	114.85
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.413	2.34	0.97	1.33	0.55	1.57	0.65	4.24	1.75	0.34	0.14	2.83	1.17
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.085	0.29	0.02	0.29	0.02	0.01	0.00	0.38	0.03	0.05	0.00	0.14	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.565	8.48	4.79	13.74	7.76	10.13	5.72	11.29	6.38	9.52	5.38	26.36	14.89
-	Peppers, sweet, dried	PP	1.4	0.42	0.59	0.53	0.74	0.84	1.18	0.50	0.70	0.95	1.33	0.37	0.52
VO 2046	Subgroup of eggplants	RAC	0.565	5.58	3.15	4.31	2.44	0.89	0.50	9.31	5.26	13.64	7.71	20.12	11.37
VL 0053	Group of Leafy vegetables, raw	RAC	2.95	8.47	24.99	22.36	65.96	7.74	22.83	25.51	75.25	45.77	135.02	21.22	62.60

VP 0060	Group of Legume vegetables, raw	RAC	0.5	7.73	3.87	1.53	0.77	0.51	0.26	2.95	1.48	5.08	2.54	12.86	6.43
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.12	87.29	10.47	64.04	7.68	37.15	4.46	89.82	10.78	91.02	10.92	98.20	11.78
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.305	87.83	26.79	374.04	114.08	668.92	204.02	121.64	37.10	94.20	28.73	247.11	75.37
VS 0078	Group of Stalk and stem vegetables, raw	RAC	8.85	6.03	53.37	9.47	83.81	5.86	51.86	14.55	128.77	2.61	23.10	8.27	73.19
GC 0648	Quinoa, raw	RAC	0.1	NC	-	NC	-	NC	-	NC	-	0.07	0.01	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.075	0.13	0.01	19.38	1.45	0.10	0.01	0.12	0.01	0.03	0.00	2.15	0.16
GC 0653	Triticale, raw	RAC	0.075	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.075	0.01	0.00	1.12	0.08	NC	-	0.03	0.00	0.56	0.04	NC	-
CF 1210	Wheat, germ	PP	0.1	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.01	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.092	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.026	0.25	0.01	0.63	0.02	0.12	0.00	0.43	0.01	1.39	0.04	0.22	0.01
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.026	301.24	7.83	268.64	6.98	30.21	0.79	222.51	5.79	134.73	3.50	343.12	8.92
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl beer, excl pot&pearled, excl malt)	RAC	0.075	8.83	0.66	18.46	1.38	4.76	0.36	2.60	0.20	8.68	0.65	3.86	0.29
-	Barley, pot&pearled	PP	0.026	7.12	0.19	7.34	0.19	0.02	0.00	0.03	0.00	0.67	0.02	0.20	0.01
GC 0647	Oats, raw (incl rolled)	RAC	0.075	0.05	0.00	7.05	0.53	0.10	0.01	1.71	0.13	0.96	0.07	0.04	0.00
GC 2088	Subgroup of rice cereals	REP	0.1	45.40	4.54	14.99	1.50	84.88	8.49	111.73	11.17	194.75	19.48	93.12	9.31
GC 2091	Subgroup of Maize Cereals	RAC	0.1	29.81	2.98	44.77	4.48	108.95	10.90	52.37	5.24	60.28	6.03	75.69	7.57
GC 2090	Subgroup of Sweet Corns	RAC	0.1	0.14	0.01	0.94	0.09	5.70	0.57	2.61	0.26	1.94	0.19	0.22	0.02
TN 0660	Almonds, nutmeat	RAC	0.05	1.38	0.07	0.08	0.00	0.01	0.00	1.00	0.05	0.06	0.00	0.81	0.04
TN 0662	Brazil nuts, nutmeat	RAC	0.05	0.01	0.00	0.01	0.00	0.03	0.00	0.02	0.00	0.02	0.00	0.01	0.00
TN 0295	Cashew nuts, nutmeat	RAC	0.05	0.01	0.00	0.02	0.00	0.24	0.01	0.47	0.02	0.32	0.02	0.05	0.00
TN 0664	Chestnut, raw	RAC	0.05	0.03	0.00	0.02	0.00	0.01	0.00	0.31	0.02	0.09	0.00	0.67	0.03
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.05	1.73	0.09	1.20	0.06	6.63	0.33	10.18	0.51	13.07	0.65	2.98	0.15
TN 0666	Hazelnuts, nutmeat	RAC	0.05	0.03	0.00	0.13	0.01	0.01	0.00	0.11	0.01	0.01	0.00	1.11	0.06

TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.05	0.01	0.00	0.01	0.00	0.01	0.00	0.04	0.00	NC	-	0.03	0.00
TN 0672	Pecan, nutmeat	RAC	0.05	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.01	0.09	0.00	0.13	0.01
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.05	0.18	0.01	0.18	0.01	0.08	0.00	0.49	0.02	0.25	0.01	0.43	0.02
TN 0675	Pistachio nut, nutmeat	RAC	0.27	0.41	0.11	0.07	0.02	0.01	0.00	0.85	0.23	0.02	0.01	1.08	0.29
TN 0678	Walnut, nutmeat	RAC	0.05	0.23	0.01	1.49	0.07	0.01	0.00	0.33	0.02	0.07	0.00	2.06	0.10
SO 0088	Group of Oilseeds & Oilfruits, raw (incl processed)	RAC	0.145	78.79	11.42	54.57	7.91	96.08	13.93	137.03	19.87	60.49	8.77	88.56	12.84
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	1.36	0.07	3.59	0.18	1.44	0.07	5.18	0.26	2.02	0.10	1.70	0.09
DH 1100	Hops, dry	RAC	21.5	0.01	0.22	0.04	0.86	0.01	0.22	0.01	0.22	NC	-	0.01	0.22
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.035	24.96	0.87	57.95	2.03	16.70	0.58	38.38	1.34	26.46	0.93	29.00	1.02
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.18	6.24	1.12	14.49	2.61	4.18	0.75	9.60	1.73	6.62	1.19	7.25	1.31
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.18	3.29	0.59	6.14	1.11	0.82	0.15	1.57	0.28	2.23	0.40	1.07	0.19
MO 0105	Edible offal (mammalian), raw	RAC	0.16	4.79	0.77	9.68	1.55	2.97	0.48	5.49	0.88	3.84	0.61	5.03	0.80
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.066	289.65	19.12	485.88	32.07	26.92	1.78	239.03	15.78	199.91	13.19	180.53	11.91
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	13.17	0.26	26.78	0.54	7.24	0.14	116.71	2.33	22.54	0.45	32.09	0.64
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.02	1.46	0.03	2.98	0.06	0.80	0.02	12.97	0.26	2.50	0.05	3.57	0.07
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.02	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.11	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	7.84	0.16	23.08	0.46	2.88	0.06	14.89	0.30	9.81	0.20	14.83	0.30
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				317.2		607.0		363.7		546.7		353.6		726.4
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				2400		2400		2400		2400		2400		2400
	%ADI=				13.2%		25.3%		15.2%		22.8%		14.7%		30.3%
	Rounded %ADI=				10%		30%		20%		20%		10%		30%

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.05	10.12	0.51	15.69	0.78	2.88	0.14	12.30	0.62	22.32	1.12	6.59	0.33
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.05	12.42	0.62	14.99	0.75	16.08	0.80	10.78	0.54	9.94	0.50	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.05	15.68	0.78	24.00	1.20	6.80	0.34	29.09	1.45	15.39	0.77	160.47	8.02
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0108	33.31	0.36	1.78	0.02	0.28	0.00	18.97	0.20	14.01	0.15	13.36	0.14
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.05	8.21	0.41	4.60	0.23	0.64	0.03	5.85	0.29	19.98	1.00	368.86	18.44
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.35	41.14	14.40	56.49	19.77	26.64	9.32	31.58	11.05	51.94	18.18	3.05	1.07
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.028	14.88	0.42	11.98	0.34	0.15	0.00	9.98	0.28	30.32	0.85	3.47	0.10
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.35	0.96	0.34	NC	-	NC	-	3.92	1.37	NC	-	2.49	0.87
FP 0229	Medlar, raw (incl processed)	RAC	0.35	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.69
FP 0230	Pear, raw	RAC	0.35	8.79	3.08	8.44	2.95	12.37	4.33	9.60	3.36	10.27	3.59	0.23	0.08
FP 0307	Persimmon, Japanese, raw (i.e. Kaki fruit)	RAC	0.35	0.01	0.00	0.30	0.11	3.59	1.26	0.15	0.05	0.02	0.01	NC	-
FP 0231	Quince, raw	RAC	0.35	0.19	0.07	0.18	0.06	0.11	0.04	0.04	0.01	0.28	0.10	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	1.5	1.40	2.10	4.21	6.32	0.04	0.06	2.93	4.40	1.50	2.25	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.25	3.75	0.94	3.33	0.83	5.94	1.49	2.64	0.66	2.50	0.63	0.06	0.02
DF 0014	Plums, dried (prunes)	PP	0.7	0.61	0.43	0.35	0.25	0.05	0.04	0.35	0.25	0.49	0.34	0.13	0.09
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.6	13.03	7.82	16.29	9.77	8.29	4.97	12.95	7.77	5.35	3.21	0.04	0.02
FB 2005	Subgroup of Caneberries, raw	RAC	2.53	0.56	1.42	1.43	3.62	0.14	0.35	1.23	3.11	1.14	2.88	0.01	0.03

FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	2.53	1.31	3.31	5.50	13.92	0.01	0.03	2.57	6.50	0.82	2.07	2.15	5.44
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	2.53	8.26	20.90	0.14	0.35	0.07	0.18	0.13	0.33	0.19	0.48	1.87	4.73
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	1.09	6.48	7.06	11.31	12.33	5.21	5.68	9.50	10.36	4.66	5.08	0.78	0.85
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2.6	3.09	8.03	1.51	3.93	0.03	0.08	1.38	3.59	4.26	11.08	0.42	1.09
JF 0269	Grape juice (from wine grapes)	PP	0.46	0.56	0.26	1.96	0.90	0.02	0.01	2.24	1.03	2.27	1.04	0.34	0.16
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.38	88.93	33.79	62.41	23.72	1.84	0.70	25.07	9.53	61.17	23.24	5.84	2.22
FB 0275	Strawberry, raw	RAC	0.555	4.49	2.49	5.66	3.14	0.02	0.01	6.63	3.68	5.75	3.19	0.05	0.03
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.05	25.76	1.29	23.65	1.18	23.83	1.19	24.37	1.22	19.43	0.97	101.55	5.08
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.255	1.80	0.46	0.63	0.16	10.05	2.56	1.07	0.27	3.52	0.90	16.44	4.19
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.041	7.91	0.32	9.72	0.40	7.67	0.31	5.26	0.22	9.04	0.37	14.43	0.59
FI 0341	Kiwifruit, raw	RAC	0.0073	2.46	0.02	3.62	0.03	0.04	0.00	1.48	0.01	7.43	0.05	0.03	0.00
VA 0035	Group of Bulb vegetables, raw	RAC	1.02	26.24	26.76	36.47	37.20	39.29	40.08	39.37	40.16	29.12	29.70	20.21	20.61
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	1.52	20.71	31.48	39.81	60.51	25.06	38.09	37.93	57.65	18.12	27.54	16.74	25.44
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.565	27.81	15.71	41.93	23.69	123.30	69.66	49.47	27.95	15.95	9.01	35.99	20.33
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.565	43.88	24.79	55.41	31.31	35.38	19.99	74.88	42.31	26.50	14.97	9.51	5.37
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.413	4.96	2.05	3.20	1.32	0.15	0.06	1.61	0.66	6.88	2.84	0.52	0.21
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.085	0.80	0.07	0.07	0.01	0.05	0.00	0.61	0.05	0.40	0.03	0.08	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.565	6.39	3.61	15.53	8.77	19.09	10.79	10.36	5.85	8.29	4.68	4.53	2.56
-	Peppers, sweet, dried	PP	1.4	0.11	0.15	0.21	0.29	0.36	0.50	0.21	0.29	0.25	0.35	0.15	0.21
VO 2046	Subgroup of eggplants	RAC	0.565	1.01	0.57	1.69	0.95	21.37	12.07	3.00	1.70	1.40	0.79	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	2.95	18.83	55.55	21.85	64.46	121.23	357.63	43.09	127.12	18.18	53.63	18.32	54.04

VP 0060	Group of Legume vegetables, raw	RAC	0.5	18.21	9.11	8.91	4.46	7.22	3.61	10.04	5.02	23.22	11.61	0.17	0.09
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.12	112.88	13.55	123.05	14.77	47.73	5.73	204.75	24.57	227.52	27.30	110.05	13.21
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.305	290.31	88.54	300.35	91.61	214.25	65.35	242.72	74.03	348.67	106.34	137.52	41.94
VS 0078	Group of Stalk and stem vegetables, raw	RAC	8.85	12.56	111.16	15.57	137.79	72.50	641.63	8.11	71.77	28.79	254.79	10.13	89.65
GC 0648	Quinoa, raw	RAC	0.1	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.075	3.21	0.24	35.38	2.65	0.21	0.02	6.50	0.49	1.49	0.11	NC	-
GC 0653	Triticale, raw	RAC	0.075	NC	-	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.075	NC	-	NC	-	0.02	0.00	0.83	0.06	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.1	0.97	0.10	0.10	0.01	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.092	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CP 1211	Wheat, white bread	PP	0.026	1.30	0.03	0.46	0.01	0.06	0.00	0.22	0.01	2.44	0.06	0.77	0.02
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.026	198.08	5.15	193.03	5.02	106.24	2.76	185.09	4.81	168.67	4.39	131.59	3.42
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl beer, excl pot&pearled, excl malt)	RAC	0.075	35.06	2.63	49.50	3.71	8.81	0.66	34.28	2.57	46.12	3.46	13.03	0.98
-	Barley, pot&pearled	PP	0.026	0.57	0.01	2.56	0.07	0.33	0.01	0.56	0.01	0.36	0.01	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.075	7.50	0.56	6.26	0.47	0.15	0.01	4.87	0.37	3.16	0.24	2.98	0.22
GC 2088	Subgroup of rice cereals	REP	0.1	20.96	2.10	16.04	1.60	339.67	33.97	75.51	7.55	16.86	1.69	86.13	8.61
GC 2091	Subgroup of Maize Cereals	RAC	0.1	18.51	1.85	26.18	2.62	26.04	2.60	39.99	4.00	7.36	0.74	64.58	6.46
GC 2090	Subgroup of Sweet Corns	RAC	0.1	11.43	1.14	3.71	0.37	0.74	0.07	13.63	1.36	3.07	0.31	1.50	0.15
TN 0660	Almonds, nutmeat	RAC	0.05	0.81	0.04	2.21	0.11	0.03	0.00	1.02	0.05	1.47	0.07	NC	-
TN 0662	Brazil nuts, nutmeat	RAC	0.05	0.12	0.01	0.05	0.00	0.01	0.00	0.05	0.00	0.13	0.01	NC	-
TN 0295	Cashew nuts, nutmeat	RAC	0.05	0.59	0.03	0.23	0.01	0.18	0.01	0.52	0.03	1.75	0.09	2.78	0.14
TN 0664	Chestnut, raw	RAC	0.05	0.34	0.02	0.21	0.01	1.14	0.06	0.52	0.03	0.09	0.00	NC	-
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.05	4.13	0.21	2.73	0.14	13.15	0.66	5.85	0.29	6.92	0.35	22.24	1.11
TN 0666	Hazelnuts, nutmeat	RAC	0.05	0.45	0.02	1.12	0.06	0.02	0.00	0.34	0.02	1.63	0.08	NC	-

TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.05	NC	-	0.40	0.02	NC	-	NC	-	NC	-	0.07	0.00
TN 0672	Pecan, nutmeat	RAC	0.05	0.38	0.02	NC	-	NC	-	0.27	0.01	NC	-	0.26	0.01
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.05	0.99	0.05	0.66	0.03	0.22	0.01	0.27	0.01	1.89	0.09	0.89	0.04
TN 0675	Pistachio nut, nutmeat	RAC	0.27	0.35	0.09	0.48	0.13	0.07	0.02	0.39	0.11	0.23	0.06	0.02	0.01
TN 0678	Walnut, nutmeat	RAC	0.05	0.34	0.02	0.84	0.04	0.28	0.01	0.39	0.02	0.45	0.02	NC	-
SO 0088	Group of Oilseeds & Oilfruits, raw (incl processed)	RAC	0.145	108.59	15.75	112.13	16.26	64.09	9.29	81.53	11.82	66.09	9.58	20.02	2.90
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	10.90	0.55	12.44	0.62	0.77	0.04	9.48	0.47	22.07	1.10	8.15	0.41
DH 1100	Hops, dry	RAC	21.5	NC	-	NC	-	0.02	0.43	0.02	0.43	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.035	112.02	3.92	120.71	4.22	63.46	2.22	88.99	3.11	96.24	3.37	41.02	1.44
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.18	28.01	5.04	30.18	5.43	15.86	2.86	22.25	4.00	24.06	4.33	10.25	1.85
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.18	6.44	1.16	15.51	2.79	3.79	0.68	8.29	1.49	18.44	3.32	8.00	1.44
MO 0105	Edible offal (mammalian), raw	RAC	0.16	15.17	2.43	5.19	0.83	6.30	1.01	6.78	1.08	3.32	0.53	3.17	0.51
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.066	388.92	25.67	335.88	22.17	49.15	3.24	331.25	21.86	468.56	30.92	245.45	16.20
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	66.38	1.33	48.47	0.97	21.58	0.43	78.41	1.57	48.04	0.96	76.01	1.52
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.02	7.38	0.15	5.39	0.11	2.40	0.05	8.71	0.17	5.34	0.11	8.45	0.17
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.02	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.01	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.33	0.01	0.72	0.01	0.27	0.01	0.35	0.01	0.80	0.02	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	25.84	0.52	29.53	0.59	28.05	0.56	33.19	0.66	36.44	0.73	8.89	0.18
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				565.6		655.3		1360.8		619.8		694.4		375.8
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				2400		2400		2200		2400		2400		2400
	%ADI=				23.6%		27.3%		61.9%		25.8%		28.9%		15.7%
	Rounded %ADI=				20%		30%		60%		30%		30%		20%

BOSCALID (221) International Estimated Daily Intake (IEDI) ADI = 0–0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: ug/person									
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.05	18.97	0.95	0.97	0.05	6.23	0.31	0.09	0.00	3.35	0.17
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.05	0.16	0.01	0.27	0.01	9.06	0.45	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.05	1.18	0.06	1.11	0.06	14.28	0.71	0.05	0.00	1.08	0.05
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0108	0.08	0.00	0.26	0.00	12.61	0.14	0.14	0.00	0.33	0.00
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.05	0.68	0.03	0.05	0.00	3.21	0.16	0.01	0.00	NC	-
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.35	66.67	23.33	2.06	0.72	55.83	19.54	188.29	65.90	1.38	0.48
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.028	0.03	0.00	0.10	0.00	7.19	0.20	0.03	0.00	NC	-
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.35	0.94	0.33	4.68	1.64	NC	-	0.50	0.18	3.08	1.08
FP 0229	Medlar, raw (incl processed)	RAC	0.35	0.75	0.26	3.73	1.31	4.87	1.70	0.40	0.14	2.45	0.86
FP 0230	Pear, raw	RAC	0.35	0.07	0.02	0.14	0.05	9.45	3.31	0.01	0.00	0.14	0.05
FP 0307	Persimmon, Japanese, raw (i.e. Kaki fruit)	RAC	0.35	0.41	0.14	0.32	0.11	0.02	0.01	0.58	0.20	12.51	4.38
FP 0231	Quince, raw	RAC	0.35	NC	-	NC	-	0.65	0.23	NC	-	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	1.5	0.01	0.02	0.01	0.02	5.96	8.94	0.01	0.02	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.25	0.07	0.02	0.01	0.00	15.56	3.89	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.7	0.01	0.01	0.01	0.01	0.37	0.26	0.01	0.01	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.6	0.02	0.01	0.01	0.01	10.76	6.46	0.01	0.01	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	2.53	0.01	0.03	7.30	18.47	2.29	5.79	0.01	0.03	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	2.53	0.82	2.07	4.05	10.25	5.94	15.03	0.43	1.09	2.66	6.73
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	2.53	0.71	1.80	7.32	18.52	NC	-	0.38	0.96	2.32	5.87

FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	1.09	0.14	0.15	0.36	0.39	15.33	16.71	0.01	0.01	0.28	0.31
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2.6	0.01	0.03	0.13	0.34	1.06	2.76	0.01	0.03	0.03	0.08
JF 0269	Grape juice (from wine grapes)	PP	0.46	0.01	0.00	0.01	0.00	0.41	0.19	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.38	0.31	0.12	0.23	0.09	60.43	22.96	0.52	0.20	31.91	12.13
FB 0275	Strawberry, raw	RAC	0.555	0.01	0.01	0.01	0.01	3.35	1.86	0.01	0.01	0.01	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.05	44.80	2.24	118.17	5.91	25.25	1.26	454.49	22.72	310.23	15.51
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.255	12.25	3.12	6.83	1.74	0.76	0.19	0.01	0.00	20.12	5.13
FI 0355	Pomegranate, raw, (incl processed)	RAC	0.041	5.49	0.23	27.17	1.11	NC	-	2.89	0.12	17.87	0.73
FI 0341	Kiwifruit, raw	RAC	0.0073	0.01	0.00	0.01	0.00	2.00	0.01	0.01	0.00	NC	-
VA 0035	Group of Bulb vegetables, raw	RAC	1.02	11.28	11.51	23.80	24.28	36.11	36.83	9.66	9.85	8.69	8.86
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	1.52	5.46	8.30	4.28	6.51	58.72	89.25	0.02	0.03	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.565	5.96	3.37	9.74	5.50	51.82	29.28	13.61	7.69	0.05	0.03
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.565	13.10	7.40	4.90	2.77	62.16	35.12	1.04	0.59	0.09	0.05
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.413	0.58	0.24	0.22	0.09	2.21	0.91	0.24	0.10	3.10	1.28
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.085	0.05	0.00	0.01	0.00	0.42	0.04	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.565	8.97	5.07	14.13	7.98	25.14	14.20	0.91	0.51	NC	-
-	Peppers, sweet, dried	PP	1.4	0.58	0.81	1.27	1.78	1.21	1.69	0.12	0.17	NC	-
VO 2046	Subgroup of eggplants	RAC	0.565	1.31	0.74	8.26	4.67	3.95	2.23	0.01	0.01	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	2.95	12.42	36.64	8.75	25.81	7.53	22.21	7.07	20.86	14.11	41.62
VP 0060	Group of Legume vegetables, raw	RAC	0.5	0.58	0.29	3.16	1.58	10.38	5.19	0.04	0.02	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.12	46.57	5.59	30.77	3.69	112.53	13.50	75.53	9.06	43.68	5.24
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.305	282.25	86.09	232.11	70.79	281.91	85.98	620.21	189.16	459.96	140.29
VS 0078	Group of Stalk and stem vegetables, raw	RAC	8.85	9.14	80.89	6.60	58.41	7.58	67.08	6.18	54.69	12.34	109.21
GC 0648	Quinoa, raw	RAC	0.1	NC	-	NC	-	NC	-	NC	-	NC	-

GC 0650	Rye, raw (incl flour)	RAC	0.075	0.03	0.00	0.01	0.00	13.95	1.05	0.01	0.00	0.88	0.07
GC 0653	Triticale, raw	RAC	0.075	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.075	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.07
CF 1210	Wheat, germ	PP	0.1	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.092	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.026	0.43	0.01	0.41	0.01	1.56	0.04	0.11	0.00	0.07	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.026	44.78	1.16	86.96	2.26	214.05	5.57	20.31	0.53	103.60	2.69
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl beer, excl pot&pearled, excl malt)	RAC	0.075	3.17	0.24	2.16	0.16	43.59	3.27	3.71	0.28	10.02	0.75
-	Barley, pot&pearled	PP	0.026	5.46	0.14	0.01	0.00	1.44	0.04	0.01	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.075	0.37	0.03	0.07	0.01	2.79	0.21	0.10	0.01	NC	-
GC 2088	Subgroup of rice cereals	REP	0.1	52.55	5.26	286.02	28.60	18.64	1.86	19.67	1.97	75.09	7.51
GC 2091	Subgroup of Maize Cereals	RAC	0.1	116.66	11.67	10.52	1.05	38.46	3.85	76.60	7.66	34.44	3.44
GC 2090	Subgroup of Sweet Corns	RAC	0.1	3.63	0.36	20.50	2.05	8.78	0.88	0.02	0.00	0.17	0.02
TN 0660	Almonds, nutmeat	RAC	0.05	0.01	0.00	0.01	0.00	0.61	0.03	0.01	0.00	NC	-
TN 0662	Brazil nuts, nutmeat	RAC	0.05	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00	NC	-
TN 0295	Cashew nuts, nutmeat	RAC	0.05	0.91	0.05	0.14	0.01	0.11	0.01	0.01	0.00	NC	-
TN 0664	Chestnut, raw	RAC	0.05	0.01	0.00	0.01	0.00	0.75	0.04	0.01	0.00	NC	-
TN 0665	Coconut, nutmeat (incl. copra, incl desiccated, incl oil)	RAC	0.05	2.77	0.14	134.37	6.72	2.81	0.14	0.70	0.04	317.67	15.88
TN 0666	Hazelnuts, nutmeat	RAC	0.05	0.01	0.00	0.01	0.00	0.21	0.01	0.01	0.00	NC	-
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.05	0.04	0.00	0.05	0.00	NC	-	0.01	0.00	0.01	0.00
TN 0672	Pecan, nutmeat	RAC	0.05	0.15	0.01	0.22	0.01	0.31	0.02	0.01	0.00	0.01	0.00
TN 0673	Pine nut, nutmeat (i.e. pignolia nuts)	RAC	0.05	0.51	0.03	0.74	0.04	0.36	0.02	0.01	0.00	0.05	0.00
TN 0675	Pistachio nut, nutmeat	RAC	0.27	0.01	0.00	0.01	0.00	0.15	0.04	0.01	0.00	NC	-
TN 0678	Walnut, nutmeat	RAC	0.05	0.01	0.00	0.01	0.00	0.81	0.04	0.01	0.00	NC	-
SO 0088	Group of Oilseeds & Oilfruits, raw (incl processed)	RAC	0.145	130.71	18.95	22.07	3.20	69.33	10.05	55.22	8.01	84.31	12.22
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.05	0.95	0.05	1.32	0.07	11.64	0.58	2.96	0.15	14.73	0.74

DH 1100	Hops, dry	RAC	21.5	NC	-	NC	-	0.04	0.86	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.035	23.34	0.82	40.71	1.42	97.15	3.40	18.06	0.63	57.71	2.02
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.18	5.84	1.05	10.18	1.83	24.29	4.37	4.52	0.81	14.43	2.60
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.18	1.05	0.19	1.14	0.21	18.69	3.36	0.94	0.17	3.12	0.56
MO 0105	Edible offal (mammalian), raw	RAC	0.16	4.64	0.74	1.97	0.32	10.01	1.60	3.27	0.52	3.98	0.64
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.066	108.75	7.18	70.31	4.64	436.11	28.78	61.55	4.06	79.09	5.22
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	3.53	0.07	10.83	0.22	51.36	1.03	4.53	0.09	50.00	1.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.02	0.39	0.01	1.20	0.02	5.71	0.11	0.50	0.01	5.56	0.11
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.02	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.02	0.10	0.00	0.70	0.01	0.97	0.02	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	3.84	0.08	4.41	0.09	27.25	0.55	1.13	0.02	7.39	0.15
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				330.2		327.6		588.4		409.3		415.8
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				2400		2400		2400		2400		2400
	%ADI=				13.8%		13.7%		24.5%		17.1%		17.3%
	Rounded %ADI=				10%		10%		20%		20%		20%

CARBOSULFAN (145) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.265	10.48	2.78	0.01	0.00	7.24	1.92	6.87	1.82	19.98	5.29	6.25	1.66
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.36	5.58	2.01	4.31	1.55	0.89	0.32	9.31	3.35	13.64	4.91	20.12	7.24
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				4.8		1.6		2.2		5.2		10.2		8.9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600		600
	%ADI=				0.8%		0.3%		0.4%		0.9%		1.7%		1.5%
	Rounded %ADI=				1%		0%		0%		1%		2%		1%

CARBOSULFAN (145) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as ug/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.265	1.80	0.48	0.63	0.17	10.05	2.66	1.07	0.28	3.52	0.93	16.44	4.36
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.36	1.01	0.36	1.69	0.61	21.37	7.69	3.00	1.08	1.40	0.50	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0.8		0.8		10.4		1.4		1.4		4.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				600		600		550		600		600		600
	%ADI=				0.1%		0.1%		1.9%		0.2%		0.2%		0.7%
	Rounded %ADI=				0%		0%		2%		0%		0%		1%

CARBOSULFAN (145) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: ug/person									
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.265	12.25	3.25	6.83	1.81	0.76	0.20	0.01	0.00	20.12	5.33
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.36	1.31	0.47	8.26	2.97	3.95	1.42	0.01	0.00	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				3.7		4.8		1.6		0.0		5.3
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600
	%ADI=				0.6%		0.8%		0.3%		0.0%		0.9%
	Rounded %ADI=				1%		1%		0%		0%		1%

CYANTRANILIROLE (263) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.00034	45.40	0.02	14.99	0.01	84.88	0.03	111.73	0.04	194.75	0.07	93.12	0.03
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	29.81	0.00	44.77	0.00	108.95	0.00	52.37	0.00	60.28	0.00	75.69	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.038	4.79	0.18	9.68	0.37	2.97	0.11	5.49	0.21	3.84	0.15	5.03	0.19
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0036	289.65	1.04	485.88	1.75	26.92	0.10	239.03	0.86	199.91	0.72	180.53	0.65
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				1.2		2.1		0.2		1.1		0.9		0.9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				1800		1800		1800		1800		1800		1800
	%ADI=				0.1%		0.1%		0.0%		0.1%		0.1%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

CYANTRANILIROLE (263) International Estimated Daily Intake (IEDI) ADI = 0–0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as ug/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.00034	20.96	0.01	16.04	0.01	339.67	0.12	75.51	0.03	16.86	0.01	86.13	0.03
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	18.51	0.00	26.18	0.00	26.04	0.00	39.99	0.00	7.36	0.00	64.58	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.038	15.17	0.58	5.19	0.20	6.30	0.24	6.78	0.26	3.32	0.13	3.17	0.12
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0036	388.92	1.40	335.88	1.21	49.15	0.18	331.25	1.19	468.56	1.69	245.45	0.88
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				2.0		1.4		0.5		1.5		1.8		1.0
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				1800		1800		1650		1800		1800		1800
	%ADI=				0.1%		0.1%		0.0%		0.1%		0.1%		0.1%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

CYANTRANILIROLE (263) International Estimated Daily Intake (IEDI) ADI = 0– 0.03 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.00034	52.55	0.02	286.02	0.10	18.64	0.01	19.67	0.01	75.09	0.03
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0	116.66	0.00	10.52	0.00	38.46	0.00	76.60	0.00	34.44	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.038	4.64	0.18	1.97	0.07	10.01	0.38	3.27	0.12	3.98	0.15
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0036	108.75	0.39	70.31	0.25	436.11	1.57	61.55	0.22	79.09	0.28
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0.6		0.4		2.0		0.4		0.5
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				1800		1800		1800		1800		1800
	%ADI=				0.0%		0.0%		0.1%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

CYFLUMETOFEN (273) International Estimated Daily Intake (IEDI) ADI = 0–0.1 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.07	32.25	2.26	11.67	0.82	16.70	1.17	76.01	5.32	33.90	2.37	92.97	6.51
JF 0001	Group of Citrus fruit, juice	PP	0.0022	1.30	0.00	2.37	0.01	0.22	0.00	13.88	0.03	0.75	0.00	2.63	0.01
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.13	19.35	2.52	34.06	4.43	17.87	2.32	25.74	3.35	7.69	1.00	56.85	7.39
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.036	0.32	0.01	3.07	0.11	0.07	0.00	5.00	0.18	0.29	0.01	5.57	0.20
FS 0013	Subgroup of cherries, raw	RAC	0.106	0.92	0.10	9.15	0.97	0.01	0.00	0.61	0.06	0.06	0.01	6.64	0.70
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.125	8.01	1.00	5.87	0.73	0.18	0.02	8.19	1.02	1.64	0.21	22.46	2.81
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.22	12.68	2.79	9.12	2.01	0.03	0.01	16.88	3.71	3.70	0.81	54.42	11.97
DF 0269	Grapes, dried (= currants. raisins and sultanas) (from table-grapes)	PP	0.51	0.51	0.26	0.51	0.26	0.01	0.01	1.27	0.65	0.12	0.06	2.07	1.06
JF 0269	Grape juice (from wine grapes)	PP	0.048	0.14	0.01	0.29	0.01	0.05	0.00	0.30	0.01	0.24	0.01	0.05	0.00
-	Graps must (from wine-grapes)	PP	0.071	0.33	0.02	0.13	0.01	0.01	0.00	0.02	0.00	0.01	0.00	0.02	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.026	0.67	0.02	12.53	0.33	2.01	0.05	1.21	0.03	3.53	0.09	4.01	0.10
FB 0275	Strawberry, raw	RAC	0.18	0.70	0.13	2.01	0.36	0.04	0.01	1.36	0.24	0.37	0.07	2.53	0.46
VC 0424	Cucumber, raw	RAC	0.085	8.01	0.68	30.66	2.61	1.45	0.12	19.84	1.69	0.27	0.02	34.92	2.97
VO 0448	Tomato, raw	RAC	0.07	41.73	2.92	75.65	5.30	10.66	0.75	82.87	5.80	24.75	1.73	200.93	14.07
-	Tomato, canned (& peeled)	PP	0.021	0.20	0.00	0.31	0.01	0.02	0.00	1.11	0.02	0.11	0.00	1.50	0.03
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.12	2.34	0.28	1.33	0.16	1.57	0.19	4.24	0.51	0.34	0.04	2.83	0.34
JF 0448	Tomato, juice (single strength. incl concentrated)	PP	0.027	0.29	0.01	0.29	0.01	0.01	0.00	0.38	0.01	0.05	0.00	0.14	0.00
TN 0085	Group of tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.043	0.96	0.04	0.16	0.01	0.91	0.04	0.27	0.01	1.37	0.06	0.46	0.02

SM 0716	Coffee bean, roasted	PP	0.026	0.19	0.00	0.91	0.02	0.16	0.00	2.50	0.07	0.39	0.01	0.40	0.01
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.01	0.07	0.00	0.94	0.01	0.07	0.00	0.70	0.01	0.07	0.00	0.29	0.00
DH 1100	Hops, dry	RAC	3.6	0.01	0.04	0.04	0.14	0.01	0.04	0.01	0.04	NC	-	0.01	0.04
MM 0095	Meat from mammals other than marine mammals. raw (incl prepared meat)	RAC	0	31.20	0.00	72.44	0.00	20.88	0.00	47.98	0.00	33.08	0.00	36.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.79	0.05	9.68	0.10	2.97	0.03	5.49	0.05	3.84	0.04	5.03	0.05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				13.2		18.4		4.8		23.0		6.7		48.8
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				6000		6000		6000		6000		6000		6000
	%ADI=				0.22%		0.31%		0.081%		0.38%		0.11%		0.81%
	Rounded %ADI=				0%		0%		0%		0%		0%		1%

CYFLUMETOFEN (273) International Estimated Daily Intake (IEDI) ADI = 0–0.1 mg/kg bw

			STMR	Diets as g/person/day			Intake as ug/person/day								
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of citrus fruit, raw (incl kumquat commodities)	RAC	0.07	38.66	2.71	54.93	3.85	26.36	1.85	51.46	3.60	51.06	3.57	466.36	32.65
JF 0001	Group of Citrus fruit, juice	PP	0.0022	36.84	0.08	3.75	0.01	0.30	0.00	21.62	0.05	21.82	0.05	46.67	0.10
FP 0009	Group of pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.13	51.09	6.64	65.40	8.50	42.71	5.55	45.29	5.89	62.51	8.13	7.74	1.01
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.036	14.88	0.54	11.98	0.43	0.15	0.01	9.98	0.36	30.32	1.09	3.47	0.12
FS 0013	Subgroup of cherries, raw	RAC	0.106	1.40	0.15	4.21	0.45	0.04	0.00	2.93	0.31	1.50	0.16	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.125	13.03	1.63	16.29	2.04	8.29	1.04	12.95	1.62	5.35	0.67	0.04	0.01
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.22	6.33	1.39	11.22	2.47	5.21	1.15	9.38	2.06	4.55	1.00	0.78	0.17
DF 0269	Grapes, dried (= currants. raisins and sultanas) (from table-grapes)	PP	0.51	3.09	1.58	1.51	0.77	0.03	0.02	1.38	0.70	4.26	2.17	0.42	0.21
JF 0269	Grape juice (from wine grapes)	PP	0.048	0.56	0.03	1.96	0.09	0.02	0.00	2.24	0.11	2.27	0.11	0.34	0.02
-	Grapes must (from wine-grapes)	PP	0.071	0.16	0.01	0.09	0.01	0.01	0.00	0.12	0.01	0.11	0.01	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.026	88.93	2.31	62.41	1.62	1.84	0.05	25.07	0.65	61.17	1.59	5.84	0.15
FB 0275	Strawberry, raw	RAC	0.18	4.49	0.81	5.66	1.02	0.02	0.00	6.63	1.19	5.75	1.04	0.05	0.01

VC 0424	Cucumber, raw	RAC	0.085	6.72	0.57	11.03	0.94	32.10	2.73	15.10	1.28	4.05	0.34	9.57	0.81
VO 0448	Tomato, raw	RAC	0.07	32.13	2.25	51.27	3.59	34.92	2.44	73.37	5.14	15.15	1.06	8.88	0.62
-	Tomato, canned (& peeled)	PP	0.021	7.57	0.16	2.66	0.06	0.30	0.01	0.97	0.02	7.31	0.15	0.41	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.12	4.96	0.60	3.20	0.38	0.15	0.02	1.61	0.19	6.88	0.83	0.52	0.06
JF 0448	Tomato, juice (single strength. incl concentrated)	PP	0.027	0.80	0.02	0.07	0.00	0.05	0.00	0.61	0.02	0.40	0.01	0.08	0.00
TN 0085	Group of tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.043	0.60	0.03	NC	-	0.62	0.03	1.71	0.07	NC	-	3.51	0.15
SM 0716	Coffee bean, roasted	PP	0.026	7.02	0.18	9.75	0.25	0.02	0.00	5.09	0.13	13.38	0.35	0.77	0.02
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.01	0.75	0.01	0.30	0.00	0.04	0.00	0.67	0.01	2.43	0.02	1.43	0.01
DH 1100	Hops, dry	RAC	3.6	NC	-	NC	-	0.02	0.07	0.02	0.07	NC	-	NC	-
MM 0095	Meat from mammals other than marine mammals. raw (incl prepared meat)	RAC	0	140.03	0.00	150.89	0.00	79.32	0.00	111.24	0.00	120.30	0.00	51.27	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.01	15.17	0.15	5.19	0.05	6.30	0.06	6.78	0.07	3.32	0.03	3.17	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00

PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				21.9		26.6		15.2		23.7		22.5		36.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				6000		6000		5500		6000		6000		6000
	%ADI=				0.37%		0.44%		0.28%		0.39%		0.38%		0.61%
	Rounded %ADI=				0%		0%		0%		0%		0%		1%

CYFLUMETOFEN (273) International Estimated Daily Intake (IEDI) ADI = 0–0.1 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of citrus fruit, raw (incl kumquat commodities)	RAC	0.07	20.93	1.47	2.35	0.16	30.71	2.15	0.15	0.01	4.45	0.31
JF 0001	Group of citrus fruit, juice	PP	0.0022	0.11	0.00	0.29	0.00	13.55	0.03	0.14	0.00	0.33	0.00
FP 0009	Group of p0ome fruits, raw (incl apple cider, excl apple juice)	RAC	0.13	68.85	8.95	10.93	1.42	70.82	9.21	189.78	24.67	19.56	2.54
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.036	0.03	0.00	0.10	0.00	7.19	0.26	0.03	0.00	NC	-
FS 0013	Subgroup of cherries, raw	RAC	0.106	0.01	0.00	0.01	0.00	5.96	0.63	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.125	0.02	0.00	0.01	0.00	10.76	1.35	0.01	0.00	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.22	0.14	0.03	0.36	0.08	15.22	3.35	0.01	0.00	0.09	0.02
DF 0269	Grapes, dried (= currants. raisins and sultanas) (from table-grapes)	PP	0.51	0.01	0.01	0.13	0.07	1.06	0.54	0.01	0.01	0.03	0.02
JF 0269	Grape juice (from wine grapes)	PP	0.048	0.01	0.00	0.01	0.00	0.41	0.02	0.01	0.00	NC	-
-	Grapes must (from wine-grapes)	PP	0.071	0.01	0.00	0.01	0.00	0.11	0.01	0.01	0.00	0.19	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.026	0.31	0.01	0.23	0.01	60.43	1.57	0.52	0.01	31.91	0.83
FB 0275	Strawberry, raw	RAC	0.18	0.01	0.00	0.01	0.00	3.35	0.60	0.01	0.00	0.01	0.00

VC 0424	Cucumber, raw	RAC	0.085	0.68	0.06	1.81	0.15	10.40	0.88	0.01	0.00	0.04	0.00
VO 0448	Tomato, raw	RAC	0.07	12.99	0.91	4.79	0.34	58.40	4.09	0.92	0.06	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.021	0.07	0.00	0.08	0.00	2.42	0.05	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.12	0.58	0.07	0.22	0.03	2.21	0.27	0.24	0.03	3.10	0.37
JF 0448	Tomato, juice (single strength. incl concentrated)	PP	0.027	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
TN 0085	Group of tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.043	0.83	0.04	0.69	0.03	1.09	0.05	2.91	0.13	0.82	0.04
SM 0716	Coffee bean, roasted	PP	0.026	0.02	0.00	0.41	0.01	7.50	0.20	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.01	0.03	0.00	0.05	0.00	0.60	0.01	0.01	0.00	5.53	0.06
DH 1100	Hops, dry	RAC	3.6	NC	-	NC	-	0.04	0.14	NC	-	NC	-
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0	29.18	0.00	50.89	0.00	121.44	0.00	22.58	0.00	72.14	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.01	4.64	0.05	1.97	0.02	10.01	0.10	3.27	0.03	3.98	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00

PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				11.6		3.7		25.6		25.0		7.4
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				6000		6000		6000		6000		6000
	%ADI=				0.19%		0.061%		0.43%		0.42%		0.12%
	Rounded %ADI=				0%		0%		0%		0%		0%

DELTAMETHRIN (135) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, excl kumquat commodities)	RAC	0.01	32.55	0.33	16.24	0.16	14.04	0.14	90.04	0.90	33.92	0.34	96.78	0.97
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.03	13.49	0.40	26.63	0.80	15.05	0.45	16.28	0.49	6.47	0.19	47.88	1.44
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0027	0.32	0.00	3.07	0.01	0.07	0.00	5.00	0.01	0.29	0.00	5.57	0.02
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.02	2.67	0.05	8.77	0.18	0.07	0.00	3.03	0.06	0.70	0.01	4.34	0.09
-	Peaches and nectarines, raw	RAC	0.02	2.87	0.06	2.21	0.04	0.15	0.00	5.94	0.12	1.47	0.03	15.66	0.31
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.04	16.25	0.65	28.96	1.16	2.87	0.11	24.22	0.97	9.33	0.37	68.64	2.75
FB 0275	Strawberry, raw	RAC	0.02	0.70	0.01	2.01	0.04	0.04	0.00	1.36	0.03	0.37	0.01	2.53	0.05
FT 0305	Table olives, raw (incl preserved)	RAC	0.21	0.70	0.15	0.32	0.07	0.01	0.00	1.53	0.32	0.17	0.04	1.85	0.39
FI 0350	Papaya, raw	RAC	0.01	0.35	0.00	0.01	0.00	3.05	0.03	0.80	0.01	7.28	0.07	1.00	0.01
-	Onions, dry, raw	RAC	0.02	29.36	0.59	37.50	0.75	3.56	0.07	34.78	0.70	18.81	0.38	43.38	0.87
VA 0384	Leek, raw	RAC	0.07	0.18	0.01	1.59	0.11	0.03	0.00	0.28	0.02	0.01	0.00	3.21	0.22
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.02	2.54	0.05	0.49	0.01	0.01	0.00	3.57	0.07	7.79	0.16	3.12	0.06
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.02	53.14	1.06	86.21	1.72	6.28	0.13	92.76	1.86	15.64	0.31	155.30	3.11
VO 0448	Tomato, raw	RAC	0.02	41.73	0.83	75.65	1.51	10.66	0.21	82.87	1.66	24.75	0.50	200.93	4.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.002	2.34	0.00	1.33	0.00	1.57	0.00	4.24	0.01	0.34	0.00	2.83	0.01
VL 0053	Group of Leafy vegetables, raw	RAC	0.125	8.47	1.06	22.36	2.80	7.74	0.97	25.51	3.19	45.77	5.72	21.22	2.65
VP 0060	Group of Legume vegetables, raw	RAC	0.01	7.73	0.08	1.53	0.02	0.51	0.01	2.95	0.03	5.08	0.05	12.86	0.13
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.5	87.29	43.65	64.04	32.02	37.15	18.58	89.82	44.91	91.02	45.51	98.20	49.10
VR 0577	Carrots, raw	RAC	0.01	9.51	0.10	30.78	0.31	0.37	0.00	8.75	0.09	2.80	0.03	6.10	0.06
VR 0494	Radish roots, raw	RAC	0.01	2.31	0.02	4.09	0.04	2.53	0.03	6.15	0.06	5.88	0.06	2.97	0.03

VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	59.74	0.60	316.14	3.16	9.78	0.10	60.26	0.60	54.12	0.54	119.82	1.20
VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.02	0.09	0.00	0.56	0.01	0.02	0.00	2.65	0.05	0.11	0.00	0.51	0.01
GC 0081	Cereal grains, excl pseudocereals, excl sweet corn (incl processed)	RAC	0.7	484.29	339.00	463.29	324.30	256.66	179.66	484.19	338.93	467.54	327.28	613.74	429.62
CF 1210	Wheat, germ	PP	0.84	NC	-	NC	-	0.01	0.01	0.01	0.01	0.14	0.12	0.01	0.01
CP 1212	Wheat, wholemeal bread	PP	0.637	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.03	0.02	0.01	0.01
CP 1211	Wheat, white bread	PP	0.098	0.25	0.02	0.63	0.06	0.12	0.01	0.43	0.04	1.39	0.14	0.22	0.02
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.217	301.24	65.37	268.64	58.29	30.21	6.56	222.51	48.28	134.73	29.24	343.12	74.46
-	Wheat, macaroni, dry	PP	0.091	0.72	0.07	2.20	0.20	1.22	0.11	3.99	0.36	0.53	0.05	1.66	0.15
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.105	1.26	0.13	1.58	0.17	31.05	3.26	5.43	0.57	0.90	0.09	2.18	0.23
CM 1205	Rice polished, dry	PP	0.042	34.21	1.44	10.39	0.44	41.72	1.75	82.38	3.46	150.24	6.31	70.47	2.96
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.231	3.91	0.90	NC	-	11.62	2.68	14.24	3.29	9.87	2.28	2.62	0.61
-	Maize, germ	PP	0.224	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	0.22	0.05	NC	-
OR 0645	Maize oil	PP	12.6	0.96	12.10	0.85	10.71	0.29	3.65	5.42	68.29	0.42	5.29	2.10	26.46
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.02	0.14	0.00	0.94	0.02	5.70	0.11	2.61	0.05	1.94	0.04	0.22	0.00
TN 0666	Hazelnuts, nutmeat	RAC	0.02	0.03	0.00	0.13	0.00	0.01	0.00	0.11	0.00	0.01	0.00	1.11	0.02
TN 0678	Walnut, nutmeat	RAC	0.02	0.23	0.00	1.49	0.03	0.01	0.00	0.33	0.01	0.07	0.00	2.06	0.04
OR 0495	Rape seed oil, edible	PP	0.07	0.35	0.02	0.44	0.03	0.19	0.01	0.97	0.07	3.28	0.23	0.77	0.05
SO 0702	Sunflower seed, raw	RAC	0.05	0.09	0.00	0.33	0.02	0.09	0.00	0.24	0.01	0.02	0.00	0.01	0.00
-	Olive oil (virgin and residue oil)	PP	0.336	2.17	0.73	0.13	0.04	0.05	0.02	1.32	0.44	0.10	0.03	2.76	0.93

DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	2.2	2.28	5.02	1.98	4.36	0.46	1.01	2.43	5.35	1.29	2.84	3.04	6.69
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.03	24.96	0.75	57.95	1.74	16.70	0.50	38.38	1.15	26.46	0.79	29.00	0.87
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.27	6.24	1.68	14.49	3.91	4.18	1.13	9.60	2.59	6.62	1.79	7.25	1.96
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.27	3.29	0.89	6.14	1.66	0.82	0.22	1.57	0.42	2.23	0.60	1.07	0.29
MO 0105	Edible offal (mammalian), raw	RAC	0.05	4.79	0.24	9.68	0.48	2.97	0.15	5.49	0.27	3.84	0.19	5.03	0.25
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.026	289.65	7.53	485.88	12.63	26.92	0.70	239.03	6.21	199.91	5.20	180.53	4.69
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	13.17	0.26	26.78	0.54	7.24	0.14	116.71	2.33	22.54	0.45	32.09	0.64
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.038	1.46	0.06	2.98	0.11	0.80	0.03	12.97	0.49	2.50	0.10	3.57	0.14
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	7.84	0.16	23.08	0.46	2.88	0.06	14.89	0.30	9.81	0.20	14.83	0.30
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.03	1.99	0.06	1.93	0.06	6.26	0.19	3.41	0.10	6.59	0.20	8.73	0.26
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				486.2		465.2		222.8		539.2		437.8		619.1
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600		600
	%ADI=				81.0%		77.5%		37.1%		89.9%		73.0%		103.2%
	Rounded %ADI=				80%		80%		40%		90%		70%		100%

DELTAMETHRIN (135) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, excl kumquat commodities)	RAC	0.01	109.75	1.10	57.06	0.57	25.01	0.25	95.27	0.95	79.17	0.79	561.83	5.62
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.03	41.14	1.23	56.49	1.69	26.64	0.80	31.58	0.95	51.94	1.56	3.05	0.09
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0027	14.88	0.04	11.98	0.03	0.15	0.00	9.98	0.03	30.32	0.08	3.47	0.01
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.02	5.55	0.11	4.37	0.09	6.08	0.12	3.66	0.07	3.93	0.08	0.46	0.01
-	Peaches and nectarines, raw	RAC	0.02	8.76	0.18	12.98	0.26	8.23	0.16	10.09	0.20	3.64	0.07	0.04	0.00
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.04	142.23	5.69	105.77	4.23	7.87	0.31	52.44	2.10	109.22	4.37	10.96	0.44
FB 0275	Strawberry, raw	RAC	0.02	4.49	0.09	5.66	0.11	0.02	0.00	6.63	0.13	5.75	0.12	0.05	0.00
FT 0305	Table olives, raw (incl preserved)	RAC	0.21	2.00	0.42	2.48	0.52	0.01	0.00	1.21	0.25	1.64	0.34	0.27	0.06
FI 0350	Papaya, raw	RAC	0.01	0.31	0.00	0.18	0.00	1.50	0.02	0.51	0.01	0.54	0.01	1.08	0.01
-	Onions, dry, raw	RAC	0.02	19.69	0.39	29.83	0.60	24.64	0.49	31.35	0.63	9.72	0.19	12.59	0.25
VA 0384	Leek, raw	RAC	0.07	4.01	0.28	4.41	0.31	0.72	0.05	0.54	0.04	16.41	1.15	0.03	0.00
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.02	9.50	0.19	6.77	0.14	NC	-	3.21	0.06	9.36	0.19	0.75	0.02
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.02	27.81	0.56	41.93	0.84	123.30	2.47	49.47	0.99	15.95	0.32	35.99	0.72
VO 0448	Tomato, raw	RAC	0.02	32.13	0.64	51.27	1.03	34.92	0.70	73.37	1.47	15.15	0.30	8.88	0.18
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.002	4.96	0.01	3.20	0.01	0.15	0.00	1.61	0.00	6.88	0.01	0.52	0.00
VL 0053	Group of Leafy vegetables, raw	RAC	0.125	18.83	2.35	21.85	2.73	121.23	15.15	43.09	5.39	18.18	2.27	18.32	2.29
VP 0060	Group of Legume vegetables, raw	RAC	0.01	18.21	0.18	8.91	0.09	7.22	0.07	10.04	0.10	23.22	0.23	0.17	0.00
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.5	112.88	56.44	123.05	61.53	47.73	23.87	204.75	102.38	227.52	113.76	110.05	55.03
VR 0577	Carrots, raw	RAC	0.01	26.26	0.26	27.13	0.27	10.07	0.10	16.49	0.16	44.69	0.45	8.75	0.09
VR 0494	Radish roots, raw	RAC	0.01	3.83	0.04	11.99	0.12	NC	-	5.26	0.05	2.19	0.02	4.37	0.04
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38

VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.02	7.31	0.15	5.92	0.12	1.26	0.03	3.73	0.07	14.85	0.30	0.57	0.01
GC 0081	Cereal grains, excl pseudocereals, excl sweet corn (incl processed)	RAC	0.7	334.19	233.93	381.67	267.17	513.41	359.39	388.74	272.12	292.24	204.57	358.47	250.93
CF 1210	Wheat, germ	PP	0.84	0.97	0.81	0.10	0.08	0.03	0.03	0.01	0.01	NC	-	0.04	0.03
CP 1212	Wheat, wholemeal bread	PP	0.637	0.03	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.05	0.03	0.02	0.01
CP 1211	Wheat, white bread	PP	0.098	1.30	0.13	0.46	0.05	0.06	0.01	0.22	0.02	2.44	0.24	0.77	0.08
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.217	198.08	42.98	193.03	41.89	106.24	23.05	185.09	40.16	168.67	36.60	131.59	28.56
-	Wheat, macaroni, dry	PP	0.091	6.71	0.61	4.98	0.45	2.12	0.19	1.90	0.17	2.89	0.26	4.12	0.37
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.105	3.70	0.39	2.11	0.22	1.51	0.16	1.75	0.18	0.29	0.03	5.12	0.54
CM 1205	Rice polished, dry	PP	0.042	13.38	0.56	10.80	0.45	262.08	11.01	57.16	2.40	12.83	0.54	62.78	2.64
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.231	NC	-	NC	-	1.29	0.30	0.01	0.00	NC	-	NC	-
-	Maize, germ	PP	0.224	0.01	0.00	NC	-	NC	-	0.01	0.00	NC	-	0.01	0.00
OR 0645	Maize oil	PP	12.6	0.90	11.34	0.47	5.92	0.15	1.89	3.01	37.93	1.86	23.44	0.36	4.54
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.02	11.43	0.23	3.71	0.07	0.74	0.01	13.63	0.27	3.07	0.06	1.50	0.03
TN 0666	Hazelnuts, nutmeat	RAC	0.02	0.45	0.01	1.12	0.02	0.02	0.00	0.34	0.01	1.63	0.03	NC	-
TN 0678	Walnut, nutmeat	RAC	0.02	0.34	0.01	0.84	0.02	0.28	0.01	0.39	0.01	0.45	0.01	NC	-
OR 0495	Rape seed oil, edible	PP	0.07	12.52	0.88	7.63	0.53	3.00	0.21	6.01	0.42	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.05	0.01	0.00	1.32	0.07	0.03	0.00	1.17	0.06	NC	-	0.02	0.00
-	Olive oil (virgin and residue oil)	PP	0.336	3.40	1.14	9.49	3.19	0.02	0.01	4.28	1.44	2.74	0.92	0.48	0.16
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	2.2	2.91	6.40	1.73	3.81	1.14	2.51	1.85	4.07	2.29	5.04	0.74	1.63
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.03	112.02	3.36	120.71	3.62	63.46	1.90	88.99	2.67	96.24	2.89	41.02	1.23
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.27	28.01	7.56	30.18	8.15	15.86	4.28	22.25	6.01	24.06	6.50	10.25	2.77

MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.27	6.44	1.74	15.51	4.19	3.79	1.02	8.29	2.24	18.44	4.98	8.00	2.16
MO 0105	Edible offal (mammalian), raw	RAC	0.05	15.17	0.76	5.19	0.26	6.30	0.32	6.78	0.34	3.32	0.17	3.17	0.16
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.026	388.92	10.11	335.88	8.73	49.15	1.28	331.25	8.61	468.56	12.18	245.45	6.38
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	66.38	1.33	48.47	0.97	21.58	0.43	78.41	1.57	48.04	0.96	76.01	1.52
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.038	7.38	0.28	5.39	0.20	2.40	0.09	8.71	0.33	5.34	0.20	8.45	0.32
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	25.84	0.52	29.53	0.59	28.05	0.56	33.19	0.66	36.44	0.73	8.89	0.18
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.03	4.88	0.15	2.35	0.07	27.05	0.81	3.03	0.09	0.84	0.03	2.71	0.08
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				397.9		428.4		454.8		499.6		429.4		369.6
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				600		600		550		600		600		600
	%ADI=				66.3%		71.4%		82.7%		83.3%		71.6%		61.6%
	Rounded %ADI=				70%		70%		80%		80%		70%		60%

DELTAMETHRIN (135) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, excl kumquat commodities)	RAC	0.01	2.80	0.03	2.71	0.03	56.74	0.57	0.36	0.00	1.78	0.02
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.03	66.67	2.00	2.06	0.06	55.83	1.67	188.29	5.65	1.38	0.04
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.0027	0.03	0.00	0.10	0.00	7.19	0.02	0.03	0.00	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.02	0.07	0.00	0.02	0.00	16.65	0.33	0.01	0.00	NC	-
-	Peaches and nectarines, raw	RAC	0.02	0.02	0.00	0.01	0.00	7.47	0.15	0.01	0.00	NC	-
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.04	0.60	0.02	1.26	0.05	103.25	4.13	0.74	0.03	44.23	1.77
FB 0275	Strawberry, raw	RAC	0.02	0.01	0.00	0.01	0.00	3.35	0.07	0.01	0.00	0.01	0.00
FT 0305	Table olives, raw (incl preserved)	RAC	0.21	0.01	0.00	0.01	0.00	1.75	0.37	0.01	0.00	0.24	0.05
FI 0350	Papaya, raw	RAC	0.01	6.47	0.06	0.25	0.00	0.19	0.00	0.01	0.00	26.42	0.26
-	Onions, dry, raw	RAC	0.02	9.01	0.18	20.24	0.40	30.90	0.62	9.61	0.19	2.11	0.04
VA 0384	Leek, raw	RAC	0.07	0.02	0.00	1.44	0.10	1.22	0.09	0.01	0.00	NC	-
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.02	0.02	0.00	0.02	0.00	4.86	0.10	0.01	0.00	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.02	5.96	0.12	9.74	0.19	51.82	1.04	13.61	0.27	0.05	0.00
VO 0448	Tomato, raw	RAC	0.02	12.99	0.26	4.79	0.10	58.40	1.17	0.92	0.02	0.09	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.002	0.58	0.00	0.22	0.00	2.21	0.00	0.24	0.00	3.10	0.01
VL 0053	Group of Leafy vegetables, raw	RAC	0.125	12.42	1.55	8.75	1.09	7.53	0.94	7.07	0.88	14.11	1.76
VP 0060	Group of Legume vegetables, raw	RAC	0.01	0.58	0.01	3.16	0.03	10.38	0.10	0.04	0.00	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.5	46.57	23.29	30.77	15.39	112.53	56.27	75.53	37.77	43.68	21.84
VR 0577	Carrots, raw	RAC	0.01	2.07	0.02	3.00	0.03	25.29	0.25	0.05	0.00	NC	-
VR 0494	Radish roots, raw	RAC	0.01	3.96	0.04	2.86	0.03	3.30	0.03	2.67	0.03	5.34	0.05
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.01	23.96	0.24	13.56	0.14	213.41	2.13	104.35	1.04	8.56	0.09

VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.02	0.02	0.00	0.04	0.00	3.73	0.07	0.01	0.00	NC	-
GC 0081	Cereal grains, excl pseudocereals, excl sweet corn (incl processed)	RAC	0.7	403.37	282.36	393.72	275.60	394.01	275.81	195.27	136.69	263.09	184.16
CF 1210	Wheat, germ	PP	0.84	0.04	0.03	0.01	0.01	0.01	0.01	0.01	0.01	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.637	0.01	0.01	0.01	0.01	0.03	0.02	0.01	0.01	0.01	0.01
CP 1211	Wheat, white bread	PP	0.098	0.43	0.04	0.41	0.04	1.56	0.15	0.11	0.01	0.07	0.01
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.217	44.78	9.72	86.96	18.87	214.05	46.45	20.31	4.41	103.60	22.48
-	Wheat, macaroni, dry	PP	0.091	0.52	0.05	0.63	0.06	2.99	0.27	0.26	0.02	5.18	0.47
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.105	13.58	1.43	4.29	0.45	2.17	0.23	0.01	0.00	8.84	0.93
CM 1205	Rice polished, dry	PP	0.042	30.20	1.27	218.34	9.17	12.77	0.54	15.24	0.64	51.35	2.16
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.231	75.99	17.55	1.82	0.42	NC	-	19.82	4.58	NC	-
-	Maize, germ	PP	0.224	0.01	0.00	NC	-	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	12.6	0.33	4.16	0.07	0.88	0.81	10.21	0.01	0.13	NC	-
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.02	3.63	0.07	20.50	0.41	8.78	0.18	0.02	0.00	0.17	0.00
TN 0666	Hazelnuts, nutmeat	RAC	0.02	0.01	0.00	0.01	0.00	0.21	0.00	0.01	0.00	NC	-
TN 0678	Walnut, nutmeat	RAC	0.02	0.01	0.00	0.01	0.00	0.81	0.02	0.01	0.00	NC	-
OR 0495	Rape seed oil, edible	PP	0.07	0.07	0.00	0.03	0.00	4.62	0.32	0.03	0.00	NC	-
SO 0702	Sunflower seed, raw	RAC	0.05	0.02	0.00	0.01	0.00	0.03	0.00	2.23	0.11	NC	-
-	Olive oil (virgin and residue oil)	PP	0.336	0.03	0.01	0.02	0.01	2.14	0.72	0.01	0.00	0.10	0.03
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	2.2	0.53	1.17	5.25	11.55	0.86	1.89	0.56	1.23	0.88	1.94
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.03	23.34	0.70	40.71	1.22	97.15	2.91	18.06	0.54	57.71	1.73
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.27	5.84	1.58	10.18	2.75	24.29	6.56	4.52	1.22	14.43	3.90
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.27	1.05	0.28	1.14	0.31	18.69	5.05	0.94	0.25	3.12	0.84

MO 0105	Edible offal (mammalian), raw	RAC	0.05	4.64	0.23	1.97	0.10	10.01	0.50	3.27	0.16	3.98	0.20
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.026	108.75	2.83	70.31	1.83	436.11	11.34	61.55	1.60	79.09	2.06
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.02	3.53	0.07	10.83	0.22	51.36	1.03	4.53	0.09	50.00	1.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.038	0.39	0.01	1.20	0.05	5.71	0.22	0.50	0.02	5.56	0.21
PE 0112	Eggs, raw, (incl dried)	RAC	0.02	3.84	0.08	4.41	0.09	27.25	0.55	1.13	0.02	7.39	0.15
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.03	3.43	0.10	4.13	0.12	1.77	0.05	18.43	0.55	0.10	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				351.6		341.8		435.1		198.2		248.2
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600
	%ADI=				58.6%		57.0%		72.5%		33.0%		41.4%
	Rounded %ADI=				60%		60%		70%		30%		40%

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0–000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.16	32.25	5.16	11.67	1.87	16.70	2.67	76.01	12.16	33.90	5.42	92.97	14.88
JF 0001	Group of Citrus fruit, juice	PP	0.002	1.30	0.00	2.37	0.00	0.22	0.00	13.88	0.03	0.75	0.00	2.63	0.01
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.86	19.79	17.02	38.25	32.90	17.96	15.45	32.56	28.00	8.08	6.95	64.45	55.43
FS 0013	Subgroup of Cherries, raw	RAC	0.365	0.92	0.34	9.15	3.34	0.01	0.00	0.61	0.22	0.06	0.02	6.64	2.42
FS 0014	Subgroup of Plums, raw	RAC	0.365	2.40	0.88	8.60	3.14	0.06	0.02	2.52	0.92	0.58	0.21	4.16	1.52
DF 0014	Plums, dried (prunes)	PP	0.94	0.09	0.08	0.06	0.06	0.01	0.01	0.18	0.17	0.04	0.04	0.06	0.06
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.365	8.01	2.92	5.87	2.14	0.18	0.07	8.19	2.99	1.64	0.60	22.46	8.20
FB 2005	Subgroup of Caneberries, raw	RAC	0.69	0.42	0.29	1.05	0.72	0.01	0.01	0.02	0.01	0.02	0.01	1.24	0.86
FB 0020	Blueberries, raw	RAC	1	0.01	0.01	0.03	0.03	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.52	13.02	6.77	9.25	4.81	0.03	0.02	16.91	8.79	3.70	1.92	54.44	28.31
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.1	0.51	0.56	0.51	0.56	0.01	0.01	1.27	1.40	0.12	0.13	2.07	2.28
JF 0269	Grape juice (from wine grapes)	PP	0.24	0.14	0.03	0.29	0.07	0.05	0.01	0.30	0.07	0.24	0.06	0.05	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.094	0.67	0.06	12.53	1.18	2.01	0.19	1.21	0.11	3.53	0.33	4.01	0.38
FB 0265	Cranberry, raw	RAC	0.2	0.02	0.00	0.01	0.00	NC	-	0.03	0.01	0.01	0.00	0.01	0.00
FB 0275	Strawberry, raw	RAC	0.42	0.70	0.29	2.01	0.84	0.04	0.02	1.36	0.57	0.37	0.16	2.53	1.06
FT 0305	Table olives, raw (incl preserved)	RAC	0.465	0.70	0.33	0.32	0.15	0.01	0.00	1.53	0.71	0.17	0.08	1.85	0.86
FT 0336	Guava, raw	RAC	0.0335	0.47	0.02	0.01	0.00	0.48	0.02	0.49	0.02	4.42	0.15	0.06	0.00
FI 0326	Avocado, raw	RAC	0.05	0.13	0.01	0.03	0.00	2.05	0.10	2.54	0.13	2.34	0.12	0.12	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	5.23	0.10	6.94	0.14	99.45	1.99	32.47	0.65	48.30	0.97	24.70	0.49
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	10.48	0.31	0.01	0.00	7.24	0.22	6.87	0.21	19.98	0.60	6.25	0.19
FI 0350	Papaya, raw	RAC	0.065	0.35	0.02	0.01	0.00	3.05	0.20	0.80	0.05	7.28	0.47	1.00	0.07
FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.034	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
FI 0351	Passion fruit, raw	RAC	0.01	0.58	0.01	0.01	0.00	0.59	0.01	0.60	0.01	0.18	0.00	0.08	0.00

-	Onions, dry, raw	RAC	0.015	29.36	0.44	37.50	0.56	3.56	0.05	34.78	0.52	18.81	0.28	43.38	0.65
VA 0384	Leek, raw	RAC	0.08	0.18	0.01	1.59	0.13	0.03	0.00	0.28	0.02	0.01	0.00	3.21	0.26
-	Onions, green, raw	RAC	2.8	2.45	6.86	1.49	4.17	1.02	2.86	2.60	7.28	0.60	1.68	2.03	5.68
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.35	6.43	2.25	40.26	14.09	0.80	0.28	9.94	3.48	12.07	4.22	17.73	6.21
VC 0424	Cucumber, raw	RAC	0.04	8.01	0.32	30.66	1.23	1.45	0.06	19.84	0.79	0.27	0.01	34.92	1.40
VC 0425	Gherkin, raw	RAC	0.04	1.73	0.07	6.64	0.27	0.31	0.01	4.29	0.17	0.29	0.01	7.56	0.30
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.04	0.78	0.03	2.06	0.08	0.30	0.01	1.61	0.06	2.25	0.09	2.36	0.09
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.14	8.90	1.25	8.64	1.21	0.80	0.11	17.90	2.51	2.80	0.39	29.17	4.08
VC 0432	Watermelon, raw	RAC	0.01	28.96	0.29	25.65	0.26	1.56	0.02	39.26	0.39	4.94	0.05	66.90	0.67
VO 0448	Tomato, raw	RAC	0.1	41.73	4.17	75.65	7.57	10.66	1.07	82.87	8.29	24.75	2.48	200.93	20.09
-	Tomato, canned (& peeled)	PP	0.01	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.01	0.11	0.00	1.50	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	2.34	0.51	1.33	0.29	1.57	0.35	4.24	0.93	0.34	0.07	2.83	0.62
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.29	0.01	0.29	0.01	0.01	0.00	0.38	0.01	0.05	0.00	0.14	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.14	1.97	0.28	NC	-	3.68	0.52	3.24	0.45	5.72	0.80	1.57	0.22
VO 0444	Peppers, chili, raw	RAC	0.24	3.99	0.96	7.30	1.75	2.93	0.70	5.62	1.35	NC	-	17.44	4.19
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.14	4.49	0.63	6.44	0.90	7.21	1.01	5.68	0.80	9.52	1.33	8.92	1.25
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.14	5.58	0.78	4.31	0.60	0.89	0.12	9.31	1.30	13.64	1.91	20.12	2.82
VL 0483	Lettuce, leaf, raw	RAC	0.41	0.53	0.22	0.36	0.15	0.16	0.07	6.21	2.55	1.90	0.78	6.05	2.48
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.6	0.03	0.05	0.31	0.50	0.01	0.02	0.05	0.08	0.47	0.75	0.11	0.18
VL 0494	Radish leaves, raw	RAC	1.6	0.26	0.42	0.45	0.72	0.28	0.45	0.68	1.09	NC	-	0.33	0.53
VP 0060	Group of Legume vegetables, raw	RAC	0.07	7.73	0.54	1.53	0.11	0.51	0.04	2.95	0.21	5.08	0.36	12.86	0.90
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.011	2.39	0.03	1.61	0.02	10.47	0.12	1.84	0.02	12.90	0.14	7.44	0.08
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.011	1.27	0.01	0.01	0.00	0.12	0.00	2.49	0.03	0.23	0.00	5.54	0.06
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.01	0.63	0.01	1.09	0.01	0.40	0.00	1.40	0.01	1.68	0.02	0.48	0.00
OR 0541	Soya oil, refined	PP	0.08	12.99	1.04	10.43	0.83	3.63	0.29	13.10	1.05	10.70	0.86	13.10	1.05

-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.028	1.70	0.05	0.01	0.00	3.00	0.08	1.80	0.05	1.64	0.05	1.33	0.04
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.028	2.12	0.06	0.01	0.00	0.03	0.00	3.21	0.09	1.60	0.04	4.90	0.14
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.028	NC	-	NC	-	0.10	0.00	0.07	0.00	3.38	0.09	NC	-
VR 0577	Carrots, raw	RAC	0.05	9.51	0.48	30.78	1.54	0.37	0.02	8.75	0.44	2.80	0.14	6.10	0.31
VR 0578	Celeriac, raw	RAC	0.12	1.70	0.20	3.01	0.36	1.87	0.22	4.53	0.54	NC	-	2.19	0.26
VR 0494	Radish roots, raw	RAC	0.17	2.31	0.39	4.09	0.70	2.53	0.43	6.15	1.05	5.88	1.00	2.97	0.50
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.02	0.13	0.00	NC	-	0.08	0.00	0.66	0.01	0.47	0.01	88.94	1.78
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.2	59.74	71.69	316.14	379.37	9.78	11.74	60.26	72.31	54.12	64.94	119.82	143.78
VR 0508	Sweet potato, raw (incl dried)	RAC	1.2	0.18	0.22	0.18	0.22	42.16	50.59	1.61	1.93	3.06	3.67	6.67	8.00
VS 0624	Celery	RAC	0.14	2.14	0.30	3.79	0.53	2.35	0.33	5.69	0.80	0.02	0.00	2.75	0.39
VS 0621	Asparagus, raw	RAC	0.02	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.07	0.00	0.21	0.00
VS 0620	Artichoke globe, raw	RAC	0.51	0.69	0.35	0.01	0.01	0.01	0.01	0.32	0.16	0.26	0.13	1.21	0.62
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.1	1.26	1.39	1.58	1.74	31.05	34.16	5.43	5.97	0.90	0.99	2.18	2.40
CM 1205	Rice polished, dry	PP	0.0086	34.21	0.29	10.39	0.09	41.72	0.36	82.38	0.71	150.24	1.29	70.47	0.61
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, incl starch, excl flour, excl oil)	RAC	0.01	0.97	0.01	0.24	0.00	1.58	0.02	4.10	0.04	2.56	0.03	13.31	0.13
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.008	22.72	0.18	35.61	0.28	87.27	0.70	34.92	0.28	46.71	0.37	49.12	0.39
OR 0645	Maize oil	PP	0.012	0.96	0.01	0.85	0.01	0.29	0.00	5.42	0.07	0.42	0.01	2.10	0.03
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 0495	Rape seed, raw	RAC	0.03	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.02	0.01	0.00

OR 0495	Rape seed oil, edible	PP	0.002	0.35	0.00	0.44	0.00	0.19	0.00	0.97	0.00	3.28	0.01	0.77	0.00
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	7.40	0.07	35.86	0.36	1.15	0.01	8.76	0.09	5.45	0.05	13.62	0.14
OR 0691	Cotton seed oil, edible	PP	0.0014	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	1.30	0.00	1.23	0.00	12.62	0.00	2.87	0.00	6.59	0.00	2.67	0.00
SO 0305	Olives for oil production, raw	RAC	0.456	1.47	0.67	0.67	0.31	NC	-	1.26	0.57	0.04	0.02	7.63	3.48
-	Olive oil (virgin and residue oil)	PP	0.7	2.17	1.52	0.13	0.09	0.05	0.04	1.32	0.92	0.10	0.07	2.76	1.93
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	1.36	0.01	3.59	0.04	1.44	0.01	5.18	0.05	2.02	0.02	1.70	0.02
HS 0784	Ginger, rhizome, raw incl dried	RAC	0.13	0.25	0.03	0.01	0.00	0.16	0.02	1.16	0.15	0.59	0.08	0.01	0.00
HS 0444	Peppers, chili, dried	PP	1.1	0.42	0.46	0.53	0.58	0.84	0.92	0.50	0.55	0.95	1.05	0.37	0.41
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.85	2.28	11.06	1.98	9.60	0.46	2.23	2.43	11.79	1.29	6.26	3.04	14.74
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.047	24.96	1.17	57.95	2.72	16.70	0.79	38.38	1.80	26.46	1.24	29.00	1.36
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.14	6.24	0.87	14.49	2.03	4.18	0.58	9.60	1.34	6.62	0.93	7.25	1.02
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.14	3.29	0.46	6.14	0.86	0.82	0.11	1.57	0.22	2.23	0.31	1.07	0.15
MO 0105	Edible offal (mammalian), raw	RAC	0.71	4.79	3.40	9.68	6.87	2.97	2.11	5.49	3.90	3.84	2.73	5.03	3.57
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	289.65	3.19	485.88	5.34	26.92	0.30	239.03	2.63	199.91	2.20	180.53	1.99
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0002	14.63	0.00	29.76	0.01	8.04	0.00	129.68	0.03	25.04	0.01	35.66	0.01
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0002	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.0002	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.011	7.84	0.09	23.08	0.25	2.88	0.03	14.89	0.16	9.81	0.11	14.83	0.16
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				155.1		501.4		135.1		199.5		122.5		359.3
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600		600
	%ADI=				25.8%		83.6%		22.5%		33.2%		20.4%		59.9%
	Rounded %ADI=				30%		80%		20%		30%		20%		60%

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0–000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.16	38.66	6.19	54.93	8.79	26.36	4.22	51.46	8.23	51.06	8.17	466.36	74.62
JF 0001	Group of Citrus fruit, juice	PP	0.002	36.84	0.07	3.75	0.01	0.30	0.00	21.62	0.04	21.82	0.04	46.67	0.09
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.86	71.38	61.39	81.73	70.29	42.91	36.90	58.89	50.65	103.85	89.31	12.48	10.73
FS 0013	Subgroup of Cherries, raw	RAC	0.365	1.40	0.51	4.21	1.54	0.04	0.01	2.93	1.07	1.50	0.55	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.365	3.75	1.37	3.33	1.22	5.94	2.17	2.64	0.96	2.50	0.91	0.06	0.02
DF 0014	Plums, dried (prunes)	PP	0.94	0.61	0.57	0.35	0.33	0.05	0.05	0.35	0.33	0.49	0.46	0.13	0.12
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.365	13.03	4.76	16.29	5.95	8.29	3.03	12.95	4.73	5.35	1.95	0.04	0.01
FB 2005	Subgroup of Caneberries, raw	RAC	0.69	0.56	0.39	1.43	0.99	0.14	0.10	1.23	0.85	1.14	0.79	0.01	0.01
FB 0020	Blueberries, raw	RAC	1	0.04	0.04	0.23	0.23	0.01	0.01	0.83	0.83	0.33	0.33	NC	-
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.52	6.48	3.37	11.31	5.88	5.21	2.71	9.50	4.94	4.66	2.42	0.78	0.41
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.1	3.09	3.40	1.51	1.66	0.03	0.03	1.38	1.52	4.26	4.69	0.42	0.46
JF 0269	Grape juice (from wine grapes)	PP	0.24	0.56	0.13	1.96	0.47	0.02	0.00	2.24	0.54	2.27	0.54	0.34	0.08
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.094	88.93	8.36	62.41	5.87	1.84	0.17	25.07	2.36	61.17	5.75	5.84	0.55
FB 0265	Cranberry, raw	RAC	0.2	0.06	0.01	0.01	0.00	0.01	0.00	1.22	0.24	0.11	0.02	NC	-
FB 0275	Strawberry, raw	RAC	0.42	4.49	1.89	5.66	2.38	0.02	0.01	6.63	2.78	5.75	2.42	0.05	0.02
FT 0305	Table olives, raw (incl preserved)	RAC	0.465	2.00	0.93	2.48	1.15	0.01	0.00	1.21	0.56	1.64	0.76	0.27	0.13
FT 0336	Guava, raw	RAC	0.0335	0.01	0.00	NC	-	0.42	0.01	NC	-	NC	-	NC	-
FI 0326	Avocado, raw	RAC	0.05	2.65	0.13	0.87	0.04	0.46	0.02	1.64	0.08	1.30	0.07	0.96	0.05
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	25.76	0.52	23.65	0.47	23.83	0.48	24.37	0.49	19.43	0.39	101.55	2.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	1.80	0.05	0.63	0.02	10.05	0.30	1.07	0.03	3.52	0.11	16.44	0.49
FI 0350	Papaya, raw	RAC	0.065	0.31	0.02	0.18	0.01	1.50	0.10	0.51	0.03	0.54	0.04	1.08	0.07

FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.034	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
FI 0351	Passion fruit, raw	RAC	0.01	0.01	0.00	0.01	0.00	NC	-	NC	-	0.02	0.00	NC	-
-	Onions, dry, raw	RAC	0.015	19.69	0.30	29.83	0.45	24.64	0.37	31.35	0.47	9.72	0.15	12.59	0.19
VA 0384	Leek, raw	RAC	0.08	4.01	0.32	4.41	0.35	0.72	0.06	0.54	0.04	16.41	1.31	0.03	0.00
-	Onions, green, raw	RAC	2.8	1.55	4.34	0.74	2.07	1.05	2.94	3.74	10.47	0.94	2.63	6.45	18.06
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.35	20.71	7.25	39.81	13.93	25.06	8.77	37.93	13.28	18.12	6.34	16.74	5.86
VC 0424	Cucumber, raw	RAC	0.04	6.72	0.27	11.03	0.44	32.10	1.28	15.10	0.60	4.05	0.16	9.57	0.38
VC 0425	Gherkin, raw	RAC	0.04	0.41	0.02	5.89	0.24	NC	-	0.06	0.00	0.37	0.01	2.07	0.08
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.04	NC	-	NC	-	5.48	0.22	NC	-	NC	-	1.03	0.04
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.14	9.20	1.29	11.95	1.67	14.63	2.05	8.99	1.26	7.86	1.10	2.46	0.34
VC 0432	Watermelon, raw	RAC	0.01	4.60	0.05	9.82	0.10	68.50	0.69	13.19	0.13	1.99	0.02	14.56	0.15
VO 0448	Tomato, raw	RAC	0.1	32.13	3.21	51.27	5.13	34.92	3.49	73.37	7.34	15.15	1.52	8.88	0.89
-	Tomato, canned (& peeled)	PP	0.01	7.57	0.08	2.66	0.03	0.30	0.00	0.97	0.01	7.31	0.07	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	4.96	1.09	3.20	0.70	0.15	0.03	1.61	0.35	6.88	1.51	0.52	0.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.80	0.02	0.07	0.00	0.05	0.00	0.61	0.02	0.40	0.01	0.08	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.14	NC	-	NC	-	0.04	0.01	0.17	0.02	NC	-	0.72	0.10
VO 0444	Peppers, chili, raw	RAC	0.24	5.57	1.34	14.00	3.36	8.25	1.98	5.77	1.38	6.44	1.55	2.53	0.61
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.14	0.82	0.11	1.53	0.21	10.85	1.52	4.59	0.64	1.84	0.26	2.00	0.28
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.14	1.01	0.14	1.69	0.24	21.37	2.99	3.00	0.42	1.40	0.20	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.41	14.50	5.95	11.76	4.82	13.14	5.39	19.50	8.00	4.81	1.97	2.23	0.91
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.6	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.21
VL 0494	Radish leaves, raw	RAC	1.6	NC	-	NC	-	NC	-	3.78	6.05	NC	-	0.48	0.77
VP 0060	Group of Legume vegetables, raw	RAC	0.07	18.21	1.27	8.91	0.62	7.22	0.51	10.04	0.70	23.22	1.63	0.17	0.01
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.011	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.06	1.36	0.01	23.43	0.26
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.011	0.02	0.00	0.01	0.00	1.16	0.01	0.40	0.00	NC	-	0.06	0.00
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.01	0.47	0.00	0.77	0.01	9.12	0.09	8.05	0.08	0.04	0.00	6.06	0.06

OR 0541	Soya oil, refined	PP	0.08	19.06	1.52	21.06	1.68	5.94	0.48	33.78	2.70	40.05	3.20	13.39	1.07
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.028	0.01	0.00	NC	-	0.57	0.02	0.11	0.00	0.16	0.00	0.94	0.03
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.028	0.95	0.03	1.18	0.03	0.40	0.01	0.96	0.03	0.71	0.02	1.28	0.04
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.028	NC	-	NC	-	0.20	0.01	NC	-	NC	-	NC	-
VR 0577	Carrots, raw	RAC	0.05	26.26	1.31	27.13	1.36	10.07	0.50	16.49	0.82	44.69	2.23	8.75	0.44
VR 0578	Celeriac, raw	RAC	0.12	2.97	0.36	1.79	0.21	NC	-	0.06	0.01	16.91	2.03	3.22	0.39
VR 0494	Radish roots, raw	RAC	0.17	3.83	0.65	11.99	2.04	NC	-	5.26	0.89	2.19	0.37	4.37	0.74
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.02	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.2	225.03	270.04	234.24	281.09	71.48	85.78	177.55	213.06	234.55	281.46	37.71	45.25
VR 0508	Sweet potato, raw (incl dried)	RAC	1.2	0.93	1.12	0.32	0.38	64.65	77.58	5.37	6.44	0.30	0.36	3.13	3.76
VS 0624	Celery	RAC	0.14	7.68	1.08	2.85	0.40	NC	-	3.34	0.47	16.83	2.36	4.04	0.57
VS 0621	Asparagus, raw	RAC	0.02	0.84	0.02	2.08	0.04	7.11	0.14	1.01	0.02	1.69	0.03	0.04	0.00
VS 0620	Artichoke globe, raw	RAC	0.51	0.98	0.50	3.65	1.86	0.07	0.04	1.67	0.85	0.26	0.13	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.1	3.70	4.07	2.11	2.32	1.51	1.66	1.75	1.93	0.29	0.32	5.12	5.63
CM 1205	Rice polished, dry	PP	0.0086	13.38	0.12	10.80	0.09	262.08	2.25	57.16	0.49	12.83	0.11	62.78	0.54
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, incl starch, excl flour, excl oil)	RAC	0.01	0.10	0.00	9.93	0.10	1.71	0.02	21.57	0.22	0.33	0.00	0.05	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.008	14.27	0.11	12.86	0.10	19.71	0.16	12.55	0.10	4.21	0.03	52.30	0.42
OR 0645	Maize oil	PP	0.012	0.90	0.01	0.47	0.01	0.15	0.00	3.01	0.04	1.86	0.02	0.36	0.00
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26

SO 0495	Rape seed, raw	RAC	0.03	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.002	12.52	0.03	7.63	0.02	3.00	0.01	6.01	0.01	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	23.40	0.23	29.33	0.29	1.24	0.01	13.85	0.14	6.48	0.06	6.91	0.07
OR 0691	Cotton seed oil, edible	PP	0.0014	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	5.63	0.00	2.75	0.00	9.58	0.00	5.82	0.00	13.71	0.00	1.84	0.00
SO 0305	Olives for oil production, raw	RAC	0.456	0.35	0.16	0.01	0.00	0.01	0.00	0.57	0.26	0.06	0.03	NC	-
-	Olive oil (virgin and residue oil)	PP	0.7	3.40	2.38	9.49	6.64	0.02	0.01	4.28	3.00	2.74	1.92	0.48	0.34
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	10.90	0.11	12.44	0.12	0.77	0.01	9.48	0.09	22.07	0.22	8.15	0.08
HS 0784	Ginger, rhizome, raw incl dried	RAC	0.13	0.27	0.04	0.07	0.01	0.54	0.07	0.69	0.09	0.58	0.08	0.56	0.07
HS 0444	Peppers, chili, dried	PP	1.1	0.11	0.12	0.21	0.23	0.36	0.40	0.21	0.23	0.25	0.28	0.15	0.17
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.85	2.91	14.11	1.73	8.39	1.14	5.53	1.85	8.97	2.29	11.11	0.74	3.59
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.047	112.02	5.27	120.71	5.67	63.46	2.98	88.99	4.18	96.24	4.52	41.02	1.93
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.14	28.01	3.92	30.18	4.22	15.86	2.22	22.25	3.11	24.06	3.37	10.25	1.44
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.14	6.44	0.90	15.51	2.17	3.79	0.53	8.29	1.16	18.44	2.58	8.00	1.12
MO 0105	Edible offal (mammalian), raw	RAC	0.71	15.17	10.77	5.19	3.68	6.30	4.47	6.78	4.81	3.32	2.36	3.17	2.25
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	388.92	4.28	335.88	3.69	49.15	0.54	331.25	3.64	468.56	5.15	245.45	2.70
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0002	73.76	0.01	53.86	0.01	23.98	0.00	87.12	0.02	53.38	0.01	84.45	0.02
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0002	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.0002	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.011	25.84	0.28	29.53	0.32	28.05	0.31	33.19	0.37	36.44	0.40	8.89	0.10
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				444.9		469.0		268.6		391.0		465.1		192.2
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				600		600		550		600		600		600
	%ADI=				74.1%		78.2%		48.8%		65.2%		77.5%		32.0%
	Rounded %ADI=				70%		80%		50%		70%		80%		30%

DIFENOCONAZOLE (224) International Estimated Daily Intake (IEDI) ADI = 0–000 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	Intake = daily intake: ug/person G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl kumquat commodities)	RAC	0.16	20.93	3.35	2.35	0.38	30.71	4.91	0.15	0.02	4.45	0.71
JF 0001	Group of Citrus fruit, juice	PP	0.002	0.11	0.00	0.29	0.00	13.55	0.03	0.14	0.00	0.33	0.00
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.86	68.89	59.25	11.06	9.51	80.62	69.33	189.82	163.25	19.56	16.82
FS 0013	Subgroup of Cherries, raw	RAC	0.365	0.01	0.00	0.01	0.00	5.96	2.18	0.01	0.00	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.365	0.07	0.03	0.01	0.00	15.56	5.68	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.94	0.01	0.01	0.01	0.01	0.37	0.35	0.01	0.01	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.365	0.02	0.01	0.01	0.00	10.76	3.93	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.69	0.01	0.01	7.30	5.04	2.29	1.58	0.01	0.01	NC	-
FB 0020	Blueberries, raw	RAC	1	NC	-	NC	-	0.20	0.20	NC	-	NC	-
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.52	0.14	0.07	0.36	0.19	15.33	7.97	0.01	0.01	0.28	0.15
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.1	0.01	0.01	0.13	0.14	1.06	1.17	0.01	0.01	0.03	0.03
JF 0269	Grape juice (from wine grapes)	PP	0.24	0.01	0.00	0.01	0.00	0.41	0.10	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.094	0.31	0.03	0.23	0.02	60.43	5.68	0.52	0.05	31.91	3.00
FB 0265	Cranberry, raw	RAC	0.2	NC	-	NC	-	0.03	0.01	NC	-	NC	-
FB 0275	Strawberry, raw	RAC	0.42	0.01	0.00	0.01	0.00	3.35	1.41	0.01	0.00	0.01	0.00
FT 0305	Table olives, raw (incl preserved)	RAC	0.465	0.01	0.00	0.01	0.00	1.75	0.81	0.01	0.00	0.24	0.11
FT 0336	Guava, raw	RAC	0.0335	0.10	0.00	0.08	0.00	NC	-	0.14	0.00	3.11	0.10
FI 0326	Avocado, raw	RAC	0.05	1.12	0.06	0.01	0.00	0.84	0.04	0.01	0.00	6.60	0.33
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	44.80	0.90	118.17	2.36	25.25	0.51	454.49	9.09	310.23	6.20
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	12.25	0.37	6.83	0.20	0.76	0.02	0.01	0.00	20.12	0.60
FI 0350	Papaya, raw	RAC	0.065	6.47	0.42	0.25	0.02	0.19	0.01	0.01	0.00	26.42	1.72

FI 2540	Pitaya, raw (i.e dragon fruit or pitahaya)	RAC	0.034	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	0.04	0.00
FI 0351	Passion fruit, raw	RAC	0.01	0.12	0.00	0.10	0.00	0.01	0.00	0.18	0.00	3.81	0.04
-	Onions, dry, raw	RAC	0.015	9.01	0.14	20.24	0.30	30.90	0.46	9.61	0.14	2.11	0.03
VA 0384	Leek, raw	RAC	0.08	0.02	0.00	1.44	0.12	1.22	0.10	0.01	0.00	NC	-
-	Onions, green, raw	RAC	2.8	1.43	4.00	0.05	0.14	0.20	0.56	NC	-	6.30	17.64
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.35	5.46	1.91	4.28	1.50	58.72	20.55	0.02	0.01	NC	-
VC 0424	Cucumber, raw	RAC	0.04	0.68	0.03	1.81	0.07	10.40	0.42	0.01	0.00	0.04	0.00
VC 0425	Gherkin, raw	RAC	0.04	0.15	0.01	0.39	0.02	3.15	0.13	0.01	0.00	0.01	0.00
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.04	0.09	0.00	1.01	0.04	NC	-	1.91	0.08	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.14	0.19	0.03	0.10	0.01	4.98	0.70	0.01	0.00	NC	-
VC 0432	Watermelon, raw	RAC	0.01	4.29	0.04	0.30	0.00	28.70	0.29	0.01	0.00	NC	-
VO 0448	Tomato, raw	RAC	0.1	12.99	1.30	4.79	0.48	58.40	5.84	0.92	0.09	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.01	0.07	0.00	0.08	0.00	2.42	0.02	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.22	0.58	0.13	0.22	0.05	2.21	0.49	0.24	0.05	3.10	0.68
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.031	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.14	6.23	0.87	0.10	0.01	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.24	3.47	0.83	3.56	0.85	16.30	3.91	0.01	0.00	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.14	5.49	0.77	10.57	1.48	8.84	1.24	0.91	0.13	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.14	1.31	0.18	8.26	1.16	3.95	0.55	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.41	0.29	0.12	0.03	0.01	6.71	2.75	0.01	0.00	NC	-
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.6	0.04	0.06	0.03	0.05	NC	-	0.01	0.02	NC	-
VL 0494	Radish leaves, raw	RAC	1.6	0.44	0.70	0.32	0.51	NC	-	0.30	0.48	0.59	0.94
VP 0060	Group of Legume vegetables, raw	RAC	0.07	0.58	0.04	3.16	0.22	10.38	0.73	0.04	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.011	7.11	0.08	2.33	0.03	3.76	0.04	44.70	0.49	3.27	0.04
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.011	3.70	0.04	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.01	2.89	0.03	0.21	0.00	0.48	0.00	3.16	0.03	0.26	0.00

OR 0541	Soya oil, refined	PP	0.08	2.32	0.19	2.54	0.20	18.70	1.50	2.51	0.20	6.29	0.50
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.028	2.54	0.07	1.77	0.05	0.03	0.00	0.03	0.00	3.99	0.11
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.028	0.67	0.02	7.26	0.20	0.37	0.01	0.08	0.00	NC	-
VD 0537	Pigeon pea (dry) (Cajanus spp), raw	RAC	0.028	1.14	0.03	0.03	0.00	NC	-	5.53	0.15	NC	-
VR 0577	Carrots, raw	RAC	0.05	2.07	0.10	3.00	0.15	25.29	1.26	0.05	0.00	NC	-
VR 0578	Celeriac, raw	RAC	0.12	2.91	0.35	2.10	0.25	7.59	0.91	1.97	0.24	3.93	0.47
VR 0494	Radish roots, raw	RAC	0.17	3.96	0.67	2.86	0.49	3.30	0.56	2.67	0.45	5.34	0.91
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.02	3.93	0.08	1.68	0.03	NC	-	NC	-	36.12	0.72
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	1.2	23.96	28.75	13.56	16.27	213.41	256.09	104.35	125.22	8.56	10.27
VR 0508	Sweet potato, raw (incl dried)	RAC	1.2	28.83	34.60	61.55	73.86	0.15	0.18	221.94	266.33	NC	-
VS 0624	Celery	RAC	0.14	3.66	0.51	2.65	0.37	4.84	0.68	2.47	0.35	4.94	0.69
VS 0621	Asparagus, raw	RAC	0.02	0.01	0.00	0.01	0.00	0.17	0.00	0.01	0.00	NC	-
VS 0620	Artichoke globe, raw	RAC	0.51	0.01	0.01	NC	-	0.08	0.04	0.01	0.01	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.1	13.58	14.94	4.29	4.72	2.17	2.39	0.01	0.01	8.84	9.72
CM 1205	Rice polished, dry	PP	0.0086	30.20	0.26	218.34	1.88	12.77	0.11	15.24	0.13	51.35	0.44
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, incl starch, excl flour, excl oil)	RAC	0.01	0.58	0.01	0.52	0.01	3.26	0.03	7.96	0.08	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.008	94.34	0.75	8.09	0.06	28.03	0.22	55.94	0.45	28.07	0.22
OR 0645	Maize oil	PP	0.012	0.33	0.00	0.07	0.00	0.81	0.01	0.01	0.00	NC	-
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0495	Rape seed, raw	RAC	0.03	NC	-	0.01	0.00	NC	-	NC	-	NC	-

OR 0495	Rape seed oil, edible	PP	0.002	0.07	0.00	0.03	0.00	4.62	0.01	0.03	0.00	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	0.94	0.01	0.22	0.00	32.01	0.32	12.12	0.12	0.48	0.00
OR 0691	Cotton seed oil, edible	PP	0.0014	1.28	0.00	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0	18.82	0.00	0.57	0.00	2.28	0.00	6.90	0.00	0.53	0.00
SO 0305	Olives for oil production, raw	RAC	0.456	NC	-	NC	-	0.02	0.01	NC	-	NC	-
-	Olive oil (virgin and residue oil)	PP	0.7	0.03	0.02	0.02	0.01	2.14	1.50	0.01	0.01	0.10	0.07
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	0.95	0.01	1.32	0.01	11.64	0.12	2.96	0.03	14.73	0.15
HS 0784	Ginger, rhizome, raw incl dried	RAC	0.13	0.75	0.10	0.68	0.09	0.06	0.01	0.02	0.00	0.01	0.00
HS 0444	Peppers, chili, dried	PP	1.1	0.58	0.64	1.27	1.40	1.21	1.33	0.12	0.13	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.85	0.53	2.57	5.25	25.46	0.86	4.17	0.56	2.72	0.88	4.27
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.047	23.34	1.10	40.71	1.91	97.15	4.57	18.06	0.85	57.71	2.71
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.14	5.84	0.82	10.18	1.42	24.29	3.40	4.52	0.63	14.43	2.02
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.14	1.05	0.15	1.14	0.16	18.69	2.62	0.94	0.13	3.12	0.44
MO 0105	Edible offal (mammalian), raw	RAC	0.71	4.64	3.29	1.97	1.40	10.01	7.11	3.27	2.32	3.98	2.83
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	108.75	1.20	70.31	0.77	436.11	4.80	61.55	0.68	79.09	0.87
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0002	3.92	0.00	12.03	0.00	57.07	0.01	5.03	0.00	55.56	0.01
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0002	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.0002	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.011	3.84	0.04	4.41	0.05	27.25	0.30	1.13	0.01	7.39	0.08
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				167.2		157.8		439.1		575.3		89.9
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600
	%ADI=				27.9%		26.3%		73.2%		95.9%		15.0%
	Rounded %ADI=				30%		30%		70%		100%		10%

DIFLUBENZURON (130) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.26	114.42	29.75	62.91	16.36	26.97	7.01	96.72	25.15	96.22	25.02	563.19	146.43
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.6	71.38	42.83	81.73	49.04	42.91	25.75	58.89	35.33	103.85	62.31	12.48	7.49
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.17	5.55	0.94	4.37	0.74	6.08	1.03	3.66	0.62	3.93	0.67	0.46	0.08
-	Peaches and nectarines, raw	RAC	0.17	8.76	1.49	12.98	2.21	8.23	1.40	10.09	1.72	3.64	0.62	0.04	0.01
VO 0444	Peppers, chili, raw	RAC	0.92	5.57	5.12	14.00	12.88	8.25	7.59	5.77	5.31	6.44	5.92	2.53	2.33
VO 0445	Peppers, sweet, raw	RAC	0.16	NC	-	NC	-	8.25	1.32	3.03	0.48	NC	-	0.91	0.15
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.4	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.18
VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.075	7.31	0.55	5.92	0.44	1.26	0.09	3.73	0.28	14.85	1.11	0.57	0.04
GC 0653	Triticale, raw (incl flour)	RAC	0.05	0.01	0.00	0.17	0.01	0.29	0.01	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.05	252.06	12.60	244.62	12.23	134.41	6.72	235.10	11.76	216.33	10.82	167.34	8.37
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.05	36.18	1.81	53.45	2.67	9.39	0.47	35.25	1.76	46.68	2.33	15.92	0.80
GC 0647	Oats, raw (incl rolled)	RAC	0.05	7.50	0.38	6.26	0.31	0.15	0.01	4.87	0.24	3.16	0.16	2.98	0.15
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.01	20.96	0.21	16.04	0.16	339.67	3.40	75.51	0.76	16.86	0.17	86.13	0.86
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	8.52	0.43	8.94	0.45	15.09	0.75	9.60	0.48	14.57	0.73	26.26	1.31
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.05	5.63	0.28	2.75	0.14	9.58	0.48	5.82	0.29	13.71	0.69	1.84	0.09
HS 0444	Peppers, chili, dried	PP	6.44	0.11	0.71	0.21	1.35	0.36	2.32	0.21	1.35	0.25	1.61	0.15	0.97

DT 1114	Tea, green or black, fermented and dried	RAC	9.4	2.71	25.47	0.82	7.71	1.14	10.72	1.59	14.95	1.82	17.11	0.53	4.98
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.1	140.03	14.00	150.89	15.09	79.32	7.93	111.24	11.12	120.30	12.03	51.27	5.13
MO 0105	Edible offal (mammalian), raw	RAC	0.1	15.17	1.52	5.19	0.52	6.30	0.63	6.78	0.68	3.32	0.33	3.17	0.32
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.02	388.92	7.78	335.88	6.72	49.15	0.98	331.25	6.63	468.56	9.37	245.45	4.91
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.05	73.76	3.69	53.86	2.69	23.98	1.20	87.12	4.36	53.38	2.67	84.45	4.22
PE 0112	Eggs, raw, (incl dried)	RAC	0.05	25.84	1.29	29.53	1.48	28.05	1.40	33.19	1.66	36.44	1.82	8.89	0.44
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.01111	4.88	0.05	2.35	0.03	27.05	0.30	3.03	0.03	0.84	0.01	2.71	0.03
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				150.9		133.2		81.5		125.0		155.5		189.3
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				1200		1200		1100		1200		1200		1200
	%ADI=				12.6%		11.1%		7.4%		10.4%		13.0%		15.8%
	Rounded %ADI=				10%		10%		7%		10%		10%		20%

DIFLUBENZURON
(130)

International Estimated Daily Intake (IEDI)

ADI = 0–0.02
mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.26	21.16	5.50	2.94	0.76	58.52	15.22	0.44	0.11	5.13	1.33
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.6	68.89	41.33	11.06	6.64	80.62	48.37	189.82	113.89	19.56	11.74
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.17	0.07	0.01	0.02	0.00	16.65	2.83	0.01	0.00	NC	-
-	Peaches and nectarines, raw	RAC	0.17	0.02	0.00	0.01	0.00	7.47	1.27	0.01	0.00	NC	-
VO 0444	Peppers, chili, raw	RAC	0.92	3.47	3.19	3.56	3.28	16.30	15.00	0.01	0.01	NC	-
VO 0445	Peppers, sweet, raw	RAC	0.16	1.24	0.20	1.27	0.20	NC	-	0.01	0.00	NC	-

VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.4	0.04	0.06	0.03	0.04	NC	-	0.01	0.01	NC	-
VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.075	0.02	0.00	0.04	0.00	3.73	0.28	0.01	0.00	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.05	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.05	57.15	2.86	110.46	5.52	272.58	13.63	25.81	1.29	132.04	6.60
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.05	11.58	0.58	2.33	0.12	46.71	2.34	3.72	0.19	16.26	0.81
GC 0647	Oats, raw (incl rolled)	RAC	0.05	0.37	0.02	0.07	0.00	2.79	0.14	0.10	0.01	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl polished, incl flour, incl starch, incl oil, incl beverages)	REP	0.01	52.55	0.53	286.02	2.86	18.64	0.19	19.67	0.20	75.09	0.75
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	4.39	0.22	135.53	6.78	6.11	0.31	0.72	0.04	317.74	15.89
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.05	18.82	0.94	0.57	0.03	2.28	0.11	6.90	0.35	0.53	0.03
HS 0444	Peppers, chili, dried	PP	6.44	0.58	3.74	1.27	8.18	1.21	7.79	0.12	0.77	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	9.4	0.53	4.98	5.25	49.35	0.63	5.92	0.56	5.26	0.82	7.71
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.1	29.18	2.92	50.89	5.09	121.44	12.14	22.58	2.26	72.14	7.21
MO 0105	Edible offal (mammalian), raw	RAC	0.1	4.64	0.46	1.97	0.20	10.01	1.00	3.27	0.33	3.98	0.40
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.02	108.75	2.18	70.31	1.41	436.11	8.72	61.55	1.23	79.09	1.58
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.05	3.92	0.20	12.03	0.60	57.07	2.85	5.03	0.25	55.56	2.78
PE 0112	Eggs, raw, (incl dried)	RAC	0.05	3.84	0.19	4.41	0.22	27.25	1.36	1.13	0.06	7.39	0.37
WD 0120	Diadromous fish (e.g. salmon, trout)	RAC	0.01111	3.43	0.04	4.13	0.05	1.77	0.02	18.43	0.20	0.10	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				70.1		91.3		139.5		126.5		57.2
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				1200		1200		1200		1200		1200
	%ADI=				5.8%		7.6%		11.6%		10.5%		4.8%
	Rounded %ADI=				6%		8%		10%		10%		5%

1,4-DIMETHYLNAPHTHALENE (331) International Estimated Daily Intake (IEDI) ADI = 0–0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VR 0589	Potato, raw	RAC	8.65	59.07	510.96	313.97	2715.84	9.23	79.84	48.16	416.58	52.38	453.09	117.43	1015.77
-	Potato, flour	PP	1.3	0.05	0.07	0.10	0.13	0.09	0.12	0.88	1.14	0.09	0.12	0.06	0.08
-	Potato, frozen	PP	8.65	0.13	1.12	0.87	7.53	0.05	0.43	3.60	31.14	0.69	5.97	1.10	9.52
-	Potato, starch	PP	3.9	0.03	0.12	0.01	0.04	0.01	0.04	0.15	0.59	0.01	0.04	0.01	0.04
-	Potato, tapioca	PP	3.9	0.01	0.04	0.01	0.04	0.01	0.04	0.11	0.43	0.01	0.04	0.01	0.04
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.014	24.96	0.35	57.95	0.81	16.70	0.23	38.38	0.54	26.46	0.37	29.00	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.018	6.24	0.11	14.49	0.26	4.18	0.08	9.60	0.17	6.62	0.12	7.25	0.13
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	3.29	0.06	6.14	0.11	0.82	0.01	1.57	0.03	2.23	0.04	1.07	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.22	4.79	1.05	9.68	2.13	2.97	0.65	5.49	1.21	3.84	0.84	5.03	1.11
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.02	289.65	5.79	485.88	9.72	26.92	0.54	239.03	4.78	199.91	4.00	180.53	3.61
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.043	13.17	0.57	26.78	1.15	7.24	0.31	116.71	5.02	22.54	0.97	32.09	1.38
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.11	1.46	0.16	2.98	0.33	0.80	0.09	12.97	1.43	2.50	0.28	3.57	0.39
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.11	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	0.10	0.01
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.12	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.64	0.24	0.03	0.10	0.01
PE 0112	Eggs, raw, (incl dried)	RAC	0.017	7.84	0.13	23.08	0.39	2.88	0.05	14.89	0.25	9.81	0.17	14.83	0.25
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				520.6		2738.5		82.4		464.0		466.1		1032.8
	Bodyweight per region (kg bw) =				60		60		60		60		60		60

		1800		1800	1800	1800	
ADI (ug/person)=		0	18000	0	0	0	18000
%ADI=		2.9%	15.2%	0.5%	2.6%	2.6%	5.7%
Rounded %ADI=		3%	20%	0%	3%	3%	6%

1,4-DIMETHYLNAPHTHALENE
(331) International Estimated Daily Intake (IEDI) ADI = 0–0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VR 0589	Potato, raw	RAC	8.65	202.90	1755.09	215.82	1866.84	69.98	605.33	166.61	1441.18	214.41	1854.65	25.32	219.02
-	Potato, flour	PP	1.3	0.81	1.05	0.48	0.62	0.19	0.25	0.25	0.33	1.57	2.04	0.07	0.09
-	Potato, frozen	PP	8.65	9.51	82.26	4.33	37.45	0.23	1.99	2.80	24.22	6.60	57.09	6.29	54.41
-	Potato, starch	PP	3.9	NC	-	1.74	6.79	0.05	0.20	0.92	3.59	NC	-	NC	-
-	Potato, tapioca	PP	3.9	0.03	0.12	0.01	0.04	0.01	0.04	0.05	0.20	0.06	0.23	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.014	112.02	1.57	120.71	1.69	63.46	0.89	88.99	1.25	96.24	1.35	41.02	0.57
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.018	28.01	0.50	30.18	0.54	15.86	0.29	22.25	0.40	24.06	0.43	10.25	0.18
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	6.44	0.12	15.51	0.28	3.79	0.07	8.29	0.15	18.44	0.33	8.00	0.14
MO 0105	Edible offal (mammalian), raw	RAC	0.22	15.17	3.34	5.19	1.14	6.30	1.39	6.78	1.49	3.32	0.73	3.17	0.70
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.02	388.92	7.78	335.88	6.72	49.15	0.98	331.25	6.63	468.56	9.37	245.45	4.91
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.043	66.38	2.85	48.47	2.08	21.58	0.93	78.41	3.37	48.04	2.07	76.01	3.27
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.11	7.38	0.81	5.39	0.59	2.40	0.26	8.71	0.96	5.34	0.59	8.45	0.93
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.11	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.71	0.08	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.12	0.33	0.04	0.72	0.09	0.27	0.03	0.35	0.04	0.80	0.10	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.017	25.84	0.44	29.53	0.50	28.05	0.48	33.19	0.56	36.44	0.62	8.89	0.15
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				1856.0		1925.4		613.1		1484.4		1929.7		284.4

Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (ug/person)=	18000	18000	16500	18000	18000	18000
%ADI=	10.3%	10.7%	3.7%	8.2%	10.7%	1.6%
Rounded %ADI=	10%	10%	4%	8%	10%	2%

1,4-DIMETHYLNAPHTHALENE (331) International Estimated Daily Intake (IEDI) ADI = 0–0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0589	Potato, raw	RAC	8.65	22.45	194.19	10.47	90.57	193.10	1670.32	98.00	847.70	8.03	69.46
-	Potato, flour	PP	1.3	0.05	0.07	0.20	0.26	0.52	0.68	0.54	0.70	0.01	0.01
-	Potato, frozen	PP	8.65	0.64	5.54	1.11	9.60	8.79	76.03	1.98	17.13	0.11	0.95
-	Potato, starch	PP	3.9	0.01	0.04	0.01	0.04	NC	-	NC	-	NC	-
-	Potato, tapioca	PP	3.9	0.01	0.04	0.01	0.04	0.23	0.90	0.02	0.08	0.06	0.23
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.014	23.34	0.33	40.71	0.57	97.15	1.36	18.06	0.25	57.71	0.81
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.018	5.84	0.11	10.18	0.18	24.29	0.44	4.52	0.08	14.43	0.26
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	1.05	0.02	1.14	0.02	18.69	0.34	0.94	0.02	3.12	0.06
MO 0105	Edible offal (mammalian), raw	RAC	0.22	4.64	1.02	1.97	0.43	10.01	2.20	3.27	0.72	3.98	0.88
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.02	108.75	2.18	70.31	1.41	436.11	8.72	61.55	1.23	79.09	1.58
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.043	3.53	0.15	10.83	0.47	51.36	2.21	4.53	0.19	50.00	2.15
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.11	0.39	0.04	1.20	0.13	5.71	0.63	0.50	0.06	5.56	0.61
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.11	NC	-	NC	-	0.32	0.04	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.12	0.10	0.01	0.70	0.08	0.97	0.12	0.10	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.017	3.84	0.07	4.41	0.07	27.25	0.46	1.13	0.02	7.39	0.13
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				203.8		103.9		1764.4		868.2		77.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				18000		18000		18000		18000		18000
	%ADI=				1.1%		0.6%		9.8%		4.8%		0.4%
	Rounded %ADI=				1%		1%		10%		5%		0%

FLORYLPICOXAMID (332) International Estimated Daily Intake (IEDI) ADI = 0–00 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.375	16.25	6.09	28.96	10.86	2.87	1.08	24.22	9.08	9.33	3.50	68.64	25.74
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.375	12.68	4.76	9.12	3.42	0.03	0.01	16.88	6.33	3.70	1.39	54.42	20.41
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.8	0.51	0.41	0.51	0.41	0.01	0.01	1.27	1.02	0.12	0.10	2.07	1.66
JF 0269	Grape juice (from wine grapes)	PP	0.1	0.14	0.01	0.29	0.03	0.05	0.01	0.30	0.03	0.24	0.02	0.05	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.02	0.67	0.01	12.53	0.25	2.01	0.04	1.21	0.02	3.53	0.07	4.01	0.08
FB 1235	Table grapes, raw	RAC	0.375	12.68	4.76	9.12	3.42	0.03	0.01	16.88	6.33	3.70	1.39	54.42	20.41
FB 0275	Strawberry, raw	RAC	0.26	0.70	0.18	2.01	0.52	0.04	0.01	1.36	0.35	0.37	0.10	2.53	0.66
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.021	5.23	0.11	6.94	0.15	99.45	2.09	32.47	0.68	48.30	1.01	24.70	0.52
FI 0327	Banana, raw (incl raw plantains)	RAC	0.021	4.90	0.10	6.94	0.15	99.37	2.09	32.44	0.68	48.24	1.01	24.67	0.52
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.021	10.48	0.22	0.01	0.00	7.24	0.15	6.87	0.14	19.98	0.42	6.25	0.13
FI 0345	Mango, raw (incl canned mango, excl mango juice)	RAC	0.021	10.40	0.22	0.01	0.00	7.24	0.15	6.85	0.14	19.64	0.41	5.95	0.12
FI 0345	Mango, raw (incl mango juice, excl canned mango)	RAC	0.021	10.46	0.22	0.01	0.00	7.24	0.15	6.87	0.14	19.88	0.42	4.83	0.10
FI 0345	Mango, raw	RAC	0.021	10.38	0.22	0.01	0.00	7.24	0.15	6.85	0.14	19.53	0.41	4.52	0.09
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.063	10.52	0.66	39.36	2.48	2.07	0.13	25.74	1.62	2.80	0.18	44.83	2.82
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.0795	42.62	3.39	46.85	3.72	4.21	0.33	67.02	5.33	12.84	1.02	110.47	8.78
VO 0448	Tomato, raw	RAC	0.12	41.73	5.01	75.65	9.08	10.66	1.28	82.87	9.94	24.75	2.97	200.93	24.11
-	Tomato, canned (& peeled)	PP	0.004	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.00	0.11	0.00	1.50	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.076	2.34	0.18	1.33	0.10	1.57	0.12	4.24	0.32	0.34	0.03	2.83	0.22
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.01	0.29	0.00	0.29	0.00	0.01	0.00	0.38	0.00	0.05	0.00	0.14	0.00
VO 0444	Peppers, chili, raw	RAC	0.15	3.99	0.60	7.30	1.10	2.93	0.44	5.62	0.84	NC	-	17.44	2.62
VO 0445	Peppers, sweet, raw	RAC	0.15	1.43	0.21	2.61	0.39	1.05	0.16	2.01	0.30	2.59	0.39	6.24	0.94
-	Peppers, sweet, dried	PP	1.5	0.42	0.63	0.53	0.80	0.84	1.26	0.50	0.75	0.95	1.43	0.37	0.56

VO 2046	Subgroup of eggplants	RAC	0.12	5.58	0.67	4.31	0.52	0.89	0.11	9.31	1.12	13.64	1.64	20.12	2.41
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0	2.12	0.00	0.01	0.00	0.03	0.00	3.21	0.00	1.60	0.00	4.90	0.00
VR 0596	Sugar beet, raw	RAC	0.021	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar beet, sugar	PP	0.004	0.02	0.00	NC	-	0.01	0.00	0.09	0.00	0.07	0.00	12.63	0.05
GC 0654	Wheat, raw (incl meslin)	RAC	0.021	0.01	0.00	1.12	0.02	NC	-	0.01	0.00	0.56	0.01	NC	-
-	Wheat, bulgur	PP	0.021	NC	-	NC	-	NC	-	0.03	0.00	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.019	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.021	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CF 1211	Wheat, white flour	PP	0.019	299.27	5.69	263.32	5.00	27.93	0.53	214.18	4.07	133.47	2.54	340.03	6.46
-	Wheat, starch	PP	0.019	0.02	0.00	NC	-	0.01	0.00	0.05	0.00	0.13	0.00	0.01	0.00
-	Wheat, gluten	PP	0.027	0.01	0.00	0.01	0.00	0.01	0.00	0.27	0.01	0.01	0.00	0.03	0.00
SO 0495	Rape seed, raw	RAC	0.021	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.02	0.01	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.024	24.96	0.60	57.95	1.39	16.70	0.40	38.38	0.92	26.46	0.64	29.00	0.70
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.043	6.24	0.27	14.49	0.62	4.18	0.18	9.60	0.41	6.62	0.28	7.25	0.31
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.043	3.29	0.14	6.14	0.26	0.82	0.04	1.57	0.07	2.23	0.10	1.07	0.05
MO 0105	Edible offal (mammalian), raw	RAC	0.023	4.79	0.11	9.68	0.22	2.97	0.07	5.49	0.13	3.84	0.09	5.03	0.12
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.013	289.65	3.77	485.88	6.32	26.92	0.35	239.03	3.11	199.91	2.60	180.53	2.35
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14.63	0.00	29.76	0.00	8.04	0.00	129.68	0.00	25.04	0.00	35.66	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	1.46	0.00	2.98	0.00	0.80	0.00	12.97	0.00	2.50	0.00	3.57	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				39.2		51.2		11.3		54.1		24.2		122.9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				6000		6000		6000		6000		6000		6000
	%ADI=				0.7%		0.9%		0.2%		0.9%		0.4%		2.0%
	Rounded %ADI=				1%		1%		0%		1%		0%		2%

FLORYLPICOXAMID (332) International Estimated Daily Intake (IEDI) ADI = 0–00 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.375	142.23	53.34	105.77	39.66	7.87	2.95	52.44	19.67	109.22	40.96	10.96	4.11
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.375	6.33	2.37	11.22	4.21	5.21	1.95	9.38	3.52	4.55	1.71	0.78	0.29
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.8	3.09	2.47	1.51	1.21	0.03	0.02	1.38	1.10	4.26	3.41	0.42	0.34
JF 0269	Grape juice (from wine grapes)	PP	0.1	0.56	0.06	1.96	0.20	0.02	0.00	2.24	0.22	2.27	0.23	0.34	0.03
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.02	88.93	1.78	62.41	1.25	1.84	0.04	25.07	0.50	61.17	1.22	5.84	0.12
FB 1235	Table grapes, raw	RAC	0.375	6.33	2.37	11.22	4.21	5.21	1.95	9.38	3.52	4.55	1.71	0.78	0.29
FB 0275	Strawberry, raw	RAC	0.26	4.49	1.17	5.66	1.47	0.02	0.01	6.63	1.72	5.75	1.50	0.05	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.021	25.76	0.54	23.65	0.50	23.83	0.50	24.37	0.51	19.43	0.41	101.55	2.13
FI 0327	Banana, raw (incl raw plantains)	RAC	0.021	25.61	0.54	23.59	0.50	23.58	0.50	24.26	0.51	18.88	0.40	101.55	2.13
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.021	1.80	0.04	0.63	0.01	10.05	0.21	1.07	0.02	3.52	0.07	16.44	0.35
FI 0345	Mango, raw (incl canned mango, excl mango juice)	RAC	0.021	1.80	0.04	0.63	0.01	9.93	0.21	1.07	0.02	3.52	0.07	16.44	0.35
FI 0345	Mango, raw (incl mango juice, excl canned mango)	RAC	0.021	1.80	0.04	0.63	0.01	9.85	0.21	1.07	0.02	3.52	0.07	16.44	0.35
FI 0345	Mango, raw	RAC	0.021	1.80	0.04	0.63	0.01	9.73	0.20	1.07	0.02	3.52	0.07	16.44	0.35
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.063	7.14	0.45	16.92	1.07	37.58	2.37	15.16	0.96	4.42	0.28	12.67	0.80
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.0795	20.68	1.64	25.00	1.99	85.72	6.81	34.31	2.73	11.54	0.92	23.32	1.85
VO 0448	Tomato, raw	RAC	0.12	32.13	3.86	51.27	6.15	34.92	4.19	73.37	8.80	15.15	1.82	8.88	1.07
-	Tomato, canned (& peeled)	PP	0.004	7.57	0.03	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.03	0.41	0.00

-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.076	4.96	0.38	3.20	0.24	0.15	0.01	1.61	0.12	6.88	0.52	0.52	0.04
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.01	0.80	0.01	0.07	0.00	0.05	0.00	0.61	0.01	0.40	0.00	0.08	0.00
VO 0444	Peppers, chili, raw	RAC	0.15	5.57	0.84	14.00	2.10	8.25	1.24	5.77	0.87	6.44	0.97	2.53	0.38
VO 0445	Peppers, sweet, raw	RAC	0.15	NC	-	NC	-	8.25	1.24	3.03	0.45	NC	-	0.91	0.14
-	Peppers, sweet, dried	PP	1.5	0.11	0.17	0.21	0.32	0.36	0.54	0.21	0.32	0.25	0.38	0.15	0.23
VO 2046	Subgroup of eggplants	RAC	0.12	1.01	0.12	1.69	0.20	21.37	2.56	3.00	0.36	1.40	0.17	NC	-
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0	0.95	0.00	1.18	0.00	0.40	0.00	0.96	0.00	0.71	0.00	1.28	0.00
VR 0596	Sugar beet, raw	RAC	0.021	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Sugar beet, sugar	PP	0.004	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.021	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
-	Wheat, bulgur	PP	0.021	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.019	0.97	0.02	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.021	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CF 1211	Wheat, white flour	PP	0.019	182.77	3.47	187.54	3.56	103.82	1.97	180.42	3.43	164.00	3.12	118.84	2.26
-	Wheat, starch	PP	0.019	NC	-	NC	-	0.01	0.00	0.31	0.01	NC	-	NC	-
-	Wheat, gluten	PP	0.027	0.68	0.02	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
SO 0495	Rape seed, raw	RAC	0.021	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.024	112.02	2.69	120.71	2.90	63.46	1.52	88.99	2.14	96.24	2.31	41.02	0.98
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.043	28.01	1.20	30.18	1.30	15.86	0.68	22.25	0.96	24.06	1.03	10.25	0.44
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.043	6.44	0.28	15.51	0.67	3.79	0.16	8.29	0.36	18.44	0.79	8.00	0.34
MO 0105	Edible offal (mammalian), raw	RAC	0.023	15.17	0.35	5.19	0.12	6.30	0.14	6.78	0.16	3.32	0.08	3.17	0.07
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.013	388.92	5.06	335.88	4.37	49.15	0.64	331.25	4.31	468.56	6.09	245.45	3.19
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73.76	0.00	53.86	0.00	23.98	0.00	87.12	0.00	53.38	0.00	84.45	0.00

PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	7.38	0.00	5.39	0.00	2.40	0.00	8.71	0.00	5.34	0.00	8.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				85.4		78.2		32.8		57.3		70.3		22.6
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				6000		6000		5500		6000		6000		6000
	%ADI=				1.4%		1.3%		0.6%		1.0%		1.2%		0.4%
	Rounded %ADI=				1%		1%		1%		1%		1%		0%

FLORYLPICOXAMID (332) International Estimated Daily Intake (IEDI) ADI = 0–00 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.375	0.60	0.23	1.26	0.47	103.25	38.72	0.74	0.28	44.23	16.59
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.375	0.14	0.05	0.36	0.14	15.22	5.71	0.01	0.00	0.09	0.03
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.8	0.01	0.01	0.13	0.10	1.06	0.85	0.01	0.01	0.03	0.02
JF 0269	Grape juice (from wine grapes)	PP	0.1	0.01	0.00	0.01	0.00	0.41	0.04	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.02	0.31	0.01	0.23	0.00	60.43	1.21	0.52	0.01	31.91	0.64
FB 1235	Table grapes, raw	RAC	0.375	0.14	0.05	0.36	0.14	15.22	5.71	0.01	0.00	0.09	0.03
FB 0275	Strawberry, raw	RAC	0.26	0.01	0.00	0.01	0.00	3.35	0.87	0.01	0.00	0.01	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.021	44.80	0.94	118.17	2.48	25.25	0.53	454.49	9.54	310.23	6.51
FI 0327	Banana, raw (incl raw plantains)	RAC	0.021	44.76	0.94	118.16	2.48	25.19	0.53	454.49	9.54	310.23	6.51

FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.021	12.25	0.26	6.83	0.14	0.76	0.02	0.01	0.00	20.12	0.42
FI 0345	Mango, raw (incl canned mango, excl mango juice)	RAC	0.021	12.25	0.26	6.74	0.14	0.76	0.02	0.01	0.00	20.12	0.42
FI 0345	Mango, raw (incl mango juice, excl canned mango)	RAC	0.021	12.25	0.26	6.83	0.14	0.76	0.02	0.01	0.00	20.12	0.42
FI 0345	Mango, raw	RAC	0.021	12.25	0.26	6.74	0.14	0.76	0.02	0.01	0.00	20.12	0.42
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.063	0.92	0.06	3.20	0.20	13.55	0.85	1.91	0.12	0.05	0.00
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.0795	5.04	0.40	6.54	0.52	38.26	3.04	11.70	0.93	NC	-
VO 0448	Tomato, raw	RAC	0.12	12.99	1.56	4.79	0.57	58.40	7.01	0.92	0.11	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.004	0.07	0.00	0.08	0.00	2.42	0.01	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.076	0.58	0.04	0.22	0.02	2.21	0.17	0.24	0.02	3.10	0.24
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.01	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00
VO 0444	Peppers, chili, raw	RAC	0.15	3.47	0.52	3.56	0.53	16.30	2.45	0.01	0.00	NC	-
VO 0445	Peppers, sweet, raw	RAC	0.15	1.24	0.19	1.27	0.19	NC	-	0.01	0.00	NC	-
-	Peppers, sweet, dried	PP	1.5	0.58	0.87	1.27	1.91	1.21	1.82	0.12	0.18	NC	-
VO 2046	Subgroup of eggplants	RAC	0.12	1.31	0.16	8.26	0.99	3.95	0.47	0.01	0.00	NC	-
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0	0.67	0.00	7.26	0.00	0.37	0.00	0.08	0.00	NC	-
VR 0596	Sugar beet, raw	RAC	0.021	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.004	0.56	0.00	0.24	0.00	NC	-	NC	-	5.13	0.02
GC 0654	Wheat, raw (incl meslin)	RAC	0.021	NC	-	NC	-	NC	-	NC	-	0.97	0.02
-	Wheat, bulgur	PP	0.021	0.01	0.00	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.019	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.021	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CF 1211	Wheat, white flour	PP	0.019	43.75	0.83	85.81	1.63	206.68	3.93	19.38	0.37	92.92	1.77
-	Wheat, starch	PP	0.019	0.01	0.00	0.02	0.00	NC	-	NC	-	NC	-
-	Wheat, gluten	PP	0.027	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.01
SO 0495	Rape seed, raw	RAC	0.021	NC	-	0.01	0.00	NC	-	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.024	23.34	0.56	40.71	0.98	97.15	2.33	18.06	0.43	57.71	1.39
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.043	5.84	0.25	10.18	0.44	24.29	1.04	4.52	0.19	14.43	0.62
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.043	1.05	0.05	1.14	0.05	18.69	0.80	0.94	0.04	3.12	0.13

MO 0105	Edible offal (mammalian), raw	RAC	0.023	4.64	0.11	1.97	0.05	10.01	0.23	3.27	0.08	3.98	0.09
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.013	108.75	1.41	70.31	0.91	436.11	5.67	61.55	0.80	79.09	1.03
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3.92	0.00	12.03	0.00	57.07	0.00	5.03	0.00	55.56	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	0.39	0.00	1.20	0.00	5.71	0.00	0.50	0.00	5.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				10.3		15.4		84.1		22.7		37.4
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				6000		6000		6000		6000		6000
	%ADI=				0.2%		0.3%		1.4%		0.4%		0.6%
	Rounded %ADI=				0%		0%		1%		0%		1%

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.325	4.82	1.57	2.45	0.80	3.93	1.28	25.44	8.27	8.74	2.84	16.23	5.27
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.15	6.18	0.93	3.66	0.55	0.25	0.04	6.82	1.02	3.49	0.52	19.38	2.91
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.15	23.26	3.49	9.71	1.46	12.09	1.81	62.02	9.30	22.09	3.31	59.91	8.99
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.14	0.66	0.09	0.69	0.10	0.96	0.13	10.20	1.43	1.25	0.18	2.97	0.42
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.135	19.35	2.61	34.06	4.60	17.87	2.41	25.74	3.47	7.69	1.04	56.85	7.67
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.01	0.32	0.00	3.07	0.03	0.07	0.00	5.00	0.05	0.29	0.00	5.57	0.06
FS 0013	Subgroup of Cherries, raw	RAC	0.57	0.92	0.52	9.15	5.22	0.01	0.01	0.61	0.35	0.06	0.03	6.64	3.78
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.13	2.67	0.35	8.77	1.14	0.07	0.01	3.03	0.39	0.70	0.09	4.34	0.56
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.22	8.01	1.76	5.87	1.29	0.18	0.04	8.19	1.80	1.64	0.36	22.46	4.94
FB 2005	Subgroup of Caneberries, raw	RAC	0.83	0.42	0.35	1.05	0.87	0.01	0.01	0.02	0.02	0.02	0.02	1.24	1.03
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.15	0.53	0.61	1.31	1.51	0.40	0.46	1.66	1.91	0.01	0.01	0.99	1.14
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.58	13.02	7.55	9.25	5.37	0.03	0.02	16.91	9.81	3.70	2.15	54.44	31.58
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	0.51	0.86	0.51	0.86	0.01	0.02	1.27	2.13	0.12	0.20	2.07	3.48
JF 0269	Grape juice (from wine grapes)	PP	0.012	0.14	0.00	0.29	0.00	0.05	0.00	0.30	0.00	0.24	0.00	0.05	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.1	0.67	0.07	12.53	1.25	2.01	0.20	1.21	0.12	3.53	0.35	4.01	0.40
FB 0275	Strawberry, raw	RAC	0.025	0.70	0.02	2.01	0.05	0.04	0.00	1.36	0.03	0.37	0.01	2.53	0.06
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.175	5.23	0.92	6.94	1.21	99.45	17.40	32.47	5.68	48.30	8.45	24.70	4.32

FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	10.48	0.21	0.01	0.00	7.24	0.14	6.87	0.14	19.98	0.40	6.25	0.13
VA 0381	Garlic, raw	RAC	0.01	2.29	0.02	5.78	0.06	0.11	0.00	3.69	0.04	1.65	0.02	3.91	0.04
-	Onions, dry, raw	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
VA 0384	Leek, raw	RAC	0.01	0.18	0.00	1.59	0.02	0.03	0.00	0.28	0.00	0.01	0.00	3.21	0.03
-	Onions, green, raw	RAC	5.1	2.45	12.50	1.49	7.60	1.02	5.20	2.60	13.26	0.60	3.06	2.03	10.35
VB 0400	Broccoli, raw	RAC	0.05	0.88	0.04	0.17	0.01	0.01	0.00	1.25	0.06	3.00	0.15	1.09	0.05
VB 0404	Cauliflower, raw	RAC	0.01	1.65	0.02	0.32	0.00	0.01	0.00	2.33	0.02	4.79	0.05	2.03	0.02
VB 0402	Brussels sprouts, raw	RAC	0.06	0.63	0.04	6.41	0.38	0.13	0.01	1.03	0.06	NC	-	2.35	0.14
VB 0041	Cabbages, head, raw	RAC	0.01	2.73	0.03	27.92	0.28	0.55	0.01	4.47	0.04	4.27	0.04	10.25	0.10
VC 0424	Cucumber, raw	RAC	0.11	8.01	0.88	30.66	3.37	1.45	0.16	19.84	2.18	0.27	0.03	34.92	3.84
VO 0448	Tomato, raw	RAC	0.11	41.73	4.59	75.65	8.32	10.66	1.17	82.87	9.12	24.75	2.72	200.93	22.10
-	Tomato, canned (& peeled)	PP	0.023	0.20	0.00	0.31	0.01	0.02	0.00	1.11	0.03	0.11	0.00	1.50	0.03
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.08	2.34	0.19	1.33	0.11	1.57	0.13	4.24	0.34	0.34	0.03	2.83	0.23
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.04	0.29	0.01	0.29	0.01	0.01	0.00	0.38	0.02	0.05	0.00	0.14	0.01
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.14	8.48	1.19	13.74	1.92	10.13	1.42	11.29	1.58	9.52	1.33	26.36	3.69
VO 2046	Subgroup of eggplants	RAC	0.11	5.58	0.61	4.31	0.47	0.89	0.10	9.31	1.02	13.64	1.50	20.12	2.21
VL 0483	Lettuce, leaf, raw	RAC	2.2	0.53	1.17	0.36	0.79	0.16	0.35	6.21	13.66	1.90	4.18	6.05	13.31
VL 2832	Witloof chicory (sprouts)	RAC	0.02	0.03	0.00	0.02	0.00	0.01	0.00	0.36	0.01	0.06	0.00	0.35	0.01
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.2	0.68	0.14	NC	-	NC	-	0.39	0.08	0.22	0.04	0.49	0.10
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.03	5.07	0.15	1.02	0.03	0.49	0.01	1.78	0.05	1.19	0.04	8.57	0.26
VP 2063	Subgroup of succulent peas without pods	RAC	0.03	1.97	0.06	0.51	0.02	0.02	0.00	0.79	0.02	3.68	0.11	3.80	0.11
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.015	2.39	0.04	1.61	0.02	10.47	0.16	1.84	0.03	12.90	0.19	7.44	0.11
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.015	1.27	0.02	0.01	0.00	0.12	0.00	2.49	0.04	0.23	0.00	5.54	0.08
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.015	0.05	0.00	NC	-	1.74	0.03	0.01	0.00	0.01	0.00	0.07	0.00

VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.0205	0.63	0.01	1.09	0.02	0.40	0.01	1.40	0.03	1.68	0.03	0.48	0.01
OR 0541	Soya oil, refined	PP	0.00041	12.99	0.01	10.43	0.00	3.63	0.00	13.10	0.01	10.70	0.00	13.10	0.01
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.015	1.70	0.03	0.01	0.00	3.00	0.05	1.80	0.03	1.64	0.02	1.33	0.02
VD 2066	Subgroup of dry peas, raw	RAC	0.058	9.09	0.53	3.35	0.19	1.06	0.06	9.48	0.55	15.11	0.88	10.58	0.61
VR 0577	Carrots, raw	RAC	0.09	9.51	0.86	30.78	2.77	0.37	0.03	8.75	0.79	2.80	0.25	6.10	0.55
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.13	0.00	NC	-	0.08	0.00	0.66	0.01	0.47	0.00	88.94	0.89
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.021	59.74	1.25	316.14	6.64	9.78	0.21	60.26	1.27	54.12	1.14	119.82	2.52
VS 0621	Asparagus, raw	RAC	0	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.07	0.00	0.21	0.00
VS 0620	Artichoke globe, raw	RAC	0.13	0.69	0.09	0.01	0.00	0.01	0.00	0.32	0.04	0.26	0.03	1.21	0.16
GC 0650	Rye, raw (incl flour)	RAC	0.035	0.13	0.00	19.38	0.68	0.10	0.00	0.12	0.00	0.03	0.00	2.15	0.08
GC 0653	Triticale, raw (incl flour)	RAC	0.035	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.01	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.035	0.01	0.00	1.12	0.04	NC	-	0.01	0.00	0.56	0.02	NC	-
-	Wheat, bulgur	PP	0.035	NC	-	NC	-	NC	-	0.03	0.00	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.084	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.01	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.035	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.035	0.25	0.01	0.63	0.02	0.12	0.00	0.43	0.02	1.39	0.05	0.22	0.01
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.035	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0042	301.24	1.27	268.64	1.13	30.21	0.13	222.51	0.93	134.73	0.57	343.12	1.44
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.041	19.91	0.82	31.16	1.28	5.04	0.21	3.10	0.13	9.77	0.40	4.31	0.18
GC 0641	Buckwheat, raw (incl flour)	RAC	0.041	NC	-	0.40	0.02	0.01	0.00	0.01	0.00	0.07	0.00	0.09	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.041	0.05	0.00	7.05	0.29	0.10	0.00	1.71	0.07	0.96	0.04	0.04	0.00

CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.178	1.26	0.22	1.58	0.28	31.05	5.53	5.43	0.97	0.90	0.16	2.18	0.39
CM 1205	Rice polished, dry	PP	0.0676	34.21	2.31	10.39	0.70	41.72	2.82	82.38	5.57	150.24	10.16	70.47	4.76
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.84	0.01	0.24	0.00	1.56	0.02	0.46	0.00	2.44	0.02	13.13	0.13
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0085	22.72	0.19	35.61	0.30	87.27	0.74	34.92	0.30	46.71	0.40	49.12	0.42
OR 0645	Maize oil	PP	0.0058	0.96	0.01	0.85	0.00	0.29	0.00	5.42	0.03	0.42	0.00	2.10	0.01
GC 2090	Subgroup of Sweet Corns	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 0495	Rape seed, raw	RAC	0.33	0.02	0.01	NC	-	NC	-	0.01	0.00	0.75	0.25	0.01	0.00
OR 0495	Rape seed oil, edible	PP	0.23	0.35	0.08	0.44	0.10	0.19	0.04	0.97	0.22	3.28	0.75	0.77	0.18
SO 0702	Sunflower seed, raw	RAC	0.0066	0.09	0.00	0.33	0.00	0.09	0.00	0.24	0.00	0.02	0.00	0.01	0.00
OR 0702	Sunflower seed oil, edible	PP	0.00066	2.97	0.00	14.42	0.01	0.43	0.00	3.46	0.00	2.20	0.00	5.53	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.0585	20.53	1.20	9.80	0.57	6.42	0.38	4.73	0.28	7.14	0.42	18.68	1.09
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.033	0.46	0.02	1.21	0.04	6.64	0.22	2.52	0.08	1.25	0.04	1.83	0.06
OR 0697	Peanut oil, edible	PP	0.00033	0.36	0.00	0.01	0.00	2.57	0.00	0.07	0.00	2.29	0.00	0.36	0.00
-	Peanut butter	PP	0.0073	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.00	0.01	0.00	0.01	0.00
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.1	1.36	0.14	3.59	0.36	1.44	0.14	5.18	0.52	2.02	0.20	1.70	0.17
HH 0722	Basil leaves, raw (incl dried)	RAC	19	0.14	2.66	0.26	4.94	0.16	3.04	0.38	7.22	NC	-	0.19	3.61
HS 0444	Peppers, chili, dried	PP	1.4	0.42	0.59	0.53	0.74	0.84	1.18	0.50	0.70	0.95	1.33	0.37	0.52
DH 1100	Hops, dry	RAC	10.35	0.01	0.10	0.04	0.41	0.01	0.10	0.01	0.10	NC	-	0.01	0.10
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.51	24.96	12.73	57.95	29.56	16.70	8.52	38.38	19.58	26.46	13.50	29.00	14.79
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.67	6.24	4.18	14.49	9.71	4.18	2.80	9.60	6.43	6.62	4.43	7.25	4.86
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.67	3.29	2.20	6.14	4.11	0.82	0.55	1.57	1.05	2.23	1.49	1.07	0.72

MO 0105	Edible offal (mammalian), raw	RAC	3.8	4.79	18.20	9.68	36.78	2.97	11.29	5.49	20.86	3.84	14.59	5.03	19.11
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.48	289.65	139.03	485.88	233.22	26.92	12.92	239.03	114.73	199.91	95.96	180.53	86.65
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.19	13.17	2.50	26.78	5.09	7.24	1.37	116.71	22.18	22.54	4.28	32.09	6.10
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.28	1.46	0.41	2.98	0.83	0.80	0.23	12.97	3.63	2.50	0.70	3.57	1.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.28	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	0.10	0.03	0.10	0.03
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.88	0.12	0.11	0.12	0.11	0.11	0.10	5.37	4.73	0.24	0.21	0.10	0.09
PE 0112	Eggs, raw, (incl dried)	RAC	0.46	7.84	3.61	23.08	10.62	2.88	1.32	14.89	6.85	9.81	4.51	14.83	6.82
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				239.3		401.8		86.9		308.0		190.7		292.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600		600
	%ADI=				39.9%		67.0%		14.5 %		51.3%		31.8%		48.7%
	Rounded %ADI=				40%		70%		10%		50%		30%		50%

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.325	10.12	3.29	15.69	5.10	2.88	0.94	12.30	4.00	22.32	7.25	6.59	2.14
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.15	12.42	1.86	14.99	2.25	16.08	2.41	10.78	1.62	9.94	1.49	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.15	83.66	12.55	27.64	4.15	7.37	1.11	67.80	10.17	43.97	6.60	187.74	28.16
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.14	8.21	1.15	4.60	0.64	0.64	0.09	5.85	0.82	19.98	2.80	368.86	51.64
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.135	51.09	6.90	65.40	8.83	42.71	5.77	45.29	6.11	62.51	8.44	7.74	1.04
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.01	14.88	0.15	11.98	0.12	0.15	0.00	9.98	0.10	30.32	0.30	3.47	0.03
FS 0013	Subgroup of Cherries, raw	RAC	0.57	1.40	0.80	4.21	2.40	0.04	0.02	2.93	1.67	1.50	0.86	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.13	5.55	0.72	4.37	0.57	6.08	0.79	3.66	0.48	3.93	0.51	0.46	0.06
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.22	13.03	2.87	16.29	3.58	8.29	1.82	12.95	2.85	5.35	1.18	0.04	0.01
FB 2005	Subgroup of Caneberries, raw	RAC	0.83	0.56	0.46	1.43	1.19	0.14	0.12	1.23	1.02	1.14	0.95	0.01	0.01
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.15	1.31	1.51	5.50	6.33	0.01	0.01	2.57	2.96	0.82	0.94	2.15	2.47
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.58	6.48	3.76	11.31	6.56	5.21	3.02	9.50	5.51	4.66	2.70	0.78	0.45
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	3.09	5.19	1.51	2.54	0.03	0.05	1.38	2.32	4.26	7.16	0.42	0.71
JF 0269	Grape juice (from wine grapes)	PP	0.012	0.56	0.01	1.96	0.02	0.02	0.00	2.24	0.03	2.27	0.03	0.34	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.1	88.93	8.89	62.41	6.24	1.84	0.18	25.07	2.51	61.17	6.12	5.84	0.58
FB 0275	Strawberry, raw	RAC	0.025	4.49	0.11	5.66	0.14	0.02	0.00	6.63	0.17	5.75	0.14	0.05	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.175	25.76	4.51	23.65	4.14	23.83	4.17	24.37	4.26	19.43	3.40	101.55	17.77

FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	1.80	0.04	0.63	0.01	10.05	0.20	1.07	0.02	3.52	0.07	16.44	0.33
VA 0381	Garlic, raw	RAC	0.01	0.98	0.01	1.49	0.01	12.88	0.13	3.74	0.04	2.05	0.02	1.14	0.01
-	Onions, dry, raw	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
VA 0384	Leek, raw	RAC	0.01	4.01	0.04	4.41	0.04	0.72	0.01	0.54	0.01	16.41	0.16	0.03	0.00
-	Onions, green, raw	RAC	5.1	1.55	7.91	0.74	3.77	1.05	5.36	3.74	19.07	0.94	4.79	6.45	32.90
VB 0400	Broccoli, raw	RAC	0.05	4.24	0.21	1.76	0.09	NC	-	0.51	0.03	3.79	0.19	0.26	0.01
VB 0404	Cauliflower, raw	RAC	0.01	5.27	0.05	5.01	0.05	NC	-	2.70	0.03	5.57	0.06	0.49	0.00
VB 0402	Brussels sprouts, raw	RAC	0.06	2.24	0.13	2.67	0.16	6.23	0.37	0.32	0.02	4.19	0.25	2.58	0.15
VB 0041	Cabbages, head, raw	RAC	0.01	8.97	0.09	27.12	0.27	1.44	0.01	24.96	0.25	4.55	0.05	11.23	0.11
VC 0424	Cucumber, raw	RAC	0.11	6.72	0.74	11.03	1.21	32.10	3.53	15.10	1.66	4.05	0.45	9.57	1.05
VO 0448	Tomato, raw	RAC	0.11	32.13	3.53	51.27	5.64	34.92	3.84	73.37	8.07	15.15	1.67	8.88	0.98
-	Tomato, canned (& peeled)	PP	0.023	7.57	0.17	2.66	0.06	0.30	0.01	0.97	0.02	7.31	0.17	0.41	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.08	4.96	0.40	3.20	0.26	0.15	0.01	1.61	0.13	6.88	0.55	0.52	0.04
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.04	0.80	0.03	0.07	0.00	0.05	0.00	0.61	0.02	0.40	0.02	0.08	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.14	6.39	0.89	15.53	2.17	19.09	2.67	10.36	1.45	8.29	1.16	4.53	0.63
VO 2046	Subgroup of eggplants	RAC	0.11	1.01	0.11	1.69	0.19	21.37	2.35	3.00	0.33	1.40	0.15	NC	-
VL 0483	Lettuce, leaf, raw	RAC	2.2	14.50	31.90	11.76	25.87	13.14	28.91	19.50	42.90	4.81	10.58	2.23	4.91
VL 2832	Witloof chicory (sprouts)	RAC	0.02	1.50	0.03	0.95	0.02	NC	-	1.84	0.04	0.65	0.01	0.13	0.00
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.2	5.07	1.01	0.83	0.17	0.17	0.03	3.70	0.74	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.03	2.42	0.07	6.09	0.18	4.33	0.13	2.09	0.06	18.99	0.57	0.17	0.01
VP 2063	Subgroup of succulent peas without pods	RAC	0.03	10.72	0.32	1.99	0.06	2.72	0.08	4.26	0.13	4.23	0.13	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.015	1.51	0.02	1.50	0.02	1.90	0.03	5.11	0.08	1.36	0.02	23.43	0.35
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.015	0.02	0.00	0.01	0.00	1.16	0.02	0.40	0.01	NC	-	0.06	0.00
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.015	NC	-	NC	-	0.16	0.00	0.01	0.00	NC	-	NC	-

VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.0205	0.47	0.01	0.77	0.02	9.12	0.19	8.05	0.17	0.04	0.00	6.06	0.12
OR 0541	Soya oil, refined	PP	0.00041	19.06	0.01	21.06	0.01	5.94	0.00	33.78	0.01	40.05	0.02	13.39	0.01
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.015	0.01	0.00	NC	-	0.57	0.01	0.11	0.00	0.16	0.00	0.94	0.01
VD 2066	Subgroup of dry peas, raw	RAC	0.058	5.01	0.29	3.76	0.22	1.82	0.11	3.44	0.20	3.49	0.20	5.15	0.30
VR 0577	Carrots, raw	RAC	0.09	26.26	2.36	27.13	2.44	10.07	0.91	16.49	1.48	44.69	4.02	8.75	0.79
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.021	225.03	4.73	234.24	4.92	71.48	1.50	177.55	3.73	234.55	4.93	37.71	0.79
VS 0621	Asparagus, raw	RAC	0	0.84	0.00	2.08	0.00	7.11	0.00	1.01	0.00	1.69	0.00	0.04	0.00
VS 0620	Artichoke globe, raw	RAC	0.13	0.98	0.13	3.65	0.47	0.07	0.01	1.67	0.22	0.26	0.03	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.035	3.21	0.11	35.38	1.24	0.21	0.01	6.50	0.23	1.49	0.05	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.035	0.01	0.00	0.17	0.01	0.29	0.01	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.035	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
-	Wheat, bulgur	PP	0.035	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.084	0.97	0.08	0.10	0.01	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.035	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CP 1211	Wheat, white bread	PP	0.035	1.30	0.05	0.46	0.02	0.06	0.00	0.22	0.01	2.44	0.09	0.77	0.03
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.035	NC	-	NC	-	NC	-	4.36	0.15	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0042	198.08	0.83	193.03	0.81	106.24	0.45	185.09	0.78	168.67	0.71	131.59	0.55
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.041	36.18	1.48	53.45	2.19	9.39	0.38	35.25	1.45	46.68	1.91	15.92	0.65
GC 0641	Buckwheat, raw (incl flour)	RAC	0.041	0.01	0.00	0.79	0.03	0.18	0.01	0.35	0.01	NC	-	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.041	7.50	0.31	6.26	0.26	0.15	0.01	4.87	0.20	3.16	0.13	2.98	0.12

CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.178	3.70	0.66	2.11	0.38	1.51	0.27	1.75	0.31	0.29	0.05	5.12	0.91
CM 1205	Rice polished, dry	PP	0.0676	13.38	0.90	10.80	0.73	262.08	17.72	57.16	3.86	12.83	0.87	62.78	4.24
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.10	0.00	9.93	0.10	1.40	0.01	10.26	0.10	0.33	0.00	0.05	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0085	14.27	0.12	12.86	0.11	19.71	0.17	12.55	0.11	4.21	0.04	52.30	0.44
OR 0645	Maize oil	PP	0.0058	0.90	0.01	0.47	0.00	0.15	0.00	3.01	0.02	1.86	0.01	0.36	0.00
GC 2090	Subgroup of Sweet Corns	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SO 0495	Rape seed, raw	RAC	0.33	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.23	12.52	2.88	7.63	1.75	3.00	0.69	6.01	1.38	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.0066	0.01	0.00	1.32	0.01	0.03	0.00	1.17	0.01	NC	-	0.02	0.00
OR 0702	Sunflower seed oil, edible	PP	0.00066	9.50	0.01	11.37	0.01	0.49	0.00	5.15	0.00	2.63	0.00	2.80	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.0585	10.71	0.63	4.23	0.25	7.19	0.42	7.54	0.44	5.66	0.33	2.38	0.14
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.033	3.19	0.11	2.19	0.07	5.36	0.18	4.82	0.16	1.40	0.05	1.06	0.03
OR 0697	Peanut oil, edible	PP	0.00033	1.02	0.00	0.23	0.00	1.81	0.00	0.42	0.00	5.23	0.00	0.01	0.00
-	Peanut butter	PP	0.0073	0.07	0.00	0.04	0.00	0.01	0.00	0.03	0.00	0.15	0.00	0.75	0.01
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.1	10.90	1.09	12.44	1.24	0.77	0.08	9.48	0.95	22.07	2.21	8.15	0.82
HH 0722	Basil leaves, raw (incl dried)	RAC	19	0.52	9.88	0.05	0.95	3.23	61.37	0.18	3.42	0.12	2.28	0.27	5.13
HS 0444	Peppers, chili, dried	PP	1.4	0.11	0.15	0.21	0.29	0.36	0.50	0.21	0.29	0.25	0.35	0.15	0.21
DH 1100	Hops, dry	RAC	10.35	NC	-	NC	-	0.02	0.21	0.02	0.21	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.51	112.02	57.13	120.71	61.56	63.46	32.36	88.99	45.39	96.24	49.08	41.02	20.92
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.67	28.01	18.76	30.18	20.22	15.86	10.63	22.25	14.91	24.06	16.12	10.25	6.87
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.67	6.44	4.31	15.51	10.39	3.79	2.54	8.29	5.55	18.44	12.35	8.00	5.36
MO 0105	Edible offal (mammalian), raw	RAC	3.8	15.17	57.65	5.19	19.72	6.30	23.94	6.78	25.76	3.32	12.62	3.17	12.05

ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.48	388.92	186.68	335.88	161.22	49.15	23.59	331.25	159.00	468.56	224.91	245.45	117.82
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.19	66.38	12.61	48.47	9.21	21.58	4.10	78.41	14.90	48.04	9.13	76.01	14.44
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.28	7.38	2.07	5.39	1.51	2.40	0.67	8.71	2.44	5.34	1.49	8.45	2.36
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.28	0.10	0.03	0.10	0.03	NC	-	0.10	0.03	0.71	0.20	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.88	0.33	0.29	0.72	0.63	0.27	0.24	0.35	0.31	0.80	0.70	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.46	25.84	11.89	29.53	13.58	28.05	12.90	33.19	15.27	36.44	16.76	8.89	4.09
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				481.1		412.1		264.8		425.7		433.8		346.2
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				600		600		550		600		600		600
	%ADI=				80.2%		68.7%		48.1%		70.9%		72.3%		57.7%
	Rounded %ADI=				80%		70%		50%		70%		70%		60%

FLUOPYRAM (243) International Estimated Daily Intake (IEDI) ADI = 0–0.01 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: ug/person									
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.325	18.97	6.17	0.97	0.32	6.23	2.02	0.09	0.03	3.35	1.09
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.15	0.16	0.02	0.27	0.04	9.06	1.36	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.15	1.34	0.20	1.65	0.25	40.03	6.00	0.33	0.05	1.76	0.26
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.14	0.68	0.10	0.05	0.01	3.21	0.45	0.01	0.00	NC	-
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.135	68.85	9.29	10.93	1.48	70.82	9.56	189.78	25.62	19.56	2.64
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.01	0.03	0.00	0.10	0.00	7.19	0.07	0.03	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.57	0.01	0.01	0.01	0.01	5.96	3.40	0.01	0.01	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.13	0.07	0.01	0.02	0.00	16.65	2.16	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.22	0.02	0.00	0.01	0.00	10.76	2.37	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.83	0.01	0.01	7.30	6.06	2.29	1.90	0.01	0.01	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.15	0.82	0.94	4.05	4.66	5.94	6.83	0.43	0.49	2.66	3.06
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.58	0.14	0.08	0.36	0.21	15.33	8.89	0.01	0.01	0.28	0.16
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	1.68	0.01	0.02	0.13	0.22	1.06	1.78	0.01	0.02	0.03	0.05
JF 0269	Grape juice (from wine grapes)	PP	0.012	0.01	0.00	0.01	0.00	0.41	0.00	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.1	0.31	0.03	0.23	0.02	60.43	6.04	0.52	0.05	31.91	3.19
FB 0275	Strawberry, raw	RAC	0.025	0.01	0.00	0.01	0.00	3.35	0.08	0.01	0.00	0.01	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.175	44.80	7.84	118.17	20.68	25.25	4.42	454.49	79.54	310.23	54.29

FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	12.25	0.25	6.83	0.14	0.76	0.02	0.01	0.00	20.12	0.40
VA 0381	Garlic, raw	RAC	0.01	0.82	0.01	2.06	0.02	3.79	0.04	0.03	0.00	0.29	0.00
-	Onions, dry, raw	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
VA 0384	Leek, raw	RAC	0.01	0.02	0.00	1.44	0.01	1.22	0.01	0.01	0.00	NC	-
-	Onions, green, raw	RAC	5.1	1.43	7.29	0.05	0.26	0.20	1.02	NC	-	6.30	32.13
VB 0400	Broccoli, raw	RAC	0.05	0.01	0.00	0.01	0.00	2.13	0.11	0.01	0.00	NC	-
VB 0404	Cauliflower, raw	RAC	0.01	0.01	0.00	0.01	0.00	2.73	0.03	0.01	0.00	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.06	0.88	0.05	0.69	0.04	2.89	0.17	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.01	3.82	0.04	2.99	0.03	49.16	0.49	0.01	0.00	NC	-
VC 0424	Cucumber, raw	RAC	0.11	0.68	0.07	1.81	0.20	10.40	1.14	0.01	0.00	0.04	0.00
VO 0448	Tomato, raw	RAC	0.11	12.99	1.43	4.79	0.53	58.40	6.42	0.92	0.10	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.023	0.07	0.00	0.08	0.00	2.42	0.06	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.08	0.58	0.05	0.22	0.02	2.21	0.18	0.24	0.02	3.10	0.25
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.04	0.05	0.00	0.01	0.00	0.42	0.02	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.14	8.97	1.26	14.13	1.98	25.14	3.52	0.91	0.13	NC	-
VO 2046	Subgroup of eggplants	RAC	0.11	1.31	0.14	8.26	0.91	3.95	0.43	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	2.2	0.29	0.64	0.03	0.07	6.71	14.76	0.01	0.02	NC	-
VL 2832	Witloof chicory (sprouts)	RAC	0.02	0.02	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.2	NC	-	NC	-	NC	-	NC	-	NC	-
VP 2062	Subgroup of succulent beans without pods (all commodities within this group)	RAC	0.03	0.37	0.01	3.14	0.09	4.88	0.15	0.01	0.00	NC	-
VP 2063	Subgroup of succulent peas without pods	RAC	0.03	0.21	0.01	0.02	0.00	5.51	0.17	0.02	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.015	7.11	0.11	2.33	0.03	3.76	0.06	44.70	0.67	3.27	0.05
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.015	3.70	0.06	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.015	12.77	0.19	0.99	0.01	0.01	0.00	4.33	0.06	NC	-

VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.0205	2.89	0.06	0.21	0.00	0.48	0.01	3.16	0.06	0.26	0.01
OR 0541	Soya oil, refined	PP	0.00041	2.32	0.00	2.54	0.00	18.70	0.01	2.51	0.00	6.29	0.00
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.015	2.54	0.04	1.77	0.03	0.03	0.00	0.03	0.00	3.99	0.06
VD 2066	Subgroup of dry peas, raw	RAC	0.058	4.43	0.26	11.36	0.66	4.22	0.24	9.36	0.54	1.21	0.07
VR 0577	Carrots, raw	RAC	0.09	2.07	0.19	3.00	0.27	25.29	2.28	0.05	0.00	NC	-
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	3.93	0.04	1.68	0.02	NC	-	NC	-	36.12	0.36
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.021	23.96	0.50	13.56	0.28	213.41	4.48	104.35	2.19	8.56	0.18
VS 0621	Asparagus, raw	RAC	0	0.01	0.00	0.01	0.00	0.17	0.00	0.01	0.00	NC	-
VS 0620	Artichoke globe, raw	RAC	0.13	0.01	0.00	NC	-	0.08	0.01	0.01	0.00	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.035	0.03	0.00	0.01	0.00	13.95	0.49	0.01	0.00	0.88	0.03
GC 0653	Triticale, raw (incl flour)	RAC	0.035	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.035	NC	-	NC	-	NC	-	NC	-	0.97	0.03
-	Wheat, bulgur	PP	0.035	0.01	0.00	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.084	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.035	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.035	0.43	0.02	0.41	0.01	1.56	0.05	0.11	0.00	0.07	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.035	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0042	44.78	0.19	86.96	0.37	214.05	0.90	20.31	0.09	103.60	0.44
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.041	11.58	0.47	2.33	0.10	46.71	1.92	3.72	0.15	16.26	0.67
GC 0641	Buckwheat, raw (incl flour)	RAC	0.041	0.04	0.00	2.82	0.12	0.01	0.00	0.01	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.041	0.37	0.02	0.07	0.00	2.79	0.11	0.10	0.00	NC	-

CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.178	13.58	2.42	4.29	0.76	2.17	0.39	0.01	0.00	8.84	1.57
CM 1205	Rice polished, dry	PP	0.0676	30.20	2.04	218.34	14.76	12.77	0.86	15.24	1.03	51.35	3.47
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, incl germ, excl flour, excl oil, excl starch)	RAC	0.01	0.55	0.01	0.51	0.01	3.26	0.03	7.96	0.08	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.0085	94.34	0.80	8.09	0.07	28.03	0.24	55.94	0.48	28.07	0.24
OR 0645	Maize oil	PP	0.0058	0.33	0.00	0.07	0.00	0.81	0.00	0.01	0.00	NC	-
GC 2090	Subgroup of Sweet Corns	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0495	Rape seed, raw	RAC	0.33	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.23	0.07	0.02	0.03	0.01	4.62	1.06	0.03	0.01	NC	-
SO 0702	Sunflower seed, raw	RAC	0.0066	0.02	0.00	0.01	0.00	0.03	0.00	2.23	0.01	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.00066	0.37	0.00	0.09	0.00	12.98	0.01	4.01	0.00	0.20	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.0585	8.14	0.48	0.32	0.02	2.84	0.17	2.69	0.16	0.97	0.06
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.033	7.14	0.24	0.42	0.01	1.83	0.06	6.22	0.21	0.53	0.02
OR 0697	Peanut oil, edible	PP	0.00033	5.02	0.00	0.05	0.00	0.17	0.00	0.29	0.00	NC	-
-	Peanut butter	PP	0.0073	0.01	0.00	0.03	0.00	0.05	0.00	NC	-	NC	-
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.1	0.95	0.10	1.32	0.13	11.64	1.16	2.96	0.30	14.73	1.47
HH 0722	Basil leaves, raw (incl dried)	RAC	19	0.25	4.75	0.18	3.42	0.13	2.47	0.17	3.23	0.33	6.27
HS 0444	Peppers, chili, dried	PP	1.4	0.58	0.81	1.27	1.78	1.21	1.69	0.12	0.17	NC	-
DH 1100	Hops, dry	RAC	10.35	NC	-	NC	-	0.04	0.41	NC	-	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.51	23.34	11.91	40.71	20.76	97.15	49.55	18.06	9.21	57.71	29.43
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.67	5.84	3.91	10.18	6.82	24.29	16.27	4.52	3.03	14.43	9.67
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.67	1.05	0.70	1.14	0.76	18.69	12.52	0.94	0.63	3.12	2.09
MO 0105	Edible offal (mammalian), raw	RAC	3.8	4.64	17.63	1.97	7.49	10.01	38.04	3.27	12.43	3.98	15.12

ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.48	108.75	52.20	70.31	33.75	436.11	209.33	61.55	29.54	79.09	37.96
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.19	3.53	0.67	10.83	2.06	51.36	9.76	4.53	0.86	50.00	9.50
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.28	0.39	0.11	1.20	0.34	5.71	1.60	0.50	0.14	5.56	1.56
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.28	NC	-	NC	-	0.32	0.09	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.88	0.10	0.09	0.70	0.62	0.97	0.85	0.10	0.09	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.46	3.84	1.77	4.41	2.03	27.25	12.54	1.13	0.52	7.39	3.40
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				138.9		137.5		456.2		172.1		224.5
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				600		600		600		600		600
	%ADI=				23.2%		22.9%		76.0%		28.7%		37.4%
	Rounded %ADI=				20%		20%		80%		30%		40%

IMAZAPYR (267) International Estimated Daily Intake (IEDI) ADI = 0–3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day								Intake as ug/person/day					
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake		
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.69	0.63	0.43	1.09	0.75	0.40	0.28	1.40	0.97	1.68	1.16	0.48	0.33		
OR 0541	Soya oil, refined	PP	0	12.99	0.00	10.43	0.00	3.63	0.00	13.10	0.00	10.70	0.00	13.10	0.00		
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.07	2.12	0.15	0.01	0.00	0.03	0.00	3.21	0.22	1.60	0.11	4.90	0.34		
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.079	381.15	30.11	341.54	26.98	38.34	3.03	281.87	22.27	172.65	13.64	434.06	34.29		
CF 1210	Wheat, germ	PP	0.11	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.02	0.01	0.00		
CP 1212	Wheat, wholemeal bread	PP	0.062	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00		
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.175	19.91	3.48	31.16	5.45	5.04	0.88	3.10	0.54	9.77	1.71	4.31	0.75		
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.01	1.26	0.01	1.58	0.02	31.05	0.31	5.43	0.05	0.90	0.01	2.18	0.02		
CM 1205	Rice polished, dry	PP	0.01	34.21	0.34	10.39	0.10	41.72	0.42	82.38	0.82	150.24	1.50	70.47	0.70		
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.05	28.85	1.44	43.93	2.20	108.66	5.43	46.94	2.35	59.87	2.99	73.58	3.68		
OR 0645	Maize oil	PP	0.025	0.96	0.02	0.85	0.02	0.29	0.01	5.42	0.14	0.42	0.01	2.10	0.05		
SO 0495	Rape seed, raw (incl oil)	RAC	0	0.93	0.00	1.16	0.00	0.49	0.00	2.53	0.00	9.32	0.00	2.02	0.00		
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	7.40	0.07	35.86	0.36	1.15	0.01	8.76	0.09	5.45	0.05	13.62	0.14		
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	24.96	0.00	57.95	0.00	16.70	0.00	38.38	0.00	26.46	0.00	29.00	0.00		

MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	6.24	0.00	14.49	0.00	4.18	0.00	9.60	0.00	6.62	0.00	7.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.041	4.79	0.20	9.68	0.40	2.97	0.12	5.49	0.23	3.84	0.16	5.03	0.21
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	1.46	0.00	2.98	0.00	0.80	0.00	12.97	0.00	2.50	0.00	3.57	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				36.3		36.3		10.5		27.7		21.4		40.5
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				180000		180000		180000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

IMAZAPYR (267) International Estimated Daily Intake (IEDI) ADI = 0–3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.69	0.47	0.32	0.77	0.53	9.12	6.29	8.05	5.55	0.04	0.03	6.06	4.18
OR 0541	Soya oil, refined	PP	0	19.06	0.00	21.06	0.00	5.94	0.00	33.78	0.00	40.05	0.00	13.39	0.00
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.07	0.95	0.07	1.18	0.08	0.40	0.03	0.96	0.07	0.71	0.05	1.28	0.09
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.079	252.06	19.91	244.62	19.32	134.41	10.62	235.10	18.57	216.33	17.09	167.34	13.22
CF 1210	Wheat, germ	PP	0.11	0.97	0.11	0.10	0.01	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.062	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.175	36.18	6.33	53.45	9.35	9.39	1.64	35.25	6.17	46.68	8.17	15.92	2.79
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.01	3.70	0.04	2.11	0.02	1.51	0.02	1.75	0.02	0.29	0.00	5.12	0.05
CM 1205	Rice polished, dry	PP	0.01	13.38	0.13	10.80	0.11	262.08	2.62	57.16	0.57	12.83	0.13	62.78	0.63
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.05	17.61	0.88	25.71	1.29	25.89	1.29	36.98	1.85	5.49	0.27	64.23	3.21
OR 0645	Maize oil	PP	0.025	0.90	0.02	0.47	0.01	0.15	0.00	3.01	0.08	1.86	0.05	0.36	0.01
SO 0495	Rape seed, raw (incl oil)	RAC	0	32.68	0.00	19.91	0.00	7.83	0.00	15.69	0.00	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	23.40	0.23	29.33	0.29	1.24	0.01	13.85	0.14	6.48	0.06	6.91	0.07

MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	112.02	0.00	120.71	0.00	63.46	0.00	88.99	0.00	96.24	0.00	41.02	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	28.01	0.00	30.18	0.00	15.86	0.00	22.25	0.00	24.06	0.00	10.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.041	15.17	0.62	5.19	0.21	6.30	0.26	6.78	0.28	3.32	0.14	3.17	0.13
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	7.38	0.00	5.39	0.00	2.40	0.00	8.71	0.00	5.34	0.00	8.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				28.7		31.2		22.8		33.3		26.0		24.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
					18000		18000		16500		18000		18000		18000
	ADI (ug/person)=				0		0		0		0		0		0
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

IMAZAPYR (267) International Estimated Daily Intake (IEDI) ADI = 0–3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.69	2.89	1.99	0.21	0.14	0.48	0.33	3.16	2.18	0.26	0.18
OR 0541	Soya oil, refined	PP	0	2.32	0.00	2.54	0.00	18.70	0.00	2.51	0.00	6.29	0.00
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.07	0.67	0.05	7.26	0.51	0.37	0.03	0.08	0.01	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.079	57.15	4.51	110.46	8.73	272.58	21.53	25.81	2.04	132.04	10.43
CF 1210	Wheat, germ	PP	0.11	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.062	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.175	11.58	2.03	2.33	0.41	46.71	8.17	3.72	0.65	16.26	2.85
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.01	13.58	0.14	4.29	0.04	2.17	0.02	0.01	0.00	8.84	0.09
CM 1205	Rice polished, dry	PP	0.01	30.20	0.30	218.34	2.18	12.77	0.13	15.24	0.15	51.35	0.51
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.05	116.33	5.82	10.45	0.52	37.65	1.88	76.60	3.83	34.44	1.72
OR 0645	Maize oil	PP	0.025	0.33	0.01	0.07	0.00	0.81	0.02	0.01	0.00	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0	0.19	0.00	0.07	0.00	12.07	0.00	0.08	0.00	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	0.94	0.01	0.22	0.00	32.01	0.32	12.12	0.12	0.48	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	23.34	0.00	40.71	0.00	97.15	0.00	18.06	0.00	57.71	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	5.84	0.00	10.18	0.00	24.29	0.00	4.52	0.00	14.43	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00

MO 0105	Edible offal (mammalian), raw	RAC	0.041	4.64	0.19	1.97	0.08	10.01	0.41	3.27	0.13	3.98	0.16
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	0.39	0.00	1.20	0.00	5.71	0.00	0.50	0.00	5.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				15.0		12.6		32.9		9.1		15.9
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				180000		180000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

IPRODIONE (111) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FS 0013	Subgroup of Cherries, raw	RAC	0.042	0.92	0.04	9.15	0.38	0.01	0.00	0.61	0.03	0.06	0.00	6.64	0.28
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.05	8.01	0.40	5.87	0.29	0.18	0.01	8.19	0.41	1.64	0.08	22.46	1.12
FB 2005	Subgroup of Caneberries, raw	RAC	13.5	0.42	5.67	1.05	14.18	0.01	0.14	0.02	0.27	0.02	0.27	1.24	16.74
-	Onions, dry, raw	RAC	0.05	29.36	1.47	37.50	1.88	3.56	0.18	34.78	1.74	18.81	0.94	43.38	2.17
VB 0400	Broccoli, raw	RAC	9.4	0.88	8.27	0.17	1.60	0.01	0.09	1.25	11.75	3.00	28.20	1.09	10.25
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.31	0.68	0.21	NC	-	NC	-	0.39	0.12	0.22	0.07	0.49	0.15
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	59.74	2.99	316.14	15.81	9.78	0.49	60.26	3.01	54.12	2.71	119.82	5.99
TN 0660	Almonds, nutmeat	RAC	0.0395	1.38	0.05	0.08	0.00	0.01	0.00	1.00	0.04	0.06	0.00	0.81	0.03
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				19.1		34.1		0.9		17.4		32.3		36.7
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				3600		3600		3600		3600		3600		3600
	%ADI=				0.5%		0.9%		0.0%		0.5%		0.9%		1.0%
	Rounded %ADI=				1%		1%		0%		0%		1%		1%

IPRODIONE (111) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as ug/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FS 0013	Subgroup of Cherries, raw	RAC	0.042	1.40	0.06	4.21	0.18	0.04	0.00	2.93	0.12	1.50	0.06	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.05	13.03	0.65	16.29	0.81	8.29	0.41	12.95	0.65	5.35	0.27	0.04	0.00
FB 2005	Subgroup of Caneberries, raw	RAC	13.5	0.56	7.56	1.43	19.31	0.14	1.89	1.23	16.61	1.14	15.39	0.01	0.14

-	Onions, dry, raw	RAC	0.05	19.69	0.98	29.83	1.49	24.64	1.23	31.35	1.57	9.72	0.49	12.59	0.63
VB 0400	Broccoli, raw	RAC	9.4	4.24	39.86	1.76	16.54	NC	-	0.51	4.79	3.79	35.63	0.26	2.44
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.31	5.07	1.57	0.83	0.26	0.17	0.05	3.70	1.15	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	225.03	11.25	234.24	11.71	71.48	3.57	177.55	8.88	234.55	11.73	37.71	1.89
TN 0660	Almonds, nutmeat	RAC	0.0395	0.81	0.03	2.21	0.09	0.03	0.00	1.02	0.04	1.47	0.06	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				62.0		50.4		7.2		33.8		63.6		5.1
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				3600		3600		3300		3600		3600		3600
	%ADI=				1.7%		1.4%		0.2%		0.9%		1.8%		0.1%
	Rounded %ADI=				2%		1%		0%		1%		2%		0%

IPRODIONE (111) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

			STMR	**Diets: g/person/day**		**Intake = daily intake: ug/person**							
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FS 0013	Subgroup of Cherries, raw	RAC	0.042	0.01	0.00	0.01	0.00	5.96	0.25	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.05	0.02	0.00	0.01	0.00	10.76	0.54	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	13.5	0.01	0.14	7.30	98.55	2.29	30.92	0.01	0.14	NC	-
-	Onions, dry, raw	RAC	0.05	9.01	0.45	20.24	1.01	30.90	1.55	9.61	0.48	2.11	0.11
VB 0400	Broccoli, raw	RAC	9.4	0.01	0.09	0.01	0.09	2.13	20.02	0.01	0.09	NC	-
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.31	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.05	23.96	1.20	13.56	0.68	213.41	10.67	104.35	5.22	8.56	0.43
TN 0660	Almonds, nutmeat	RAC	0.0395	0.01	0.00	0.01	0.00	0.61	0.02	0.01	0.00	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				1.9		100.3		64.0		5.9		0.5
	Bodyweight per region (kg bw) =				60		60		60		60		60

ADI (ug/person)=	3600	3600	3600	3600	3600
%ADI=	0.1%	2.8%	1.8%	0.2%	0.0%
Rounded %ADI=	0%	3%	2%	0%	0%

ISOCYCLSOSERAM (334) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.052	4.82	0.25	2.45	0.13	3.93	0.20	25.44	1.32	8.74	0.45	16.23	0.84
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.088	6.18	0.54	3.66	0.32	0.25	0.02	6.82	0.60	3.49	0.31	19.38	1.71
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.064	23.26	1.49	9.71	0.62	12.09	0.77	62.02	3.97	22.09	1.41	59.91	3.83
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0645	0.66	0.04	0.69	0.04	0.96	0.06	10.20	0.66	1.25	0.08	2.97	0.19
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.105	19.79	2.08	38.25	4.02	17.96	1.89	32.56	3.42	8.08	0.85	64.45	6.77
FS 0013	Subgroup of Cherries, raw	RAC	0.344	0.92	0.32	9.15	3.15	0.01	0.00	0.61	0.21	0.06	0.02	6.64	2.28
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.071	2.67	0.19	8.77	0.62	0.07	0.00	3.03	0.22	0.70	0.05	4.34	0.31
DF 0014	Plums, dried (prunes)	PP	0.22	0.09	0.02	0.06	0.01	0.01	0.00	0.18	0.04	0.04	0.01	0.06	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.0985	8.01	0.79	5.87	0.58	0.18	0.02	8.19	0.81	1.64	0.16	22.46	2.21
-	Onions, dry, raw	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
VB 0400	Broccoli, raw	RAC	0.211	0.88	0.19	0.17	0.04	0.01	0.00	1.25	0.26	3.00	0.63	1.09	0.23
VB 0404	Cauliflower, raw	RAC	0.051	1.65	0.08	0.32	0.02	0.01	0.00	2.33	0.12	4.79	0.24	2.03	0.10
VB 0402	Brussels sprouts, raw	RAC	0.072	0.63	0.05	6.41	0.46	0.13	0.01	1.03	0.07	NC	-	2.35	0.17
VB 0041	Cabbages, head, raw	RAC	0.0385	2.73	0.11	27.92	1.07	0.55	0.02	4.47	0.17	4.27	0.16	10.25	0.39
VC 0424	Cucumber, raw	RAC	0.024	8.01	0.19	30.66	0.74	1.45	0.03	19.84	0.48	0.27	0.01	34.92	0.84
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.012	0.78	0.01	2.06	0.02	0.30	0.00	1.61	0.02	2.25	0.03	2.36	0.03
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.024	8.90	0.21	8.64	0.21	0.80	0.02	17.90	0.43	2.80	0.07	29.17	0.70
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.1	51.75	5.18	81.80	8.18	16.99	1.70	102.02	10.20	26.32	2.63	214.77	21.48
VO 0444	Peppers, chili, raw	RAC	0.15	3.99	0.60	7.30	1.10	2.93	0.44	5.62	0.84	NC	-	17.44	2.62

VO 0445	Peppers, sweet, raw	RAC	0.0935	1.43	0.13	2.61	0.24	1.05	0.10	2.01	0.19	2.59	0.24	6.24	0.58
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.07	5.58	0.39	4.31	0.30	0.89	0.06	9.31	0.65	13.64	0.95	20.12	1.41
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.0225	72.79	1.64	59.05	1.33	20.55	0.46	74.20	1.67	61.12	1.38	73.24	1.65
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0	59.74	0.00	316.14	0.00	9.78	0.00	60.26	0.00	54.12	0.00	119.82	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	29.81	0.30	44.77	0.45	108.95	1.09	52.37	0.52	60.28	0.60	75.69	0.76
SO 0691	Cotton seed, raw (incl oil)	RAC	0.11	20.53	2.26	9.80	1.08	6.42	0.71	4.73	0.52	7.14	0.79	18.68	2.05
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	1.36	0.01	3.59	0.04	1.44	0.01	5.18	0.05	2.02	0.02	1.70	0.02
HS 0444	Peppers, chili, dried	PP	1.1	0.42	0.46	0.53	0.58	0.84	0.92	0.50	0.55	0.95	1.05	0.37	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.0022	31.20	0.07	72.44	0.16	20.88	0.05	47.98	0.11	33.08	0.07	36.25	0.08
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.024	3.29	0.08	6.14	0.15	0.82	0.02	1.57	0.04	2.23	0.05	1.07	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.011	4.79	0.05	9.68	0.11	2.97	0.03	5.49	0.06	3.84	0.04	5.03	0.06
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0021	289.65	0.61	485.88	1.02	26.92	0.06	239.03	0.50	199.91	0.42	180.53	0.38
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				18.6		27.2		8.8		29.0		12.9		52.6
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				1200		1200		1200		1200		1200		1200
	%ADI=				1.6%		2.3%		0.7%		2.4%		1.1%		4.4%
	Rounded %ADI=				2%		2%		1%		2%		1%		4%

ISOCYCLSOSERAM (334) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.052	10.12	0.53	15.69	0.82	2.88	0.15	12.30	0.64	22.32	1.16	6.59	0.34
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.088	12.42	1.09	14.99	1.32	16.08	1.42	10.78	0.95	9.94	0.87	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.064	83.66	5.35	27.64	1.77	7.37	0.47	67.80	4.34	43.97	2.81	187.74	12.02
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0645	8.21	0.53	4.60	0.30	0.64	0.04	5.85	0.38	19.98	1.29	368.86	23.79
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.105	71.38	7.49	81.73	8.58	42.91	4.51	58.89	6.18	103.85	10.90	12.48	1.31
FS 0013	Subgroup of Cherries, raw	RAC	0.344	1.40	0.48	4.21	1.45	0.04	0.01	2.93	1.01	1.50	0.52	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.071	5.55	0.39	4.37	0.31	6.08	0.43	3.66	0.26	3.93	0.28	0.46	0.03
DF 0014	Plums, dried (prunes)	PP	0.22	0.61	0.13	0.35	0.08	0.05	0.01	0.35	0.08	0.49	0.11	0.13	0.03
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.0985	13.03	1.28	16.29	1.60	8.29	0.82	12.95	1.28	5.35	0.53	0.04	0.00
-	Onions, dry, raw	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
VB 0400	Broccoli, raw	RAC	0.211	4.24	0.89	1.76	0.37	NC	-	0.51	0.11	3.79	0.80	0.26	0.05
VB 0404	Cauliflower, raw	RAC	0.051	5.27	0.27	5.01	0.26	NC	-	2.70	0.14	5.57	0.28	0.49	0.02
VB 0402	Brussels sprouts, raw	RAC	0.072	2.24	0.16	2.67	0.19	6.23	0.45	0.32	0.02	4.19	0.30	2.58	0.19
VB 0041	Cabbages, head, raw	RAC	0.0385	8.97	0.35	27.12	1.04	1.44	0.06	24.96	0.96	4.55	0.18	11.23	0.43
VC 0424	Cucumber, raw	RAC	0.024	6.72	0.16	11.03	0.26	32.10	0.77	15.10	0.36	4.05	0.10	9.57	0.23
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.012	NC	-	NC	-	5.48	0.07	NC	-	NC	-	1.03	0.01
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.024	9.20	0.22	11.95	0.29	14.63	0.35	8.99	0.22	7.86	0.19	2.46	0.06
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.1	64.74	6.47	68.31	6.83	36.05	3.61	82.09	8.21	54.50	5.45	11.69	1.17

VO 0444	Peppers, chili, raw	RAC	0.15	5.57	0.84	14.00	2.10	8.25	1.24	5.77	0.87	6.44	0.97	2.53	0.38
VO 0445	Peppers, sweet, raw	RAC	0.0935	NC	-	NC	-	8.25	0.77	3.03	0.28	NC	-	0.91	0.09
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.07	1.01	0.07	1.69	0.12	21.37	1.50	3.00	0.21	1.40	0.10	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.0225	106.33	2.39	117.78	2.65	42.12	0.95	195.70	4.40	222.52	5.01	80.47	1.81
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0	225.03	0.00	234.24	0.00	71.48	0.00	177.55	0.00	234.55	0.00	37.71	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	18.51	0.19	26.18	0.26	26.04	0.26	39.99	0.40	7.36	0.07	64.58	0.65
SO 0691	Cotton seed, raw (incl oil)	RAC	0.11	10.71	1.18	4.23	0.47	7.19	0.79	7.54	0.83	5.66	0.62	2.38	0.26
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	10.90	0.11	12.44	0.12	0.77	0.01	9.48	0.09	22.07	0.22	8.15	0.08
HS 0444	Peppers, chili, dried	PP	1.1	0.11	0.12	0.21	0.23	0.36	0.40	0.21	0.23	0.25	0.28	0.15	0.17
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.0022	140.03	0.31	150.89	0.33	79.32	0.17	111.24	0.24	120.30	0.26	51.27	0.11
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.024	6.44	0.15	15.51	0.37	3.79	0.09	8.29	0.20	18.44	0.44	8.00	0.19
MO 0105	Edible offal (mammalian), raw	RAC	0.011	15.17	0.17	5.19	0.06	6.30	0.07	6.78	0.07	3.32	0.04	3.17	0.03
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0021	388.92	0.82	335.88	0.71	49.15	0.10	331.25	0.70	468.56	0.98	245.45	0.52
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				32.4		33.2		19.7		34.0		34.9		44.1
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				1200		1200		1100		1200		1200		1200
	%ADI=				2.7%		2.8%		1.8%		2.8%		2.9%		3.7%
	Rounded %ADI=				3%		3%		2%		3%		3%		4%

ISOCYCLSOSERAM (334) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: ug/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.052	18.97	0.99	0.97	0.05	6.23	0.32	0.09	0.00	3.35	0.17
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.088	0.16	0.01	0.27	0.02	9.06	0.80	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.064	1.34	0.09	1.65	0.11	40.03	2.56	0.33	0.02	1.76	0.11
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.0645	0.68	0.04	0.05	0.00	3.21	0.21	0.01	0.00	NC	-
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.105	68.89	7.23	11.06	1.16	80.62	8.47	189.82	19.93	19.56	2.05
FS 0013	Subgroup of Cherries, raw	RAC	0.344	0.01	0.00	0.01	0.00	5.96	2.05	0.01	0.00	NC	-
FS 0014	Subgroup of Plums, raw (incl dried plums)	RAC	0.071	0.07	0.00	0.02	0.00	16.65	1.18	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.22	0.01	0.00	0.01	0.00	0.37	0.08	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.0985	0.02	0.00	0.01	0.00	10.76	1.06	0.01	0.00	NC	-
-	Onions, dry, raw	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
VB 0400	Broccoli, raw	RAC	0.211	0.01	0.00	0.01	0.00	2.13	0.45	0.01	0.00	NC	-
VB 0404	Cauliflower, raw	RAC	0.051	0.01	0.00	0.01	0.00	2.73	0.14	0.01	0.00	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.072	0.88	0.06	0.69	0.05	2.89	0.21	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.0385	3.82	0.15	2.99	0.12	49.16	1.89	0.01	0.00	NC	-
VC 0424	Cucumber, raw	RAC	0.024	0.68	0.02	1.81	0.04	10.40	0.25	0.01	0.00	0.04	0.00
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.012	0.09	0.00	1.01	0.01	NC	-	1.91	0.02	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.024	0.19	0.00	0.10	0.00	4.98	0.12	0.01	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.1	15.50	1.55	5.78	0.58	71.52	7.15	2.00	0.20	12.50	1.25
VO 0444	Peppers, chili, raw	RAC	0.15	3.47	0.52	3.56	0.53	16.30	2.45	0.01	0.00	NC	-

VO 0445	Peppers, sweet, raw	RAC	0.0935	1.24	0.12	1.27	0.12	NC	-	0.01	0.00	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.07	1.31	0.09	8.26	0.58	3.95	0.28	0.01	0.00	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.0225	15.80	0.36	14.29	0.32	104.36	2.35	17.11	0.38	35.20	0.79
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0	23.96	0.00	13.56	0.00	213.41	0.00	104.35	0.00	8.56	0.00
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.01	116.66	1.17	10.52	0.11	38.46	0.38	76.60	0.77	34.44	0.34
SO 0691	Cotton seed, raw (incl oil)	RAC	0.11	8.14	0.90	0.32	0.04	2.84	0.31	2.69	0.30	0.97	0.11
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.01	0.95	0.01	1.32	0.01	11.64	0.12	2.96	0.03	14.73	0.15
HS 0444	Peppers, chili, dried	PP	1.1	0.58	0.64	1.27	1.40	1.21	1.33	0.12	0.13	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.0022	29.18	0.06	50.89	0.11	121.44	0.27	22.58	0.05	72.14	0.16
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.024	1.05	0.03	1.14	0.03	18.69	0.45	0.94	0.02	3.12	0.07
MO 0105	Edible offal (mammalian), raw	RAC	0.011	4.64	0.05	1.97	0.02	10.01	0.11	3.27	0.04	3.98	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0021	108.75	0.23	70.31	0.15	436.11	0.92	61.55	0.13	79.09	0.17
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				14.4		5.8		36.2		22.1		5.4
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				1200		1200		1200		1200		1200
	%ADI=				1.2%		0.5%		3.0%		1.8%		0.5%
	Rounded %ADI=				1%		0%		3%		2%		0%

ISOFLUCYPRAM (330) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
GC 0653	Triticale, raw (incl flour)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.00	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	0.01	0.00	1.12	0.01	NC	-	0.03	0.00	0.56	0.01	NC	-
CF 1210	Wheat, germ	PP	0.011	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.0063	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.0063	0.25	0.00	0.63	0.00	0.12	0.00	0.43	0.00	1.39	0.01	0.22	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0063	301.24	1.90	268.64	1.69	30.21	0.19	222.51	1.40	134.73	0.85	343.12	2.16
CF 1211	Wheat, white flour	PP	0.0063	299.27	1.89	263.32	1.66	27.93	0.18	214.18	1.35	133.47	0.84	340.03	2.14
-	Wheat, starch	PP	0.0063	0.02	0.00	NC	-	0.01	0.00	0.05	0.00	0.13	0.00	0.01	0.00
-	Wheat, gluten	PP	0.0094	0.01	0.00	0.01	0.00	0.01	0.00	0.27	0.00	0.01	0.00	0.03	0.00
-	Wheat, macaroni, dry	PP	0.0063	0.72	0.00	2.20	0.01	1.22	0.01	3.99	0.03	0.53	0.00	1.66	0.01
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl malt, excl pot&pearled, excl beer)	RAC	0.01	8.03	0.08	2.05	0.02	0.39	0.00	0.62	0.01	1.27	0.01	0.56	0.01
-	Barley, pot&pearled	PP	0.0067	7.12	0.05	7.34	0.05	0.02	0.00	0.03	0.00	0.67	0.00	0.20	0.00
-	Barley beer	PP	0.0067	4.87	0.03	93.78	0.63	24.28	0.16	12.76	0.09	39.28	0.26	18.15	0.12
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.018	31.20	0.56	72.44	1.30	20.88	0.38	47.98	0.86	33.08	0.60	36.25	0.65
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	3.29	0.06	6.14	0.11	0.82	0.01	1.57	0.03	2.23	0.04	1.07	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.018	4.79	0.09	9.68	0.17	2.97	0.05	5.49	0.10	3.84	0.07	5.03	0.09
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0081	289.65	2.35	485.88	3.94	26.92	0.22	239.03	1.94	199.91	1.62	180.53	1.46
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.006	14.63	0.09	29.76	0.18	8.04	0.05	129.68	0.78	25.04	0.15	35.66	0.21
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.006	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00

PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.006	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.03	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.006	7.84	0.05	23.08	0.14	2.88	0.02	14.89	0.09	9.81	0.06	14.83	0.09
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				7.1		9.9		1.3		6.7		4.5		7.0
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				3600		3600		3600		3600		3600		3600
	%ADI=				0.2%		0.3%		0.0%		0.2%		0.1%		0.2%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

ISOFLUCYPRAM (330) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

			STMR	**Diets as g/person/day**						**Intake as ug/person/day**					
Codex Code	Commodity description	Expr as	mg/kg	G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.01	0.00	0.17	0.00	0.29	0.00	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	NC	-	NC	-	0.02	0.00	0.83	0.01	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.011	0.97	0.01	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.0063	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CP 1211	Wheat, white bread	PP	0.0063	1.30	0.01	0.46	0.00	0.06	0.00	0.22	0.00	2.44	0.02	0.77	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0063	198.08	1.25	193.03	1.22	106.24	0.67	185.09	1.17	168.67	1.06	131.59	0.83
CF 1211	Wheat, white flour	PP	0.0063	182.77	1.15	187.54	1.18	103.82	0.65	180.42	1.14	164.00	1.03	118.84	0.75
-	Wheat, starch	PP	0.0063	NC	-	NC	-	0.01	0.00	0.31	0.00	NC	-	NC	-
-	Wheat, gluten	PP	0.0094	0.68	0.01	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Wheat, macaroni, dry	PP	0.0063	6.71	0.04	4.98	0.03	2.12	0.01	1.90	0.01	2.89	0.02	4.12	0.03
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl malt, excl pot&pearled, excl beer)	RAC	0.01	1.07	0.01	0.21	0.00	0.15	0.00	1.64	0.02	1.58	0.02	3.52	0.04
-	Barley, pot&pearled	PP	0.0067	0.57	0.00	2.56	0.02	0.33	0.00	0.56	0.00	0.36	0.00	NC	-
-	Barley beer	PP	0.0067	180.21	1.21	259.46	1.74	45.91	0.31	172.36	1.15	234.42	1.57	65.30	0.44

MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.018	140.03	2.52	150.89	2.72	79.32	1.43	111.24	2.00	120.30	2.17	51.27	0.92
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	6.44	0.12	15.51	0.28	3.79	0.07	8.29	0.15	18.44	0.33	8.00	0.14
MO 0105	Edible offal (mammalian), raw	RAC	0.018	15.17	0.27	5.19	0.09	6.30	0.11	6.78	0.12	3.32	0.06	3.17	0.06
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0081	388.92	3.15	335.88	2.72	49.15	0.40	331.25	2.68	468.56	3.80	245.45	1.99
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.006	73.76	0.44	53.86	0.32	23.98	0.14	87.12	0.52	53.38	0.32	84.45	0.51
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.006	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.006	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.006	25.84	0.16	29.53	0.18	28.05	0.17	33.19	0.20	36.44	0.22	8.89	0.05
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				10.3		10.5		4.0		9.2		10.6		5.8
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				3600		3600		3300		3600		3600		3600
	%ADI=				0.3%		0.3%		0.1%		0.3%		0.3%		0.2%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

ISOFLUCYPRAM (330) International Estimated Daily Intake (IEDI) ADI = 0–0.06 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: ug/person									
GC 0653	Triticale, raw (incl flour)	RAC	0.01	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.01
CF 1210	Wheat, germ	PP	0.011	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.0063	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.0063	0.43	0.00	0.41	0.00	1.56	0.01	0.11	0.00	0.07	0.00

CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.0063	44.78	0.28	86.96	0.55	214.05	1.35	20.31	0.13	103.60	0.65
CF 1211	Wheat, white flour	PP	0.0063	43.75	0.28	85.81	0.54	206.68	1.30	19.38	0.12	92.92	0.59
-	Wheat, starch	PP	0.0063	0.01	0.00	0.02	0.00	NC	-	NC	-	NC	-
-	Wheat, gluten	PP	0.0094	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.00
-	Wheat, macaroni, dry	PP	0.0063	0.52	0.00	0.63	0.00	2.99	0.02	0.26	0.00	5.18	0.03
GC 0640	Barley, raw (incl malt extract, incl flour & grits, incl malt, excl pot&pearled, excl beer)	RAC	0.01	0.10	0.00	0.15	0.00	1.71	0.02	0.02	0.00	6.34	0.06
-	Barley, pot&pearled	PP	0.0067	5.46	0.04	0.01	0.00	1.44	0.01	0.01	0.00	NC	-
-	Barley beer	PP	0.0067	16.25	0.11	11.36	0.08	225.21	1.51	19.49	0.13	52.17	0.35
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.018	29.18	0.53	50.89	0.92	121.44	2.19	22.58	0.41	72.14	1.30
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.018	1.05	0.02	1.14	0.02	18.69	0.34	0.94	0.02	3.12	0.06
MO 0105	Edible offal (mammalian), raw	RAC	0.018	4.64	0.08	1.97	0.04	10.01	0.18	3.27	0.06	3.98	0.07
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0081	108.75	0.88	70.31	0.57	436.11	3.53	61.55	0.50	79.09	0.64
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.006	3.92	0.02	12.03	0.07	57.07	0.34	5.03	0.03	55.56	0.33
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.006	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.006	0.10	0.00	0.70	0.00	0.97	0.01	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.006	3.84	0.02	4.41	0.03	27.25	0.16	1.13	0.01	7.39	0.04
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				2.3		2.8		11.0		1.4		4.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				3600		3600		3600		3600		3600
	%ADI=				0.1%		0.1%		0.3%		0.0%		0.1%
	Rounded %ADI=				0%		0%		0%		0%		0%

ISOTIANIL (335) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day	Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.012	4.82	0.06	2.45	0.03	3.93	0.05	25.44	0.31	8.74	0.10	16.23	0.19
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.012	6.18	0.07	3.66	0.04	0.25	0.00	6.82	0.08	3.49	0.04	19.38	0.23
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.012	23.26	0.28	9.71	0.12	12.09	0.15	62.02	0.74	22.09	0.27	59.91	0.72
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.00715	0.66	0.00	0.69	0.00	0.96	0.01	10.20	0.07	1.25	0.01	2.97	0.02
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0	5.23	0.00	6.94	0.00	99.45	0.00	32.47	0.00	48.30	0.00	24.70	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	24.96	0.00	57.95	0.00	16.70	0.00	38.38	0.00	26.46	0.00	29.00	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	6.24	0.00	14.49	0.00	4.18	0.00	9.60	0.00	6.62	0.00	7.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.79	0.00	9.68	0.00	2.97	0.00	5.49	0.00	3.84	0.00	5.03	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	1.46	0.00	2.98	0.00	0.80	0.00	12.97	0.00	2.50	0.00	3.57	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
038	**POULTRY, EDIBLE OFFAL OF**	-	0	-	-	-	-	-	-	-	-	-	-	-	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0.4		0.2		0.2		1.2		0.4		1.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				3000		3000		3000		3000		3000		3000

%ADI=				0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Rounded %ADI=				0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%

ISOTIANIL (335) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.012	10.12	0.12	15.69	0.19	2.88	0.03	12.30	0.15	22.32	0.27	6.59	0.08
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.012	12.42	0.15	14.99	0.18	16.08	0.19	10.78	0.13	9.94	0.12	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.012	83.66	1.00	27.64	0.33	7.37	0.09	67.80	0.81	43.97	0.53	187.74	2.25
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.00715	8.21	0.06	4.60	0.03	0.64	0.00	5.85	0.04	19.98	0.14	368.86	2.64
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0	25.76	0.00	23.65	0.00	23.83	0.00	24.37	0.00	19.43	0.00	101.55	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	112.02	0.00	120.71	0.00	63.46	0.00	88.99	0.00	96.24	0.00	41.02	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	28.01	0.00	30.18	0.00	15.86	0.00	22.25	0.00	24.06	0.00	10.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	7.38	0.00	5.39	0.00	2.40	0.00	8.71	0.00	5.34	0.00	8.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
038	**POULTRY, EDIBLE OFFAL OF**	-	0	-	-	-	-	-	-	-	-	-	-	-	-

PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				1.3		0.7		0.3		1.1		1.1		5.0
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				3000		3000		2750		3000		3000		3000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.2%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

ISOTIANIL (335) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: ug/person									
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.012	18.97	0.23	0.97	0.01	6.23	0.07	0.09	0.00	3.35	0.04
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.012	0.16	0.00	0.27	0.00	9.06	0.11	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.012	1.34	0.02	1.65	0.02	40.03	0.48	0.33	0.00	1.76	0.02
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.00715	0.68	0.00	0.05	0.00	3.21	0.02	0.01	0.00	NC	-
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0	44.80	0.00	118.17	0.00	25.25	0.00	454.49	0.00	310.23	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	23.34	0.00	40.71	0.00	97.15	0.00	18.06	0.00	57.71	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	5.84	0.00	10.18	0.00	24.29	0.00	4.52	0.00	14.43	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0	4.64	0.00	1.97	0.00	10.01	0.00	3.27	0.00	3.98	0.00
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00

PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	0.39	0.00	1.20	0.00	5.71	0.00	0.50	0.00	5.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
038	**POULTRY, EDIBLE OFFAL OF**	-	0	-	-	-	-	-	-	-	-	-	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0.3		0.0		0.7		0.0		0.1
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				3000		3000		3000		3000		3000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

OXATHIAPIPROLIN (291) International Estimated Daily Intake (IEDI) ADI = 0–4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0001	Group of Citrus fruit, raw (excl kumquat commodities)	RAC	**0.056**	29.89	1.67	11.40	0.64	13.51	0.76	61.57	3.45	32.24	1.81	91.26	5.11
JF 0001	Group of Citrus fruit, juice	PP	**0.032**	1.30	0.04	2.37	0.08	0.22	0.01	13.88	0.44	0.75	0.02	2.63	0.08
FC 0303	Kumquats, raw (incl juice)	RAC	**0.057**	2.36	0.13	0.27	0.02	3.19	0.18	14.44	0.82	1.66	0.09	1.71	0.10
FB 2005	Subgroup of Caneberries, raw	RAC	**0.056**	0.42	0.02	1.05	0.06	0.01	0.00	0.02	0.00	0.02	0.00	1.24	0.07
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.056	0.53	0.03	1.31	0.07	0.40	0.02	1.66	0.09	0.01	0.00	0.99	0.06
FB 0269	Grapes, raw (i.e. table grapes)	RAC	*0.21*	12.68	2.66	9.12	1.92	0.03	0.01	16.88	3.54	3.70	0.78	54.42	11.43
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	*0.29*	0.51	0.15	0.51	0.15	0.01	0.00	1.27	0.37	0.12	0.03	2.07	0.60
JF 0269	Grape juice (from wine grapes)	PP	*0.034*	0.14	0.00	0.29	0.01	0.05	0.00	0.30	0.01	0.24	0.01	0.05	0.00
-	Graps must (from wine-grapes)	PP	*0.13*	0.33	0.04	0.13	0.02	0.01	0.00	0.02	0.00	0.01	0.00	0.02	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	*0.029*	0.67	0.02	12.53	0.36	2.01	0.06	1.21	0.04	3.53	0.10	4.01	0.12
FI 0326	Avocado, raw	RAC	0.0575	0.13	0.01	0.03	0.00	2.05	0.12	2.54	0.15	2.34	0.13	0.12	0.01
VA 0381	Garlic, raw	RAC	*0.066*	2.29	0.15	5.78	0.38	0.11	0.01	3.69	0.24	1.65	0.11	3.91	0.26
-	Onions, dry, raw	RAC	0.066	29.36	1.94	37.50	2.48	3.56	0.23	34.78	2.30	18.81	1.24	43.38	2.86
VA 0384	Leek, raw	RAC	*0.656*	0.18	0.12	1.59	1.04	0.03	0.02	0.28	0.18	0.01	0.01	3.21	2.11
-	Onions, green, raw	RAC	*0.656*	2.45	1.61	1.49	0.98	1.02	0.67	2.60	1.71	0.60	0.39	2.03	1.33
VB 0400	Broccoli, raw	RAC	*0.276*	0.88	0.24	0.17	0.05	0.01	0.00	1.25	0.35	3.00	0.83	1.09	0.30
VB 0404	Cauliflower, raw	RAC	*0.136*	1.65	0.22	0.32	0.04	0.01	0.00	2.33	0.32	4.79	0.65	2.03	0.28
VB 0041	Cabbages, head, raw	RAC	*0.196*	2.73	0.54	27.92	5.47	0.55	0.11	4.47	0.88	4.27	0.84	10.25	2.01
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	*0.03*	53.14	1.59	86.21	2.59	6.28	0.19	92.76	2.78	15.64	0.47	155.30	4.66
VO 0448	Tomato, raw	RAC	*0.04*	41.73	1.67	75.65	3.03	10.66	0.43	82.87	3.31	24.75	0.99	200.93	8.04
-	Tomato, canned (& peeled)	PP	*0.0016*	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.00	0.11	0.00	1.50	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	*0.044*	2.34	0.10	1.33	0.06	1.57	0.07	4.24	0.19	0.34	0.01	2.83	0.12

JF 0448	Tomato, juice (single strength, incl concentrated)	PP	*0.006*	0.29	0.00	0.29	0.00	0.01	0.00	0.38	0.00	0.05	0.00	0.14	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	*0.04*	1.97	0.08	NC	-	3.68	0.15	3.24	0.13	5.72	0.23	1.57	0.06
VO 0445	Peppers, sweet, raw (incl dried)	RAC	*0.04*	4.49	0.18	6.44	0.26	7.21	0.29	5.68	0.23	9.52	0.38	8.92	0.36
VO 0445	Peppers, sweet, raw	RAC	*0.04*	1.43	0.06	2.61	0.10	1.05	0.04	2.01	0.08	2.59	0.10	6.24	0.25
-	Peppers, sweet, dried	PP	*0.4*	0.42	0.17	0.53	0.21	0.84	0.34	0.50	0.20	0.95	0.38	0.37	0.15
VO 2046	Subgroup of eggplants	RAC	0.04	5.58	0.22	4.31	0.17	0.89	0.04	9.31	0.37	13.64	0.55	20.12	0.80
VL 0483	Lettuce, leaf, raw	RAC	2.3	0.53	1.22	0.36	0.83	0.16	0.37	6.21	14.28	1.90	4.37	6.05	13.92
VL 0502	Spinach, raw	RAC	3.8	0.74	2.81	0.22	0.84	0.02	0.08	0.91	3.46	0.04	0.15	2.92	11.10
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.28	2.63	8.63	9.27	30.41	1.86	6.10	5.82	19.09	19.53	64.06	4.90	16.07
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	*1.2*	0.68	0.82	NC	-	NC	-	0.39	0.47	0.22	0.26	0.49	0.59
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.1	1.97	0.20	0.51	0.05	0.02	0.00	0.79	0.08	3.68	0.37	3.80	0.38
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.04	2.39	0.10	1.61	0.06	10.47	0.42	1.84	0.07	12.90	0.52	7.44	0.30
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.04	1.27	0.05	0.01	0.00	0.12	0.00	2.49	0.10	0.23	0.01	5.54	0.22
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.04	0.05	0.00	NC	-	1.74	0.07	0.01	0.00	0.01	0.00	0.07	0.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	*0.176*	72.79	12.81	59.05	10.39	20.55	3.62	74.20	13.06	61.12	10.76	73.24	12.89
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.04	1.70	0.07	0.01	0.00	3.00	0.12	1.80	0.07	1.64	0.07	1.33	0.05
VD 2066	Subgroup of dry peas, raw	RAC	*0.04*	9.09	0.36	3.35	0.13	1.06	0.04	9.48	0.38	15.11	0.60	10.58	0.42
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.04	NC	-	NC	-	0.20	0.01	NC	-	NC	-	NC	-
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.116	63.11	7.32	316.33	36.69	651.91	75.62	72.06	8.36	84.88	9.85	132.70	15.39
VS 2081	Subgroup of young shoots	RAC	0.681	1.84	1.25	3.25	2.21	2.01	1.37	4.90	3.34	0.07	0.05	2.56	1.74

GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.112	29.81	3.34	44.77	5.01	108.95	12.20	52.37	5.87	60.28	6.75	75.69	8.48
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 0698	Poppy seed, raw (incl oil)	RAC	0.102	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
SO 0702	Sunflower seed, raw (incl oil)	RAC	**0.118**	7.40	0.87	35.86	4.23	1.15	0.14	8.76	1.03	5.45	0.64	13.62	1.61
HH 0722	Basil leaves, raw (incl dried)	RAC	3.08	0.14	0.43	0.26	0.80	0.16	0.49	0.38	1.17	NC	-	0.19	0.59
HS 0444	Peppers, chili, dried	PP	0.4	0.42	0.17	0.53	0.21	0.84	0.34	0.50	0.20	0.95	0.38	0.37	0.15
DH 1100	Hops, dry	RAC	1.55	0.01	0.02	0.04	0.06	0.01	0.02	0.01	0.02	NC	-	0.01	0.02
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				54.2		112.2		104.8		93.4		109.1		125.2
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				240000		240000		240000		240000		240000		240000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.1%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

OXATHIAPIPROLIN (291) International Estimated Daily Intake (IEDI) ADI = 0–4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	Intake as ug/person/day G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (excl kumquat commodities)	RAC	**0.056**	33.99	1.90	49.07	2.75	24.40	1.37	50.01	2.80	34.01	1.90	464.99	26.04
JF 0001	Group of Citrus fruit, juice	PP	**0.032**	36.84	1.18	3.75	0.12	0.30	0.01	21.62	0.69	21.82	0.70	46.67	1.49
FC 0303	Kumquats, raw (incl juice)	RAC	**0.057**	4.67	0.27	5.86	0.33	1.96	0.11	1.45	0.08	17.05	0.97	1.37	0.08
FB 2005	Subgroup of Caneberries, raw	RAC	**0.056**	0.56	0.03	1.43	0.08	0.14	0.01	1.23	0.07	1.14	0.06	0.01	0.00
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.056	1.31	0.07	5.50	0.31	0.01	0.00	2.57	0.14	0.82	0.05	2.15	0.12
FB 0269	Grapes, raw (i.e. table grapes)	RAC	*0.21*	6.33	1.33	11.22	2.36	5.21	1.09	9.38	1.97	4.55	0.96	0.78	0.16

DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	*0.29*	3.09	0.90	1.51	0.44	0.03	0.01	1.38	0.40	4.26	1.24	0.42	0.12
JF 0269	Grape juice (from wine grapes)	PP	*0.034*	0.56	0.02	1.96	0.07	0.02	0.00	2.24	0.08	2.27	0.08	0.34	0.01
-	Graps must (from wine-grapes)	PP	*0.13*	0.16	0.02	0.09	0.01	0.01	0.00	0.12	0.02	0.11	0.01	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	*0.029*	88.93	2.58	62.41	1.81	1.84	0.05	25.07	0.73	61.17	1.77	5.84	0.17
FI 0326	Avocado, raw	RAC	0.0575	2.65	0.15	0.87	0.05	0.46	0.03	1.64	0.09	1.30	0.07	0.96	0.06
VA 0381	Garlic, raw	RAC	*0.066*	0.98	0.06	1.49	0.10	12.88	0.85	3.74	0.25	2.05	0.14	1.14	0.08
-	Onions, dry, raw	RAC	0.066	19.69	1.30	29.83	1.97	24.64	1.63	31.35	2.07	9.72	0.64	12.59	0.83
VA 0384	Leek, raw	RAC	*0.656*	4.01	2.63	4.41	2.89	0.72	0.47	0.54	0.35	16.41	10.76	0.03	0.02
-	Onions, green, raw	RAC	*0.656*	1.55	1.02	0.74	0.49	1.05	0.69	3.74	2.45	0.94	0.62	6.45	4.23
VB 0400	Broccoli, raw	RAC	*0.276*	4.24	1.17	1.76	0.49	NC	-	0.51	0.14	3.79	1.05	0.26	0.07
VB 0404	Cauliflower, raw	RAC	*0.136*	5.27	0.72	5.01	0.68	NC	-	2.70	0.37	5.57	0.76	0.49	0.07
VB 0041	Cabbages, head, raw	RAC	*0.196*	8.97	1.76	27.12	5.32	1.44	0.28	24.96	4.89	4.55	0.89	11.23	2.20
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	*0.03*	27.81	0.83	41.93	1.26	123.30	3.70	49.47	1.48	15.95	0.48	35.99	1.08
VO 0448	Tomato, raw	RAC	*0.04*	32.13	1.29	51.27	2.05	34.92	1.40	73.37	2.93	15.15	0.61	8.88	0.36
-	Tomato, canned (& peeled)	PP	*0.0016*	7.57	0.01	2.66	0.00	0.30	0.00	0.97	0.00	7.31	0.01	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	*0.044*	4.96	0.22	3.20	0.14	0.15	0.01	1.61	0.07	6.88	0.30	0.52	0.02
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	*0.006*	0.80	0.00	0.07	0.00	0.05	0.00	0.61	0.00	0.40	0.00	0.08	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	*0.04*	NC	-	NC	-	0.04	0.00	0.17	0.01	NC	-	0.72	0.03
VO 0445	Peppers, sweet, raw (incl dried)	RAC	*0.04*	0.82	0.03	1.53	0.06	10.85	0.43	4.59	0.18	1.84	0.07	2.00	0.08
VO 0445	Peppers, sweet, raw	RAC	*0.04*	NC	-	NC	-	8.25	0.33	3.03	0.12	NC	-	0.91	0.04
-	Peppers, sweet, dried	PP	*0.4*	0.11	0.04	0.21	0.08	0.36	0.14	0.21	0.08	0.25	0.10	0.15	0.06
VO 2046	Subgroup of eggplants	RAC	0.04	1.01	0.04	1.69	0.07	21.37	0.85	3.00	0.12	1.40	0.06	NC	-

VL 0483	Lettuce, leaf, raw	RAC	2.3	14.50	33.35	11.76	27.05	13.14	30.22	19.50	44.85	4.81	11.06	2.23	5.13
VL 0502	Spinach, raw	RAC	3.8	2.20	8.36	1.76	6.69	13.38	50.84	2.94	11.17	5.53	21.01	0.02	0.08
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.28	0.10	0.33	NC	-	26.78	87.84	5.00	16.40	0.58	1.90	5.68	18.63
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	*1.2*	5.07	6.08	0.83	1.00	0.17	0.20	3.70	4.44	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.1	10.72	1.07	1.99	0.20	2.72	0.27	4.26	0.43	4.23	0.42	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.04	1.51	0.06	1.50	0.06	1.90	0.08	5.11	0.20	1.36	0.05	23.43	0.94
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.04	0.02	0.00	0.01	0.00	1.16	0.05	0.40	0.02	NC	-	0.06	0.00
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.04	NC	-	NC	-	0.16	0.01	0.01	0.00	NC	-	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	*0.176*	106.33	18.71	117.78	20.73	42.12	7.41	195.70	34.44	222.52	39.16	80.47	14.16
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.04	0.01	0.00	NC	-	0.57	0.02	0.11	0.00	0.16	0.01	0.94	0.04
VD 2066	Subgroup of dry peas, raw	RAC	*0.04*	5.01	0.20	3.76	0.15	1.82	0.07	3.44	0.14	3.49	0.14	5.15	0.21
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.04	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.116	226.09	26.23	234.58	27.21	161.10	18.69	185.04	21.46	234.85	27.24	100.25	11.63
VS 2081	Subgroup of young shoots	RAC	0.681	1.76	1.20	2.63	1.79	68.89	46.91	2.55	1.74	3.41	2.32	3.50	2.38
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.112	18.51	2.07	26.18	2.93	26.04	2.92	39.99	4.48	7.36	0.82	64.58	7.23
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SO 0698	Poppy seed, raw (incl oil)	RAC	0.102	0.02	0.00	0.25	0.03	0.01	0.00	0.02	0.00	NC	-	NC	-

SO 0702	Sunflower seed, raw (incl oil)	RAC	**0.118**	23.40	2.76	29.33	3.46	1.24	0.15	13.85	1.63	6.48	0.76	6.91	0.82
HH 0722	Basil leaves, raw (incl dried)	RAC	3.08	0.52	1.60	0.05	0.15	3.23	9.95	0.18	0.55	0.12	0.37	0.27	0.83
HS 0444	Peppers, chili, dried	PP	0.4	0.11	0.04	0.21	0.08	0.36	0.14	0.21	0.08	0.25	0.10	0.15	0.06
DH 1100	Hops, dry	RAC	1.55	NC	-	NC	-	0.02	0.03	0.02	0.03	NC	-	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				121.7		115.5		269.4		164.8		129.8		99.8
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				24000		24000		22000		24000		24000		24000
	%ADI=				0.1%		0.0%		0.1%		0.1%		0.1%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

OXATHIAPIPROLIN (291) International Estimated Daily Intake (IEDI) ADI = 0–4 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
				Intake = daily intake: ug/person									
FC 0001	Group of Citrus fruit, raw (excl kumquat commodities)	RAC	**0.056**	2.57	0.14	2.12	0.12	28.93	1.62	0.07	0.00	1.10	0.06
JF 0001	Group of Citrus fruit, juice	PP	**0.032**	0.11	0.00	0.29	0.01	13.55	0.43	0.14	0.00	0.33	0.01
FC 0303	Kumquats, raw (incl juice)	RAC	**0.057**	18.35	1.05	0.23	0.01	1.78	0.10	0.08	0.00	3.35	0.19
FB 2005	Subgroup of Caneberries, raw	RAC	**0.056**	0.01	0.00	7.30	0.41	2.29	0.13	0.01	0.00	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.056	0.82	0.05	4.05	0.23	5.94	0.33	0.43	0.02	2.66	0.15
FB 0269	Grapes, raw (i.e. table grapes)	RAC	*0.21*	0.14	0.03	0.36	0.08	15.22	3.20	0.01	0.00	0.09	0.02
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	*0.29*	0.01	0.00	0.13	0.04	1.06	0.31	0.01	0.00	0.03	0.01
JF 0269	Grape juice (from wine grapes)	PP	*0.034*	0.01	0.00	0.01	0.00	0.41	0.01	0.01	0.00	NC	-
-	Graps must (from wine-grapes)	PP	*0.13*	0.01	0.00	0.01	0.00	0.11	0.01	0.01	0.00	0.19	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	*0.029*	0.31	0.01	0.23	0.01	60.43	1.75	0.52	0.02	31.91	0.93
FI 0326	Avocado, raw	RAC	0.0575	1.12	0.06	0.01	0.00	0.84	0.05	0.01	0.00	6.60	0.38
VA 0381	Garlic, raw	RAC	*0.066*	0.82	0.05	2.06	0.14	3.79	0.25	0.03	0.00	0.29	0.02
-	Onions, dry, raw	RAC	0.066	9.01	0.59	20.24	1.34	30.90	2.04	9.61	0.63	2.11	0.14
VA 0384	Leek, raw	RAC	*0.656*	0.02	0.01	1.44	0.94	1.22	0.80	0.01	0.01	NC	-
-	Onions, green, raw	RAC	*0.656*	1.43	0.94	0.05	0.03	0.20	0.13	NC	-	6.30	4.13
VB 0400	Broccoli, raw	RAC	*0.276*	0.01	0.00	0.01	0.00	2.13	0.59	0.01	0.00	NC	-
VB 0404	Cauliflower, raw	RAC	*0.136*	0.01	0.00	0.01	0.00	2.73	0.37	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	*0.196*	3.82	0.75	2.99	0.59	49.16	9.64	0.01	0.00	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	*0.03*	5.96	0.18	9.74	0.29	51.82	1.55	13.61	0.41	0.05	0.00
VO 0448	Tomato, raw	RAC	*0.04*	12.99	0.52	4.79	0.19	58.40	2.34	0.92	0.04	0.09	0.00
-	Tomato, canned (& peeled)	PP	*0.0016*	0.07	0.00	0.08	0.00	2.42	0.00	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	*0.044*	0.58	0.03	0.22	0.01	2.21	0.10	0.24	0.01	3.10	0.14
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	*0.006*	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	*0.04*	6.23	0.25	0.10	0.00	NC	-	NC	-	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	*0.04*	5.49	0.22	10.57	0.42	8.84	0.35	0.91	0.04	NC	-

VO 0445	Peppers, sweet, raw	RAC	*0.04*	1.24	0.05	1.27	0.05	NC	-	0.01	0.00	NC	-
-	Peppers, sweet, dried	PP	*0.4*	0.58	0.23	1.27	0.51	1.21	0.48	0.12	0.05	NC	-
VO 2046	Subgroup of eggplants	RAC	0.04	1.31	0.05	8.26	0.33	3.95	0.16	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	2.3	0.29	0.67	0.03	0.07	6.71	15.43	0.01	0.02	NC	-
VL 0502	Spinach, raw	RAC	3.8	0.17	0.65	0.01	0.04	0.81	3.08	0.01	0.04	NC	-
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.28	3.58	11.74	2.64	8.66	NC	-	1.83	6.00	3.65	11.97
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	*1.2*	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.1	0.21	0.02	0.02	0.00	5.51	0.55	0.02	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.04	7.11	0.28	2.33	0.09	3.76	0.15	44.70	1.79	3.27	0.13
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.04	3.70	0.15	0.03	0.00	0.17	0.01	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.04	12.77	0.51	0.99	0.04	0.01	0.00	4.33	0.17	NC	-
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	*0.176*	15.80	2.78	14.29	2.52	104.36	18.37	17.11	3.01	35.20	6.20
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrrhizus erosus)	RAC	0.04	2.54	0.10	1.77	0.07	0.03	0.00	0.03	0.00	3.99	0.16
VD 2066	Subgroup of dry peas, raw	RAC	*0.04*	4.43	0.18	11.36	0.45	4.22	0.17	9.36	0.37	1.21	0.05
VD 2067	Subgroup of dry underground pulses, raw	RAC	0.04	0.20	0.01	NC	-	NC	-	NC	-	NC	-
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.116	250.41	29.05	208.74	24.21	213.64	24.78	602.70	69.91	388.95	45.12
VS 2081	Subgroup of young shoots	RAC	0.681	3.13	2.13	2.26	1.54	1.69	1.15	2.12	1.44	4.23	2.88
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.112	116.66	13.07	10.52	1.18	38.46	4.31	76.60	8.58	34.44	3.86
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0698	Poppy seed, raw (incl oil)	RAC	0.102	0.01	0.00	0.01	0.00	0.11	0.01	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	**0.118**	0.94	0.11	0.22	0.03	32.01	3.78	12.12	1.43	0.48	0.06

HH 0722	Basil leaves, raw (incl dried)	RAC	3.08	0.25	0.77	0.18	0.55	0.13	0.40	0.17	0.52	0.33	1.02
HS 0444	Peppers, chili, dried	PP	0.4	0.58	0.23	1.27	0.51	1.21	0.48	0.12	0.05	NC	-
DH 1100	Hops, dry	RAC	1.55	NC	-	NC	-	0.04	0.06	NC	-	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				67.7		47.1		99.5		94.6		80.8
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				240000		240000		240000		240000		240000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0–0.07 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.22	4.82	1.06	2.45	0.54	3.93	0.86	25.44	5.60	8.74	1.92	16.23	3.57
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.22	6.18	1.36	3.66	0.81	0.25	0.06	6.82	1.50	3.49	0.77	19.38	4.26
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.22	20.66	4.55	5.23	1.15	11.90	2.62	37.90	8.34	21.16	4.66	56.46	12.42
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.046	1.27	0.06	2.20	0.10	0.09	0.00	11.81	0.54	0.46	0.02	1.69	0.08
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.11	0.66	0.07	0.69	0.08	0.96	0.11	10.20	1.12	1.25	0.14	2.97	0.33
FS 0013	Subgroup of Cherries, raw	RAC	1	0.92	0.92	9.15	9.15	0.01	0.01	0.61	0.61	0.06	0.06	6.64	6.64
FS 0014	Subgroup of Plums, raw	RAC	0.15	2.40	0.36	8.60	1.29	0.06	0.01	2.52	0.38	0.58	0.09	4.16	0.62
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.59	8.01	4.73	5.87	3.46	0.18	0.11	8.19	4.83	1.64	0.97	22.46	13.25
FB 0265	Cranberry, raw	RAC	0.3	0.02	0.01	0.01	0.00	NC	-	0.03	0.01	0.01	0.00	0.01	0.00
FI 0326	Avocado, raw	RAC	0.085	0.13	0.01	0.03	0.00	2.05	0.17	2.54	0.22	2.34	0.20	0.12	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.06	5.23	0.31	6.94	0.42	99.45	5.97	32.47	1.95	48.30	2.90	24.70	1.48
FI 0353	Pineapple, raw (incl canned pineapple, incl dried pineapple, excl pineapple juice)	RAC	0.16	0.54	0.09	0.58	0.09	7.69	1.23	6.02	0.96	8.26	1.32	0.82	0.13
JF 0341	Pineapple juice (single strength, incl concentrated)	PP	0.16	0.04	0.01	0.57	0.09	0.12	0.02	1.96	0.31	0.29	0.05	0.28	0.04
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.8	51.75	41.40	81.80	65.44	16.99	13.59	102.02	81.62	26.32	21.06	214.77	171.82
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.03	72.79	2.18	59.05	1.77	20.55	0.62	74.20	2.23	61.12	1.83	73.24	2.20
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.06	0.13	0.01	NC	-	0.08	0.00	0.66	0.04	0.47	0.03	88.94	5.34
GC 0650	Rye, raw (incl flour)	RAC	0.06	0.13	0.01	19.38	1.16	0.10	0.01	0.12	0.01	0.03	0.00	2.15	0.13
GC 0653	Triticale, raw (incl flour)	RAC	0.06	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.02	NC	-

GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.06	381.15	22.87	341.55	20.49	38.35	2.30	281.89	16.91	172.83	10.37	434.07	26.04
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.255	19.91	5.08	31.16	7.95	5.04	1.29	3.10	0.79	9.77	2.49	4.31	1.10
GC 0647	Oats, raw (incl rolled)	RAC	0.26	0.05	0.01	7.05	1.83	0.10	0.03	1.71	0.44	0.96	0.25	0.04	0.01
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	16.5	1.26	20.79	1.58	26.07	31.05	512.33	5.43	89.60	0.90	14.85	2.18	35.97
CM 1205	Rice polished, dry	PP	1.95	34.21	66.71	10.39	20.26	41.72	81.35	82.38	160.64	150.24	292.97	70.47	137.42
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.05	29.81	1.49	44.77	2.24	108.95	5.45	52.37	2.62	60.28	3.01	75.69	3.78
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.05	0.14	0.01	0.94	0.05	5.70	0.29	2.61	0.13	1.94	0.10	0.22	0.01
TN 0672	Pecan, nutmeat	RAC	0.02	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.00	0.09	0.00	0.13	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0.06	0.93	0.06	1.16	0.07	0.49	0.03	2.53	0.15	9.32	0.56	2.02	0.12
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.03	1.30	0.04	1.23	0.04	12.62	0.38	2.87	0.09	6.59	0.20	2.67	0.08
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.06	1.36	0.08	3.59	0.22	1.44	0.09	5.18	0.31	2.02	0.12	1.70	0.10
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.07	24.96	1.75	57.95	4.06	16.70	1.17	38.38	2.69	26.46	1.85	29.00	2.03
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.11	6.24	0.69	14.49	1.59	4.18	0.46	9.60	1.06	6.62	0.73	7.25	0.80
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.11	3.29	0.36	6.14	0.68	0.82	0.09	1.57	0.17	2.23	0.25	1.07	0.12
MO 0105	Edible offal (mammalian), raw	RAC	2.4	4.79	11.50	9.68	23.23	2.97	7.13	5.49	13.18	3.84	9.22	5.03	12.07
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.03	289.65	8.69	485.88	14.58	26.92	0.81	239.03	7.17	199.91	6.00	180.53	5.42
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.05	13.17	0.66	26.78	1.34	7.24	0.36	116.71	5.84	22.54	1.13	32.09	1.60
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.05	1.46	0.07	2.98	0.15	0.80	0.04	12.97	0.65	2.50	0.13	3.57	0.18

PF 0111	Poultry fat, raw (incl rendered)	RAC	0.05	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.10	0.01	0.10	0.01
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.11	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.59	0.24	0.03	0.10	0.01
PE 0112	Eggs, raw, (incl dried)	RAC	0.08	7.84	0.63	23.08	1.85	2.88	0.23	14.89	1.19	9.81	0.78	14.83	1.19
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
		Total intake (ug/person)=			198.6		212.3		639.2		414.5		381.1		450.4
		Bodyweight per region (kg bw) =			60		60		60		60		60		60
		ADI (ug/person)=			4200		4200		4200		4200		4200		4200
		%ADI=			4.7%		5.1%		15.2%		9.9%		9.1%		10.7%
		Rounded %ADI=			5%		5%		20%		10%		9%		10%

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0–0.07 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.22	10.12	2.23	15.69	3.45	2.88	0.63	12.30	2.71	22.32	4.91	6.59	1.45
FC 0003	Subgroup of mandarins, raw (incl mandarin juice)	RAC	0.22	12.42	2.73	14.99	3.30	16.08	3.54	10.78	2.37	9.94	2.19	NC	-
FC 0004	Subgroup of oranges, sweet, sour, raw	RAC	0.22	15.68	3.45	24.00	5.28	6.80	1.50	29.09	6.40	15.39	3.39	160.47	35.30
JF 0004	Subgroup of oranges, juice (single strength, incl. concentrated)	PP	0.046	33.31	1.53	1.78	0.08	0.28	0.01	18.97	0.87	14.01	0.64	13.36	0.61
FC 0005	Subgroup of pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.11	8.21	0.90	4.60	0.51	0.64	0.07	5.85	0.64	19.98	2.20	368.86	40.57
FS 0013	Subgroup of cherries, raw	RAC	1	1.40	1.40	4.21	4.21	0.04	0.04	2.93	2.93	1.50	1.50	NC	-
FS 0014	Subgroup of plums, raw	RAC	0.15	3.75	0.56	3.33	0.50	5.94	0.89	2.64	0.40	2.50	0.38	0.06	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.59	13.03	7.69	16.29	9.61	8.29	4.89	12.95	7.64	5.35	3.16	0.04	0.02
FB 0265	Cranberry, raw	RAC	0.3	0.06	0.02	0.01	0.00	0.01	0.00	1.22	0.37	0.11	0.03	NC	-

FI 0326	Avocado, raw	RAC	0.085	2.65	0.23	0.87	0.07	0.46	0.04	1.64	0.14	1.30	0.11	0.96	0.08
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.06	25.76	1.55	23.65	1.42	23.83	1.43	24.37	1.46	19.43	1.17	101.55	6.09
FI 0353	Pineapple, raw (incl canned pineapple, incl dried pineapple, excl pineapple juice)	RAC	0.16	8.17	1.31	7.53	1.20	5.95	0.95	7.61	1.22	8.17	1.31	16.18	2.59
JF 0341	Pineapple juice (single strength, incl concentrated)	PP	0.16	2.91	0.47	2.11	0.34	0.58	0.09	3.95	0.63	16.73	2.68	1.54	0.25
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.8	64.74	51.79	68.31	54.65	36.05	28.84	82.09	65.67	54.50	43.60	11.69	9.35
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.03	106.33	3.19	117.78	3.53	42.12	1.26	195.70	5.87	222.52	6.68	80.47	2.41
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.06	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.06	3.21	0.19	35.38	2.12	0.21	0.01	6.50	0.39	1.49	0.09	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.06	0.01	0.00	0.17	0.01	0.29	0.02	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.06	253.07	15.18	244.73	14.68	134.44	8.07	235.10	14.11	216.39	12.98	167.40	10.04
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.255	36.18	9.23	53.45	13.63	9.39	2.39	35.25	8.99	46.68	11.90	15.92	4.06
GC 0647	Oats, raw (incl rolled)	RAC	0.26	7.50	1.95	6.26	1.63	0.15	0.04	4.87	1.27	3.16	0.82	2.98	0.77
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	16.5	3.70	61.05	2.11	34.82	1.51	24.92	1.75	28.88	0.29	4.79	5.12	84.48
CM 1205	Rice polished, dry	PP	1.95	13.38	26.09	10.80	21.06	262.08	511.06	57.16	111.46	12.83	25.02	62.78	122.42
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.05	18.51	0.93	26.18	1.31	26.04	1.30	39.99	2.00	7.36	0.37	64.58	3.23
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.05	11.43	0.57	3.71	0.19	0.74	0.04	13.63	0.68	3.07	0.15	1.50	0.08
TN 0672	Pecan, nutmeat	RAC	0.02	0.38	0.01	NC	-	NC	-	0.27	0.01	NC	-	0.26	0.01

SO 0495	Rape seed, raw (incl oil)	RAC	0.06	32.68	1.96	19.91	1.19	7.83	0.47	15.69	0.94	NC	-	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.03	5.63	0.17	2.75	0.08	9.58	0.29	5.82	0.17	13.71	0.41	1.84	0.06
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.06	10.90	0.65	12.44	0.75	0.77	0.05	9.48	0.57	22.07	1.32	8.15	0.49
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.07	112.02	7.84	120.71	8.45	63.46	4.44	88.99	6.23	96.24	6.74	41.02	2.87
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.11	28.01	3.08	30.18	3.32	15.86	1.75	22.25	2.45	24.06	2.65	10.25	1.13
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.11	6.44	0.71	15.51	1.71	3.79	0.42	8.29	0.91	18.44	2.03	8.00	0.88
MO 0105	Edible offal (mammalian), raw	RAC	2.4	15.17	36.41	5.19	12.46	6.30	15.12	6.78	16.27	3.32	7.97	3.17	7.61
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.03	388.92	11.67	335.88	10.08	49.15	1.47	331.25	9.94	468.56	14.06	245.45	7.36
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.05	66.38	3.32	48.47	2.42	21.58	1.08	78.41	3.92	48.04	2.40	76.01	3.80
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.05	7.38	0.37	5.39	0.27	2.40	0.12	8.71	0.44	5.34	0.27	8.45	0.42
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.05	0.10	0.01	0.10	0.01	NC	-	0.10	0.01	0.71	0.04	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.11	0.33	0.04	0.72	0.08	0.27	0.03	0.35	0.04	0.80	0.09	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.08	25.84	2.07	29.53	2.36	28.05	2.24	33.19	2.66	36.44	2.92	8.89	0.71
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				262.5		220.8		619.5		311.6		170.9		349.2
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				4200		4200		3850		4200		4200		4200
	%ADI=				6.3%		5.3%		16.1%		7.4%		4.1%		8.3%
	Rounded %ADI=				6%		5%		20%		7%		4%		8%

PROPICONAZOLE (160) International Estimated Daily Intake (IEDI) ADI = 0–0.07 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.22	18.97	4.17	0.97	0.21	6.23	1.37	0.09	0.02	3.35	0.74
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.22	0.16	0.04	0.27	0.06	9.06	1.99	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.22	1.18	0.26	1.11	0.24	14.28	3.14	0.05	0.01	1.08	0.24
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.046	0.08	0.00	0.26	0.01	12.61	0.58	0.14	0.01	0.33	0.02
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.11	0.68	0.07	0.05	0.01	3.21	0.35	0.01	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	1	0.01	0.01	0.01	0.01	5.96	5.96	0.01	0.01	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.15	0.07	0.01	0.01	0.00	15.56	2.33	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.59	0.02	0.01	0.01	0.01	10.76	6.35	0.01	0.01	NC	-
FB 0265	Cranberry, raw	RAC	0.3	NC	-	NC	-	0.03	0.01	NC	-	NC	-
FI 0326	Avocado, raw	RAC	0.085	1.12	0.10	0.01	0.00	0.84	0.07	0.01	0.00	6.60	0.56
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.06	44.80	2.69	118.17	7.09	25.25	1.52	454.49	27.27	310.23	18.61
FI 0353	Pineapple, raw (incl canned pineapple, incl dried pineapple, excl pineapple juice)	RAC	0.16	7.68	1.23	6.15	0.98	4.79	0.77	0.15	0.02	24.94	3.99
JF 0341	Pineapple juice (single strength, incl concentrated)	PP	0.16	0.49	0.08	0.07	0.01	1.23	0.20	0.02	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.8	15.50	12.40	5.78	4.62	71.52	57.22	2.00	1.60	12.50	10.00
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.03	15.80	0.47	14.29	0.43	104.36	3.13	17.11	0.51	35.20	1.06
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.06	3.93	0.24	1.68	0.10	NC	-	NC	-	36.12	2.17
GC 0650	Rye, raw (incl flour)	RAC	0.06	0.03	0.00	0.01	0.00	13.95	0.84	0.01	0.00	0.88	0.05
GC 0653	Triticale, raw (incl flour)	RAC	0.06	0.01	0.00	NC	-	NC	-	NC	-	NC	-

GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.06	57.20	3.43	110.47	6.63	272.62	16.36	25.82	1.55	132.04	7.92
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.255	11.58	2.95	2.33	0.59	46.71	11.91	3.72	0.95	16.26	4.15
GC 0647	Oats, raw (incl rolled)	RAC	0.26	0.37	0.10	0.07	0.02	2.79	0.73	0.10	0.03	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	16.5	13.58	224.07	4.29	70.79	2.17	35.81	0.01	0.17	8.84	145.86
CM 1205	Rice polished, dry	PP	1.95	30.20	58.89	218.34	425.76	12.77	24.90	15.24	29.72	51.35	100.13
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.05	116.66	5.83	10.52	0.53	38.46	1.92	76.60	3.83	34.44	1.72
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.05	3.63	0.18	20.50	1.03	8.78	0.44	0.02	0.00	0.17	0.01
TN 0672	Pecan, nutmeat	RAC	0.02	0.15	0.00	0.22	0.00	0.31	0.01	0.01	0.00	0.01	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0.06	0.19	0.01	0.07	0.00	12.07	0.72	0.08	0.00	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.03	18.82	0.56	0.57	0.02	2.28	0.07	6.90	0.21	0.53	0.02
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.06	0.95	0.06	1.32	0.08	11.64	0.70	2.96	0.18	14.73	0.88
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.07	23.34	1.63	40.71	2.85	97.15	6.80	18.06	1.26	57.71	4.04
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.11	5.84	0.64	10.18	1.12	24.29	2.67	4.52	0.50	14.43	1.59
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.11	1.05	0.12	1.14	0.13	18.69	2.06	0.94	0.10	3.12	0.34
MO 0105	Edible offal (mammalian), raw	RAC	2.4	4.64	11.14	1.97	4.73	10.01	24.02	3.27	7.85	3.98	9.55
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.03	108.75	3.26	70.31	2.11	436.11	13.08	61.55	1.85	79.09	2.37
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.05	3.53	0.18	10.83	0.54	51.36	2.57	4.53	0.23	50.00	2.50
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.05	0.39	0.02	1.20	0.06	5.71	0.29	0.50	0.03	5.56	0.28
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.05	NC	-	NC	-	0.32	0.02	NC	-	NC	-

PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.11	0.10	0.01	0.70	0.08	0.97	0.11	0.10	0.01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.08	3.84	0.31	4.41	0.35	27.25	2.18	1.13	0.09	7.39	0.59
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				335.2		531.2		233.2		78.0		319.4
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				4200		4200		4200		4200		4200
	%ADI=				8.0%		12.6%		5.6%		1.9%		7.6%
	Rounded %ADI=				8%		10%		6%		2%		8%

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0–0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.028	4.82	0.13	2.45	0.07	3.93	0.11	25.44	0.71	8.74	0.24	16.23	0.45
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.028	6.18	0.17	3.66	0.10	0.25	0.01	6.82	0.19	3.49	0.10	19.38	0.54
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.028	20.66	0.58	5.23	0.15	11.90	0.33	37.90	1.06	21.16	0.59	56.46	1.58
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.007	1.27	0.01	2.20	0.02	0.09	0.00	11.81	0.08	0.46	0.00	1.69	0.01
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.028	0.66	0.02	0.69	0.02	0.96	0.03	10.20	0.29	1.25	0.04	2.97	0.08
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.07	13.49	0.94	26.63	1.86	15.05	1.05	16.28	1.14	6.47	0.45	47.88	3.35
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	0.32	0.02	3.07	0.20	0.07	0.00	5.00	0.33	0.29	0.02	5.57	0.36
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.07	0.59	0.04	0.36	0.03	0.46	0.03	1.88	0.13	NC	-	1.15	0.08
FP 0229	Medlar, raw (incl processed)	RAC	0.07	0.47	0.03	0.29	0.02	0.36	0.03	1.49	0.10	NC	-	0.92	0.06
FP 0230	Pear, raw	RAC	0.07	2.16	0.15	6.24	0.44	0.05	0.00	4.07	0.28	1.16	0.08	5.34	0.37
FP 0307	Persimmon, Japanese, raw (i.e. Kaki fruit)	RAC	0.165	1.91	0.32	0.01	0.00	1.94	0.32	1.96	0.32	NC	-	0.25	0.04
FP 0231	Quince, raw	RAC	0.07	0.73	0.05	0.54	0.04	0.01	0.00	0.07	0.00	0.06	0.00	1.31	0.09
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.195	11.33	2.21	23.62	4.61	0.24	0.05	11.32	2.21	2.28	0.44	33.26	6.49
DF 0014	Plums, dried (prunes)	PP	0.16	0.09	0.01	0.06	0.01	0.01	0.00	0.18	0.03	0.04	0.01	0.06	0.01
FB 2005	Subgroup of Caneberries, raw	RAC	0.055	0.42	0.02	1.05	0.06	0.01	0.00	0.02	0.00	0.02	0.00	1.24	0.07
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.055	0.53	0.03	1.31	0.07	0.40	0.02	1.66	0.09	0.01	0.00	0.99	0.05
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	0.055	0.62	0.03	0.33	0.02	0.34	0.02	1.42	0.08	0.01	0.00	1.51	0.08
FB 0269	Grapes, raw (incl must, incl dried, incl juice, excl wine)	RAC	0.055	15.33	0.84	11.75	0.65	0.11	0.01	22.55	1.24	4.49	0.25	63.13	3.47

-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.055	0.67	0.04	12.53	0.69	2.01	0.11	1.21	0.07	3.53	0.19	4.01	0.22
FB 2009	Subgroup of Low growing berries, raw	RAC	0.055	0.71	0.04	2.02	0.11	0.04	0.00	1.39	0.08	0.37	0.02	2.53	0.14
FI 0326	Avocado, raw	RAC	0.08	0.13	0.01	0.03	0.00	2.05	0.16	2.54	0.20	2.34	0.19	0.12	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	5.23	0.10	6.94	0.14	99.45	1.99	32.47	0.65	48.30	0.97	24.70	0.49
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	10.48	0.31	0.01	0.00	7.24	0.22	6.87	0.21	19.98	0.60	6.25	0.19
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.01	0.61	0.01	1.56	0.02	7.89	0.08	9.36	0.09	8.76	0.09	1.30	0.01
-	Onions, dry, raw	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.53	6.43	3.41	40.26	21.34	0.80	0.42	9.94	5.27	12.07	6.40	17.73	9.40
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.105	53.14	5.58	86.21	9.05	6.28	0.66	92.76	9.74	15.64	1.64	155.30	16.31
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.08	42.04	3.36	76.13	6.09	10.69	0.86	84.59	6.77	24.92	1.99	203.27	16.26
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.24	2.34	0.56	1.33	0.32	1.57	0.38	4.24	1.02	0.34	0.08	2.83	0.68
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.054	0.29	0.02	0.29	0.02	0.01	0.00	0.38	0.02	0.05	0.00	0.14	0.01
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.08	1.97	0.16	NC	-	3.68	0.29	3.24	0.26	5.72	0.46	1.57	0.13
VO 0444	Peppers, chili, raw	RAC	0.08	3.99	0.32	7.30	0.58	2.93	0.23	5.62	0.45	NC	-	17.44	1.40
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	4.49	0.36	6.44	0.52	7.21	0.58	5.68	0.45	9.52	0.76	8.92	0.71
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.08	5.58	0.45	4.31	0.34	0.89	0.07	9.31	0.74	13.64	1.09	20.12	1.61
VL 2050	Subgroup of Leafy greens	RAC	0.54	3.93	2.12	5.28	2.85	3.07	1.66	14.53	7.85	8.25	4.46	12.75	6.89
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.08	0.68	0.05	NC	-	NC	-	0.39	0.03	0.22	0.02	0.49	0.04
014B	**Peas with pods**	**-**	0.01	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	1.56	0.02	0.60	0.01	0.49	0.00	1.18	0.01	0.90	0.01	7.79	0.08
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	3.51	0.04	0.43	0.00	0.01	0.00	0.60	0.01	0.29	0.00	0.78	0.01
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.01	1.97	0.02	0.51	0.01	0.02	0.00	0.79	0.01	3.68	0.04	3.80	0.04

VD 0070	Group of Pulses, raw (incl processed)	RAC	0.02	87.29	1.75	64.04	1.28	37.15	0.74	89.82	1.80	91.02	1.82	98.20	1.96
VD 0520	Bambara groundnut (dry) (Vigna subterranea), raw	RAC	0.01	NC	-	NC	-	0.20	0.00	NC	-	NC	-	NC	-
VR 0075	Group of root and tuber vegetables, raw (incl processed)	RAC	0.01	87.83	0.88	374.04	3.74	668.92	6.69	121.64	1.22	94.20	0.94	247.11	2.47
VS 2080	Subgroup of stems and petioles	RAC	0.215	3.11	0.67	5.52	1.19	3.42	0.74	8.29	1.78	0.02	0.00	4.00	0.86
VS 0620	Artichoke globe, raw	RAC	0.23	0.69	0.16	0.01	0.00	0.01	0.00	0.32	0.07	0.26	0.06	1.21	0.28
VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.08	0.09	0.01	0.56	0.04	0.02	0.00	2.65	0.21	0.11	0.01	0.51	0.04
GC 0653	Triticale, raw	RAC	0.032	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.032	0.01	0.00	1.12	0.04	NC	-	0.01	0.00	0.56	0.02	NC	-
-	Wheat, bulgur	PP	0.14	NC	-	NC	-	NC	-	0.03	0.00	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.0493	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.01	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.014	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.014	0.25	0.00	0.63	0.01	0.12	0.00	0.43	0.01	1.39	0.02	0.22	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00336	301.24	1.01	268.64	0.90	30.21	0.10	222.51	0.75	134.73	0.45	343.12	1.15
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.4	19.91	7.96	31.16	12.46	5.04	2.02	3.10	1.24	9.77	3.91	4.31	1.72
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl beer, incl malt, excl flour & grits)	RAC	0.112	14.50	1.62	30.61	3.43	5.01	0.56	3.08	0.34	8.88	0.99	4.29	0.48
-	Barley, pot&pearled	PP	0.03	7.12	0.21	7.34	0.22	0.02	0.00	0.03	0.00	0.67	0.02	0.20	0.01
-	Barley, flour (white flour and wholemeal flour)	PP	0.01	2.93	0.03	0.30	0.00	0.02	0.00	0.01	0.00	0.48	0.00	0.01	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.112	0.05	0.01	7.05	0.79	0.10	0.01	1.71	0.19	0.96	0.11	0.04	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.7	1.26	2.14	1.58	2.69	31.05	52.79	5.43	9.23	0.90	1.53	2.18	3.71
CM 1205	Rice polished, dry	PP	0.704	34.21	24.08	10.39	7.31	41.72	29.37	82.38	58.00	150.24	105.77	70.47	49.61
GC 0651	Sorghum, raw (incl beer, excl flour)(i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.079	NC	-	0.01	0.00	3.34	0.26	0.01	0.00	NC	-	NC	-

-	Sorghum, flour (white flour and wholemeal flour)	PP	0.0548	3.91	0.21	NC	-	11.62	0.64	14.24	0.78	9.87	0.54	2.62	0.14
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	29.81	0.60	44.77	0.90	108.95	2.18	52.37	1.05	60.28	1.21	75.69	1.51
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
GC 0447	Sweet corn on the cob, raw (i.e kernels plus cob without husks)	RAC	0.01	0.08	0.00	0.09	0.00	5.67	0.06	0.05	0.00	1.77	0.02	NC	-
-	Sugar crops NES, raw (incl sugar, syrup and others): sugar maple, sweet sorghum, sugar palm	RAC	0.033	1.30	0.04	2.72	0.09	0.92	0.03	3.26	0.11	0.71	0.02	0.90	0.03
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
TN 0672	Pecan, nutmeat	RAC	0.01	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.00	0.09	0.00	0.13	0.00
SO 0091	Subgroup of Oilseeds, raw	RAC	0.02	1.34	0.03	1.35	0.03	8.56	0.17	3.76	0.08	2.22	0.04	3.38	0.07
SO 0090	Subgroup of Mustard seeds, raw (incl flour, incl oil)	RAC	0.02	0.02	0.00	0.05	0.00	0.01	0.00	0.31	0.01	0.03	0.00	0.04	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.02	0.02	0.00	NC	-	NC	-	0.01	0.00	0.13	0.00	NC	-
SO 0698	Poppy seed, raw (incl oil)	RAC	0.02	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.93	0.02	1.16	0.02	0.49	0.01	2.53	0.05	9.32	0.19	2.02	0.04
SO 0700	Sesame seed, raw (incl oil)	RAC	0.02	1.22	0.02	0.01	0.00	0.54	0.01	4.23	0.08	0.82	0.02	2.77	0.06
SO 0699	Safflower seed, raw (incl oil)	RAC	0.02	0.03	0.00	0.20	0.00	0.01	0.00	0.01	0.00	0.29	0.01	0.01	0.00
OR 0691	Cotton seed oil, edible	PP	0.0004	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
-	Castor bean, raw (incl oil)	RAC	0.02	NC	-	0.07	0.00	NC	-	NC	-	NC	-	0.01	0.00
SO 0696	Palm kernels, raw (incl oil)	RAC	0.02	5.81	0.12	3.77	0.08	20.07	0.40	24.53	0.49	5.94	0.12	8.99	0.18
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	1.30	0.03	1.23	0.02	12.62	0.25	2.87	0.06	6.59	0.13	2.67	0.05
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.02	NC	-	NC	-	0.34	0.01	NC	-	NC	-	NC	-
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.02	12.61	0.25	1.35	0.03	0.27	0.01	8.04	0.16	0.58	0.01	21.80	0.44
SO 0696	Palm fruit (African Oil Palm), raw (incl oil)	RAC	0.02	28.87	0.58	1.09	0.02	53.08	1.06	80.61	1.61	24.20	0.48	17.72	0.35
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.72	0.01	4.20	0.08	0.60	0.01	4.21	0.08	0.42	0.01	0.78	0.02
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.035	0.96	0.03	0.16	0.01	0.91	0.03	0.27	0.01	1.37	0.05	0.46	0.02

SM 0716	Coffee bean, roasted	PP	0.0049	0.19	0.00	0.91	0.00	0.16	0.00	2.50	0.01	0.39	0.00	0.40	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.035	0.07	0.00	0.94	0.03	0.07	0.00	0.70	0.02	0.07	0.00	0.29	0.01
-	Coffee bean, substitutes, containing coffee	PP	0.035	0.01	0.00	0.01	0.00	0.16	0.01	0.17	0.01	0.02	0.00	0.03	0.00
HH 0738	Mint, raw	RAC	0.34	0.50	0.17	0.01	0.00	NC	-	NC	-	NC	-	NC	-
HS 0780	Cumin, seed	RAC	0.26	0.08	0.02	0.01	0.00	0.01	0.00	0.19	0.05	0.04	0.01	0.05	0.01
HS 0444	Peppers, chili, dried	PP	0.8	0.42	0.34	0.53	0.42	0.84	0.67	0.50	0.40	0.95	0.76	0.37	0.30
DH 1100	Hops, dry	RAC	0.028	0.01	0.00	0.04	0.00	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.1	2.28	9.35	1.98	8.12	0.46	1.89	2.43	9.96	1.29	5.29	3.04	12.46
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0.062	31.20	1.93	72.44	4.49	20.88	1.29	47.98	2.97	33.08	2.05	36.25	2.25
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	3.29	0.03	6.14	0.06	0.82	0.01	1.57	0.02	2.23	0.02	1.07	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.041	4.79	0.20	9.68	0.40	2.97	0.12	5.49	0.23	3.84	0.16	5.03	0.21
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.096	289.65	27.81	485.88	46.64	26.92	2.58	239.03	22.95	199.91	19.19	180.53	17.33
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.064	14.63	0.94	29.76	1.90	8.04	0.51	129.68	8.30	25.04	1.60	35.66	2.28
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.033	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.36	0.12	0.04	0.12	0.04	0.11	0.04	5.37	1.93	0.24	0.09	0.10	0.04
PE 0112	Eggs, raw, (incl dried)	RAC	0.028	7.84	0.22	23.08	0.65	2.88	0.08	14.89	0.42	9.81	0.27	14.83	0.42
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				106.5		149.0		115.3		169.4		169.5		172.9
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				4800		4800		4800		4800		4800		4800
	%ADI=				2.2%		3.1%		2.4%		3.5%		3.5%		3.6%
	Rounded %ADI=				2%		3%		2%		4%		4%		4%

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.028	10.12	0.28	15.69	0.44	2.88	0.08	12.30	0.34	22.32	0.62	6.59	0.18
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.028	12.42	0.35	14.99	0.42	16.08	0.45	10.78	0.30	9.94	0.28	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.028	15.68	0.44	24.00	0.67	6.80	0.19	29.09	0.81	15.39	0.43	160.47	4.49
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.007	33.31	0.23	1.78	0.01	0.28	0.00	18.97	0.13	14.01	0.10	13.36	0.09
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.028	8.21	0.23	4.60	0.13	0.64	0.02	5.85	0.16	19.98	0.56	368.86	10.33
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.07	41.14	2.88	56.49	3.95	26.64	1.86	31.58	2.21	51.94	3.64	3.05	0.21
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	14.88	0.97	11.98	0.78	0.15	0.01	9.98	0.65	30.32	1.97	3.47	0.23
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.07	0.96	0.07	NC	-	NC	-	3.92	0.27	NC	-	2.49	0.17
FP 0229	Medlar, raw (incl processed)	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.14
FP 0230	Pear, raw	RAC	0.07	8.79	0.62	8.44	0.59	12.37	0.87	9.60	0.67	10.27	0.72	0.23	0.02
FP 0307	Persimmon, Japanese, raw (i.e. Kaki fruit)	RAC	0.165	0.01	0.00	0.30	0.05	3.59	0.59	0.15	0.02	0.02	0.00	NC	-
FP 0231	Quince, raw	RAC	0.07	0.19	0.01	0.18	0.01	0.11	0.01	0.04	0.00	0.28	0.02	NC	-
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.195	18.18	3.55	23.83	4.65	14.27	2.78	18.52	3.61	9.35	1.82	0.11	0.02
DF 0014	Plums, dried (prunes)	PP	0.16	0.61	0.10	0.35	0.06	0.05	0.01	0.35	0.06	0.49	0.08	0.13	0.02
FB 2005	Subgroup of Caneberries, raw	RAC	0.055	0.56	0.03	1.43	0.08	0.14	0.01	1.23	0.07	1.14	0.06	0.01	0.00

FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.055	1.31	0.07	5.50	0.30	0.01	0.00	2.57	0.14	0.82	0.05	2.15	0.12
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	0.055	8.26	0.45	0.14	0.01	0.07	0.00	0.13	0.01	0.19	0.01	1.87	0.10
FB 0269	Grapes, raw (incl must, incl dried, incl juice, excl wine)	RAC	0.055	20.07	1.10	20.04	1.10	5.35	0.29	18.01	0.99	25.20	1.39	2.94	0.16
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.055	88.93	4.89	62.41	3.43	1.84	0.10	25.07	1.38	61.17	3.36	5.84	0.32
FB 2009	Subgroup of Low growing berries, raw	RAC	0.055	4.55	0.25	5.66	0.31	0.02	0.00	7.85	0.43	5.86	0.32	0.05	0.00
FI 0326	Avocado, raw	RAC	0.08	2.65	0.21	0.87	0.07	0.46	0.04	1.64	0.13	1.30	0.10	0.96	0.08
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	25.76	0.52	23.65	0.47	23.83	0.48	24.37	0.49	19.43	0.39	101.55	2.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	1.80	0.05	0.63	0.02	10.05	0.30	1.07	0.03	3.52	0.11	16.44	0.49
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.01	13.13	0.13	11.13	0.11	6.94	0.07	14.36	0.14	36.74	0.37	18.81	0.19
-	Onions, dry, raw	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.53	20.71	10.98	39.81	21.10	25.06	13.28	37.93	20.10	18.12	9.60	16.74	8.87
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.105	27.81	2.92	41.93	4.40	123.30	12.95	49.47	5.19	15.95	1.67	35.99	3.78
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.08	43.88	3.51	55.41	4.43	35.38	2.83	74.88	5.99	26.50	2.12	9.51	0.76
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.24	4.96	1.19	3.20	0.77	0.15	0.04	1.61	0.39	6.88	1.65	0.52	0.12
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.054	0.80	0.04	0.07	0.00	0.05	0.00	0.61	0.03	0.40	0.02	0.08	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.08	NC	-	NC	-	0.04	0.00	0.17	0.01	NC	-	0.72	0.06
VO 0444	Peppers, chili, raw	RAC	0.08	5.57	0.45	14.00	1.12	8.25	0.66	5.77	0.46	6.44	0.52	2.53	0.20
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	0.82	0.07	1.53	0.12	10.85	0.87	4.59	0.37	1.84	0.15	2.00	0.16
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.08	1.01	0.08	1.69	0.14	21.37	1.71	3.00	0.24	1.40	0.11	NC	-

VL 2050	Subgroup of Leafy greens	RAC	0.54	18.38	9.93	18.73	10.11	82.36	44.47	25.32	13.67	17.60	9.50	7.37	3.98
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.08	5.07	0.41	0.83	0.07	0.17	0.01	3.70	0.30	NC	-	NC	-
014B	**Peas with pods**	**-**	0.01	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	2.21	0.02	5.25	0.05	4.17	0.04	1.61	0.02	16.95	0.17	0.17	0.00
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	0.22	0.00	0.84	0.01	0.15	0.00	0.48	0.00	2.04	0.02	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.01	10.72	0.11	1.99	0.02	2.72	0.03	4.26	0.04	4.23	0.04	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.02	112.88	2.26	123.05	2.46	47.73	0.95	204.75	4.10	227.52	4.55	110.05	2.20
VD 0520	Bambara groundnut (dry) (Vigna subterranea), raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.01	290.31	2.90	300.35	3.00	214.25	2.14	242.72	2.43	348.67	3.49	137.52	1.38
VS 2080	Subgroup of stems and petioles	RAC	0.215	9.31	2.00	8.57	1.84	NC	-	3.88	0.83	24.46	5.26	5.89	1.27
VS 0620	Artichoke globe, raw	RAC	0.23	0.98	0.23	3.65	0.84	0.07	0.02	1.67	0.38	0.26	0.06	NC	-
VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.08	7.31	0.58	5.92	0.47	1.26	0.10	3.73	0.30	14.85	1.19	0.57	0.05
GC 0653	Triticale, raw	RAC	0.032	NC	-	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.032	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
-	Wheat, bulgur	PP	0.14	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.0493	0.97	0.05	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.014	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CP 1211	Wheat, white bread	PP	0.014	1.30	0.02	0.46	0.01	0.06	0.00	0.22	0.00	2.44	0.03	0.77	0.01
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	4.36	0.09	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00336	198.08	0.67	193.03	0.65	106.24	0.36	185.09	0.62	168.67	0.57	131.59	0.44
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.4	36.18	14.47	53.45	21.38	9.39	3.76	35.25	14.10	46.68	18.67	15.92	6.37

GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl beer, incl malt, excl flour & grits)	RAC	0.112	36.04	4.04	53.39	5.98	9.38	1.05	35.17	3.94	45.43	5.09	15.82	1.77
-	Barley, pot&pearled	PP	0.03	0.57	0.02	2.56	0.08	0.33	0.01	0.56	0.02	0.36	0.01	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.01	0.08	0.00	0.03	0.00	0.01	0.00	0.05	0.00	0.68	0.01	0.05	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.112	7.50	0.84	6.26	0.70	0.15	0.02	4.87	0.55	3.16	0.35	2.98	0.33
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.7	3.70	6.29	2.11	3.59	1.51	2.57	1.75	2.98	0.29	0.49	5.12	8.70
CM 1205	Rice polished, dry	PP	0.704	13.38	9.42	10.80	7.60	262.08	184.50	57.16	40.24	12.83	9.03	62.78	44.20
GC 0651	Sorghum, raw (incl beer, excl flour)(i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.079	NC	-	NC	-	0.01	0.00	1.15	0.09	NC	-	7.12	0.56
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.0548	NC	-	NC	-	1.29	0.07	0.01	0.00	NC	-	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	18.51	0.37	26.18	0.52	26.04	0.52	39.99	0.80	7.36	0.15	64.58	1.29
GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
GC 0447	Sweet corn on the cob, raw (i.e kernels plus cob without husks)	RAC	0.01	4.94	0.05	0.30	0.00	0.58	0.01	5.33	0.05	0.07	0.00	NC	-
-	Sugar crops NES, raw (incl sugar, syrup and others): sugar maple, sweet sorghum, sugar palm	RAC	0.033	4.87	0.16	2.50	0.08	0.89	0.03	40.03	1.32	1.05	0.03	2.83	0.09
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
TN 0672	Pecan, nutmeat	RAC	0.01	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00
SO 0091	Subgroup of Oilseeds, raw	RAC	0.02	2.58	0.05	4.10	0.08	5.77	0.12	6.63	0.13	1.81	0.04	0.64	0.01
SO 0090	Subgroup of Mustard seeds, raw (incl flour, incl oil)	RAC	0.02	0.30	0.01	0.48	0.01	0.33	0.01	0.63	0.01	1.03	0.02	0.40	0.01
SO 0693	Linseed, raw (incl oil)	RAC	0.02	NC	-	NC	-	0.02	0.00	0.01	0.00	NC	-	NC	-
SO 0698	Poppy seed, raw (incl oil)	RAC	0.02	0.02	0.00	0.25	0.01	0.01	0.00	0.02	0.00	NC	-	NC	-

SO 0495	Rape seed, raw (incl oil)	RAC	0.02	32.68	0.65	19.91	0.40	7.83	0.16	15.69	0.31	NC	-	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.02	0.61	0.01	0.09	0.00	1.53	0.03	0.85	0.02	0.08	0.00	0.14	0.00
SO 0699	Safflower seed, raw (incl oil)	RAC	0.02	0.02	0.00	0.01	0.00	0.01	0.00	0.16	0.00	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0004	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
-	Castor bean, raw (incl oil)	RAC	0.02	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
SO 0696	Palm kernels, raw (incl oil)	RAC	0.02	5.33	0.11	5.04	0.10	11.83	0.24	7.94	0.16	10.77	0.22	4.53	0.09
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	5.63	0.11	2.75	0.06	9.58	0.19	5.82	0.12	13.71	0.27	1.84	0.04
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.02	17.78	0.36	48.67	0.97	0.10	0.00	22.50	0.45	14.09	0.28	2.46	0.05
SO 0696	Palm fruit (African Oil Palm), raw (incl oil)	RAC	0.02	12.11	0.24	1.38	0.03	24.43	0.49	6.52	0.13	14.27	0.29	1.35	0.03
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	7.54	0.15	5.59	0.11	0.29	0.01	4.14	0.08	1.27	0.03	5.29	0.11
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.035	0.60	0.02	NC	-	0.62	0.02	1.71	0.06	NC	-	3.51	0.12
SM 0716	Coffee bean, roasted	PP	0.0049	7.02	0.03	9.75	0.05	0.02	0.00	5.09	0.02	13.38	0.07	0.77	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.035	0.75	0.03	0.30	0.01	0.04	0.00	0.67	0.02	2.43	0.09	1.43	0.05
-	Coffee bean, substitutes, containing coffee	PP	0.035	0.08	0.00	0.09	0.00	0.02	0.00	0.02	0.00	0.07	0.00	0.15	0.01
HH 0738	Mint, raw	RAC	0.34	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
HS 0780	Cumin, seed	RAC	0.26	0.11	0.03	0.04	0.01	NC	-	0.02	0.01	0.06	0.02	0.01	0.00
HS 0444	Peppers, chili, dried	PP	0.8	0.11	0.09	0.21	0.17	0.36	0.29	0.21	0.17	0.25	0.20	0.15	0.12
DH 1100	Hops, dry	RAC	0.028	NC	-	NC	-	0.02	0.00	0.02	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.1	2.91	11.93	1.73	7.09	1.14	4.67	1.85	7.59	2.29	9.39	0.74	3.03
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0.062	140.03	8.68	150.89	9.36	79.32	4.92	111.24	6.90	120.30	7.46	51.27	3.18

MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	6.44	0.06	15.51	0.16	3.79	0.04	8.29	0.08	18.44	0.18	8.00	0.08
MO 0105	Edible offal (mammalian), raw	RAC	0.041	15.17	0.62	5.19	0.21	6.30	0.26	6.78	0.28	3.32	0.14	3.17	0.13
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.096	388.92	37.34	335.88	32.24	49.15	4.72	331.25	31.80	468.56	44.98	245.45	23.56
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.064	73.76	4.72	53.86	3.45	23.98	1.53	87.12	5.58	53.38	3.42	84.45	5.40
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.033	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.02	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.36	0.33	0.12	0.72	0.26	0.27	0.10	0.35	0.13	0.80	0.29	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.028	25.84	0.72	29.53	0.83	28.05	0.79	33.19	0.93	36.44	1.02	8.89	0.25
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				158.0		165.3		300.1		188.3		159.6		142.7
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				4800		4800		4400		4800		4800		4800
	%ADI=				3.3%		3.4%		6.8%		3.9%		3.3%		3.0%
	Rounded %ADI=				3%		3%		7%		4%		3%		3%

THIAMETHOXAM (245) International Estimated Daily Intake (IEDI) ADI = 0–0.08 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.028	18.97	0.53	0.97	0.03	6.23	0.17	0.09	0.00	3.35	0.09
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.028	0.16	0.00	0.27	0.01	9.06	0.25	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.028	1.18	0.03	1.11	0.03	14.28	0.40	0.05	0.00	1.08	0.03
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.007	0.08	0.00	0.26	0.00	12.61	0.09	0.14	0.00	0.33	0.00

FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.028	0.68	0.02	0.05	0.00	3.21	0.09	0.01	0.00	NC	-
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.07	66.67	4.67	2.06	0.14	55.83	3.91	188.29	13.18	1.38	0.10
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.065	0.03	0.00	0.10	0.01	7.19	0.47	0.03	0.00	NC	-
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.07	0.94	0.07	4.68	0.33	NC	-	0.50	0.04	3.08	0.22
FP 0229	Medlar, raw (incl processed)	RAC	0.07	0.75	0.05	3.73	0.26	4.87	0.34	0.40	0.03	2.45	0.17
FP 0230	Pear, raw	RAC	0.07	0.07	0.00	0.14	0.01	9.45	0.66	0.01	0.00	0.14	0.01
FP 0307	Persimmon, Japanese, raw (i.e. Kaki fruit)	RAC	0.165	0.41	0.07	0.32	0.05	0.02	0.00	0.58	0.10	12.51	2.06
FP 0231	Quince, raw	RAC	0.07	NC	-	NC	-	0.65	0.05	NC	-	NC	-
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.195	0.09	0.02	0.02	0.00	32.27	6.29	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.16	0.01	0.00	0.01	0.00	0.37	0.06	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.055	0.01	0.00	7.30	0.40	2.29	0.13	0.01	0.00	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.055	0.82	0.05	4.05	0.22	5.94	0.33	0.43	0.02	2.66	0.15
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	0.055	0.71	0.04	7.32	0.40	NC	-	0.38	0.02	2.32	0.13
FB 0269	Grapes, raw (incl must, incl dried, incl juice, excl wine)	RAC	0.055	0.17	0.01	0.94	0.05	20.24	1.11	0.03	0.00	0.40	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.055	0.31	0.02	0.23	0.01	60.43	3.32	0.52	0.03	31.91	1.76
FB 2009	Subgroup of Low growing berries, raw	RAC	0.055	0.01	0.00	0.01	0.00	3.37	0.19	0.01	0.00	0.01	0.00
FI 0326	Avocado, raw	RAC	0.08	1.12	0.09	0.01	0.00	0.84	0.07	0.01	0.00	6.60	0.53
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	44.80	0.90	118.17	2.36	25.25	0.51	454.49	9.09	310.23	6.20
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.03	12.25	0.37	6.83	0.20	0.76	0.02	0.01	0.00	20.12	0.60
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0.01	8.51	0.09	6.27	0.06	6.89	0.07	0.18	0.00	24.94	0.25
-	Onions, dry, raw	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02

VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.53	5.46	2.89	4.28	2.27	58.72	31.12	0.02	0.01	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.105	5.96	0.63	9.74	1.02	51.82	5.44	13.61	1.43	0.05	0.01
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.08	13.10	1.05	4.90	0.39	62.16	4.97	1.04	0.08	0.09	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.24	0.58	0.14	0.22	0.05	2.21	0.53	0.24	0.06	3.10	0.74
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.054	0.05	0.00	0.01	0.00	0.42	0.02	0.01	0.00	0.02	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.08	6.23	0.50	0.10	0.01	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.08	3.47	0.28	3.56	0.28	16.30	1.30	0.01	0.00	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.08	5.49	0.44	10.57	0.85	8.84	0.71	0.91	0.07	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.08	1.31	0.10	8.26	0.66	3.95	0.32	0.01	0.00	NC	-
VL 2050	Subgroup of Leafy greens	RAC	0.54	4.99	2.69	3.29	1.78	7.53	4.07	3.05	1.65	6.09	3.29
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.08	NC	-	NC	-	NC	-	NC	-	NC	-
014B	**Peas with pods**	**-**	0.01	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	0.30	0.00	3.13	0.03	4.11	0.04	0.01	0.00	NC	-
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	0.07	0.00	0.01	0.00	0.76	0.01	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.01	0.21	0.00	0.02	0.00	5.51	0.06	0.02	0.00	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.02	46.57	0.93	30.77	0.62	112.53	2.25	75.53	1.51	43.68	0.87
VD 0520	Bambara groundnut (dry) (Vigna subterranea), raw	RAC	0.01	0.20	0.00	NC	-	NC	-	NC	-	NC	-
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.01	282.25	2.82	232.11	2.32	281.91	2.82	620.21	6.20	459.96	4.60
VS 2080	Subgroup of stems and petioles	RAC	0.215	5.33	1.15	3.85	0.83	5.80	1.25	3.60	0.77	7.20	1.55
VS 0620	Artichoke globe, raw	RAC	0.23	0.01	0.00	NC	-	0.08	0.02	0.01	0.00	NC	-

VF 2084	Group of edible fungi (cultivated & wild), raw (incl canned, incl dried)	RAC	0.08	0.02	0.00	0.04	0.00	3.73	0.30	0.01	0.00	NC	-
GC 0653	Triticale, raw	RAC	0.032	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	0.032	NC	-	NC	-	NC	-	NC	-	0.97	0.03
-	Wheat, bulgur	PP	0.14	0.01	0.00	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.0493	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.014	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.014	0.43	0.01	0.41	0.01	1.56	0.02	0.11	0.00	0.07	0.00
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00336	44.78	0.15	86.96	0.29	214.05	0.72	20.31	0.07	103.60	0.35
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.4	11.58	4.63	2.33	0.93	46.71	18.68	3.72	1.49	16.26	6.50
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl beer, incl malt, excl flour & grits)	RAC	0.112	11.54	1.29	2.33	0.26	46.13	5.17	3.72	0.42	16.26	1.82
-	Barley, pot&pearled	PP	0.03	5.46	0.16	0.01	0.00	1.44	0.04	0.01	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.01	0.02	0.00	NC	-	0.32	0.00	0.01	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.112	0.37	0.04	0.07	0.01	2.79	0.31	0.10	0.01	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	1.7	13.58	23.09	4.29	7.29	2.17	3.69	0.01	0.02	8.84	15.03
CM 1205	Rice polished, dry	PP	0.704	30.20	21.26	218.34	153.71	12.77	8.99	15.24	10.73	51.35	36.15
GC 0651	Sorghum, raw (incl beer, excl flour)(i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.079	4.73	0.37	NC	-	NC	-	13.36	1.06	NC	-
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.0548	75.99	4.16	1.82	0.10	NC	-	19.82	1.09	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl oil, incl beer, incl germ, incl starch)	RAC	0.02	116.66	2.33	10.52	0.21	38.46	0.77	76.60	1.53	34.44	0.69

GC 0447	Sweet corn on the cob, raw (incl frozen kernels, incl canned kernels)	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
GC 0447	Sweet corn on the cob, raw (i.e kernels plus cob without husks)	RAC	0.01	3.61	0.04	20.45	0.20	6.00	0.06	0.01	0.00	0.17	0.00
-	Sugar crops NES, raw (incl sugar, syrup and others): sugar maple, sweet sorghum, sugar palm	RAC	0.033	0.49	0.02	0.63	0.02	4.52	0.15	0.40	0.01	5.87	0.19
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
TN 0672	Pecan, nutmeat	RAC	0.01	0.15	0.00	0.22	0.00	0.31	0.00	0.01	0.00	0.01	0.00
SO 0091	Subgroup of Oilseeds, raw	RAC	0.02	9.97	0.20	0.84	0.02	1.73	0.03	13.57	0.27	0.53	0.01
SO 0090	Subgroup of Mustard seeds, raw (incl flour, incl oil)	RAC	0.02	0.04	0.00	0.19	0.00	0.32	0.01	0.06	0.00	0.01	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.02	0.07	0.00	NC	-	0.03	0.00	NC	-	NC	-
SO 0698	Poppy seed, raw (incl oil)	RAC	0.02	0.01	0.00	0.01	0.00	0.11	0.00	NC	-	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0.02	0.19	0.00	0.07	0.00	12.07	0.24	0.08	0.00	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.02	2.34	0.05	0.66	0.01	0.26	0.01	9.84	0.20	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.02	0.05	0.00	NC	-	NC	-	NC	-	NC	-
OR 0691	Cotton seed oil, edible	PP	0.0004	1.28	0.00	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
-	Castor bean, raw (incl oil)	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0696	Palm kernels, raw (incl oil)	RAC	0.02	60.84	1.22	12.77	0.26	5.41	0.11	0.57	0.01	53.45	1.07
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, incl butter)	RAC	0.02	18.82	0.38	0.57	0.01	2.28	0.05	6.90	0.14	0.53	0.01
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.02	0.95	0.02	NC	-	NC	-	NC	-	NC	-
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.02	0.18	0.00	0.11	0.00	11.00	0.22	0.06	0.00	0.49	0.01
SO 0696	Palm fruit (African Oil Palm), raw (incl oil)	RAC	0.02	36.35	0.73	7.16	0.14	2.99	0.06	22.89	0.46	28.38	0.57
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.11	0.00	0.89	0.02	6.28	0.13	0.17	0.00	2.31	0.05
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.035	0.83	0.03	0.69	0.02	1.09	0.04	2.91	0.10	0.82	0.03
SM 0716	Coffee bean, roasted	PP	0.0049	0.02	0.00	0.41	0.00	7.50	0.04	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.035	0.03	0.00	0.05	0.00	0.60	0.02	0.01	0.00	5.53	0.19

-	Coffee bean, substitutes, containing coffee	PP	0.035	0.01	0.00	0.03	0.00	0.13	0.00	0.01	0.00	NC	-
HH 0738	Mint, raw	RAC	0.34	NC	-	NC	-	NC	-	NC	-	NC	-
HS 0780	Cumin, seed	RAC	0.26	0.01	0.00	0.25	0.07	NC	-	0.01	0.00	0.01	0.00
HS 0444	Peppers, chili, dried	PP	0.8	0.58	0.46	1.27	1.02	1.21	0.97	0.12	0.10	NC	-
DH 1100	Hops, dry	RAC	0.028	NC	-	NC	-	0.04	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	4.1	0.53	2.17	5.25	21.53	0.86	3.53	0.56	2.30	0.88	3.61
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0.062	29.18	1.81	50.89	3.16	121.44	7.53	22.58	1.40	72.14	4.47
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.01	1.05	0.01	1.14	0.01	18.69	0.19	0.94	0.01	3.12	0.03
MO 0105	Edible offal (mammalian), raw	RAC	0.041	4.64	0.19	1.97	0.08	10.01	0.41	3.27	0.13	3.98	0.16
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.096	108.75	10.44	70.31	6.75	436.11	41.87	61.55	5.91	79.09	7.59
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.064	3.92	0.25	12.03	0.77	57.07	3.65	5.03	0.32	55.56	3.56
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.033	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.36	0.10	0.04	0.70	0.25	0.97	0.35	0.10	0.04	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.028	3.84	0.11	4.41	0.12	27.25	0.76	1.13	0.03	7.39	0.21
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				96.5		214.8		173.0		62.3		108.9
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				4800		4800		4800		4800		4800
	%ADI=				2.0%		4.5%		3.6%		1.3%		2.3%
	Rounded %ADI=				2%		4%		4%		1%		2%

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0–0.1 mg/kg bw

			STMR	**Diets as g/person/day**		**Intake as ug/person/day**									
Codex Code	Commodity description	Expr as	mg/kg	G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake

FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.02	34.91	0.70	16.51	0.33	17.23	0.34	104.48	2.09	35.57	0.71	98.49	1.97
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.1	19.79	1.98	38.25	3.83	17.96	1.80	32.56	3.26	8.08	0.81	64.45	6.45
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.04	11.33	0.45	23.62	0.94	0.24	0.01	11.32	0.45	2.28	0.09	33.26	1.33
DF 0014	Plums, dried (prunes)	PP	0.07	0.09	0.01	0.06	0.00	0.01	0.00	0.18	0.01	0.04	0.00	0.06	0.00
FB 2005	Subgroup of Caneberries, raw	RAC	0.01	0.42	0.00	1.05	0.01	0.01	0.00	0.02	0.00	0.02	0.00	1.24	0.01
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.01	0.53	0.01	1.31	0.01	0.40	0.00	1.66	0.02	0.01	0.00	0.99	0.01
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	0.01	0.62	0.01	0.33	0.00	0.34	0.00	1.42	0.01	0.01	0.00	1.51	0.02
FB 0269	Grapes, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.12	13.94	1.67	26.46	3.18	2.79	0.33	18.58	2.23	8.54	1.02	59.95	7.19
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	0.51	0.16	0.51	0.16	0.01	0.00	1.27	0.39	0.12	0.04	2.07	0.64
JF 0269	Grape juice (from wine grapes)	PP	0.18	0.14	0.03	0.29	0.05	0.05	0.01	0.30	0.05	0.24	0.04	0.05	0.01
FI 0326	Avocado, raw	RAC	0.01	0.13	0.00	0.03	0.00	2.05	0.02	2.54	0.03	2.34	0.02	0.12	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	5.23	0.10	6.94	0.14	99.45	1.99	32.47	0.65	48.30	0.97	24.70	0.49
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	10.48	0.21	0.01	0.00	7.24	0.14	6.87	0.14	19.98	0.40	6.25	0.13
FI 0350	Papaya, raw	RAC	0	0.35	0.00	0.01	0.00	3.05	0.00	0.80	0.00	7.28	0.00	1.00	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	0.61	0.00	1.56	0.00	7.89	0.00	9.36	0.00	8.76	0.00	1.30	0.00
-	Onions, dry, raw	RAC	0.01	29.36	0.29	37.50	0.38	3.56	0.04	34.78	0.35	18.81	0.19	43.38	0.43
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.015	6.43	0.10	40.26	0.60	0.80	0.01	9.94	0.15	12.07	0.18	17.73	0.27
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.02	53.14	1.06	86.21	1.72	6.28	0.13	92.76	1.86	15.64	0.31	155.30	3.11
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.02	67.79	1.36	99.85	2.00	31.70	0.63	125.86	2.52	55.22	1.10	262.82	5.26
VL 0053	Group of Leafy vegetables, raw	RAC	0.52	8.47	4.40	22.36	11.63	7.74	4.02	25.51	13.27	45.77	23.80	21.22	11.03

VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.07	0.68	0.05	NC	-	NC	-	0.39	0.03	0.22	0.02	0.49	0.03
014B	**Peas with pods**	**-**	0.01	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	1.56	0.02	0.60	0.01	0.49	0.00	1.18	0.01	0.90	0.01	7.79	0.08
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	3.51	0.04	0.43	0.00	0.01	0.00	0.60	0.01	0.29	0.00	0.78	0.01
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.01	1.97	0.02	0.51	0.01	0.02	0.00	0.79	0.01	3.68	0.04	3.80	0.04
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.02	87.29	1.75	64.04	1.28	37.15	0.74	89.82	1.80	91.02	1.82	98.20	1.96
VD 0520	Bambara groundnut (dry) (Vigna subterranea), raw	RAC	0.01	NC	-	NC	-	0.20	0.00	NC	-	NC	-	NC	-
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.02	87.83	1.76	374.04	7.48	668.92	13.38	121.64	2.43	94.20	1.88	247.11	4.94
VS 2080	Subgroup of stems and petioles	RAC	0.01	3.11	0.03	5.52	0.06	3.42	0.03	8.29	0.08	0.02	0.00	4.00	0.04
VS 0621	Asparagus, raw	RAC	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.07	0.00	0.21	0.00
VS 0622	Bamboo shoots, raw	RAC	0.01	1.72	0.02	3.05	0.03	1.89	0.02	4.59	0.05	NC	-	2.21	0.02
VS 0620	Artichoke globe, raw	RAC	0.025	0.69	0.02	0.01	0.00	0.01	0.00	0.32	0.01	0.26	0.01	1.21	0.03
VS 0626	Palm hearts, raw	RAC	0.01	0.39	0.00	0.70	0.01	0.43	0.00	1.05	0.01	2.27	0.02	0.51	0.01
GC 0650	Rye, raw	RAC	0.01	NC	-	NC	-	0.02	0.00	0.01	0.00	0.01	0.00	0.01	0.00
CF 1250	Rye, flour (white flour and wholemeal flour)	PP	0.00645	0.11	0.00	15.51	0.10	0.06	0.00	0.10	0.00	0.03	0.00	1.72	0.01
GC 0653	Triticale, raw	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-
GC 0653	Triticale, flour (white flour and wholemeal flour)	PP	0.00645	NC	-	NC	-	NC	-	NC	-	0.31	0.00	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	0.01	0.00	1.12	0.01	NC	-	0.03	0.00	0.56	0.01	NC	-
CF 1210	Wheat, germ	PP	0.018	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.01	0.25	0.00	0.63	0.01	0.12	0.00	0.43	0.00	1.39	0.01	0.22	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00645	301.24	1.94	268.64	1.73	30.21	0.19	222.51	1.44	134.73	0.87	343.12	2.21
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.015	3.55	0.05	19.31	0.29	4.98	0.07	3.02	0.05	7.85	0.12	3.98	0.06

-	Barley, flour (white flour and wholemeal flour)	PP	0.0097	2.93	0.03	0.30	0.00	0.02	0.00	0.01	0.00	0.48	0.00	0.01	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.015	0.05	0.00	7.05	0.11	0.10	0.00	1.71	0.03	0.96	0.01	0.04	0.00
CM 0649 (GC 0649)	Rice, husked, dry (incl beverages, incl starch, excl polished, excl flour, excl oil)	REP	0.145	1.17	0.17	1.30	0.19	31.05	4.50	4.79	0.69	0.25	0.04	2.16	0.31
CM 1205	Rice polished, dry	PP	0.0725	34.21	2.48	10.39	0.75	41.72	3.02	82.38	5.97	150.24	10.89	70.47	5.11
-	Rice bran oil	PP	0.159	0.03	0.00	NC	-	NC	-	NC	-	0.36	0.06	NC	-
GC 0651	Sorghum, raw (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.015	NC	-	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.0095	3.91	0.04	NC	-	11.62	0.11	14.24	0.14	9.87	0.09	2.62	0.02
GC 2090	Subgroup of Sweet Corns	RAC	0.01	0.14	0.00	0.94	0.01	5.70	0.06	2.61	0.03	1.94	0.02	0.22	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.03	99.68	2.99	86.27	2.59	31.38	0.94	80.36	2.41	84.18	2.53	99.10	2.97
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.06	0.04	3.27	0.03	7.01	0.07	13.93	0.14	14.01	0.14	9.36	0.09
SO 0091	Subgroup of Oilseeds, raw (incl processed)	RAC	0.02	37.31	0.75	52.14	1.04	42.74	0.85	48.38	0.97	35.71	0.71	49.05	0.98
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.72	0.01	4.20	0.08	0.60	0.01	4.21	0.08	0.42	0.01	0.78	0.02
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	1.36	0.02	3.59	0.05	1.44	0.02	5.18	0.08	2.02	0.03	1.70	0.03
HH 0738	Mint, raw	RAC	0.11	0.50	0.06	0.01	0.00	NC	-	NC	-	NC	-	NC	-
HS 0780	Cumin, seed	RAC	0.25	0.08	0.02	0.01	0.00	0.01	0.00	0.19	0.05	0.04	0.01	0.05	0.01
HS 0444	Peppers, chili, dried	PP	0.2	0.42	0.08	0.53	0.11	0.84	0.17	0.50	0.10	0.95	0.19	0.37	0.07
DH 1100	Hops, dry	RAC	0.026	0.01	0.00	0.04	0.00	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
DT 1114	Tea, green or black, fermented and dried	RAC	0.12	2.28	0.27	1.92	0.23	0.46	0.06	2.40	0.29	1.29	0.15	3.04	0.36
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0.02	31.20	0.62	72.44	1.45	20.88	0.42	47.98	0.96	33.08	0.66	36.25	0.73
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.02	3.29	0.07	6.14	0.12	0.82	0.02	1.57	0.03	2.23	0.04	1.07	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.035	4.79	0.17	9.68	0.34	2.97	0.10	5.49	0.19	3.84	0.13	5.03	0.18

ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	289.65	1.16	485.88	1.94	26.92	0.11	239.03	0.96	199.91	0.80	180.53	0.72
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0014	14.63	0.02	29.76	0.04	8.04	0.01	129.68	0.18	25.04	0.04	35.66	0.05
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0014	13.17	0.02	26.78	0.04	7.24	0.01	116.71	0.16	22.54	0.03	32.09	0.04
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0033	1.46	0.00	2.98	0.01	0.80	0.00	12.97	0.04	2.50	0.01	3.57	0.01
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0033	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.37	0.12	0.04	0.12	0.04	0.11	0.04	5.37	1.99	0.24	0.09	0.10	0.04
PE 0112	Eggs, raw, (incl dried)	RAC	0.0062	7.84	0.05	23.08	0.14	2.88	0.02	14.89	0.09	9.81	0.06	14.83	0.09
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				27.3		45.3		34.5		49.0		51.3		59.7
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				6000		6000		6000		6000		6000		6000
	%ADI=				0.5%		0.8%		0.6%		0.8%		0.9%		1.0%
	Rounded %ADI=				0%		1%		1%		1%		1%		1%

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0–0.1 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.02	114.42	2.29	62.91	1.26	26.97	0.54	96.72	1.93	96.22	1.92	563.19	11.26
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.1	71.38	7.14	81.73	8.17	42.91	4.29	58.89	5.89	103.85	10.39	12.48	1.25
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.04	18.18	0.73	23.83	0.95	14.27	0.57	18.52	0.74	9.35	0.37	0.11	0.00
DF 0014	Plums, dried (prunes)	PP	0.07	0.61	0.04	0.35	0.02	0.05	0.00	0.35	0.02	0.49	0.03	0.13	0.01
FB 2005	Subgroup of Caneberries, raw	RAC	0.01	0.56	0.01	1.43	0.01	0.14	0.00	1.23	0.01	1.14	0.01	0.01	0.00
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.01	1.31	0.01	5.50	0.06	0.01	0.00	2.57	0.03	0.82	0.01	2.15	0.02

FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	0.01	8.26	0.08	0.14	0.00	0.07	0.00	0.13	0.00	0.19	0.00	1.87	0.02
FB 0269	Grapes, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.12	128.64	15.44	97.04	11.64	7.74	0.93	43.94	5.27	88.68	10.64	8.80	1.06
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	3.09	0.96	1.51	0.47	0.03	0.01	1.38	0.43	4.26	1.32	0.42	0.13
JF 0269	Grape juice (from wine grapes)	PP	0.18	0.56	0.10	1.96	0.35	0.02	0.00	2.24	0.40	2.27	0.41	0.34	0.06
FI 0326	Avocado, raw	RAC	0.01	2.65	0.03	0.87	0.01	0.46	0.00	1.64	0.02	1.30	0.01	0.96	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	25.76	0.52	23.65	0.47	23.83	0.48	24.37	0.49	19.43	0.39	101.55	2.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	1.80	0.04	0.63	0.01	10.05	0.20	1.07	0.02	3.52	0.07	16.44	0.33
FI 0350	Papaya, raw	RAC	0	0.31	0.00	0.18	0.00	1.50	0.00	0.51	0.00	0.54	0.00	1.08	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	13.13	0.00	11.13	0.00	6.94	0.00	14.36	0.00	36.74	0.00	18.81	0.00
-	Onions, dry, raw	RAC	0.01	19.69	0.20	29.83	0.30	24.64	0.25	31.35	0.31	9.72	0.10	12.59	0.13
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.015	20.71	0.31	39.81	0.60	25.06	0.38	37.93	0.57	18.12	0.27	16.74	0.25
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.02	27.81	0.56	41.93	0.84	123.30	2.47	49.47	0.99	15.95	0.32	35.99	0.72
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.02	72.14	1.44	85.53	1.71	76.55	1.53	95.63	1.91	64.19	1.28	16.94	0.34
VL 0053	Group of Leafy vegetables, raw	RAC	0.52	18.83	9.79	21.85	11.36	121.23	63.04	43.09	22.41	18.18	9.45	18.32	9.53
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.07	5.07	0.35	0.83	0.06	0.17	0.01	3.70	0.26	NC	-	NC	-
014B	**Peas with pods**	**-**	0.01	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	2.21	0.02	5.25	0.05	4.17	0.04	1.61	0.02	16.95	0.17	0.17	0.00
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	0.22	0.00	0.84	0.01	0.15	0.00	0.48	0.00	2.04	0.02	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.01	10.72	0.11	1.99	0.02	2.72	0.03	4.26	0.04	4.23	0.04	NC	-

VD 0070	Group of Pulses, raw (incl processed)	RAC	0.02	112.88	2.26	123.05	2.46	47.73	0.95	204.75	4.10	227.52	4.55	110.05	2.20
VD 0520	Bambara groundnut (dry) (Vigna subterranea), raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.02	290.31	5.81	300.35	6.01	214.25	4.29	242.72	4.85	348.67	6.97	137.52	2.75
VS 2080	Subgroup of stems and petioles	RAC	0.01	9.31	0.09	8.57	0.09	NC	-	3.88	0.04	24.46	0.24	5.89	0.06
VS 0621	Asparagus, raw	RAC	0.01	0.84	0.01	2.08	0.02	7.11	0.07	1.01	0.01	1.69	0.02	0.04	0.00
VS 0622	Bamboo shoots, raw	RAC	0.01	0.92	0.01	0.55	0.01	61.79	0.62	NC	-	1.72	0.02	3.26	0.03
VS 0620	Artichoke globe, raw	RAC	0.025	0.98	0.02	3.65	0.09	0.07	0.00	1.67	0.04	0.26	0.01	NC	-
VS 0626	Palm hearts, raw	RAC	0.01	0.51	0.01	0.73	0.01	3.54	0.04	0.01	0.00	0.66	0.01	0.75	0.01
GC 0650	Rye, raw	RAC	0.01	0.01	0.00	NC	-	0.06	0.00	0.01	0.00	NC	-	NC	-
CF 1250	Rye, flour (white flour and wholemeal flour)	PP	0.00645	2.57	0.02	28.31	0.18	0.12	0.00	5.20	0.03	1.20	0.01	NC	-
GC 0653	Triticale, raw	RAC	0.01	NC	-	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
GC 0653	Triticale, flour (white flour and wholemeal flour)	PP	0.00645	0.01	0.00	0.14	0.00	0.23	0.00	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	NC	-	NC	-	0.02	0.00	0.83	0.01	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.018	0.97	0.02	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.01	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
CP 1211	Wheat, white bread	PP	0.01	1.30	0.01	0.46	0.00	0.06	0.00	0.22	0.00	2.44	0.02	0.77	0.01
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00645	198.08	1.28	193.03	1.25	106.24	0.69	185.09	1.19	168.67	1.09	131.59	0.85
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.015	35.17	0.53	49.45	0.74	8.86	0.13	34.31	0.51	44.87	0.67	15.82	0.24
-	Barley, flour (white flour and wholemeal flour)	PP	0.0097	0.08	0.00	0.03	0.00	0.01	0.00	0.05	0.00	0.68	0.01	0.05	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.015	7.50	0.11	6.26	0.09	0.15	0.00	4.87	0.07	3.16	0.05	2.98	0.04
CM 0649 (GC 0649)	Rice, husked, dry (incl beverages, incl starch, excl polished, excl flour, excl oil)	REP	0.145	2.43	0.35	1.62	0.23	0.43	0.06	1.59	0.23	NC	-	5.03	0.73
CM 1205	Rice polished, dry	PP	0.0725	13.38	0.97	10.80	0.78	262.08	19.00	57.16	4.14	12.83	0.93	62.78	4.55
-	Rice bran oil	PP	0.159	NC	-	NC	-	0.15	0.02	0.10	0.02	NC	-	NC	-
GC 0651	Sorghum, raw (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.015	NC	-	NC	-	0.01	0.00	1.15	0.02	NC	-	7.12	0.11

-	Sorghum, flour (white flour and wholemeal flour)	PP	0.0095	NC	-	NC	-	1.29	0.01	0.01	0.00	NC	-	NC	-
GC 2090	Subgroup of Sweet Corns	RAC	0.01	11.43	0.11	3.71	0.04	0.74	0.01	13.63	0.14	3.07	0.03	1.50	0.02
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.03	92.24	2.77	95.72	2.87	28.47	0.85	77.39	2.32	117.73	3.53	103.90	3.12
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	8.52	0.09	8.94	0.09	15.09	0.15	9.60	0.10	14.57	0.15	26.26	0.26
SO 0091	Subgroup of Oilseeds, raw (incl processed)	RAC	0.02	78.69	1.57	62.08	1.24	39.56	0.79	52.51	1.05	37.72	0.75	16.21	0.32
SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	7.54	0.15	5.59	0.11	0.29	0.01	4.14	0.08	1.27	0.03	5.29	0.11
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	10.90	0.16	12.44	0.19	0.77	0.01	9.48	0.14	22.07	0.33	8.15	0.12
HH 0738	Mint, raw	RAC	0.11	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
HS 0780	Cumin, seed	RAC	0.25	0.11	0.03	0.04	0.01	NC	-	0.02	0.01	0.06	0.02	0.01	0.00
HS 0444	Peppers, chili, dried	PP	0.2	0.11	0.02	0.21	0.04	0.36	0.07	0.21	0.04	0.25	0.05	0.15	0.03
DH 1100	Hops, dry	RAC	0.026	NC	-	NC	-	0.02	0.00	0.02	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	0.12	2.71	0.33	0.82	0.10	1.14	0.14	1.59	0.19	1.82	0.22	0.53	0.06
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0.02	140.03	2.80	150.89	3.02	79.32	1.59	111.24	2.22	120.30	2.41	51.27	1.03
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.02	6.44	0.13	15.51	0.31	3.79	0.08	8.29	0.17	18.44	0.37	8.00	0.16
MO 0105	Edible offal (mammalian), raw	RAC	0.035	15.17	0.53	5.19	0.18	6.30	0.22	6.78	0.24	3.32	0.12	3.17	0.11
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	388.92	1.56	335.88	1.34	49.15	0.20	331.25	1.33	468.56	1.87	245.45	0.98
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0014	73.76	0.10	53.86	0.08	23.98	0.03	87.12	0.12	53.38	0.07	84.45	0.12
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0014	66.38	0.09	48.47	0.07	21.58	0.03	78.41	0.11	48.04	0.07	76.01	0.11
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0033	7.38	0.02	5.39	0.02	2.40	0.01	8.71	0.03	5.34	0.02	8.45	0.03
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0033	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.37	0.33	0.12	0.72	0.27	0.27	0.10	0.35	0.13	0.80	0.30	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.0062	25.84	0.16	29.53	0.18	28.05	0.17	33.19	0.21	36.44	0.23	8.89	0.06
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				62.4		60.5		105.1		65.7		62.4		45.4

Bodyweight per region (kg bw) =				60	60	55	60	60	60				
ADI (ug/person)=				6000	6000	5500	6000	6000	6000				
%ADI=				1.0%	1.0%	1.9%	1.1%	1.0%	0.8%				
Rounded %ADI=				1%	1%	2%	1%	1%	1%				

CLOTHIANIDIN (238) International Estimated Daily Intake (IEDI) ADI = 0–0.1 mg/kg bw

			STMR	**Diets: g/person/day**		**Intake = daily intake: ug/person**							
Codex Code	Commodity description	Expr as	mg/kg	G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0001	Group of Citrus fruit, raw (incl citrus fruit juice, incl kumquat commodities)	RAC	0.02	21.16	0.42	2.94	0.06	58.52	1.17	0.44	0.01	5.13	0.10
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.1	68.89	6.89	11.06	1.11	80.62	8.06	189.82	18.98	19.56	1.96
FS 0012	Group of Stone fruits, raw (incl dried apricots, excl dried plums)	RAC	0.04	0.09	0.00	0.02	0.00	32.27	1.29	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.07	0.01	0.00	0.01	0.00	0.37	0.03	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.01	0.01	0.00	7.30	0.07	2.29	0.02	0.01	0.00	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.01	0.82	0.01	4.05	0.04	5.94	0.06	0.43	0.00	2.66	0.03
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	0.01	0.71	0.01	7.32	0.07	NC	-	0.38	0.00	2.32	0.02
FB 0269	Grapes, raw (incl must, incl wine, excl dried, excl juice)	RAC	0.12	0.57	0.07	0.69	0.08	98.34	11.80	0.73	0.09	44.12	5.29
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.31	0.01	0.00	0.13	0.04	1.06	0.33	0.01	0.00	0.03	0.01
JF 0269	Grape juice (from wine grapes)	PP	0.18	0.01	0.00	0.01	0.00	0.41	0.07	0.01	0.00	NC	-
FI 0326	Avocado, raw	RAC	0.01	1.12	0.01	0.01	0.00	0.84	0.01	0.01	0.00	6.60	0.07
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.02	44.80	0.90	118.17	2.36	25.25	0.51	454.49	9.09	310.23	6.20
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.02	12.25	0.25	6.83	0.14	0.76	0.02	0.01	0.00	20.12	0.40

FI 0350	Papaya, raw	RAC	0	6.47	0.00	0.25	0.00	0.19	0.00	0.01	0.00	26.42	0.00
FI 0353	Pineapple, raw (incl canned pineapple, incl pineapple juice, incl dried pineapple)	RAC	0	8.51	0.00	6.27	0.00	6.89	0.00	0.18	0.00	24.94	0.00
-	Onions, dry, raw	RAC	0.01	9.01	0.09	20.24	0.20	30.90	0.31	9.61	0.10	2.11	0.02
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.015	5.46	0.08	4.28	0.06	58.72	0.88	0.02	0.00	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.02	5.96	0.12	9.74	0.19	51.82	1.04	13.61	0.27	0.05	0.00
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.02	32.01	0.64	28.27	0.57	100.61	2.01	2.91	0.06	12.50	0.25
VL 0053	Group of Leafy vegetables, raw	RAC	0.52	12.42	6.46	8.75	4.55	7.53	3.92	7.07	3.68	14.11	7.34
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.07	NC	-	NC	-	NC	-	NC	-	NC	-
014B	**Peas with pods**	**-**	0.01	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.01	0.30	0.00	3.13	0.03	4.11	0.04	0.01	0.00	NC	-
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp), raw	RAC	0.01	0.07	0.00	0.01	0.00	0.76	0.01	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.01	0.21	0.00	0.02	0.00	5.51	0.06	0.02	0.00	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.02	46.57	0.93	30.77	0.62	112.53	2.25	75.53	1.51	43.68	0.87
VD 0520	Bambara groundnut (dry) (Vigna subterranea), raw	RAC	0.01	0.20	0.00	NC	-	NC	-	NC	-	NC	-
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.02	282.25	5.65	232.11	4.64	281.91	5.64	620.21	12.40	459.96	9.20
VS 2080	Subgroup of stems and petioles	RAC	0.01	5.33	0.05	3.85	0.04	5.80	0.06	3.60	0.04	7.20	0.07
VS 0621	Asparagus, raw	RAC	0.01	0.01	0.00	0.01	0.00	0.17	0.00	0.01	0.00	NC	-
VS 0622	Bamboo shoots, raw	RAC	0.01	2.95	0.03	2.13	0.02	1.52	0.02	2.00	0.02	3.99	0.04
VS 0620	Artichoke globe, raw	RAC	0.025	0.01	0.00	NC	-	0.08	0.00	0.01	0.00	NC	-
VS 0626	Palm hearts, raw	RAC	0.01	0.67	0.01	0.49	0.00	NC	-	0.46	0.00	0.91	0.01
GC 0650	Rye, raw	RAC	0.01	0.01	0.00	NC	-	NC	-	0.01	0.00	NC	-

CF 1250	Rye, flour (white flour and wholemeal flour)	PP	0.00645	0.02	0.00	0.01	0.00	11.16	0.07	0.01	0.00	0.70	0.00
GC 0653	Triticale, raw	RAC	0.01	0.01	0.00	NC	-	NC	-	NC	-	NC	-
GC 0653	Triticale, flour (white flour and wholemeal flour)	PP	0.00645	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.01	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.01
CF 1210	Wheat, germ	PP	0.018	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.01	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
CP 1211	Wheat, white bread	PP	0.01	0.43	0.00	0.41	0.00	1.56	0.02	0.11	0.00	0.07	0.00
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.00645	44.78	0.29	86.96	0.56	214.05	1.38	20.31	0.13	103.60	0.67
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.015	3.15	0.05	2.31	0.03	43.92	0.66	3.72	0.06	16.26	0.24
-	Barley, flour (white flour and wholemeal flour)	PP	0.0097	0.02	0.00	NC	-	0.32	0.00	0.01	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.015	0.37	0.01	0.07	0.00	2.79	0.04	0.10	0.00	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl beverages, incl starch, excl polished, excl flour, excl oil)	REP	0.145	13.54	1.96	3.52	0.51	1.96	0.28	0.01	0.00	8.84	1.28
CM 1205	Rice polished, dry	PP	0.0725	30.20	2.19	218.34	15.83	12.77	0.93	15.24	1.10	51.35	3.72
-	Rice bran oil	PP	0.159	NC	-	0.60	0.10	NC	-	NC	-	NC	-
GC 0651	Sorghum, raw (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.015	NC	-	NC	-	NC	-	NC	-	NC	-
-	Sorghum, flour (white flour and wholemeal flour)	PP	0.0095	75.99	0.72	1.82	0.02	NC	-	19.82	0.19	NC	-
GC 2090	Subgroup of Sweet Corns	RAC	0.01	3.63	0.04	20.50	0.21	8.78	0.09	0.02	0.00	0.17	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.03	33.75	1.01	106.29	3.19	78.09	2.34	29.09	0.87	45.70	1.37
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.01	4.39	0.04	135.53	1.36	6.11	0.06	0.72	0.01	317.74	3.18
SO 0091	Subgroup of Oilseeds, raw (incl processed)	RAC	0.02	94.19	1.88	14.81	0.30	55.34	1.11	32.27	0.65	55.44	1.11

SB 0715	Cacao bean, raw (incl roasted, incl powder, incl butter, incl paste, incl nes products)	RAC	0.02	0.11	0.00	0.89	0.02	6.28	0.13	0.17	0.00	2.31	0.05
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.015	0.95	0.01	1.32	0.02	11.64	0.17	2.96	0.04	14.73	0.22
HH 0738	Mint, raw	RAC	0.11	NC	-	NC	-	NC	-	NC	-	NC	-
HS 0780	Cumin, seed	RAC	0.25	0.01	0.00	0.25	0.06	NC	-	0.01	0.00	0.01	0.00
HS 0444	Peppers, chili, dried	PP	0.2	0.58	0.12	1.27	0.25	1.21	0.24	0.12	0.02	NC	-
DH 1100	Hops, dry	RAC	0.026	NC	-	NC	-	0.04	0.00	NC	-	NC	-
DT 1114	Tea, green or black, fermented and dried	RAC	0.12	0.53	0.06	5.25	0.63	0.63	0.08	0.56	0.07	0.82	0.10
MM 0095	Meat from mammals other than marine mammals, raw (incl prepared meat)	RAC	0.02	29.18	0.58	50.89	1.02	121.44	2.43	22.58	0.45	72.14	1.44
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.02	1.05	0.02	1.14	0.02	18.69	0.37	0.94	0.02	3.12	0.06
MO 0105	Edible offal (mammalian), raw	RAC	0.035	4.64	0.16	1.97	0.07	10.01	0.35	3.27	0.11	3.98	0.14
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.004	108.75	0.44	70.31	0.28	436.11	1.74	61.55	0.25	79.09	0.32
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.0014	3.92	0.01	12.03	0.02	57.07	0.08	5.03	0.01	55.56	0.08
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.0014	3.53	0.00	10.83	0.02	51.36	0.07	4.53	0.01	50.00	0.07
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0033	0.39	0.00	1.20	0.00	5.71	0.02	0.50	0.00	5.56	0.02
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0033	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.37	0.10	0.04	0.70	0.26	0.97	0.36	0.10	0.04	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.0062	3.84	0.02	4.41	0.03	27.25	0.17	1.13	0.01	7.39	0.05
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				32.3		39.7		52.8		50.3		46.0
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				6000		6000		6000		6000		6000
	%ADI=				0.5%		0.7%		0.9%		0.8%		0.8%
	Rounded %ADI=				1%		1%		1%		1%		1%

THIOPHANATE-METHYL (77) International Estimated Daily Intake (IEDI) ADI = 0–0.09 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
TN 0660	Almonds, nutmeat	RAC	0.05	1.38	0.07	0.08	0.00	0.01	0.00	1.00	0.05	0.06	0.00	0.81	0.04
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0.1		0.0		0.0		0.1		0.0		0.0
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				5400		5400		5400		5400		5400		5400
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

THIOPHANATE-METHYL (77) International Estimated Daily Intake (IEDI) ADI = 0–0.09 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
TN 0660	Almonds, nutmeat	RAC	0.05	0.81	0.04	2.21	0.11	0.03	0.00	1.02	0.05	1.47	0.07	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0.0		0.1		0.0		0.1		0.1		0.0
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				5400		5400		4950		5400		5400		5400
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

THIOPHANATE-METHYL (77) International Estimated Daily Intake (IEDI) ADI = 0–0.09 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day		Intake = daily intake: ug/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
TN 0660	Almonds, nutmeat	RAC	0.05	0.01	0.00	0.01	0.00	0.61	0.03	0.01	0.00	NC	-
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0.0		0.0		0.0		0.0		0.0
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				5400		5400		5400		5400		5400
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%

TRICCYCLAZOLE (337) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0,01	1,26	0,01	1,58	0,02	31,05	0,31	5,43	0,05	0,90	0,01	2,18	0,02
CM 1205	Rice polished, dry	PP	0,01	34,21	0,34	10,39	0,10	41,72	0,42	82,38	0,82	150,24	1,50	70,47	0,70
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	31,20	0,00	72,44	0,00	20,88	0,00	47,98	0,00	33,08	0,00	36,25	0,00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3,29	0,00	6,14	0,00	0,82	0,00	1,57	0,00	2,23	0,00	1,07	0,00
MO 0105	Edible offal (mammalian), raw	RAC	0,016	4,79	0,08	9,68	0,15	2,97	0,05	5,49	0,09	3,84	0,06	5,03	0,08
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289,65	0,00	485,88	0,00	26,92	0,00	239,03	0,00	199,91	0,00	180,53	0,00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	14,63	0,00	29,76	0,00	8,04	0,00	129,68	0,00	25,04	0,00	35,66	0,00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0,10	0,00	0,10	0,00	NC	-	0,10	0,00	0,10	0,00	0,10	0,00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0,009	0,12	0,00	0,12	0,00	0,11	0,00	5,37	0,05	0,24	0,00	0,10	0,00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7,84	0,00	23,08	0,00	2,88	0,00	14,89	0,00	9,81	0,00	14,83	0,00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0,4		0,3		0,8		1,0		1,6		0,8
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				3000		3000		3000		3000		3000		3000
	%ADI=				0,0%		0,0%		0,0%		0,0%		0,1%		0,0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

TRICCYCLAZOLE (337)

International Estimated Daily Intake (IEDI)

ADI = 0–0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day						Intake as ug/person/day					
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0,01	3,70	0,04	2,11	0,02	1,51	0,02	1,75	0,02	0,29	0,00	5,12	0,05
CM 1205	Rice polished, dry	PP	0,01	13,38	0,13	10,80	0,11	262,08	2,62	57,16	0,57	12,83	0,13	62,78	0,63
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	140,03	0,00	150,89	0,00	79,32	0,00	111,24	0,00	120,30	0,00	51,27	0,00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6,44	0,00	15,51	0,00	3,79	0,00	8,29	0,00	18,44	0,00	8,00	0,00
MO 0105	Edible offal (mammalian), raw	RAC	0,016	15,17	0,24	5,19	0,08	6,30	0,10	6,78	0,11	3,32	0,05	3,17	0,05
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388,92	0,00	335,88	0,00	49,15	0,00	331,25	0,00	468,56	0,00	245,45	0,00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	73,76	0,00	53,86	0,00	23,98	0,00	87,12	0,00	53,38	0,00	84,45	0,00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0,10	0,00	0,10	0,00	NC	-	0,10	0,00	0,71	0,00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0,009	0,33	0,00	0,72	0,01	0,27	0,00	0,35	0,00	0,80	0,01	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25,84	0,00	29,53	0,00	28,05	0,00	33,19	0,00	36,44	0,00	8,89	0,00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0,4		0,2		2,7		0,7		0,2		0,7
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				3000		3000		2750		3000		3000		3000
	%ADI=				0,0%		0,0%		0,1%		0,0%		0,0%		0,0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

TRICCYCLAZOLE (337) International Estimated Daily Intake (IEDI) ADI = 0–0.05 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0,01	13,58	0,14	4,29	0,04	2,17	0,02	0,01	0,00	8,84	0,09
CM 1205	Rice polished, dry	PP	0,01	30,20	0,30	218,34	2,18	12,77	0,13	15,24	0,15	51,35	0,51
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0	29,18	0,00	50,89	0,00	121,44	0,00	22,58	0,00	72,14	0,00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1,05	0,00	1,14	0,00	18,69	0,00	0,94	0,00	3,12	0,00
MO 0105	Edible offal (mammalian), raw	RAC	0,016	4,64	0,07	1,97	0,03	10,01	0,16	3,27	0,05	3,98	0,06
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108,75	0,00	70,31	0,00	436,11	0,00	61,55	0,00	79,09	0,00
PM 0110	Poultry meat, raw (incl prepared)	RAC	0	3,92	0,00	12,03	0,00	57,07	0,00	5,03	0,00	55,56	0,00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0,32	0,00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0,009	0,10	0,00	0,70	0,01	0,97	0,01	0,10	0,00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3,84	0,00	4,41	0,00	27,25	0,00	1,13	0,00	7,39	0,00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				0,5		2,3		0,3		0,2		0,7
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				3000		3000		3000		3000		3000
	%ADI=				0,0%		0,1%		0,0%		0,0%		0,0%
	Rounded %ADI=				0%		0%		0%		0%		0%

ZETA-CYPERMETHRIN (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G01 diet	G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.05	4.82	0.24	2.45	0.12	3.93	0.20	25.44	1.27	8.74	0.44	16.23	0.81
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.05	6.18	0.31	3.66	0.18	0.25	0.01	6.82	0.34	3.49	0.17	19.38	0.97
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.05	23.26	1.16	9.71	0.49	12.09	0.60	62.02	3.10	22.09	1.10	59.91	3.00
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.05	0.66	0.03	0.69	0.03	0.96	0.05	10.20	0.51	1.25	0.06	2.97	0.15
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.205	19.79	4.06	38.25	7.84	17.96	3.68	32.56	6.67	8.08	1.66	64.45	13.21
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.59	11.60	6.84	23.79	14.04	0.25	0.15	11.84	6.99	2.41	1.42	33.44	19.73
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.4	0.53	0.21	1.31	0.52	0.40	0.16	1.66	0.66	0.01	0.00	0.99	0.40
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.01	13.19	0.13	9.61	0.10	0.09	0.00	17.28	0.17	4.00	0.04	54.50	0.55
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.033	0.51	0.02	0.51	0.02	0.01	0.00	1.27	0.04	0.12	0.00	2.07	0.07
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.001	0.67	0.00	12.53	0.01	2.01	0.00	1.21	0.00	3.53	0.00	4.01	0.00
FB 0275	Strawberry, raw	RAC	0.01	0.70	0.01	2.01	0.02	0.04	0.00	1.36	0.01	0.37	0.00	2.53	0.03
FT 0305	Table olives, raw (incl preserved)	RAC	0.05	0.70	0.04	0.32	0.02	0.01	0.00	1.53	0.08	0.17	0.01	1.85	0.09
FT 0289	Carambola, raw	RAC	0.02	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
FI 0343	Litchi, raw (incl processed)	RAC	0.495	2.32	1.15	1.43	0.71	1.81	0.90	7.42	3.67	NC	-	4.54	2.25

FI 0342	Longan, raw	RAC	0.3	0.04	0.01	0.01	0.00	0.04	0.01	0.04	0.01	NC	-	0.01	0.00
FI 0326	Avocado, raw	RAC	0.14	0.13	0.02	0.03	0.00	2.05	0.29	2.54	0.36	2.34	0.33	0.12	0.02
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.19	10.48	1.99	0.01	0.00	7.24	1.38	6.87	1.31	19.98	3.80	6.25	1.19
FI 0350	Papaya, raw	RAC	0.135	0.35	0.05	0.01	0.00	3.05	0.41	0.80	0.11	7.28	0.98	1.00	0.14
FI 0334	Durian, raw	RAC	0.135	0.04	0.01	0.01	0.00	0.04	0.01	0.04	0.01	NC	-	0.01	0.00
VA 2031	Subgroup of bulb onions	RAC	0	31.65	0.00	43.28	0.00	3.68	0.00	38.48	0.00	20.46	0.00	47.29	0.00
VA 0384	Leek, raw	RAC	0.01	0.18	0.00	1.59	0.02	0.03	0.00	0.28	0.00	0.01	0.00	3.21	0.03
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.02	6.43	0.13	40.26	0.81	0.80	0.02	9.94	0.20	12.07	0.24	17.73	0.35
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.01	10.52	0.11	39.36	0.39	2.07	0.02	25.74	0.26	2.80	0.03	44.83	0.45
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	42.62	0.43	46.85	0.47	4.21	0.04	67.02	0.67	12.84	0.13	110.47	1.10
VO 0448	Tomato, raw	RAC	0.05	41.73	2.09	75.65	3.78	10.66	0.53	82.87	4.14	24.75	1.24	200.93	10.05
-	Tomato, canned (& peeled)	PP	0.0006	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.00	0.11	0.00	1.50	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.025	2.34	0.06	1.33	0.03	1.57	0.04	4.24	0.11	0.34	0.01	2.83	0.07
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.015	0.29	0.00	0.29	0.00	0.01	0.00	0.38	0.01	0.05	0.00	0.14	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.08	1.97	0.16	NC	-	3.68	0.29	3.24	0.26	5.72	0.46	1.57	0.13
VO 0444	Peppers, chili, raw	RAC	0.495	3.99	1.98	7.30	3.61	2.93	1.45	5.62	2.78	NC	-	17.44	8.63
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.05	4.49	0.22	6.44	0.32	7.21	0.36	5.68	0.28	9.52	0.48	8.92	0.45
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.01	5.58	0.06	4.31	0.04	0.89	0.01	9.31	0.09	13.64	0.14	20.12	0.20
VL 0053	Group of Leafy vegetables, raw	RAC	0.07	8.47	0.59	22.36	1.57	7.74	0.54	25.51	1.79	45.77	3.20	21.22	1.49

VP 0060	Group of Legume vegetables, raw	RAC	0.22	7.73	1.70	1.53	0.34	0.51	0.11	2.95	0.65	5.08	1.12	12.86	2.83
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.05	87.29	4.36	64.04	3.20	37.15	1.86	89.82	4.49	91.02	4.55	98.20	4.91
VR 0574	Beetroot, raw	RAC	0.01	3.42	0.03	6.06	0.06	3.75	0.04	9.11	0.09	NC	-	4.39	0.04
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.03	0.00	0.06	0.00	0.04	0.00	0.09	0.00	NC	-	0.04	0.00
VR 0577	Carrots, raw	RAC	0.01	9.51	0.10	30.78	0.31	0.37	0.00	8.75	0.09	2.80	0.03	6.10	0.06
VR 0578	Celeriac, raw	RAC	0.01	1.70	0.02	3.01	0.03	1.87	0.02	4.53	0.05	NC	-	2.19	0.02
VR 0469	Chicory, roots, raw	RAC	0.01	0.01	0.00	0.20	0.00	0.01	0.00	0.01	0.00	0.02	0.00	0.01	0.00
VR 0583	Horseradish, raw	RAC	0.01	0.51	0.01	0.91	0.01	0.56	0.01	1.37	0.01	NC	-	0.66	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.32	0.00	0.57	0.01	0.35	0.00	0.85	0.01	NC	-	0.41	0.00
VR 0588	Parsnip, raw	RAC	0.01	0.59	0.01	1.05	0.01	0.65	0.01	1.58	0.02	NC	-	0.76	0.01
VR 0494	Radish roots, raw	RAC	0.01	2.31	0.02	4.09	0.04	2.53	0.03	6.15	0.06	5.88	0.06	2.97	0.03
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	1.90	0.02	3.36	0.03	2.08	0.02	5.06	0.05	NC	-	2.44	0.02
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	0.21	0.00	0.37	0.00	0.23	0.00	0.55	0.01	NC	-	0.27	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.13	0.00	NC	-	0.08	0.00	0.66	0.01	0.47	0.00	88.94	0.89
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	1.58	0.02	2.80	0.03	1.74	0.02	4.21	0.04	NC	-	2.03	0.02
VR 0506	Turnip, garden, raw	RAC	0.01	2.50	0.03	4.44	0.04	2.75	0.03	6.67	0.07	0.14	0.00	3.22	0.03
VS 0621	Asparagus, raw	RAC	0.09	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.07	0.01	0.21	0.02
VS 0620	Artichoke globe, raw	RAC	0.025	0.69	0.02	0.01	0.00	0.01	0.00	0.32	0.01	0.26	0.01	1.21	0.03
GC 0650	Rye, raw (incl flour)	RAC	1.38	0.13	0.18	19.38	26.74	0.10	0.14	0.12	0.17	0.03	0.04	2.15	2.97

GC 0654	Wheat, raw (incl meslin)	RAC	1.38	0.01	0.01	1.12	1.55	NC	-	0.01	0.01	0.56	0.77	NC	-
-	Wheat, bulgur	PP	1.38	NC	-	NC	-	NC	-	0.03	0.04	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.02	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	1.38	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.03	0.04	0.01	0.01
CP 1211	Wheat, white bread	PP	1.38	0.25	0.35	0.63	0.87	0.12	0.17	0.43	0.59	1.39	1.92	0.22	0.30
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	1.38	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.015	301.24	4.52	268.64	4.03	30.21	0.45	222.51	3.34	134.73	2.02	343.12	5.15
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl malt, excl beer)	RAC	1.38	18.98	26.19	13.35	18.42	0.42	0.58	0.67	0.92	2.30	3.17	0.86	1.19
-	Barley beer	PP	0.04	4.87	0.19	93.78	3.75	24.28	0.97	12.76	0.51	39.28	1.57	18.15	0.73
GC 0647	Oats, raw (incl rolled)	RAC	1.38	0.05	0.07	7.05	9.73	0.10	0.14	1.71	2.36	0.96	1.32	0.04	0.06
GC 2088	Subgroup of rice cereals	REP	0.57	45.40	25.88	14.99	8.54	84.88	48.38	111.73	63.69	194.75	111.01	93.12	53.08
GC 2091	Subgroup of Maize Cereals	RAC	0.035	29.81	1.04	44.77	1.57	108.95	3.81	52.37	1.83	60.28	2.11	75.69	2.65
GC 2090	Subgroup of Sweet Corns	RAC	0	0.14	0.00	0.94	0.00	5.70	0.00	2.61	0.00	1.94	0.00	0.22	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.05	99.68	4.98	86.27	4.31	31.38	1.57	80.36	4.02	84.18	4.21	99.10	4.96
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	4.06	0.20	3.27	0.16	7.01	0.35	13.93	0.70	14.01	0.70	9.36	0.47
SO 0091	Subgroup of Oilseeds, raw (incl processed)	RAC	0.05	37.31	1.87	52.14	2.61	42.74	2.14	48.38	2.42	35.71	1.79	49.05	2.45
OR 0495	Rape seed oil, edible	PP	0.06	0.35	0.02	0.44	0.03	0.19	0.01	0.97	0.06	3.28	0.20	0.77	0.05
-	Olive oil (virgin and residue oil)	PP	0.38	2.17	0.82	0.13	0.05	0.05	0.02	1.32	0.50	0.10	0.04	2.76	1.05
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0	1.36	0.00	3.59	0.00	1.44	0.00	5.18	0.00	2.02	0.00	1.70	0.00

HS 0775	Cardamom, pods and seeds	RAC	0.43	0.01	0.00	0.01	0.00	0.01	0.00	0.22	0.09	0.01	0.00	0.01	0.00
HS 0444	Peppers, chili, dried	PP	3.5	0.42	1.47	0.53	1.86	0.84	2.94	0.50	1.75	0.95	3.33	0.37	1.30
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	3.75	2.28	8.55	1.98	7.43	0.46	1.73	2.43	9.11	1.29	4.84	3.04	11.40
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.014	24.96	0.35	57.95	0.81	16.70	0.23	38.38	0.54	26.46	0.37	29.00	0.41
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.15	6.24	0.94	14.49	2.17	4.18	0.63	9.60	1.44	6.62	0.99	7.25	1.09
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.15	3.29	0.49	6.14	0.92	0.82	0.12	1.57	0.24	2.23	0.33	1.07	0.16
MO 0105	Edible offal (mammalian), raw	RAC	0.014	4.79	0.07	9.68	0.14	2.97	0.04	5.49	0.08	3.84	0.05	5.03	0.07
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	289.65	3.19	485.88	5.34	26.92	0.30	239.03	2.63	199.91	2.20	180.53	1.99
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.002	13.17	0.03	26.78	0.05	7.24	0.01	116.71	0.23	22.54	0.05	32.09	0.06
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0038	1.46	0.01	2.98	0.01	0.80	0.00	12.97	0.05	2.50	0.01	3.57	0.01
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0038	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.01	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0.0042	7.84	0.03	23.08	0.10	2.88	0.01	14.89	0.06	9.81	0.04	14.83	0.06
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				109.9		140.5		78.1		139.0		164.8		166.1
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				1200		1200		1200		1200		1200		1200
	%ADI=				9.2%		11.7 %		6.5%		11.6 %		13.7%		13.8 %
	Rounded %ADI=				9%		10%		7%		10%		10%		10%

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.05	10.12	0.51	15.69	0.78	2.88	0.14	12.30	0.62	22.32	1.12	6.59	0.33
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.05	12.42	0.62	14.99	0.75	16.08	0.80	10.78	0.54	9.94	0.50	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.05	83.66	4.18	27.64	1.38	7.37	0.37	67.80	3.39	43.97	2.20	187.74	9.39
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.05	8.21	0.41	4.60	0.23	0.64	0.03	5.85	0.29	19.98	1.00	368.86	18.44
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.205	71.38	14.63	81.73	16.75	42.91	8.80	58.89	12.07	103.85	21.29	12.48	2.56
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.59	19.98	11.79	24.87	14.67	14.41	8.50	19.54	11.53	10.78	6.36	0.50	0.30
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.4	1.31	0.52	5.50	2.20	0.01	0.00	2.57	1.03	0.82	0.33	2.15	0.86
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.01	7.18	0.07	13.73	0.14	5.24	0.05	12.27	0.12	7.46	0.07	1.21	0.01
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.033	3.09	0.10	1.51	0.05	0.03	0.00	1.38	0.05	4.26	0.14	0.42	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.001	88.93	0.09	62.41	0.06	1.84	0.00	25.07	0.03	61.17	0.06	5.84	0.01
FB 0275	Strawberry, raw	RAC	0.01	4.49	0.04	5.66	0.06	0.02	0.00	6.63	0.07	5.75	0.06	0.05	0.00
FT 0305	Table olives, raw (incl preserved)	RAC	0.05	2.00	0.10	2.48	0.12	0.01	0.00	1.21	0.06	1.64	0.08	0.27	0.01
FT 0289	Carambola, raw	RAC	0.02	NC	-	0.01	0.00	0.05	0.00	NC	-	NC	-	NC	-

FI 0343	Litchi, raw (incl processed)	RAC	0.495	8.00	3.96	3.70	1.83	2.91	1.44	0.05	0.02	11.86	5.87	9.83	4.87
FI 0342	Longan, raw	RAC	0.3	NC	-	NC	-	0.61	0.18	NC	-	NC	-	NC	-
FI 0326	Avocado, raw	RAC	0.14	2.65	0.37	0.87	0.12	0.46	0.06	1.64	0.23	1.30	0.18	0.96	0.13
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.19	1.80	0.34	0.63	0.12	10.05	1.91	1.07	0.20	3.52	0.67	16.44	3.12
FI 0350	Papaya, raw	RAC	0.135	0.31	0.04	0.18	0.02	1.50	0.20	0.51	0.07	0.54	0.07	1.08	0.15
FI 0334	Durian, raw	RAC	0.135	NC	-	NC	-	0.55	0.07	NC	-	NC	-	NC	-
VA 2031	Subgroup of bulb onions	RAC	0	20.67	0.00	31.32	0.00	37.52	0.00	35.08	0.00	11.77	0.00	13.74	0.00
VA 0384	Leek, raw	RAC	0.01	4.01	0.04	4.41	0.04	0.72	0.01	0.54	0.01	16.41	0.16	0.03	0.00
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.02	20.71	0.41	39.81	0.80	25.06	0.50	37.93	0.76	18.12	0.36	16.74	0.33
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.01	7.14	0.07	16.92	0.17	37.58	0.38	15.16	0.15	4.42	0.04	12.67	0.13
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	20.68	0.21	25.00	0.25	85.72	0.86	34.31	0.34	11.54	0.12	23.32	0.23
VO 0448	Tomato, raw	RAC	0.05	32.13	1.61	51.27	2.56	34.92	1.75	73.37	3.67	15.15	0.76	8.88	0.44
-	Tomato, canned (& peeled)	PP	0.0006	7.57	0.00	2.66	0.00	0.30	0.00	0.97	0.00	7.31	0.00	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.025	4.96	0.12	3.20	0.08	0.15	0.00	1.61	0.04	6.88	0.17	0.52	0.01
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.015	0.80	0.01	0.07	0.00	0.05	0.00	0.61	0.01	0.40	0.01	0.08	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.08	NC	-	NC	-	0.04	0.00	0.17	0.01	NC	-	0.72	0.06
VO 0444	Peppers, chili, raw	RAC	0.495	5.57	2.76	14.00	6.93	8.25	4.08	5.77	2.86	6.44	3.19	2.53	1.25
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.05	0.82	0.04	1.53	0.08	10.85	0.54	4.59	0.23	1.84	0.09	2.00	0.10

VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.01	1.01	0.01	1.69	0.02	21.37	0.21	3.00	0.03	1.40	0.01	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	0.07	18.83	1.32	21.85	1.53	121.23	8.49	43.09	3.02	18.18	1.27	18.32	1.28
VP 0060	Group of Legume vegetables, raw	RAC	0.22	18.21	4.01	8.91	1.96	7.22	1.59	10.04	2.21	23.22	5.11	0.17	0.04
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.05	112.88	5.64	123.05	6.15	47.73	2.39	204.75	10.24	227.52	11.38	110.05	5.50
VR 0574	Beetroot, raw	RAC	0.01	9.91	0.10	6.34	0.06	NC	-	9.65	0.10	19.11	0.19	6.47	0.06
VR 0575	Burdock, greater or edible, raw	RAC	0.01	NC	-	NC	-	NC	-	0.48	0.00	NC	-	0.06	0.00
VR 0577	Carrots, raw	RAC	0.01	26.26	0.26	27.13	0.27	10.07	0.10	16.49	0.16	44.69	0.45	8.75	0.09
VR 0578	Celeriac, raw	RAC	0.01	2.97	0.03	1.79	0.02	NC	-	0.06	0.00	16.91	0.17	3.22	0.03
VR 0469	Chicory, roots, raw	RAC	0.01	0.01	0.00	0.51	0.01	0.01	0.00	0.01	0.00	21.12	0.21	NC	-
VR 0583	Horseradish, raw	RAC	0.01	0.01	0.00	0.42	0.00	13.01	0.13	0.26	0.00	2.70	0.03	0.97	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.01
VR 0588	Parsnip, raw	RAC	0.01	4.42	0.04	0.06	0.00	NC	-	NC	-	NC	-	1.12	0.01
VR 0494	Radish roots, raw	RAC	0.01	3.83	0.04	11.99	0.12	NC	-	5.26	0.05	2.19	0.02	4.37	0.04
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	NC	-	NC	-	26.64	0.27	18.92	0.19	NC	-	3.59	0.04
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	1.02	0.01	0.52	0.01	NC	-	NC	-	2.08	0.02	0.39	0.00
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	10.01	0.10	1.66	0.02	NC	-	NC	-	3.06	0.03	2.99	0.03
VR 0506	Turnip, garden, raw	RAC	0.01	5.78	0.06	15.35	0.15	NC	-	6.54	0.07	1.95	0.02	4.73	0.05
VS 0621	Asparagus, raw	RAC	0.09	0.84	0.08	2.08	0.19	7.11	0.64	1.01	0.09	1.69	0.15	0.04	0.00

VS 0620	Artichoke globe, raw	RAC	0.025	0.98	0.02	3.65	0.09	0.07	0.00	1.67	0.04	0.26	0.01	NC	-
GC 0650	Rye, raw (incl flour)	RAC	1.38	3.21	4.43	35.38	48.82	0.21	0.29	6.50	8.97	1.49	2.06	NC	-
GC 0654	Wheat, raw (incl meslin)	RAC	1.38	NC	-	NC	-	NC	-	0.01	0.01	NC	-	NC	-
-	Wheat, bulgur	PP	1.38	NC	-	NC	-	0.01	0.01	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.02	0.97	0.02	0.10	0.00	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	1.38	0.03	0.04	0.01	0.01	0.01	0.01	0.01	0.01	0.05	0.07	0.02	0.03
CP 1211	Wheat, white bread	PP	1.38	1.30	1.79	0.46	0.63	0.06	0.08	0.22	0.30	2.44	3.37	0.77	1.06
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	1.38	NC	-	NC	-	NC	-	4.36	6.02	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.015	198.08	2.97	193.03	2.90	106.24	1.59	185.09	2.78	168.67	2.53	131.59	1.97
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl malt, excl beer)	RAC	1.38	1.94	2.68	4.15	5.73	0.66	0.91	2.50	3.45	2.14	2.95	3.52	4.86
-	Barley beer	PP	0.04	180.21	7.21	259.46	10.38	45.91	1.84	172.36	6.89	234.42	9.38	65.30	2.61
GC 0647	Oats, raw (incl rolled)	RAC	1.38	7.50	10.35	6.26	8.64	0.15	0.21	4.87	6.72	3.16	4.36	2.98	4.11
GC 2088	Subgroup of rice cereals	REP	0.57	20.96	11.95	16.04	9.14	339.67	193.61	75.51	43.04	16.86	9.61	86.13	49.09
GC 2091	Subgroup of Maize Cereals	RAC	0.035	18.51	0.65	26.18	0.92	26.04	0.91	39.99	1.40	7.36	0.26	64.58	2.26
GC 2090	Subgroup of Sweet Corns	RAC	0	11.43	0.00	3.71	0.00	0.74	0.00	13.63	0.00	3.07	0.00	1.50	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.05	92.24	4.61	95.72	4.79	28.47	1.42	77.39	3.87	117.73	5.89	103.90	5.20
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	8.52	0.43	8.94	0.45	15.09	0.75	9.60	0.48	14.57	0.73	26.26	1.31
SO 0091	Subgroup of Oilseeds, raw (incl processed)	RAC	0.05	78.69	3.93	62.08	3.10	39.56	1.98	52.51	2.63	37.72	1.89	16.21	0.81
OR 0495	Rape seed oil, edible	PP	0.06	12.52	0.75	7.63	0.46	3.00	0.18	6.01	0.36	NC	-	NC	-
-	Olive oil (virgin and residue oil)	PP	0.38	3.40	1.29	9.49	3.61	0.02	0.01	4.28	1.63	2.74	1.04	0.48	0.18

SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0	10.90	0.00	12.44	0.00	0.77	0.00	9.48	0.00	22.07	0.00	8.15	0.00
HS 0775	Cardamom, pods and seeds	RAC	0.43	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	0.04	0.02	0.02	0.01
HS 0444	Peppers, chili, dried	PP	3.5	0.11	0.39	0.21	0.74	0.36	1.26	0.21	0.74	0.25	0.88	0.15	0.53
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	3.75	2.91	10.91	1.73	6.49	1.14	4.28	1.85	6.94	2.29	8.59	0.74	2.78
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.014	112.02	1.57	120.71	1.69	63.46	0.89	88.99	1.25	96.24	1.35	41.02	0.57
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.15	28.01	4.20	30.18	4.53	15.86	2.38	22.25	3.34	24.06	3.61	10.25	1.54
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.15	6.44	0.97	15.51	2.33	3.79	0.57	8.29	1.24	18.44	2.77	8.00	1.20
MO 0105	Edible offal (mammalian), raw	RAC	0.014	15.17	0.21	5.19	0.07	6.30	0.09	6.78	0.09	3.32	0.05	3.17	0.04
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	388.92	4.28	335.88	3.69	49.15	0.54	331.25	3.64	468.56	5.15	245.45	2.70
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.002	66.38	0.13	48.47	0.10	21.58	0.04	78.41	0.16	48.04	0.10	76.01	0.15
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0038	7.38	0.03	5.39	0.02	2.40	0.01	8.71	0.03	5.34	0.02	8.45	0.03
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0038	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.0042	25.84	0.11	29.53	0.12	28.05	0.12	33.19	0.14	36.44	0.15	8.89	0.04
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
					130.7		180.2		258.5		160.7		130.8		133.0
	Total intake (ug/person)=														
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				1200		1200		1100		1200		1200		1200

	10.9	15.0		13.4	10.9	11.1
%ADI=	%	%	23.5%	%	%	%
Rounded %ADI=	10%	20%	20%	10%	10%	10%

ZETA-CYPERMETHRIN (118) International Estimated Daily Intake (IEDI) ADI = 0–0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FC 0002	Subgroup of Lemons and limes, raw (incl lemon juice) (incl kumquat commodities)	RAC	0.05	18.97	0.95	0.97	0.05	6.23	0.31	0.09	0.00	3.35	0.17
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.05	0.16	0.01	0.27	0.01	9.06	0.45	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw (incl orange juice)	RAC	0.05	1.34	0.07	1.65	0.08	40.03	2.00	0.33	0.02	1.76	0.09
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.05	0.68	0.03	0.05	0.00	3.21	0.16	0.01	0.00	NC	-
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.205	68.89	14.12	11.06	2.27	80.62	16.53	189.82	38.91	19.56	4.01
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.59	0.09	0.05	0.03	0.02	33.36	19.68	0.01	0.01	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.4	0.82	0.33	4.05	1.62	5.94	2.38	0.43	0.17	2.66	1.06
FB 0269	Grapes, raw (incl must, incl juice, excl dried, excl wine)	RAC	0.01	0.15	0.00	0.38	0.00	15.84	0.16	0.01	0.00	0.28	0.00
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.033	0.01	0.00	0.13	0.00	1.06	0.03	0.01	0.00	0.03	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.001	0.31	0.00	0.23	0.00	60.43	0.06	0.52	0.00	31.91	0.03
FB 0275	Strawberry, raw	RAC	0.01	0.01	0.00	0.01	0.00	3.35	0.03	0.01	0.00	0.01	0.00
FT 0305	Table olives, raw (incl preserved)	RAC	0.05	0.01	0.00	0.01	0.00	1.75	0.09	0.01	0.00	0.24	0.01
FT 0289	Carambola, raw	RAC	0.02	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	0.04	0.00
FI 0343	Litchi, raw (incl processed)	RAC	0.495	3.74	1.85	18.51	9.16	4.87	2.41	1.97	0.98	12.17	6.02
FI 0342	Longan, raw	RAC	0.3	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	0.27	0.08
FI 0326	Avocado, raw	RAC	0.14	1.12	0.16	0.01	0.00	0.84	0.12	0.01	0.00	6.60	0.92
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.19	12.25	2.33	6.83	1.30	0.76	0.14	0.01	0.00	20.12	3.82
FI 0350	Papaya, raw	RAC	0.135	6.47	0.87	0.25	0.03	0.19	0.03	0.01	0.00	26.42	3.57

FI 0334	Durian, raw	RAC	0.135	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	0.24	0.03
VA 2031	Subgroup of bulb onions	RAC	0	9.83	0.00	22.30	0.00	34.69	0.00	9.65	0.00	2.39	0.00
VA 0384	Leek, raw	RAC	0.01	0.02	0.00	1.44	0.01	1.22	0.01	0.01	0.00	NC	-
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.02	5.46	0.11	4.28	0.09	58.72	1.17	0.02	0.00	NC	-
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.01	0.92	0.01	3.20	0.03	13.55	0.14	1.91	0.02	0.05	0.00
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.01	5.04	0.05	6.54	0.07	38.26	0.38	11.70	0.12	NC	-
VO 0448	Tomato, raw	RAC	0.05	12.99	0.65	4.79	0.24	58.40	2.92	0.92	0.05	0.09	0.00
-	Tomato, canned (& peeled)	PP	0.0006	0.07	0.00	0.08	0.00	2.42	0.00	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.025	0.58	0.01	0.22	0.01	2.21	0.06	0.24	0.01	3.10	0.08
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.015	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.08	6.23	0.50	0.10	0.01	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.495	3.47	1.72	3.56	1.76	16.30	8.07	0.01	0.00	NC	-
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.05	5.49	0.27	10.57	0.53	8.84	0.44	0.91	0.05	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.01	1.31	0.01	8.26	0.08	3.95	0.04	0.01	0.00	NC	-
VL 0053	Group of Leafy vegetables, raw	RAC	0.07	12.42	0.87	8.75	0.61	7.53	0.53	7.07	0.49	14.11	0.99
VP 0060	Group of Legume vegetables, raw	RAC	0.22	0.58	0.13	3.16	0.70	10.38	2.28	0.04	0.01	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.05	46.57	2.33	30.77	1.54	112.53	5.63	75.53	3.78	43.68	2.18
VR 0574	Beetroot, raw	RAC	0.01	5.86	0.06	4.23	0.04	9.46	0.09	3.96	0.04	7.91	0.08
VR 0575	Burdock, greater or edible, raw	RAC	0.01	0.06	0.00	0.04	0.00	NC	-	0.04	0.00	0.08	0.00
VR 0577	Carrots, raw	RAC	0.01	2.07	0.02	3.00	0.03	25.29	0.25	0.05	0.00	NC	-
VR 0578	Celeriac, raw	RAC	0.01	2.91	0.03	2.10	0.02	7.59	0.08	1.97	0.02	3.93	0.04
VR 0469	Chicory, roots, raw	RAC	0.01	0.01	0.00	0.03	0.00	0.10	0.00	NC	-	NC	-
VR 0583	Horseradish, raw	RAC	0.01	0.88	0.01	0.63	0.01	0.54	0.01	0.59	0.01	1.19	0.01
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	0.55	0.01	0.40	0.00	4.29	0.04	0.37	0.00	0.74	0.01
VR 0588	Parsnip, raw	RAC	0.01	1.02	0.01	0.74	0.01	3.50	0.04	0.69	0.01	1.37	0.01
VR 0494	Radish roots, raw	RAC	0.01	3.96	0.04	2.86	0.03	3.30	0.03	2.67	0.03	5.34	0.05
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.01	3.25	0.03	2.35	0.02	NC	-	2.20	0.02	4.39	0.04
VR 0498	Salsify, raw (i.e. Oysterplant)	RAC	0.01	0.36	0.00	0.26	0.00	NC	-	0.24	0.00	0.48	0.00

VR 0596	Sugar beet, raw (incl sugar)	RAC	0.01	3.93	0.04	1.68	0.02	NC	-	NC	-	36.12	0.36
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	0.01	2.71	0.03	1.96	0.02	7.80	0.08	1.83	0.02	3.66	0.04
VR 0506	Turnip, garden, raw	RAC	0.01	4.29	0.04	3.10	0.03	6.41	0.06	2.90	0.03	5.79	0.06
VS 0621	Asparagus, raw	RAC	0.09	0.01	0.00	0.01	0.00	0.17	0.02	0.01	0.00	NC	-
VS 0620	Artichoke globe, raw	RAC	0.025	0.01	0.00	NC	-	0.08	0.00	0.01	0.00	NC	-
GC 0650	Rye, raw (incl flour)	RAC	1.38	0.03	0.04	0.01	0.01	13.95	19.25	0.01	0.01	0.88	1.21
GC 0654	Wheat, raw (incl meslin)	RAC	1.38	NC	-	NC	-	NC	-	NC	-	0.97	1.34
-	Wheat, bulgur	PP	1.38	0.01	0.01	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.02	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	1.38	0.01	0.01	0.01	0.01	0.03	0.04	0.01	0.01	0.01	0.01
CP 1211	Wheat, white bread	PP	1.38	0.43	0.59	0.41	0.57	1.56	2.15	0.11	0.15	0.07	0.10
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	1.38	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.015	44.78	0.67	86.96	1.30	214.05	3.21	20.31	0.30	103.60	1.55
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl malt, excl beer)	RAC	1.38	8.50	11.73	0.17	0.23	3.92	5.41	0.02	0.03	6.34	8.75
-	Barley beer	PP	0.04	16.25	0.65	11.36	0.45	225.21	9.01	19.49	0.78	52.17	2.09
GC 0647	Oats, raw (incl rolled)	RAC	1.38	0.37	0.51	0.07	0.10	2.79	3.85	0.10	0.14	NC	-
GC 2088	Subgroup of rice cereals	REP	0.57	52.55	29.95	286.02	163.03	18.64	10.62	19.67	11.21	75.09	42.80
GC 2091	Subgroup of Maize Cereals	RAC	0.035	116.66	4.08	10.52	0.37	38.46	1.35	76.60	2.68	34.44	1.21
GC 2090	Subgroup of Sweet Corns	RAC	0	3.63	0.00	20.50	0.00	8.78	0.00	0.02	0.00	0.17	0.00
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.05	33.75	1.69	106.29	5.31	78.09	3.90	29.09	1.45	45.70	2.29
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.05	4.39	0.22	135.53	6.78	6.11	0.31	0.72	0.04	317.74	15.89
SO 0091	Subgroup of Oilseeds, raw (incl processed)	RAC	0.05	94.19	4.71	14.81	0.74	55.34	2.77	32.27	1.61	55.44	2.77
OR 0495	Rape seed oil, edible	PP	0.06	0.07	0.00	0.03	0.00	4.62	0.28	0.03	0.00	NC	-
-	Olive oil (virgin and residue oil)	PP	0.38	0.03	0.01	0.02	0.01	2.14	0.81	0.01	0.00	0.10	0.04
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0	0.95	0.00	1.32	0.00	11.64	0.00	2.96	0.00	14.73	0.00
HS 0775	Cardamom, pods and seeds	RAC	0.43	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-

HS 0444	Peppers, chili, dried	PP	3.5	0.58	2.03	1.27	4.45	1.21	4.24	0.12	0.42	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	3.75	0.53	1.99	5.25	19.69	0.86	3.23	0.56	2.10	0.88	3.30
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.014	23.34	0.33	40.71	0.57	97.15	1.36	18.06	0.25	57.71	0.81
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.15	5.84	0.88	10.18	1.53	24.29	3.64	4.52	0.68	14.43	2.16
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.15	1.05	0.16	1.14	0.17	18.69	2.80	0.94	0.14	3.12	0.47
MO 0105	Edible offal (mammalian), raw	RAC	0.014	4.64	0.06	1.97	0.03	10.01	0.14	3.27	0.05	3.98	0.06
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.011	108.75	1.20	70.31	0.77	436.11	4.80	61.55	0.68	79.09	0.87
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0.002	3.53	0.01	10.83	0.02	51.36	0.10	4.53	0.01	50.00	0.10
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.0038	0.39	0.00	1.20	0.00	5.71	0.02	0.50	0.00	5.56	0.02
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0038	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.002	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.0042	3.84	0.02	4.41	0.02	27.25	0.11	1.13	0.00	7.39	0.03
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				89.3		226.6		150.4		67.6		111.7
	Bodyweight per region (kg bw) =				60		60		60		60		60
	ADI (ug/person)=				1200		1200		1200		1200		1200
	%ADI=				7.4%		18.9%		12.5%		5.6%		9.3%
	Rounded %ADI=				7%		20%		10%		6%		9%

Annex 4: International Estimate of Short-Term Intake of pesticide residues

ACETAMIPRID (246)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD: 0% all 0% gen pop 0% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0,01	0	1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0 - 0.15	0% - 0%	0% - 0%	0% - 0%

CARBOSULFAN
(145)

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD:

															310% all	120% gen pop	310% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0345	Mango	Total		1.3	1.000	PRIMO-NL	toddler	P90	160.40	289	3	2b	61.329	310%	100%	310%
FI 0345	Mango	raw without peel		1.3	1.000	NL	toddler, 8-20 m	11	160.43	289	3	2b	61.339	310%	100%	310%
FI 0345	Mango (all other commodities)	highest utilisation: juice (pasteurised)	0.52		1.000	BR	Gen pop, > 10 yrs	864	720.00	NR	NR	3	0.14 - 5.8	1 - 30%	0 - 30%	1 - 10%
VO 0440	Egg plant (Aubergine) (all other commodities)	highest utilisation: Total	0.71	0.91	1.000	AU	Child, 2-6 yrs	29	128.25	318	3	2b	0.8 - 18.43	4 - 90%	2 - 80%	4 - 90%
VO 0440	Egg plant (Aubergine)	raw with skin		0.91	1.000	CN	Child, 1-6 yrs	969	253.44	444	3	2b	42.880	210%	120%	210%

CLOTHIANIDIN (238)

Acute RfD= 0.6 mg/kg bw (600 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD: 0% all | 0% gen pop | 0% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.01	0.01	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0 - 0.19	0% - 0%	0% - 0%	0% - 0%
VO 2704	Goji berry (all commodities)	highest utilisation: Dried	0.05	0.034 - 0.18	3.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0.03 - 0.81	0% - 0%	0% - 0%	0% - 0%
VS 0623	Cardoon (all commodities)	highest utilisation: cooked/boiled	0	0.02	1.000	PRIMO-NL	Gen pop	E	200.00	100	3	2a	0.09 - 0.12	0% - 0%	0% - 0%	0% - 0%
VS 0624	Celery (all commodities)	highest utilisation: raw	0.01	0.02	1.000	CN	Child, 1-6 yrs	454	180.29	861	3	2b	0 - 0.67	0% - 0%	0% - 0%	0% - 0%
VS 0380	Fennel, bulb (Florence fennel) (all commodities)	highest utilisation: cooked/boiled	0.01	0.02	1.000	PRIMO-NL	child	E	166.80	251	3	2b	0 - 0.54	0% - 0%	0% - 0%	0% - 0%
VS 0627	Rhubarb (all commodities)	highest utilisation: Total	0.01	0.02	1.000	AU	gen pop, > 2 yrs	58	539.42	57	3	2a	0.08 - 0.19	0% - 0%	0% - 0%	0% - 0%
TN 0660	Almonds (all commodities)	highest utilisation: Total	0.01	0.01	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0 - 0.04	0% - 0%	0% - 0%	0% - 0%
TN 0662	Brazil nut (all commodities)	highest utilisation: Total	0	0.01	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0.01 - 0.01	0% - 0%	0% - 0%	0% - 0%

TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted	0.01	0.01	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0.03 - 0.06	0% - 0%	0% - 0%	0% - 0%
TN 0664	Chestnut (all commodities)	highest utilisation: Total	0	0.01	1.000	CN	Gen pop, > 1 yrs	807	475.25	<25	NR	1	0.02 - 0.09	0% - 0%	0% - 0%	0% - 0%
TN 0665	Coconut (all commodities)	highest utilisation: raw (i.e. nutmeat)	0.01	0.01	1.000	TH	child, 3-6 yrs	826	423.40	383	3	2a	0.01 - 0.7	0% - 0%	0% - 0%	0% - 0%
TN 0666	Hazelnut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-IE	child	P97.5	65.42	<25	NR	1	0.01 - 0.03	0% - 0%	0% - 0%	0% - 0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0 - 0.02	0% - 0%	0% - 0%	0% - 0%
TN 0672	Pecan (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-DE	child	P100	44.41	<25	NR	1	0.01 - 0.03	0% - 0%	0% - 0%	0% - 0%
TN 0673	Pine nut (all commodities)	highest utilisation: Total	0	0.01	1.000	BR	Gen pop, > 10 yrs	47	200.00	<25	NR	1	0.01 - 0.03	0% - 0%	0% - 0%	0% - 0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-IE	child	P97.5	115.86	<25	NR	1	0 - 0.06	0% - 0%	0% - 0%	0% - 0%
TN 0678	Walnut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0 - 0.03	0% - 0%	0% - 0%	0% - 0%
HS 0780	Cumin, seed (all commodities)	highest utilisation: Total	0.25	1	1.000	AU	Child, 2-16 yrs	584	3.99	<25	NR	1	0.01 - 0.1	0% - 0%	0% - 0%	0% - 0%

DELTAMETHRIN (135)

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

international estimate of short-term intakes
Maximum %ARfD :

															1% all	1% gen pop	1% child
Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Coun try	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0350	Papaya (all commodities)	highest utilisation: Total	0.01	0.01	1.000	US	Child, < 6 yrs	86	167.57	204	3	2b	0.02 - 0.35	0% - 1%	0% - 1%	0% - 1%

DIFENOCONAZOLE (224)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD: 100% all | 40% gen pop | 100% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Subgroup of Cherries (all commodities)	highest utilisation: Total	0.37	1.02	1.000	PRIMO-DK	child	P97.5	269.00	<25	NR	1	0.15 - 12.47	0% - 4%	0% - 4%	0% - 4%
FS 0014	Subgroup of Plums (all commodities)	highest utilisation: dried (prunes)	0.37	1.02 - 2.6	3.500	AU	Child, 2-6 yrs	13	447.59	10	NR	1	0.17 - 214.37	0% - 70%	0% - 20%	0% - 70%
FS 0240	Apricot (all commodities)	highest utilisation: Total	0.37	1.02	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	0.16 - 23.04	0% - 8%	0% - 6%	0% - 8%
FS 2237	Japanese apricot (ume)	Total		1.02	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	1.437	0%	0%	0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.37	1.02	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	0.15 - 44.55	0% - 10%	0% - 4%	0% - 10%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.37	1.02	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0.15 - 53.7	0% - 20%	0% - 7%	0% - 20%

FB 0264	Blackberries (all commodities)	highest utilisation: Total	0.69	1.7	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0.12 - 18.22	0% - 6%	0% - 5%	0% - 6%
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilisation: Total	0	1.7	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	2.99 - 2.99	1% - 1%	1% - 1%	1% - 1%
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: raw with skin	0.69	1.7	1.000	NL	toddler, 8-20 m	E	59.40	4	NR	1	0.47 - 9.9	0% - 3%	0% - 2%	0% - 3%
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards) (all other commodities)	highest utilisation: Total		6.1	1.000	PRIMO-BE	toddler	P100	114.40	245	3	2b	73.54 - 117.61	20 - 40%	20 - 30%	40%
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards)	raw		6.1	1.000	CN	Child, 1-6 yrs	635	299.31	245	3	2a	298.211	100%	40%	100%
VL 0494	Radish leaves (all commodities)	highest utilisation: Total	0.17	0.31 - 6.1	1.000	PRIMO-DE	child	P100	142.12	<25	NR	1	0.02 - 53.68	0% - 20%	0% - 8%	0% - 20%

VR 0508	Sweet potato (all commodities)	highest utilisation: Total	1.2	1.9	1.000	CA	Child, <6 yrs	91	358.61	546	3	2b	8.45 - 160.11	3% - 50%	3% - 20%	10% - 50%
GC 0645	Maize (corn) (all commodities)	highest utilisation: Flour (cereals)	0.008 - 0.032	0	1.000	CN	Child, 1-6 yrs	213	361.24	NR	NR	3	0.02 - 0.18	0% - 0%	0% - 0%	0% - 0%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation)	popcorn	0.01		1.000	NL	Gen pop, > 1 yrs	51	204.70	<25	NR	3	0.031	0%	0%	0%

FLUOPYRAM (243)

international estimate of short-term intakes

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw) Maximum %ARfD: 10% all 10% gen pop 10% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0650	Rye (all commodities)	highest utilisation: flakes	0.035	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.05 - 1.2	0% - 0%	0% - 0%	0% - 0%
GC 0653	Triticale	Total	0.035		1.000	DE	Gen pop, 14-80 yrs	27100	394.70	<25	NR	3	0.181	0%	0%	0%
GC 0654	Wheat (all commodities)	highest utilisation: flakes	0.035	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.02 - 1.2	0% - 0%	0% - 0%	0% - 0%
GC 0640	Barley (all commodities)	highest utilisation: beer	0.041	0	0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0 - 2.11	0% - 0%	0% - 0%	0% - 0%
GC 0641	Buckwheat (all commodities)	highest utilisation: flakes	0.041	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.02 - 1.41	0% - 0%	0% - 0%	0% - 0%
GC 0647	Oats (all commodities)	highest utilisation: flakes (rolled oats)	0.041	0	1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.02 - 1.41	0% - 0%	0% - 0%	0% - 0%
GC 0651	Sorghum grain (Chicken corn, Dari	highest utilisation:	0.18	0	0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.28 - 1.82	0% - 0%	0% - 0%	0% - 0%

	seed, Durra, Feterita) (all commodities)	cooked/ boiled														
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		1.5	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	4.924	1%	1%	1%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		1	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	13.131	3%	2%	3%
MF 0100	Mammalian fats (except milk fats)	Total		1.5	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	3.045	1%	1%	1%
MO 0105	Edible offal (mammalian)	Total		7.4	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	69.560	10%	10%	10%
ML 0106	Milks	Total	0.48		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	59.625	10%	5%	10%
PM 0110	Poultry meat: 10% as fat	Total		0.9	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	1.935	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.97	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	18.774	4%	2%	4%
PF 0111	Poultry, fats	Total		0.9	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	2.612	1%	0%	1%

PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		3.1	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	20.130	4%	4%	2%
PE 0112	Eggs	Total		1.5	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	18.621	4%	2%	4%

IMAZAPYR (267) International Estimated Daily Intake (IEDI) ADI = 0 - 3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day G01 diet	Intake as ug/person/day G01 intake	G02 diet	G02 intake	G03 diet	G03 intake	G04 diet	G04 intake	G05 diet	G05 intake	G06 diet	G06 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.69	0.63	0.43	1.09	0.75	0.40	0.28	1.40	0.97	1.68	1.16	0.48	0.33
OR 0541	Soya oil, refined	PP	0	12.99	0.00	10.43	0.00	3.63	0.00	13.10	0.00	10.70	0.00	13.10	0.00
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.07	2.12	0.15	0.01	0.00	0.03	0.00	3.21	0.22	1.60	0.11	4.90	0.34
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.079	381.15	30.11	341.54	26.98	38.34	3.03	281.87	22.27	172.65	13.64	434.06	34.29
CF 1210	Wheat, germ	PP	0.11	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.02	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.062	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.175	19.91	3.48	31.16	5.45	5.04	0.88	3.10	0.54	9.77	1.71	4.31	0.75
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.01	1.26	0.01	1.58	0.02	31.05	0.31	5.43	0.05	0.90	0.01	2.18	0.02
CM 1205	Rice polished, dry	PP	0.01	34.21	0.34	10.39	0.10	41.72	0.42	82.38	0.82	150.24	1.50	70.47	0.70
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour,	RAC	0.05	28.85	1.44	43.93	2.20	108.66	5.43	46.94	2.35	59.87	2.99	73.58	3.68

	incl beer, incl germ, incl starch, excl oil)														
OR 0645	Maize oil	PP	0.025	0.96	0.02	0.85	0.02	0.29	0.01	5.42	0.14	0.42	0.01	2.10	0.05
SO 0495	Rape seed, raw (incl oil)	RAC	0	0.93	0.00	1.16	0.00	0.49	0.00	2.53	0.00	9.32	0.00	2.02	0.00
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	7.40	0.07	35.86	0.36	1.15	0.01	8.76	0.09	5.45	0.05	13.62	0.14
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	24.96	0.00	57.95	0.00	16.70	0.00	38.38	0.00	26.46	0.00	29.00	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	6.24	0.00	14.49	0.00	4.18	0.00	9.60	0.00	6.62	0.00	7.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	3.29	0.00	6.14	0.00	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.041	4.79	0.20	9.68	0.40	2.97	0.12	5.49	0.23	3.84	0.16	5.03	0.21
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	289.65	0.00	485.88	0.00	26.92	0.00	239.03	0.00	199.91	0.00	180.53	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	13.17	0.00	26.78	0.00	7.24	0.00	116.71	0.00	22.54	0.00	32.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	1.46	0.00	2.98	0.00	0.80	0.00	12.97	0.00	2.50	0.00	3.57	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.00	0.24	0.00	0.10	0.00
PE 0112	Eggs, raw, (incl dried)	RAC	0	7.84	0.00	23.08	0.00	2.88	0.00	14.89	0.00	9.81	0.00	14.83	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				36.3		36.3		10.5		27.7		21.4		40.5
	Bodyweight per region (kg bw) =				60		60		60		60		60		60
	ADI (ug/person)=				180000		180000		180000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day		Intake as ug/person/day									
				G07 diet	G07 intake	G08 diet	G08 intake	G09 diet	G09 intake	G10 diet	G10 intake	G11 diet	G11 intake	G12 diet	G12 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.69	0.47	0.32	0.77	0.53	9.12	6.29	8.05	5.55	0.04	0.03	6.06	4.18
OR 0541	Soya oil, refined	PP	0	19.06	0.00	21.06	0.00	5.94	0.00	33.78	0.00	40.05	0.00	13.39	0.00
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.07	0.95	0.07	1.18	0.08	0.40	0.03	0.96	0.07	0.71	0.05	1.28	0.09
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.079	252.06	19.91	244.62	19.32	134.41	10.62	235.10	18.57	216.33	17.09	167.34	13.22
CF 1210	Wheat, germ	PP	0.11	0.97	0.11	0.10	0.01	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.062	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.175	36.18	6.33	53.45	9.35	9.39	1.64	35.25	6.17	46.68	8.17	15.92	2.79
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.01	3.70	0.04	2.11	0.02	1.51	0.02	1.75	0.02	0.29	0.00	5.12	0.05
CM 1205	Rice polished, dry	PP	0.01	13.38	0.13	10.80	0.11	262.08	2.62	57.16	0.57	12.83	0.13	62.78	0.63
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.05	17.61	0.88	25.71	1.29	25.89	1.29	36.98	1.85	5.49	0.27	64.23	3.21
OR 0645	Maize oil	PP	0.025	0.90	0.02	0.47	0.01	0.15	0.00	3.01	0.08	1.86	0.05	0.36	0.01
SO 0495	Rape seed, raw (incl oil)	RAC	0	32.68	0.00	19.91	0.00	7.83	0.00	15.69	0.00	NC	-	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	23.40	0.23	29.33	0.29	1.24	0.01	13.85	0.14	6.48	0.06	6.91	0.07
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	112.02	0.00	120.71	0.00	63.46	0.00	88.99	0.00	96.24	0.00	41.02	0.00

MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	28.01	0.00	30.18	0.00	15.86	0.00	22.25	0.00	24.06	0.00	10.25	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	6.44	0.00	15.51	0.00	3.79	0.00	8.29	0.00	18.44	0.00	8.00	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.041	15.17	0.62	5.19	0.21	6.30	0.26	6.78	0.28	3.32	0.14	3.17	0.13
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	388.92	0.00	335.88	0.00	49.15	0.00	331.25	0.00	468.56	0.00	245.45	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	66.38	0.00	48.47	0.00	21.58	0.00	78.41	0.00	48.04	0.00	76.01	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	7.38	0.00	5.39	0.00	2.40	0.00	8.71	0.00	5.34	0.00	8.45	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.33	0.00	0.72	0.00	0.27	0.00	0.35	0.00	0.80	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	25.84	0.00	29.53	0.00	28.05	0.00	33.19	0.00	36.44	0.00	8.89	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				28.7		31.2		22.8		33.3		26.0		24.4
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (ug/person)=				180000		180000		165000		180000		180000		180000
	%ADI=				0.0%		0.0%		0.0%		0.0%		0.0%		0.0%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

Imazapyr (267)

International Estimated Daily Intake (IEDI)

ADI = 0 - 3 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day G13 diet	Intake = daily intake: ug/person G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.69	2.89	1.99	0.21	0.14	0.48	0.33	3.16	2.18	0.26	0.18
OR 0541	Soya oil, refined	PP	0	2.32	0.00	2.54	0.00	18.70	0.00	2.51	0.00	6.29	0.00
VD 0533	Lentil (dry) (Lens spp), raw	RAC	0.07	0.67	0.05	7.26	0.51	0.37	0.03	0.08	0.01	NC	-

GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.079	57.15	4.51	110.46	8.73	272.58	21.53	25.81	2.04	132.04	10.43
CF 1210	Wheat, germ	PP	0.11	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.062	0.01	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.175	11.58	2.03	2.33	0.41	46.71	8.17	3.72	0.65	16.26	2.85
CM 0649 (GC 0649)	Rice, husked, dry (incl flour, incl oil, incl beverages, incl starch, excl polished)	REP	0.01	13.58	0.14	4.29	0.04	2.17	0.02	0.01	0.00	8.84	0.09
CM 1205	Rice polished, dry	PP	0.01	30.20	0.30	218.34	2.18	12.77	0.13	15.24	0.15	51.35	0.51
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl flour, incl beer, incl germ, incl starch, excl oil)	RAC	0.05	116.33	5.82	10.45	0.52	37.65	1.88	76.60	3.83	34.44	1.72
OR 0645	Maize oil	PP	0.025	0.33	0.01	0.07	0.00	0.81	0.02	0.01	0.00	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0	0.19	0.00	0.07	0.00	12.07	0.00	0.08	0.00	NC	-
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.01	0.94	0.01	0.22	0.00	32.01	0.32	12.12	0.12	0.48	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0	23.34	0.00	40.71	0.00	97.15	0.00	18.06	0.00	57.71	0.00
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0	5.84	0.00	10.18	0.00	24.29	0.00	4.52	0.00	14.43	0.00
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0	1.05	0.00	1.14	0.00	18.69	0.00	0.94	0.00	3.12	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.041	4.64	0.19	1.97	0.08	10.01	0.41	3.27	0.13	3.98	0.16
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00
PM 0110	Poultry meat, raw (incl prepared) - 90% as muscle	RAC	0	3.53	0.00	10.83	0.00	51.36	0.00	4.53	0.00	50.00	0.00
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0	0.39	0.00	1.20	0.00	5.71	0.00	0.50	0.00	5.56	0.00
PF 0111	Poultry fat, raw (incl rendered)	RAC	0	NC	-	NC	-	0.32	0.00	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0	0.10	0.00	0.70	0.00	0.97	0.00	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00
-	-	-		-	-	-	-	-	-	-	-	-	-
	Total intake (ug/person)=				15.0		12.6		32.9		9.1		15.9

Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	180000	180000	180000	180000	180000
%ADI=	0.0%	0.0%	0.0%	0.0%	0.0%
Rounded %ADI=	0%	0%	0%	0%	0%

IPRODIONE (111)

international estimate of short-term intakes

Acute RfD= 0.6 mg/kg bw (600 µg/kg bw)

Maximum %ARfD: 190% all | 60% gen pop | 190% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0013	Subgroup of Cherries (all commodities)	highest utilisation: Total	0.042	0.14	1.000	PRIMO-DK	child	P97.5	269.00	<25	NR	1	0.02 - 1.71	0% - 0%	0% - 0%	0% - 0%
FS 0240	Apricot (all commodities)	highest utilisation: Total	0.05	0.05	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	0.02 - 1.13	0% - 0%	0% - 0%	0% - 0%
FS 2237	Japanese apricot (ume)	Total		0.05	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	0.070	0%	0%	0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.05	0.05	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	0.02 - 2.18	0% - 0%	0% - 0%	0% - 0%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.05	0.05	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0.02 - 2.63	0% - 0%	0% - 0%	0% - 0%
FB 0264	Blackberries (all commodities)	highest utilisation: Total	13.5	22.6	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	2.35 - 242.21	0% - 40%	0% - 30%	0% - 40%
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilisation: Total	0	22.6	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	39.74 - 39.74	7% - 7%	5% - 5%	7% - 7%

FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	13.5	22.6	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	7.44 - 208.78	1% - 30%	1% - 20%	1% - 30%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.05	0.11	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0.02 - 2.05	0% - 0%	0% - 0%	0% - 0%
VB 0400	Broccoli	Total		24	1.000	CA	Child, <6 yrs	379	194.94	388	3	2b	981.360	160%	60%	160%
VB 0400	Broccoli (all other commodities)	highest utilisation: raw	9.4	24	1.000	NL	Gen pop, > 1 yrs	13	424.54	304	3	2a	17.04 - 376.61	3 - 60%	2 - 60%	3 - 50%
VB 0400	Broccoli	cooked/boiled		24	1.000	PRIMO-NL	toddler	P97.5	160.70	286	3	2b	1134.353	190%	60%	190%
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilisation: Total	0.31	0.81	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0.47 - 10.94	0% - 2%	0% - 1%	0% - 2%
VR 0589	Potato (all commodities)	highest utilisation: Total	0.0145 - 0.05	0.05	1.000	PRIMO-UK	infant	P97.5	191.10	216	3	2b	0.03 - 3.29	0% - 1%	0% - 0%	0% - 1%
TN 0660	Almonds (all commodities)	highest utilisation: Total	0.0395	0.17	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0 - 0.67	0% - 0%	0% - 0%	0% - 0%

MEPIQUAT CATION (336)

international estimate of short-term intakes

Acute RfD= 0.4578 mg/kg bw (458 µg/kg bw)

Maximum %ARfD: 40% all | 20% gen pop | 40% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0269	Grapes (all commodities)	highest utilisation: raw with skin	0.705 - 0.78	2.6 - 10	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	4.49 - 177.27	1% - 40%	0% - 20%	0% - 40%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	1.3	0	1.000	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0.28 - 0.28	0% - 0%	0% - 0%	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total		0.0092	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	0.151	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.0092	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.019	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.047	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.442	0%	0%	0%
ML 0106	Milks	Total	0.018		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	2.236	0%	0%	0%

PM 0110	Poultry meat	Total		0	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	0.000	0%	0%	0%
PF 0111	Poultry, fats	Total		0	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.000	0%	0%	0%
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.000	0%	0%	0%
PE 0112	Eggs	Total		0	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.000	0%	0%	0%

PROPICONAZOLE (160)

international estimate of short-term intakes

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

Maximum %ARfD: 100% all | 70% gen pop | 100% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FI 0326	Avocado (all commodities)	highest utilisation: Total	0	0.12	1.000	AU	Child, 2-6 yrs	182	229.90	171	3	2a	1.85 - 3.62	1% - 1%	1% - 1%	1% - 1%
GC 0649	Rice (all other commodities)	highest utilisation: flour (cereals)	1.95 - 48		1.000	CN	Child, 1-6 yrs	416	268.93	NR	NR	3	0.96 - 275	5 - 90%	5 - 50%	2 - 90%
GC 0649	Rice	pasta/noodles (dry)	16.5		1.000	CA	Child, <6 yrs	40	268.35	NR	NR	3	302.427	100%	70%	100%
SO 0697	Peanut, shelled (groundnut) (all commodities)	highest utilisation: raw incl roasted	0.03	0	1.000	CN	Child, 1-6 yrs	290	163.07	<25	NR	3	0.02 - 0.3	0% - 0%	0% - 0%	0% - 0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	4329	261.46	NR	NR	1	NA	1%	1%	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.24	1.000	CN	Child, 1-6 yrs	4329	52.29	NR	NR	1	0.778	0%	0%	0%
MM 0095	Meat from mammals other than	Total		0.12	1.000	CN	Child, 1-6 yrs	4329	209.17	NR	NR	1	1.556	1%	0%	1%

	marine mammals: 80% as muscle															
MF 0100	Mammalian fats (except milk fats)	Total		0.24	1.000	PRIMO-UK	infant	P97.5	18.10	NR	NR	1	0.499	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		5	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	47.000	20%	20%	10%
ML 0106	Milks	Total	0.03		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	3.727	1%	0%	1%
FM 0812	Cattle milk fat	Total	0.03		1.000	BR	Gen pop, > 10 yrs	441	150.00	NR	NR	3	0.070	0%	0%	0%
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	0%	0%	0%
PM 0110	Poultry meat: 10% as fat	Total		0.05	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.108	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.05	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	0.968	0%	0%	0%
PF 0111	Poultry, fats	Total		0.05	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.145	0%	0%	0%
PO 0111	Poultry, edible offal (includes kidney and liver)	Total		0.12	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.779	0%	0%	0%
PE 0112	Eggs	Total		0.08	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.993	0%	0%	0%

PYRETHRINS (63)

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD:

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded 5% all	% acute RfD rounded 2% gen pop	% acute RfD rounded 5% child
FS 0013	Subgroup of Cherries (all commodities)	highest utilisation: Total	0.09	0.18	1.000	PRIMO-DK	child	P97.5	269.00	<25	NR	1	0.04 - 2.2	0% - 1%	0% - 1%	0% - 1%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.09	0.18	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0.04 - 9.48	0% - 5%	0% - 2%	0% - 5%
FB 0264	Blackberries (all commodities)	highest utilisation: Total	0.077	0.17	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0.01 - 1.82	0% - 1%	0% - 1%	0% - 1%
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilisation: Total	0	0.17	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	0.3 - 0.3	0% - 0%	0% - 0%	0% - 0%
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	0.077	0.17	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	0.05 - 1.57	0% - 1%	0% - 0%	0% - 1%
FB 0275	Strawberry (all commodities)	highest utilisation: Raw with skin	0.077	0.17	1.000	NL	toddler, 8-20 m	52	166.73	18	NR	1	0.04 - 2.78	0% - 1%	0% - 1%	0% - 1%

THIAMETHOXAM (245)

international estimate of short-term intakes

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

Maximum %ARfD: 1% all 1% gen pop 1% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.01	0.014	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0 - 0.26	0% - 0%	0% - 0%	0% - 0%
VO 2704	Goji berry (all commodities)	highest utilisation: Dried	0.21	0.65 - 1.7	3.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0.62 - 7.61	0% - 1%	0% - 0%	0% - 1%
VS 0623	Cardoon (all commodities)	highest utilisation: cooked/boiled	0	0.4	1.000	PRIMO-NL	Gen pop	E	200.00	100	3	2a	1.78 - 2.43	0% - 0%	0% - 0%	0% - 0%
VS 0624	Celery (all commodities)	highest utilisation: raw	0.215	0.4	1.000	CN	Child, 1-6 yrs	454	180.29	861	3	2b	0.01 - 13.41	0% - 1%	0% - 1%	0% - 1%
VS 0380	Fennel, bulb (Florence fennel) (all commodities)	highest utilisation: cooked/boiled	0.215	0.4	1.000	PRIMO-NL	child	E	166.80	251	3	2b	0.01 - 10.88	0% - 1%	0% - 0%	0% - 1%
VS 0627	Rhubarb (all commodities)	highest utilisation: Total	0.215	0.4	1.000	AU	gen pop, > 2 yrs	58	539.42	57	3	2a	1.75 - 3.9	0% - 0%	0% - 0%	0% - 1%
TN 0660	Almonds (all commodities)	highest utilisation: Total	0.01	0.01	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0 - 0.04	0% - 0%	0% - 0%	0% - 0%

TN 0662	Brazil nut (all commodities)	highest utilisation: Total	0	0.01	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0.01 - 0.01	0% - 0%	0% - 0%	0% - 0%
TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted	0.01	0.01	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0.03 - 0.06	0% - 0%	0% - 0%	0% - 0%
TN 0664	Chestnut (all commodities)	highest utilisation: Total	0	0.01	1.000	CN	Gen pop, > 1 yrs	807	475.25	<25	NR	1	0.02 - 0.09	0% - 0%	0% - 0%	0% - 0%
TN 0665	Coconut (all commodities)	highest utilisation: raw (i.e. nutmeat)	0.01	0.01	1.000	TH	child, 3-6 yrs	826	423.40	383	3	2a	0.01 - 0.7	0% - 0%	0% - 0%	0% - 0%
TN 0666	Hazelnut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-IE	child	P97.5	65.42	<25	NR	1	0.01 - 0.03	0% - 0%	0% - 0%	0% - 0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0 - 0.02	0% - 0%	0% - 0%	0% - 0%
TN 0672	Pecan (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-DE	child	P100	44.41	<25	NR	1	0.01 - 0.03	0% - 0%	0% - 0%	0% - 0%
TN 0673	Pine nut (all commodities)	highest utilisation: Total	0	0.01	1.000	BR	Gen pop, > 10 yrs	47	200.00	<25	NR	1	0.01 - 0.03	0% - 0%	0% - 0%	0% - 0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-IE	child	P97.5	115.86	<25	NR	1	0 - 0.06	0% - 0%	0% - 0%	0% - 0%
TN 0678	Walnut (all commodities)	highest utilisation: Total	0.01	0.01	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0 - 0.03	0% - 0%	0% - 0%	0% - 0%
HS 0780	Cumin, seed (all	highest utilisation: Total	0.26	1	1.000	AU	Child, 2-16 yrs	584	3.99	<25	NR	1	0.01 - 0.1	0% - 0%	0% - 0%	0% - 0%

	commodities)															

THIOPHANATE-METHYL ()

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD: 0% all | 0% gen pop | 0% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
TN 0660	Almonds (all commodities)	highest utilisation: Total	0	0.05	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0.07 - 0.2	0% - 0%	0% - 0%	0% - 0%

TRICYCLAZOLEE (337)

IESTI

Acute RfD= 0.05 mg/kg bw (50 µg/kg bw)

Maximum %ARfD: 20% women

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded
GC 0649	Rice (all commodities)	highest utilisation: Total	0.01 - 0.735	0	1.000	CA	women, 15-49 yrs	1109	810.57	<25	NR	3	0.04 - 9.13	0% - 20%
MM 0095	Meat from mammals other than marine mammals	Total		0	1.000	DE	Women, 14-50 yrs	25	521.10	NR	NR	1	0,000	0%
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	US	women, 13-49 yrs	6730	45.60	NR	NR	1	0.000	0%
MO 0105	Edible offal (mammalian)	Total		0,18	1.000	PRIMO-DE	women, 14-50 yrs	P100	188.92	NR	NR	1	0.504	1%
ML 0106	Milks	Total		0	1.000	DE	Women, 14-50 yrs	6554	1276.50	NR	NR	3	ND	-
PM 0110	Poultry meat	Total		0	1.000	CA	women, 15-49 yrs	2127	384.47	NR	NR	1	0.000	0%
PF 0111	Poultry, fats	Total		0	1.000	CA	women, 15-49 yrs	195	78.63	NR	NR	1	0.000	0%

PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0,01	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.065	0%
PE 0112	Eggs	Total		0	1.000	CA	women, 15-49 yrs	3395	136.90	NR	NR	1	0.000	0%

ZETA-CYPERMETHRIN (118)

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)

international estimate of short-term intakes

Maximum %ARfD: 30% all | 20% gen pop | 30% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	n	Large portion, g/person	Unit weight, edible portion, g	Varia-bility factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0020	Blueberries (all commodities)	highest utilisation: Total	0.4	0.53	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0.06 - 6.07	0% - 20%	0% - 10%	0% - 20%
FB 0021	Currants, black, red, white (all commodities)	highest utilisation: juice (pasteurised)	0.4	0.53	1.000	PRIMO-NL	child	E	525.80	NR	NR	3	0.26 - 11.43	1% - 30%	0% - 20%	1% - 30%
FB 0268	Gooseberry (all commodities)	highest utilisation: Total	0.4	0.53	1.000	PRIMO-DE	child	P100	94.96	<25	NR	1	0.08 - 3.12	0% - 8%	0% - 7%	0% - 8%
FB 0273	Rose hips (all commodities)	highest utilisation: jam (incl jelly)	0.4	0.53	1.000	CA	Child, <6 yrs	443	78.10	NR	NR	3	0.25 - 2.03	1% - 5%	0% - 3%	1% - 5%
FI 0326	Avocado (all commodities)	highest utilisation: Total	0	0.28	1.000	AU	Child, 2-6 yrs	182	229.90	171	3	2a	4.31 - 8.44	10% - 20%	10% - 10%	10% - 20%
VA 0381	Garlic (all commodities)	highest utilisation: raw without skin	0	0	1.000	CN	Child, 1-6 yrs	290	174.44	62	3	2a	0 - 0	0% - 0%	0% - 0%	0% - 0%
VA 0385	Onion, bulb (all	highest utilisation: raw	0	0	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0 - 0	0% - 0%	0% - 0%	0% - 0%

	commodities)	without skin														
VA 0386	Onion, Chinese (all commodities)	highest utilisation: raw	0	0	1.000	CN	Child, 1-6 yrs	196	136.53	130	3	2a	0 - 0	0% - 0%	0% - 0%	0% - 0%
VA 0388	Shallot (all commodities)	highest utilisation: raw without skin	0	0	1.000	CN	Child, 1-6 yrs	480	115.81	51	3	2a	0 - 0	0% - 0%	0% - 0%	0% - 0%

Annex 5: Reports and other documents resulting from previous joint meetings of the FAO panel of experts on pesticide residues in food and the environment and the WHO core assessment group on pesticide residues.

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.
71. Pesticide residues in food–1994. 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 127, Rome, 1995.
72. Pesticide residues in food–1994 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 131/1 and 131/2 (2 volumes), Rome, 1995.

73. Pesticide residues in food–1994 evaluations. Part II. Toxicology. World Health Organization, WHO/PCS/95.2, Geneva, 1995.
74. Pesticide residues in food–1995. 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 133, Rome, 1996.
75. Pesticide residues in food–1995 evaluations. Part I. Residues. FAO Plant Production and Protection Paper 137, 1996.
76. Pesticide residues in food–1995 evaluations. Part II. Toxicological and Environmental. World Health Organization, WHO/PCS/96.48, Geneva, 1996.
77. Pesticide residues in food–1996. 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, 140, 1997.
78. Pesticide residues in food–1996 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 142, 1997.
79. Pesticide residues in food–1996 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS/97.1, Geneva, 1997.
80. Pesticide residues in food–1997. 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, 145, 1998.
81. Pesticide residues in food–1997 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 146, 1998.
82. Pesticide residues in food–1997 evaluations. Part II. Toxicological and Environmental. World Health Organization, WHO/PCS/98.6, Geneva, 1998.
83. Pesticide residues in food–1998. 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, 148, 1999.
84. Pesticide residues in food–1998 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 152/1 and 152/2 (two volumes).
85. Pesticide residues in food–1998 evaluations. Part II. Toxicological and Environmental. World Health Organization, WHO/PCS/99.18, Geneva, 1999.
86. Pesticide residues in food–1999. 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, 153, 1999.
87. Pesticide residues in food–1999 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 157, 2000.
88. Pesticide residues in food–1999 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS/00.4, Geneva, 2000.
89. Pesticide residues in food–2000. 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, 163, 2001.
90. Pesticide residues in food–2000 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 165, 2001.
91. Pesticide residues in food–2000 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS/01.3, 2001.
92. Pesticide residues in food–2001. 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, 167, 2001.
93. Pesticide residues in food–2001 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 171, 2002.

94. Pesticide residues in food–2001 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS/02.1, 2002.
95. Pesticide residues in food–2002. 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, 172, 2002.
96. Pesticide residues in food–2002 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 175/1 and 175/2 (two volumes).
97. Pesticide residues in food–2002 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS, 2003.
98. Pesticide residues in food–2003. 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, 176, 2004.
99. Pesticide residues in food–2003 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 177, 2004.
100. Pesticide residues in food–2003 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS, 2004.
101. Pesticide residues in food–2004. 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, 178, 2004.
102. Pesticide residues in food–2004 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 182, 2005.
103. Pesticide residues in food–2004 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS, 2005.
104. Pesticide residues in food–2005. 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, 183, 2005.
105. Pesticide residues in food–2005 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 184, 2006.
106. Pesticide residues in food–2005 evaluations. Part II. Toxicological. World Health Organization, WHO/PCS/07.1, 2006.
107. Pesticide residues in food–2006. 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, 187, 2007.
108. Pesticide residues in food–2006 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 189/1 and 189/2 (two volumes), 2007.
109. Pesticide residues in food–2006 evaluations. Part II. Toxicological. World Health Organization, 2008.
110. Pesticide residues in food–2007. 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, 191, 2008.
111. Pesticide residues in food–2007 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 192, 2008.
112. Pesticide residues in food–2007 evaluations. Part II. Toxicological. World Health Organization, 2009.
113. 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.
114. Pesticide residues in food–2008 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 194, 2009.

115. Pesticide residues in food–2008 evaluations. Part II. Toxicological. World Health Organization, 2010.
116. Pesticide residues in food–2009. 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, 196, 2010.
117. Pesticide residues in food–2009 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 198, 2010.
118. Pesticide residues in food–2009 evaluations. Part II. Toxicological. World Health Organization, 2011.
119. Pesticide residues in food–2010. 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, 200, 2011.
120. Pesticide residues in food–2010 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 206, 2011.
121. Pesticide residues in food–2010 evaluations. Part II. Toxicological. World Health Organization, 2011.
122. Pesticide residues in food–2011. 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. FAO Plant Production and Protection Paper, 211, 2012.
123. Pesticide residues in food–2011 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 212, 2012.
124. Pesticide residues in food–2011 evaluations. Part II. Toxicological. World Health Organization, 2012.
125. Pesticide residues in food–2012. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper, 215, 2013.
126. Pesticide residues in food–2012 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 216, 2013.
127. Pesticide residues in food–2012 evaluations. Part II. Toxicological. World Health Organization, 2013.
128. Pesticide residues in food–2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper, 219, 2014.
129. Pesticide residues in food–2013 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 220, 2014.
130. Pesticide residues in food–2013 evaluations. Part II. Toxicological. World Health Organization, 2014.
131. Pesticide residues in food–2014. 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. FAO Plant Production and Protection Paper, 221, 2014.
132. Pesticide residues in food–2014 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 222, 2015.
133. Pesticide residues in food–2014 evaluations. Part II. Toxicological. World Health Organization, 2015.
134. Pesticide residues in food–2015. 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. FAO Plant Production and Protection Paper, 223, 2015.
135. Pesticide residues in food–2015 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 226, 2016.
136. Pesticide residues in food–2015 evaluations. Part II. Toxicological. World Health Organization, 2016.
137. Pesticide residues in food–2016. Report of a Special Session 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. FAO Plant Production and Protection Paper, 227, 2016.
138. Pesticide residues in food–2016 evaluations (Special Session). Toxicological. World Health Organization, in preparation.
139. Pesticide residues in food–2016. 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. FAO Plant Production and Protection Paper, 229, 2015.
140. Pesticide residues in food–2016 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 231, 2017.
141. Pesticide residues in food–2016 evaluations. Part II. Toxicological. World Health Organization, 2017.
142. Pesticides residues in food–2017. 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. FAO Plant Production and Protection Paper, 232, 2017.
143 Pesticide residues in food–2017 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 233, 2018.
144. Pesticide residues in food–2017 evaluations. Part II. Toxicological. World Health Organization, 2018.
145. Pesticides residues in food–2018. 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. FAO Plant Production and Protection Paper, 234, 2018.
146. Pesticide residues in food–2018 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 235, 2019.
147. Pesticide residues in food–2018 evaluations. Part II. Toxicological. World Health Organization, 2019.
148. Pesticides residues in food–2019. Report of the extra 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.
149. Pesticide residues in food–2019 Extra Joint FAO/WHO Meeting on Pesticide Residues Evaluation Part I: Residues. FAO Plant Production and Protection Paper, 2019.

150. Pesticides residues in food–2019. 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. FAO Plant Production and Protection Paper, 2020.
151. Pesticide residues in food–2019 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 235, 2019.

152. Pesticide residues in food–2019 evaluations. Part II. Toxicological (Extra). World Health Organization, 2021.
153. Pesticide residues in food–2019 evaluations. Part II. Toxicological. World Health Organization, 2021.
154. Pesticides residues in food–2021. 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. FAO Plant Production and Protection Paper, 2022
155. Pesticide residues in food–2021 evaluations. Part I. Residues. FAO Plant Production and Protection Paper, 2022.

Annex 6: Livestock dietary burden calculations

Acetamiprid (246)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, sweet stover	AF/AS	20	HR	83	24.10			40				9.638554217	
Cotton gin by-products	AM/AV	18	HR	90	20.00	5				1.000			
Corn, sweet forage	AF/AS	9.1	HR	48	18.96			60				11.375	
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		20				0.666666667		
Apple pomace, wet	AB	0.32	STMR	40	0.80		20				0.16		
Citrus dried pulp	AB	0.7	STMR	91	0.77	10				0.077			
Cotton hulls	SM	0.07	STMR	90	0.08	10				0.008			
Cotton meal	SM	0.03	STMR	89	0.03		5				0.001685393		
Bean seed	VD	0.01	STMR	88	0.01		20				0.002272727		
Soybean seed	VD	0.01	STMR	89	0.01	5			15	0.001			0.001685393
Total						30	65	100	15	1.085	0.830624787	21.01355422	0.001685393

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Corn, sweet stover	AF/AS	20	HR	83	24.10	15		20		3.614		4.819277108	
Corn, sweet forage	AF/AS	9.1	HR	48	18.96	30		20		5.688		3.791666667	
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		20				0.666666667		
Almond hulls	AM/AV	1.34	STMR	90	1.49	10		10		0.149		0.148888889	
Apple pomace, wet	AB	0.32	STMR	40	0.80	10	10	10		0.080	0.08	0.08	
Citrus dried pulp	AB	0.7	STMR	91	0.77		10	20			0.076923077	0.153846154	
Cotton undelinted seed	SO	0.09	STMR	88	0.10	10	10	20		0.010	0.010227273	0.020454545	
Cotton meal	SM	0.03	STMR	89	0.03	10	5			0.003	0.001685393		
Bean seed	VD	0.01	STMR	88	0.01		20				0.002272727		
Soybean seed	VD	0.01	STMR	89	0.01	10			10	0.001			0.001123596
Total						95	75	100	10	9.546	0.837775137	9.014133363	0.001123596

POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cotton meal	SM	0.03	STMR	89	0.03	20	5	10		0.007	0.001685393	0.003370787	
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.002272727	0.007954545	
Soybean seed	VD	0.01	STMR	89	0.01	20				0.002			
Total						40	25	80		0.009	0.003958121	0.011325332	

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	0.5	HR	15	3.33		5				0.166666667		
Cotton meal	SM	0.03	STMR	89	0.03	20	5	10		0.007	0.001685393	0.003370787	
Bean seed	VD	0.01	STMR	88	0.01		20	70			0.002272727	0.007954545	

Soybean seed	VD	0.01	STMR	89	0.01	20				0.002			
Total						40	30	80		0.009	0.170624787	0.011325332	

Acetamiprid (246)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Cotton gin by-products	AM/AV	3.6	STMR/ STMR-P	90	4.00	5				0.2			
Corn, sweet stover	AF/AS	2.8	STMR/ STMR-P	83	3.37			40				1.34939759	
Corn, sweet forage	AF/AS	1.4	STMR/ STMR-P	48	2.92			60				1.75	
Apple pomace, wet	AB	0.32	STMR/ STMR-P	40	0.80		20				0.16		
Citrus dried pulp	AB	0.7	STMR/ STMR-P	91	0.77	10				0.076923077			
Cabbage heads, leaves	AM/AV	0.09	STMR/ STMR-P	15	0.60		20				0.12		
Cotton hulls	SM	0.07	STMR/ STMR-P	90	0.08	10				0.007777778			
Cotton meal	SM	0.03	STMR/ STMR-P	89	0.03		5				0.001685393		
Bean seed	VD	0.01	STMR/ STMR-P	88	0.01		20				0.002272727		
Soybean seed	VD	0.01	STMR/ STMR-P	89	0.01	5			15	0.001			0.001685393
Total						30	65	100	15	0.285	0.283958121	3.09939759	0.001685393

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Corn, sweet stover	AF/AS	2.8	STMR/STMR-P	83	3.37	15	0	20		0.506024096	0	0.674698795	
Corn, sweet forage	AF/AS	1.4	STMR/STMR-P	48	2.92	30		20		0.875		0.583333333	
Almond hulls	AM/AV	1.34	STMR/STMR-P	90	1.49	10		10		0.148888889		0.148888889	
Apple pomace, wet	AB	0.32	STMR/STMR-P	40	0.80	10	10	10		0.08	0.08	0.08	
Citrus dried pulp	AB	0.7	STMR/STMR-P	91	0.77	0	10	20		0	0.076923077	0.153846154	
Cabbage heads, leaves	AM/AV	0.09	STMR/STMR-P	15	0.60	0	20			0	0.12		
Cotton undelinted seed	SO	0.09	STMR/STMR-P	88	0.10	10	10	20		0.010227273	0.010227273	0.020454545	
Cotton meal	SM	0.03	STMR/STMR-P	89	0.03	10	5			0.003370787	0.001685393		
Bean seed	VD	0.01	STMR/STMR-P	88	0.01	0	20			0	0.002272727		
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	10			10	0.001123596			0.001123596
Total						95	75	100	10	1.62463464	0.29110847	1.661221717	0.001123596

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Cotton meal	SM	0.03	STMR/STMR-P	89	0.03	20	5	10		0.01	0.001685393	0.003370787	
Bean seed	VD	0.01	STMR/STMR-P	88	0.01		20	70			0.002272727	0.007954545	
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	20				0.00			
Total						40	25	80		0.01	0.003958121	0.011325332	

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Cabbage heads, leaves	AM/AV	0.09	STMR/STMR-P	15	0.60		5				0.03		
Cotton meal	SM	0.03	STMR/STMR-P	89	0.03	20	5	10		0.006741573	0.001685393	0.003370787	

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Bean seed	VD	0.01	STMR/STMR-P	88	0.01		20	70			0.002272727	0.007954545	
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	20				0.002247191			
Total						40	30	80		0.008988764	0.033958121	0.011325332	

Cyantraniliprole (263)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Pea vines	AL	47.07	HR	100	47.07		20	60			9.414	28.242	
Soybean hay	AL	46.39	HR	100	46.39			40				18.556	
Pea hay	AL	28.54	HR	100	28.54		5				1.427		
Cabbage heads, leaves	AM/AV	1.1	HR	15	7.33		20				1.466666667		
Cotton gin by-products	AM/AV	5	HR	90	5.56	5				0.278			
Corn, field asp gr fn	CM/CF	1.76	STMR	85	2.07	5				0.104			
Rice straw	AF/AS	0.84	HR	100	0.84		10		55		0.084		0.462
Trefoil hay	AL	0.58	HR	85	0.68	15				0.102			
Vetch hay	AL	0.58	HR	85	0.68				5				0.034117647
Cowpea hay	AL	0.58	HR	86	0.67		10				0.06744186		
Alfalfa hay	AL	0.58	HR	89	0.65				5				0.03258427
Potato culls	VR	0.1	HR	20	0.50	30	30			0.150	0.15		
Clover forage	AL	0.14	HR	30	0.47		5				0.023333333		
Potato process waste	AB	0.046	STMR	12	0.38	30				0.115			
Corn, field stover	AF/AS	0.23	HR	83	0.28	15				0.042			
Soybean seed	VD	0.033	STMR	89	0.04				15				0.005561798
Corn, field milled bypdts	CM/CF	0.0033	STMR	85	0.00				5				0.000194118
Total						100	100	100	85	0.790	12.63244186	46.798	0.534457832

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Pea vines	AL	47.07	HR	100	47.07	10	20	40		4.707	9.414	18.828	
Soybean hay	AL	46.39	HR	100	46.39	10				4.639			
Pea hay	AL	28.54	HR	100	28.54		10	60			2.854	17.124	
Cabbage heads, leaves	AM/AV	1.1	HR	15	7.33		20				1.466666667		
Almond hulls	AM/AV	1.9	STMR	90	2.11	10				0.211			
Rice straw	AF/AS	0.84	HR	100	0.84		5		25		0.042		0.21
Trefoil hay	AL	0.58	HR	85	0.68	20	10			0.136	0.068235294		
Vetch hay	AL	0.58	HR	85	0.68				25				0.170588235
Alfalfa hay	AL	0.58	HR	89	0.65		35				0.228089888		
Potato culls	VR	0.1	HR	20	0.50	10				0.050			
Apple pomace, wet	AB	0.16	STMR	40	0.40	10				0.040			
Corn, field stover	AF/AS	0.23	HR	83	0.28	15				0.042			
Grass forage (fresh)	AF/AS	0.053	HR	25	0.21	15				0.032			
Grass hay	AF/AS	0.14	HR	88	0.16				50				0.079545455
Total						100	100	100	100	9.857	14.07299185	35.952	0.46013369

POULTRY BROILER												MEAN	
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.046	STMR/STMR-P	20	0.23		10				0.023		
Soybean seed	VD	0.033	STMR/STMR-P	89	0.04	20	20	15		0.01	0.00741573	0.00556179	
Cassava/tapioca roots	VR	0.01	STMR/STMR-P	37	0.03		10				0.00270273		
Cotton meal	SM	0.014	STMR/STMR-P	89	0.02	20	5	10		0.00	0.00078651	0.00157303	
Rice grain	GC	0.01	STMR/STMR-P	88	0.01	20		50		0.00		0.00568181	
Corn, field milled bypdts	CM/CF	0.0033	STMR/STMR-P	85	0.00	40	55			0.00	0.00213529		
Total						100	100	75		0.01	0.03604044	0.01281665	

POULTRY LAYER												MEAN	
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean forage	AL	15.59	STMR/STMR-P	100	15.59		10				1.559		
Cabbage heads, leaves	AM/AV	0.56	STMR/STMR-P	15	3.73		5				0.186666667		

Potato culls	VR	0.046	STMR/STMR-P	20	0.23		10				0.023		
Sorghum, grain stover	AF/AS	0.05	STMR/STMR-P	88	0.06		10				0.005681818		
Soybean seed	VD	0.033	STMR/STMR-P	89	0.04	20	15	15		0.00741573	0.005561798	0.005561798	
Rape forage	AM/AV	0.01	STMR/STMR-P	30	0.03		5				0.001666667		
Cassava/tapioca roots	VR	0.01	STMR/STMR-P	37	0.03		5				0.001351351		
Cotton meal	SM	0.014	STMR/STMR-P	89	0.02	20	5	10		0.003146067	0.000786517	0.001573034	
Rice grain	GC	0.01	STMR/STMR-P	88	0.01	20		50		0.002		0.006	
Corn, field milled bypdts	CM/CF	0.0033	STMR/STMR-P	85	0.00	40	35			0.001552941	0.001358824		
Total						100	100	75		0.014387466	1.785073641	0.01281665	

Cyflumetofen (273)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace, wet	AB	0.96	STMR	20	4.80			10				0.48	
Grape pomace, wet	AB	0.638	STMR	15	4.25			10				0.425333333	
Almond hulls	AM/AV	0.67	STMR	90	0.74			10				0.074444444	
Apple pomace, wet	AB	0.18	STMR	40	0.45		20				0.09		
Citrus dried pulp	AB	0.06	STMR	91	0.07	10		10		0.007		0.006593407	
Total						10	20	40		0.0066	0.090	0.986371184	

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Tomato pomace,wet	AB	0.96	STMR	20	4.80			10				0.48	
Grape pomace, wet	AB	0.638	STMR	15	4.25			10				0.425333333	
Almond hulls	AM/AV	0.67	STMR	90	0.74	10		10		0.074		0.074444444	
Apple pomace, wet	AB	0.18	STMR	40	0.45	10	10			0.045	0.045		
Citrus dried pulp	AB	0.06	STMR	91	0.07		10	10			0.006593407	0.006593407	
Total						20	20	40		0.119	0.051593407	0.986371184	

Cyflumetofen (273)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Tomato pomace,wet	AB	0.96	STMR/STMR-P	20	4.80			10				0.48	
Grape pomace, wet	AB	0.638	STMR/STMR-P	15	4.25			10				0.425333333	
Almond hulls	AM/AV	0.67	STMR/STMR-P	90	0.74			10				0.074444444	
Apple pomace, wet	AB	0.18	STMR/STMR-P	40	0.45		20				0.09		
Citrus dried pulp	AB	0.06	STMR/STMR-P	91	0.07	10		10		0.006593407		0.006593407	
Total						10	20	40		0.0066	0.090	0.986371184	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Tomato pomace,wet	AB	0.96	STMR/STMR-P	20	4.80		0	10			0	0.48	
Grape pomace, wet	AB	0.638	STMR/STMR-P	15	4.25	0		10		0		0.425333333	
Almond hulls	AM/AV	0.67	STMR/STMR-P	90	0.74	10		10		0.074444444		0.074444444	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
Apple pomace, wet	AB	0.18	STMR/STMR-P	40	0.45	10	10			0.045	0.045		
Citrus dried pulp	AB	0.06	STMR/STMR-P	91	0.07	0	10	10		0	0.006593407	0.006593407	
Total						20	20	40		0.1194	0.051593407	0.986371184	

Dimethylnapthalene (1,4) (331)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	17	HR	20	85.00	30	30	10		25.500	25.5	8.5	
Potato dried pulp	AB	28	STMR	88	31.82		10	5			3.181818182	1.590909091	
Potato process waste	AB	2.5	STMR	12	20.83	30	30			6.250	6.25		
Total						60	70	15		31.750	34.93181818	10.09090909	

DAIRY CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	17	HR	20	85.00	10	30	10		8.500	25.5	8.5	
Potato dried pulp	AB	28	STMR	88	31.82		10	5			3.181818182	1.590909091	
Potato process waste	AB	2.5	STMR	12	20.83	10	20			2.083	4.166666667		
Total						20	60	15		10.583	32.84848485	10.09090909	

POULTRY BROILER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	17	HR	20	85.00		10				8.5		
Potato dried pulp	AB	28	STMR	88	31.82		20				6.363636364		
Total							30				14.86363636		

POULTRY LAYER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	17	HR	20	85.00		10				8.5		
Potato dried pulp	AB	28	STMR	88	31.82		15				4.772727273		
Total							25				13.27272727		

Dimethylnapthalene (1,4) (331)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US- CAN	EU	AU	JP	US-CAN	EU	AU	
Potato culls	VR	8.65	STMR/STMR-P	20	43.25	30	30	10		12.975	12.975	4.325	
Potato dried pulp	AB	28	STMR/STMR-P	88	31.82		10	5			3.181818182	1.590909091	
Potato process waste	AB	2.5	STMR/STMR-P	12	20.83	30	30			6.25	6.25		
Total						60	70	15		19.225	22.40681818	5.915909091	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Corn, sweet stover	AF/AS	2.8	STMR/STMR-P	83	3.37	15	0	20		0.506024096	0	0.674698795	
Corn, sweet forage	AF/AS	1.4	STMR/STMR-P	48	2.92	30		20		0.875		0.583333333	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Potato culls	VR	8.65	STMR/STMR-P	20	43.25	10	30	10		4.325	12.975	4.325	
Potato dried pulp	AB	28	STMR/STMR-P	88	31.82	0	10	5		0	3.181818182	1.590909091	
Potato process waste	AB	2.5	STMR/STMR-P	12	20.83	10	20			2.083333333	4.166666667		
Total						20	60	15		6.408333333	20.32348485	5.915909091	

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Potato culls	VR	8.65	STMR/STMR-P	20	43.25		10				4.325		
Potato dried pulp	AB	28	STMR/STMR-P	88	31.82		20				6.363636364		
Total							30				10.68863636		

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Potato culls	VR	8.65	STMR/STMR-P	20	43.25		10				4.325		
Potato dried pulp	AB	28	STMR/STMR-P	88	31.82		15				4.772727273		
Total							25				9.097727273		

Florylpicoxamid (332)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	6	HR	25	24.00		20	100			4.8	24	
Triticale hay	AF/AS	1.6	HR	88	1.82	15				0.273			
Beet, sugar tops	AM/AV	0.2	HR	23	0.87		20				0.173913043		
Wheat milled bypdts	CM/CF	0.74	STMR	88	0.84	40	30		55	0.336	0.252272727		0.4625
Beet, sugar dried pulp	AB	0.13	STMR	88	0.15	15	20		5	0.022	0.029545455		0.007386364
Beet, sugar ensiled pulp	AB	0.02	STMR	15	0.13		10				0.013333333		
Wheat grain	GC	0.021	STMR	89	0.02	20			25	0.005			0.005898876
Beet, sugar molasses	DM	0.004	STMR	75	0.01	10				0.001			
Total						100	100	100	85	0.637	5.269064559	24	0.47578524

DAIRY CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	6	HR	25	24.00	20	20	60		4.800	4.8	14.4	
Triticale forage	AF/AS	6	HR	30	20.00			40				8	
Beet, sugar tops	AM/AV	0.2	HR	23	0.87		30				0.260869565		
Wheat milled bypdts	CM/CF	0.74	STMR	88	0.84	30	30		45	0.252	0.252272727		0.378409091
Rape forage	AM/AV	0.12	HR	30	0.40	10				0.040			
Beet, sugar dried pulp	AB	0.13	STMR	88	0.15	15	20		40	0.022	0.029545455		0.059090909
Wheat grain	GC	0.021	STMR	89	0.02	20			10	0.005			0.002359551
Beet, sugar molasses	DM	0.004	STMR	75	0.01	5				0.000			
Total						100	100	100	95	5.119	5.342687747	22.4	0.439859551

Florylpicoxamid (332)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Tomato pomace,wet	AB	1.4	STMR/STMR-P	20	7.00			10				0.7	
Grape pomace, wet	AB	0.38	STMR/STMR-P	15	2.53			10				0.253333333	
Wheat forage	AF/AS	0.22	STMR/STMR-P	25	0.88		20	80			0.176	0.704	
Wheat milled bypdts	CM/CF	0.74	STMR/STMR-P	88	0.84	40	30		55	0.336363636	0.252272727		0.4625
Rape forage	AM/AV	0.07	STMR/STMR-P	30	0.23		10				0.023333333		
Beet, sugar dried pulp	AB	0.13	STMR/STMR-P	88	0.15	15	20		5	0.022159091	0.029545455		0.007386364
Beet, sugar tops	AM/AV	0.033	STMR/STMR-P	23	0.14		10				0.014347826		
Beet, sugar ensiled pulp	AB	0.02	STMR/STMR-P	15	0.13		10				0.013333333		
Triticale hay	AF/AS	0.086	STMR/STMR-P	88	0.10	15				0.015			
Wheat grain	GC	0.021	STMR/STMR-P	89	0.02	20			25	0.005			0.005898876
Beet, sugar molasses	DM	0.004	STMR/STMR-P	75	0.01	10				0.001			
Total						100	100	100	85	0.378	0.508832675	1.657333333	0.47578524

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Corn, sweet stover	AF/AS	2.8	STMR/STMR-P	83	3.37	15	0	20		0.506024096	0	0.674698795	
Corn, sweet forage	AF/AS	1.4	STMR/STMR-P	48	2.92	30		20		0.875		0.583333333	
Almond hulls	AM/AV	1.34	STMR/STMR-P	90	1.49	10		10		0.148888889		0.148888889	
Apple pomace, wet	AB	0.32	STMR/STMR-P	40	0.80	10	10	10		0.08	0.08	0.08	
Citrus dried pulp	AB	0.7	STMR/STMR-P	91	0.77	0	10	20		0	0.076923077	0.153846154	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Cabbage heads, leaves	AM/AV	0.09	STMR/STMR-P	15	0.60	0	20			0	0.12		
Tomato pomace,wet	AB	1.4	STMR/STMR-P	20	7.00		0	10			0	0.7	
Grape pomace, wet	AB	0.38	STMR/STMR-P	15	2.53	0		10		0		0.253333333	
Wheat forage	AF/AS	0.22	STMR/STMR-P	25	0.88	20	20	60		0.176	0.176	0.528	
Wheat milled bypdts	CM/CF	0.74	STMR/STMR-P	88	0.84	30	30	20	45	0.252272727	0.252272727	0.168181818	0.378409091
Rape forage	AM/AV	0.07	STMR/STMR-P	30	0.23	10	10			0.023333333	0.023333333		
Beet, sugar dried pulp	AB	0.13	STMR/STMR-P	88	0.15	15	20		40	0.022159091	0.029545455		0.059090909
Beet, sugar tops	AM/AV	0.033	STMR/STMR-P	23	0.14	0	20			0	0.028695652		
Wheat grain	GC	0.021	STMR/STMR-P	89	0.02	20			10	0.004719101			0.002359551
Beet, sugar molasses	DM	0.004	STMR/STMR-P	75	0.01	5				0.000266667			
Total						100	100	100	95	0.478750919	0.509847167	1.649515152	0.439859551

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat milled bypdts	CM/CF	0.74	STMR/STMR-P	88	0.84	50	20	20	5	0.42	0.168181818	0.168181818	0.042045455
Wheat grain	GC	0.021	STMR/STMR-P	89	0.02	50	70	70	10	0.01	0.016516854	0.016516854	0.002359551
Total						100	90	90	15	0.43	0.184698672	0.184698672	0.044405005

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat forage	AF/AS	0.22	STMR/STMR-P	25	0.88		10				0.088		
Wheat milled bypdts	CM/CF	0.74	STMR/STMR-P	88	0.84	50	20	20	30	0.420454545	0.168181818	0.168181818	0.252272727

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Rape forage	AM/AV	0.07	STMR/STMR-P	30	0.23		10				0.023333333		
Wheat grain	GC	0.021	STMR/STMR-P	89	0.02	50	60	55		0.011797753	0.014157303	0.012977528	
Total						100	100	75	30	0.432252298	0.293672455	0.181159346	0.252272727

Isoflucypram (330)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley bran fractions	CM/CF	0.064	STMR	90	0.07				10				0.007111111
Brewer's grain dried	SM	0.028	STMR	92	0.03		10	50	45		0.003043478	0.015217391	0.013695652
Barley grain	GC	0.02	STMR	88	0.02	50	70	50	45	0.011	0.015909091	0.011363636	0.010227273
Total						50	80	100	100	0.011	0.018952569	0.026581028	0.031034036

DAIRY CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Brewer's grain dried	SM	0.028	STMR	92	0.03		15	20	40		0.004565217	0.006086957	0.012173913
Barley grain	GC	0.02	STMR	88	0.02	45	40	40	40	0.010	0.009090909	0.009090909	0.009090909
Total						45	55	60	80	0.010	0.013656126	0.015177866	0.021264822

POULTRY BROILER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley bran fractions	CM/CF	0.064	STMR	90	0.07	8				0.006			
Brewer's grain dried	SM	0.028	STMR	92	0.03		10				0.003043478		
Barley grain	GC	0.02	STMR	88	0.02	75	70	15	10	0.017	0.015909091	0.003409091	0.002272727
Wheat grain	GC	0.02	STMR	89	0.02			55				0.012359551	
Total						83	80	70	10	0.023	0.018952569	0.015768641	0.002272727

POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley bran fractions	CM/CF	0.064	STMR	90	0.07				5				0.003555556
Brewer's grain dried	SM	0.028	STMR	92	0.03		10				0.003043478		
Barley grain	GC	0.02	STMR	88	0.02	75	90	15		0.017	0.020454545	0.003409091	
Wheat grain	GC	0.02	STMR	89	0.02			40				0.008988764	
Total						75	100	55	5	0.017	0.023498024	0.012397855	0.003555556

Isoflucypram (330)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Triticale hay	AF/AS	1.1	STMR/STMR-P	100	1.10	15	20	100		0.165	0.22	1.1	
Barley straw	AF/AS	0.7	STMR/STMR-P	100	0.70		10				0.07		
Barley bran fractions	CM/CF	0.064	STMR/STMR-P	90	0.07				10				0.007111111
Brewer's grain dried	SM	0.028	STMR/STMR-P	92	0.03		10		45		0.003043478		0.013695652
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	50	60		45	0.011363636	0.013636364		0.010227273
Total						65	100	100	100	0.176363636	0.306679842	1.1	0.031034036

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										MEAN			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Triticale hay	AF/AS	1.1	STMR/STMR-P	100	1.10	20	20	70		0.22	0.22	0.77	
Barley straw	AF/AS	0.7	STMR/STMR-P	100	0.70	0	10			0	0.07		
Brewer's grain dried	SM	0.028	STMR/STMR-P	92	0.03	0	15	20	40	0	0.004565217	0.006086957	0.012173913
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	45	40	10	40	0.010227273	0.009090909	0.002272727	0.009090909
Total						65	85	100	80	0.230227273	0.303656126	0.778359684	0.021264822

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Barley bran fractions	CM/CF	0.064	STMR/STMR-P	90	0.07	8				0.01			
Brewer's grain dried	SM	0.028	STMR/STMR-P	92	0.03		10				0.003043478		
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	75	70	15	10	0.02	0.015909091	0.003409091	0.002272727
Wheat grain	GC	0.02	STMR/STMR-P	89	0.02			55				0.012359551	
Total						83	80	70	10	0.023	0.018952569	0.015768641	0.002272727

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat hay	AF/AS	1.1	STMR/STMR-P	100	1.10		10				0.11		
Barley bran fractions	CM/CF	0.064	STMR/STMR-P	90	0.07				5				0.003555556
Brewer's grain dried	SM	0.028	STMR/STMR-P	92	0.03		10				0.003043478		
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	75	80	15		0.017045455	0.018181818	0.003409091	
Wheat grain	GC	0.02	STMR/STMR-P	89	0.02			40				0.008988764	
Total						75	100	55	5	0.017045455	0.131225296	0.012397855	0.003555556

Isotianil (335)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Citrus dried pulp	AB	0.1158	STMR	91	0.13	10	5	30		0.013	0.006362637	0.038175824	
Total						10	5	30		0.013	0.006362637	0.038175824	

DAIRY CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Citrus dried pulp	AB	0.1158	STMR	91	0.13	10	20	30		0.013	0.025450549	0.038175824	
Total						10	20	30		0.013	0.025450549	0.038175824	

Isotianil (335)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Citrus dried pulp	AB	0.1158	STMR/STMR-P	91	0.13	10	5	30		0.012725275	0.006362637	0.038175824	
Total						10	5	30		0.012725275	0.006362637	0.038175824	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Citrus dried pulp	AB	0.1158	STMR/STMR-P	91	0.13	10	20	30		0.012725275	0.025450549	0.038175824	
Total						10	20	30		0.012725275	0.025450549	0.038175824	

Mepiquat chloride (336)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0,78	STMR	15	5,20			20				1,04	
Cotton meal	SM	2,5	STMR	89	2,81	5	5	30		0,140449	0,14	0,843	
Cotton undelinted seed	SO	1,6	STMR	88	1,82			30				0,545	
Cotton hulls	SM	0,36	STMR	90	0,40	5				0,02			
Total						10	5	80		0,160449	0,14	2,428	

Oxathiopiproline (291)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.5	STMR	15	3.33			20				0.666666667	
Potato process waste	AB	0.106	STMR	12	0.88	30	40			0.265	0.353333333		
Soybean seed	VD	0.166	STMR	89	0.19	5	10	20	15	0.009	0.018651685	0.037303371	0.027977528
Lupin seed meal	SM	0.12	STMR	85	0.14		20	15			0.028235294	0.021176471	
Corn gluten feed	CM/CF	0.056	STMR	40	0.14	65	30	20	25	0.091	0.042	0.028	0.035
Bean seed	VD	0.12	STMR	88	0.14			25				0.034090909	
Alfalfa meal	SM	0.12	STMR	89	0.13				10				0.013483146
Soybean meal	SM	0.12	STMR	92	0.13				50				0.065217391
Total						100	100	100	100	0.365	0.442220313	0.787237417	0.141678065

DAIRY CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			

						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.5	STMR	15	3.33			20				0.666666667	
Potato process waste	AB	0.106	STMR	12	0.88	10	30			0.088	0.265		
Beet, sugar ensiled pulp	AB	0.06	STMR	15	0.40		10				0.04		
Soybean seed	VD	0.166	STMR	89	0.19	10	10	20	10	0.019	0.018651685	0.037303371	0.018651685
Lupin seed meal	SM	0.12	STMR	85	0.14		20	15			0.028235294	0.021176471	
Peanut meal	SM	0.12	STMR	85	0.14	10				0.014			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14	25	30		25	0.035	0.042		0.035
Alfalfa meal	SM	0.12	STMR	89	0.13	5		25	25	0.007		0.033707865	0.033707865
Soybean meal	SM	0.12	STMR	92	0.13				40				0.052173913
Corn, field grain	GC	0.102	STMR	88	0.12	40		20		0.046		0.023181818	
Total						100	100	100	100	0.209	0.39388698	0.782036191	0.139533464

POULTRY BROILER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean seed	VD	0.166	STMR	89	0.19	20	20	15		0.037	0.037303371	0.027977528	
Lupin seed meal	SM	0.12	STMR	85	0.14		10	20			0.014117647	0.028235294	
Peanut meal	SM	0.12	STMR	85	0.14	25				0.035			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR	88	0.14			65				0.088636364	
Alfalfa meal	SM	0.12	STMR	89	0.13				5				0.006741573
Soybean meal	SM	0.12	STMR	92	0.13		30		30		0.039130435		0.039130435
Potato dried pulp	AB	0.106	STMR	88	0.12		20				0.024090909		
Corn, field grain	GC	0.102	STMR	88	0.12	55	10		65	0.064	0.011590909		0.075340909
Total						100	100	100	100	0.136	0.140233271	0.144849186	0.121212917

POULTRY BROILER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			

						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean seed	VD	0.166	STMR	89	0.19	20	20	15		0.037	0.037303371	0.027977528	
Lupin seed meal	SM	0.12	STMR	85	0.14		10	20			0.014117647	0.028235294	
Peanut meal	SM	0.12	STMR	85	0.14	25				0.035			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR	88	0.14			65				0.088636364	
Alfalfa meal	SM	0.12	STMR	89	0.13				5				0.006741573
Soybean meal	SM	0.12	STMR	92	0.13		30		30		0.039130435		0.039130435
Potato dried pulp	AB	0.106	STMR	88	0.12		20				0.024090909		
Corn, field grain	GC	0.102	STMR	88	0.12	55	10		65	0.064	0.011590909		0.075340909
Total						100	100	100	100	0.136	0.140233271	0.144849186	0.121212917

POULTRY LAYER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean seed	VD	0.166	STMR	89	0.19	20	15	15		0.037	0.027977528	0.027977528	
Lupin seed meal	SM	0.12	STMR	85	0.14		10	20			0.014117647	0.028235294	
Peanut meal	SM	0.12	STMR	85	0.14	25				0.035			
Corn gluten feed	CM/CF	0.056	STMR	40	0.14				10				0.014
Corn gluten meal	CM/CF	0.056	STMR	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR	88	0.14		5	65			0.006818182	0.088636364	
Soybean meal	SM	0.12	STMR	92	0.13		15		30		0.019565217		0.039130435
Potato dried pulp	AB	0.106	STMR	88	0.12		15				0.018068182		
Corn, field grain	GC	0.102	STMR	88	0.12	55	30		60	0.064	0.034772727		0.07
Total						100	100	100	100	0.136	0.135319483	0.144849186	0.122675889

Oxathiopiproline (291)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Kale leaves	AM/AV	0.63	STMR/STMR-P	15	4.20		20				0.84		
Grape pomace, wet	AB	0.5	STMR/STMR-P	15	3.33			20				0.666666667	
Sorghum, grain silage	AF/AS	0.21	STMR/STMR-P	21	1.00	15				0.15			
Potato process waste	AB	0.106	STMR/STMR-P	12	0.88	30	40			0.265	0.353333333		
Grass forage (fresh)	AF/AS	0.21	STMR/STMR-P	25	0.84		40	80	5		0.336	0.672	0.042
Grass hay	AF/AS	0.51	STMR/STMR-P	88	0.58				35				0.202840909
Potato culls	VR	0.106	STMR/STMR-P	20	0.53	30				0.159			
Trefoil hay	AL	0.3	STMR/STMR-P	85	0.35	15				0.052941176			
Lespedeza hay	AL	0.3	STMR/STMR-P	88	0.34	10				0.034			
Alfalfa hay	AL	0.3	STMR/STMR-P	89	0.34				10				0.033707865
Soybean seed	VD	0.166	STMR/STMR-P	89	0.19				15				0.027977528
Corn gluten feed	CM/CF	0.056	STMR/STMR-P	40	0.14				25				0.035
Alfalfa meal	SM	0.12	STMR/STMR-P	89	0.13				10				0.013483146
Total						100	100	100	100	0.661	1.529333333	1.338666667	0.355009448

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Kale leaves	AM/AV	0.63	STMR/STMR-P	15	4.20		20	40			0.84	1.68	
Grape pomace, wet	AB	0.5	STMR/STMR-P	15	3.33	0		20		0		0.666666667	
Sorghum, grain silage	AF/AS	0.21	STMR/STMR-P	21	1.00	40			10	0.4			0.1
Potato process waste	AB	0.106	STMR/STMR-P	12	0.88	10	30			0.088333333	0.265		
Grass forage (fresh)	AF/AS	0.21	STMR/STMR-P	25	0.84	5	50	40		0.042	0.42	0.336	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Corn, field forage/silage	AF/AS	0.256	STMR/STMR-P	40	0.64	0			40	0			0.256
Lespedeza forage	AL	0.14	STMR/STMR-P	22	0.64	40				0.254545455			
Grass hay	AF/AS	0.51	STMR/STMR-P	88	0.58	5			50	0.028977273			0.289772727
Total						100	100	100	100	0.813856061	1.525	2.682666667	0.645772727

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Potato culls	VR	0.106	STMR/STMR-P	20	0.53		10				0.053		
Soybean seed	VD	0.166	STMR/STMR-P	89	0.19	20	20	15		0.037	0.037303371	0.027977528	
Cassava/tapioca roots	VR	0.06	STMR/STMR-P	37	0.16		10				0.016216216		
Lupin seed meal	SM	0.12	STMR/STMR-P	85	0.14		10	20			0.014117647	0.028235294	
Peanut meal	SM	0.12	STMR/STMR-P	85	0.14	25				0.04			
Corn gluten feed	CM/CF	0.056	STMR/STMR-P	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR/STMR-P	88	0.14			65				0.088636364	
Alfalfa meal	SM	0.12	STMR/STMR-P	89	0.13				5				0.006741573
Soybean meal	SM	0.12	STMR/STMR-P	92	0.13		30		30		0.039130435		0.039130435
Potato dried pulp	AB	0.106	STMR/STMR-P	88	0.12		10				0.012045455		
Corn, field grain	GC	0.102	STMR/STMR-P	88	0.12	55			65	0.06375			0.075340909
Total						100	100	100	100	0.136347488	0.185813123	0.144849186	0.121212917

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat hay	AF/AS	1.1	STMR/STMR-P	100	1.10		10				0.11		
Barley bran fractions	CM/CF	0.064	STMR/STMR-P	90	0.07				5				0.003555556

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Brewer's grain dried	SM	0.028	STMR/STMR-P	92	0.03		10				0.003043478		
Barley grain	GC	0.02	STMR/STMR-P	88	0.02	75	80	15		0.017045455	0.018181818	0.003409091	
Cabbage heads, leaves	AM/AV	0.196	STMR/STMR-P	15	1.31		5				0.065333333		
Wheat forage	AF/AS	0.21	STMR/STMR-P	25	0.84		10				0.084		
Soybean silage	AL	0.186	STMR/STMR-P	30	0.62		10				0.062		
Potato culls	VR	0.106	STMR/STMR-P	20	0.53		10				0.053		
Soybean seed	VD	0.166	STMR/STMR-P	89	0.19	20	15	15		0.037303371	0.027977528	0.027977528	
Cassava/tapioca roots	VR	0.06	STMR/STMR-P	37	0.16		5				0.008108108		
Lupin seed meal	SM	0.12	STMR/STMR-P	85	0.14		10	20			0.014117647	0.028235294	
Peanut meal	SM	0.12	STMR/STMR-P	85	0.14	25				0.035294118			
Corn gluten feed	CM/CF	0.056	STMR/STMR-P	40	0.14				10				0.01
Corn gluten meal	CM/CF	0.056	STMR/STMR-P	40	0.14		10				0.014		
Bean seed	VD	0.12	STMR/STMR-P	88	0.14		5	65			0.006818182	0.088636364	
Soybean meal	SM	0.12	STMR/STMR-P	92	0.13		20		30		0.026086957		0.039130435
Corn, field grain	GC	0.102	STMR/STMR-P	88	0.12	55			60	0.06375			0.069545455
Total						100	100	100	100	0.136347488	0.361441755	0.144849186	0.122675889

Prochloraz (142)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	11	HR	25	44.00		20	100			8.8	44	
Barley forage	AF/AS	10	HR	30	33.33		10				3.333333333		
Barley straw	AF/AS	19	HR	89	21.35	10				2.135			
Beet, sugar tops	AM/AV	0.9	HR	23	3.91		20				0.782608696		
Wheat grain	GC	0.11	STMR	89	0.12	20	40		25	0.025	0.049438202		0.030898876

Barley grain	GC	0.066	STMR	88	0.08	30	10		45	0.023	0.0075		0.03375
Rape meal	SM	0.0616	STMR	88	0.07				15				0.0105
Rye grain	GC	0.03	STMR	88	0.03				15				0.005113636
Total						60	100	100	100	2.182	12.97288023	44	0.080262513

DAIRY CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	11	HR	25	44.00	20	20	60		8.800	8.8	26.4	
Barley forage	AF/AS	10	HR	30	33.33		10				3.333333333		
Oat forage	AF/AS	9	HR	30	30.00	10		40	5	3.000		12	1.5
Beet, sugar tops	AM/AV	0.9	HR	23	3.91		30				1.173913043		
Wheat grain	GC	0.11	STMR	89	0.12	20	40		10	0.025	0.049438202		0.012359551
Barley grain	GC	0.066	STMR	88	0.08	25			30	0.019			0.0225
Rape meal	SM	0.0616	STMR	88	0.07				25				0.0175
Total						75	100	100	70	11.843	13.35668458	38.4	1.552359551

POULTRY BROILER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat grain	GC	0.11	STMR	89	0.12	75	70	70	10	0.093	0.086516854	0.086516854	0.012359551
Rape meal	SM	0.0616	STMR	88	0.07			5	5			0.0035	0.0035
Total						75	70	75	15	0.093	0.086516854	0.090016854	0.015859551

POULTRY LAYER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat forage	AF/AS	11	HR	25	44.00		10				4.4		
Beet, sugar tops	AM/AV	0.9	HR	23	3.91		5				0.195652174		
Wheat grain	GC	0.11	STMR	89	0.12	75	70	55		0.093	0.086516854	0.067977528	
Barley grain	GC	0.066	STMR	88	0.08		15				0.01125		
Rape meal	SM	0.0616	STMR	88	0.07			5	15			0.0035	0.0105
Total						75	100	60	15	0.093	4.693419028	0.071477528	0.0105

Prochloraz (142)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat forage	AF/AS	8.85	STMR/STMR-P	25	35.40		20	100			7.08	35.4	
Barley forage	AF/AS	8.95	STMR/STMR-P	30	29.83		10				2.983333333		
Wheat straw	AF/AS	7.7	STMR/STMR-P	88	8.75	10				0.875			
Beet, sugar tops	AM/AV	0.24	STMR/STMR-P	23	1.04		20				0.208695652		
Wheat grain	GC	0.11	STMR/STMR-P	89	0.12	20	40		25	0.024719101	0.049438202		0.030898876
Barley grain	GC	0.066	STMR/STMR-P	88	0.08	30	10		45	0.0225	0.0075		0.03375
Rape meal	SM	0.0616	STMR/STMR-P	88	0.07				15				0.0105
Rye grain	GC	0.03	STMR/STMR-P	88	0.03				15				0.005113636
Total						60	100	100	100	0.922	10.32896719	35.4	0.080262513

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat forage	AF/AS	8.85	STMR/STMR-P	25	35.40	20	20	60		7.08	7.08	21.24	
Barley forage	AF/AS	8.95	STMR/STMR-P	30	29.83	0	10			0	2.983333333		
Oat forage	AF/AS	7.65	STMR/STMR-P	30	25.50	10		40	5	2.55		10.2	1.275
Beet, sugar tops	AM/AV	0.24	STMR/STMR-P	23	1.04	0	30			0	0.313043478		
Wheat grain	GC	0.11	STMR/STMR-P	89	0.12	20	40		10	0.024719101	0.049438202		0.012359551
Barley grain	GC	0.066	STMR/STMR-P	88	0.08	25			30	0.01875			0.0225
Rape meal	SM	0.0616	STMR/STMR-P	88	0.07	0			25	0			0.0175
Total						75	100	100	70	9.673469101	10.42581501	31.44	1.327359551

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat grain	GC	0.11	STMR/STMR-P	89	0.12	75	70	70	10	0.09	0.086516854	0.086516854	0.012359551
Rape meal	SM	0.0616	STMR/STMR-P	88	0.07			5	5			0.0035	0.0035
Total						75	70	75	15	0.09	0.086516854	0.090016854	0.015859551

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Wheat forage	AF/AS	8.85	STMR/STMR-P	25	35.40		10				3.54		
Beet, sugar tops	AM/AV	0.24	STMR/STMR-P	23	1.04		5				0.052173913		
Wheat grain	GC	0.11	STMR/STMR-P	89	0.12	75	70	55		0.092696629	0.086516854	0.067977528	
Barley grain	GC	0.066	STMR/STMR-P	88	0.08		15				0.01125		
Rape meal	SM	0.0616	STMR/STMR-P	88	0.07			5	15			0.0035	0.0105
Total						75	100	60	15	0.092696629	3.689940767	0.071477528	0.0105

Propiconazole (160)

BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Peanut hay	AL	91	HR	85	107.06			60				64.23529412	
Rice hulls	CM/CF	67	STMR	90	74.44			5				3.722222222	
Rice bran/pollard	CM/CF	48	STMR	90	53.33	15		35	20	8.000		18.66666667	10.66666667
Wheat forage	AF/AS	9	HR	25	36.00		20				7.2		
Rye straw	AF/AS	22	HR	88	25.00	10				2.500			
Triticale hay	AF/AS	22	HR	88	25.00	5				1.250			
Corn, field stover	AF/AS	17	HR	83	20.48		5				1.024096386		
Rice grain	GC	16.5	STMR	88	18.75	20				3.750			
Rice straw	AF/AS	16.5	HR	90	18.33				55				10.08333333
Barley straw	AF/AS	13	HR	89	14.61		5				0.730337079		
Corn, field forage/silage	AF/AS	5	HR	40	12.50		70				8.75		
Barley grain	GC	0.255	STMR	88	0.29	30			25	0.087			0.072443182
Corn, field grain	GC	0.05	STMR	88	0.06	20				0.011			
Total						100	100	100	100	15.598	17.70	86.62	20.82

DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Peanut hay	AL	91	HR	85	107.06	15		60		16.059		64.23529412	
Rice hulls	CM/CF	67	STMR	90	74.44			10				7.444444444	
Rice bran/pollard	CM/CF	48	STMR	90	53.33	15	20	30	10	8.000	10.66666667	16	5.333333333
Wheat forage	AF/AS	9	HR	25	36.00	20	20			7.200	7.2		
Rye straw	AF/AS	22	HR	88	25.00				5				1.25
Sorghum, grain forage	AF/AS	8.1	HR	35	23.14	20			35	4.629			8.1
Rice grain	GC	16.5	STMR	88	18.75	20				3.750			
Barley straw	AF/AS	13	HR	89	14.61		10				1.460674157		
Corn, field forage/silage	AF/AS	5	HR	40	12.50	10	50		10	1.250	6.25		1.25
Barley grain	GC	0.255	STMR	88	0.29				40				0.115909091
Total						100	100	100	100	40.887	25.57734082	87.67973856	16.04924242

POULTRY BROILER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice bran/pollard	CM/CF	48	STMR	90	53.33	10	10	20	5	5.333	5.333333333	10.66666667	2.666666667
Rice grain	GC	16.5	STMR	88	18.75	20		50		3.750		9.375	
Barley grain	GC	0.255	STMR	88	0.29	70	70		10	0.203	0.202840909		0.028977273
Oat grain	GC	0.22	STMR	89	0.25		20				0.049438202		
Wheat grain	GC	0.06	STMR	89	0.07			30				0.020224719	
Corn, field grain	GC	0.05	STMR	88	0.06				60				0.034090909
Corn, pop grain	GC	0.05	STMR	88	0.06				25				0.014204545
Total						100	100	100	100	9.286	5.585612445	20.06189139	2.743939394

POULTRY LAYER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice bran/pollard	CM/CF	48	STMR	90	53.33	10	5	20	20	5.333	2.666666667	10.66666667	10.6666666
Wheat forage	AF/AS	9	HR	25	36.00		10				3.6		
Rice grain	GC	16.5	STMR	88	18.75	20		50		3.750		9.375	
Soybean hay	AL	9.6	HR	85	11.29		10				1.129411765		
Beet, sugar tops	AM/AV	0.96	HR	23	4.17		5				0.208695652		
Barley grain	GC	0.255	STMR	88	0.29	70	70			0.203	0.202840909		
Wheat grain	GC	0.06	STMR	89	0.07			30				0.020224719	
Corn, field grain	GC	0.05	STMR	88	0.06				80				0.04545454
Total						100	100	100	100	9.29	7.807614993	20.06189139	10.71

POULTRY LAYER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice bran/pollard	CM/CF	48	STMR	90	53.33	10	5	20	20	5.333	2.666666667	10.66666667	10.66666667
Wheat forage	AF/AS	9	HR	25	36.00		10				3.6		
Rice grain	GC	16.5	STMR	88	18.75	20		50		3.750		9.375	

Soybean hay	AL	9.6	HR	85	11.29		10				1.129411765		
Beet, sugar tops	AM/AV	0.96	HR	23	4.17		5				0.208695652		
Barley grain	GC	0.255	STMR	88	0.29	70	70			0.203	0.202840909		
Wheat grain	GC	0.06	STMR	89	0.07			30				0.020224719	
Corn, field grain	GC	0.05	STMR	88	0.06				80				0.045454545
Total						100	100	100	100	9.29	7.807614993	20.06189139	10.71

Propiconazole (160)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Rice hulls	CM/CF	67	STMR/STMR-P	90	74.44			5				3.722222222	
Rice bran/pollard	CM/CF	48	STMR/STMR-P	90	53.33	15		35	20	8		18.66666667	10.66666667
Peanut hay	AL	36.5	STMR/STMR-P	85	42.94			60				25.76470588	
Rice grain	GC	16.5	STMR/STMR-P	88	18.75	20				3.75			
Sorghum, grain forage	AF/AS	4.65	STMR/STMR-P	35	13.29	15	20			1.992857143	2.657142857		
Barley straw	AF/AS	4.3	STMR/STMR-P	89	4.83		10				0.483146067		
Rice straw	AF/AS	2.575	STMR/STMR-P	90	2.86				55				1.573611111
Corn, field forage/silage	AF/AS	0.845	STMR/STMR-P	40	2.11		70				1.47875		
Barley grain	GC	0.255	STMR/STMR-P	88	0.29	30			25	0.087			0.072443182
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06	20				0.011			
Total						100	100	100	100	13.841	4.619038925	48.15359477	12.31272096

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Rice hulls	CM/CF	67	STMR/STMR-P	90	74.44		0	10			0	7.444444444	
Rice bran/pollard	CM/CF	48	STMR/STMR-P	90	53.33	15	20	30	10	8	10.66666667	16	5.333333333
Peanut hay	AL	36.5	STMR/STMR-P	85	42.94	15		60		6.441176471		25.76470588	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Rice grain	GC	16.5	STMR/STMR-P	88	18.75	20				3.75			
Sorghum, grain forage	AF/AS	4.65	STMR/STMR-P	35	13.29	40	20		40	5.314285714	2.657142857		5.314285714
Barley straw	AF/AS	4.3	STMR/STMR-P	89	4.83	0	10			0	0.483146067		
Almond hulls	AM/AV	4	STMR/STMR-P	90	4.44	10				0.444444444			
Corn, field forage/silage	AF/AS	0.845	STMR/STMR-P	40	2.11	0	50		10	0	1.05625		0.21125
Barley grain	GC	0.255	STMR/STMR-P	88	0.29	0			40	0			0.115909091
Total						100	100	100	100	23.94990663	14.86320559	49.20915033	10.97477814

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Rice bran/pollard	CM/CF	48	STMR/STMR-P	90	53.33	10	10	20	5	5.33	5.333333333	10.66666667	2.666666667
Rice grain	GC	16.5	STMR/STMR-P	88	18.75	20		50		3.75		9.375	
Barley grain	GC	0.255	STMR/STMR-P	88	0.29	70	70		10	0.20	0.202840909		0.028977273
Oat grain	GC	0.22	STMR/STMR-P	89	0.25		20				0.049438202		
Wheat grain	GC	0.06	STMR/STMR-P	89	0.07			30				0.020224719	
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06				60				0.034090909
Corn, pop grain	GC	0.05	STMR/STMR-P	88	0.06				25				0.014204545
Total						100	100	100	100	9.286174242	5.585612445	20.06189139	2.743939394

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Rice bran/pollard	CM/CF	48	STMR/STMR-P	90	53.33	10	5	20	20	5.333333333	2.666666667	10.66666667	10.66666667
Rice grain	GC	16.5	STMR/STMR-P	88	18.75	20		50		3.75		9.375	
Sorghum, grain forage	AF/AS	4.65	STMR/STMR-P	35	13.29		10				1.328571429		

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Soybean forage	AL	1.875	STMR/STMR-P	56	3.35		10				0.334821429		
Beet, sugar tops	AM/AV	0.3	STMR/STMR-P	23	1.30		5				0.065217391		
Barley grain	GC	0.255	STMR/STMR-P	88	0.29	70	70			0.202840909	0.202840909		
Wheat grain	GC	0.06	STMR/STMR-P	89	0.07			30				0.020224719	
Corn, field grain	GC	0.05	STMR/STMR-P	88	0.06				80				0.045454545
Total						100	100	100	100	9.286	4.598	20.062	10.71

Clothianidin (238)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.23	STMR	15	1.53			20				0.306666667	
Swede roots	VR	0.15	HR	10	1.50		40	10			0.6	0.15	
Rice hulls	CM/CF	1.1	STMR	90	1.22			5				0.061111111	
Sugarcane tops	AM/AV	0.27	HR	25	1.08			50				0.54	
Wheat forage	AF/AS	0.21	HR	25	0.84		20	15			0.168	0.126	
Sorghum, grain forage	AF/AS	0.29	HR	35	0.83	15				0.124			
Barley straw	AF/AS	0.72	HR	89	0.81		10				0.080898876		
Potato culls	VR	0.15	HR	20	0.75	30				0.225			
Cabbage heads, leaves	AM/AV	0.08	HR	15	0.53		20				0.106666667		
Rice grain	GC	0.3	STMR	88	0.34	20				0.068			
Rice bran/pollard	CM/CF	0.28	STMR	90	0.31	15			20	0.047			0.062222222
Pea vines	AL	0.05	HR	25	0.20		10				0.02		
Rice straw	AF/AS	0.13	HR	90	0.14				55				0.079444444
Beet, sugar molasses	DM	0.064	STMR	75	0.09	10				0.009			
Corn, field forage/silage	AF/AS	0.021	HR	40	0.05	10				0.005			
Beet, sugar dried pulp	AB	0.034	STMR	88	0.04				5				0.001931818
Corn, field grain	GC	0.02	STMR	88	0.02				20				0.004545455
Total						100	100	100	100	0.478	0.975565543	1.183777778	0.148143939

DAIRY CATTLE													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.23	STMR	15	1.53			20				0.306666667	
Swede roots	VR	0.15	HR	10	1.50		20	10			0.3	0.15	
Carrot culls	VR	0.15	HR	12	1.25	10				0.125			
Rice hulls	CM/CF	1.1	STMR	90	1.22			10				0.122222222	
Sugarcane tops	AM/AV	0.27	HR	25	1.08			25				0.27	
Wheat forage	AF/AS	0.21	HR	25	0.84	20	20	35		0.168	0.168	0.294	
Sorghum, grain forage	AF/AS	0.29	HR	35	0.83	20			40	0.166			0.331428571
Barley straw	AF/AS	0.72	HR	89	0.81		10				0.080898876		
Potato culls	VR	0.15	HR	20	0.75		10				0.075		

Cabbage heads, leaves	AM/AV	0.08	HR	15	0.53		20				0.106666667		
Corn, sweet forage	AF/AS	0.22	HR	48	0.46	5				0.023			
Rice grain	GC	0.3	STMR	88	0.34	20				0.068			
Bean vines	AL	0.11	HR	35	0.31		20				0.062857143		
Rice bran/pollard	CM/CF	0.28	STMR	90	0.31	15			10	0.047			0.031111111
Pea vines	AL	0.05	HR	25	0.20	10				0.020			
Rice whole crop silage	AF/AS	0.025	HR	40	0.06				50				0.03125
Total						100	100	100	100	0.616	0.793422686	1.142888889	0.393789683

POULTRY BROILER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Swede roots	VR	0.15	HR	10	1.50		10				0.15		
Rice grain	GC	0.3	STMR	88	0.34	20		50		0.068		0.170454545	
Rice bran/pollard	CM/CF	0.28	STMR	90	0.31	10	10	20	5	0.031	0.031111111	0.062222222	0.015555556
Bean seed	VD	0.02	STMR	88	0.02		20	30			0.004545455	0.006818182	
Corn, field grain	GC	0.02	STMR	88	0.02	70	60		70	0.016	0.013636364		0.015909091
Sorghum, grain grain	GC	0.015	STMR	86	0.02				25				0.004360465
Total						100	100	100	100	0.12	0.199292929	0.239494949	0.035825112

POULTRY LAYER													**MAX**
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Swede roots	VR	0.15	HR	10	1.50		10				0.15		
Wheat forage	AF/AS	0.21	HR	25	0.84		10				0.084		
Cabbage heads, leaves	AM/AV	0.08	HR	15	0.53		5				0.026666667		
Rice grain	GC	0.3	STMR	88	0.34	20		50		0.068		0.170454545	
Rice bran/pollard	CM/CF	0.28	STMR	90	0.31	10	5	20	20	0.031	0.015555556	0.062222222	0.062222222
Pea vines	AL	0.05	HR	25	0.20		10				0.02		
Rape forage	AM/AV	0.027	HR	30	0.09		5				0.0045		
Bean seed	VD	0.02	STMR	88	0.02		20	30			0.004545455	0.006818182	
Corn, field grain	GC	0.02	STMR	88	0.02	70	35		80	0.02	0.007954545		0.02
Total						100	100	100	100	0.115	0.313222222	0.239494949	0.08040404

Clothianidin (238)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm).			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Grape pomace, wet	AB	0.23	STMR/STMR-P	15	1.53			20				0.306666667	
Rice hulls	CM/CF	1.1	STMR/STMR-P	90	1.22			5				0.061111111	
Sugarcane tops	AM/AV	0.19	STMR/STMR-P	25	0.76			50				0.38	
Sorghum, grain forage	AF/AS	0.19	STMR/STMR-P	35	0.54	15	20	25		0.081428571	0.108571429	0.135714286	
Rice grain	GC	0.3	STMR/STMR-P	88	0.34	20				0.068181818			
Rice bran/pollard	CM/CF	0.28	STMR/STMR-P	90	0.31	15			20	0.046666667			0.062222222
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20		20				0.04		
Pea vines	AL	0.05	STMR/STMR-P	25	0.20		20				0.04		
Barley forage	AF/AS	0.057	STMR/STMR-P	30	0.19		10				0.019		
Cowpea forage	AL	0.05	STMR/STMR-P	30	0.17		30				0.05		
Potato culls	VR	0.02	STMR/STMR-P	20	0.10	30				0.030			
Beet, sugar molasses	DM	0.064	STMR/STMR-P	75	0.09	10				0.009			
Grass forage (fresh)	AF/AS	0.01	STMR/STMR-P	25	0.04				5				0.002
Beet, sugar dried pulp	AB	0.034	STMR/STMR-P	88	0.04	10			5	0.004			0.001931818
Rice straw	AF/AS	0.03	STMR/STMR-P	90	0.03				50				0.0167
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02				20				0.004545455
Total						100	100	100	100	0.238674026	0.257571429	0.883492063	0.087366162

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Grape pomace, wet	AB	0.23	STMR/STMR-P	15	1.53		0	20			0	0.306666667	
Rice hulls	CM/CF	1.1	STMR/STMR-P	90	1.22	0		10		0		0.122222222	
Sugarcane tops	AM/AV	0.19	STMR/STMR-P	25	0.76	0		25		0		0.19	

ESTIMATED MEAN DIETARY BURDEN													
DAIRY CATTLE										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
Sorghum, grain forage	AF/AS	0.19	STMR/STMR-P	35	0.54	40	20	45	40	0.217142857	0.108571429	0.244285714	0.217142857
Rice grain	GC	0.3	STMR/STMR-P	88	0.34	20				0.068181818			
Rice bran/pollard	CM/CF	0.28	STMR/STMR-P	90	0.31	15	20		10	0.046666667	0.062222222		0.031111111
Bean vines	AL	0.075	STMR/STMR-P	35	0.21	0	20			0	0.042857143		
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20	0	20			0	0.04		
Pea vines	AL	0.05	STMR/STMR-P	25	0.20	10				0.02			
Barley forage	AF/AS	0.057	STMR/STMR-P	30	0.19	0	20			0	0.038		
Corn, sweet forage	AF/AS	0.084	STMR/STMR-P	48	0.18	15				0.02625			
Beet, sugar dried pulp	AB	0.034	STMR/STMR-P	88	0.04	0			40	0			0.015454545
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40	0.03	0			10	0			0.0025
Total						100	100	100	100	0.378241342	0.291650794	0.863174603	0.266208514

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY BROILER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Rice grain	GC	0.3	STMR/STMR-P	88	0.34	20		50		0.07		0.170454545	
Rice bran/pollard	CM/CF	0.28	STMR/STMR-P	90	0.31	10	10	20	5	0.03	0.031111111	0.062222222	0.015555556
Carrot culls	VR	0.02	STMR/STMR-P	12	0.17		10				0.016666667		
Cassava/tapioca roots	VR	0.02	STMR/STMR-P	37	0.05		10				0.005405405		
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		20	30			0.004545455	0.006818182	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	70	50		70	0.02	0.011363636		0.015909091
Sorghum, grain grain	GC	0.015	STMR/STMR-P	86	0.02				25				0.004360465
Total						100	100	100	100	0.11520202	0.069092274	0.239494949	0.035825112

ESTIMATED MEAN DIETARY BURDEN													
POUTLRY LAYER										**MEAN**			
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	
Sorghum, grain forage	AF/AS	0.19	STMR/STMR-P	35	0.54		10				0.054285714		
Rice grain	GC	0.3	STMR/STMR-P	88	0.34	20		50		0.068181818		0.170454545	
Rice bran/pollard	CM/CF	0.28	STMR/STMR-P	90	0.31	10	5	20	20	0.031111111	0.015555556	0.062222222	0.062222222
Cabbage heads, leaves	AM/AV	0.03	STMR/STMR-P	15	0.20		5				0.01		
Pea vines	AL	0.05	STMR/STMR-P	25	0.20		10				0.02		
Carrot culls	VR	0.02	STMR/STMR-P	12	0.17		10				0.016666667		
Rape forage	AM/AV	0.02	STMR/STMR-P	30	0.07		5				0.003333333		
Cassava/tapioca roots	VR	0.02	STMR/STMR-P	37	0.05		5				0.002702703		
Bean seed	VD	0.02	STMR/STMR-P	88	0.02		20	30			0.005	0.007	
Corn, field grain	GC	0.02	STMR/STMR-P	88	0.02	70	30		80	0.015909091	0.006818182		0.018181818
Total						100	100	100	100	0.11520202	0.133907609	0.239494949	0.08040404

Annex 7. Errata

The following list is a compilation of errata found in previous annual reports of the WHO/FAO Joint Meeting on Pesticide Residues.

	Reads	Should read
Report 2019		
P.335	The Meeting withdraws its previous recommendation of 0.1 mg/kg for cardamom seeds.	The MRL of Acetamiprid (246) for cardamom seed is 0.1 mg/kg as recommended by JMPR 2015.
P.422	(In the summary table) Under Acetamiprid (246), in the column "new recommended maximum residue level, mg/kg", the cell currently reads „W" (withdrawn)	The cell should read 0.1 mg/kg
Report 2021		
	Reads	Should read
Pp. 269	Tetraniliprole-despyridyl-N-methyl-quinazolinone Tetraniliprole-despyridyl-N-methyl-quinazolinone gave rise to alerts for genotoxicity and is not covered by the toxicity of the parent. It is a Cramer class III compound and a TTC of 0.002 5 µg/kg bw per day was recommended.	Tetraniliprole-despyridyl-N-methyl-quinazolinone Tetraniliprole-despyridyl-N-methyl-quinazolinone gave rise to alerts for genotoxicity and is not covered by the toxicity of the parent, as such, a TTC approach for genotoxic compounds of 0.0025 µg/kg bw per day was recommended.
2022 Report		
Pp.. 147—149;	Pencil yam	The commodity names of pencil yam and pencil yam, dried, are corrected to pseudoginseng (VR 2952) and pseudoginseng, dried (DV 2952), due to an editorial error in the English translation of crop names in the residue trial data submitted.

Pp. 593—594	TTC III (< 1.5 µg/kg bw) T-quinazolinone (goat) 0.11 µg/kg bw T-pyrazole-5-carboxylic acid (goat and poultry) 0.07 µg/kg bw T-N-methyl-quinazolinone-benzylalcohol (goat) 0.033 µg/kg bw T-pyridinyl-pyrazole-5-carboxylic acid (goat) 0.03 µg/kg bw T-despyridyl-N-methyl-quinazolinone (poultry) 0.03 µg/kg bw T-pyrazole-5-N-methyl-amide (goat and poultry) 0.02 µg/kg bw T-pyrazole-5-amide (poultry and goat liver only) 0.01 µg/kg bw T-N-methyl-quinazolinone-pyrazole-3-carboxylic acid (goat) 0.0023 µg/kg bw	TTC III (< 1.5 µg/kg bw – not corrected for dietary burden) T-quinazolinone (goat) 0.11 µg/kg bw T-pyrazole-5-carboxylic acid (goat and poultry) 0.07 µg/kg bw T-N-methyl-quinazolinone-benzylalcohol (goat) 0.033 µg/kg bw T-pyridinyl-pyrazole-5-carboxylic acid (goat) 0.03 µg/kg bw T-pyrazole-5-N-methyl-amide (goat and poultry) 0.02 µg/kg bw T-pyrazole-5-amide (poultry and goat liver only) 0.01 µg/kg bw T-N-methyl-quinazolinone-pyrazole-3-carboxylic acid (goat) 0.0023 µg/kg bw
	TTC for genotoxic compounds (< 0.0025 µg/kg bw - corrected for dietary burden) T-despyridyl (poultry) 0.00034 µg/kg bw Tetrazole-conjugates (poultry) 0.00063 µg/kg bw T-despyridyl-N-methyl-quinazolinone-hydroxy/ T-despyridyl-hydroxy (poultry) 0.00019 µg/kg bw 0.00015 µg/kg bw	TTC for genotoxic compounds (< 0.0025 µg/kg bw - corrected for dietary burden) T-despyridyl (poultry) 0.00034 µg/kg bw Tetrazole-conjugates (poultry) 0.00063 µg/kg bw T-despyridyl-N-methyl-quinazolinone-hydroxy/ T-despyridyl-hydroxy (poultry) 0.00019 µg/kg bw 0.00015 µg/kg bw

	T-deschloro-desmethyl-amide (poultry)		T-deschloro-desmethyl-amide (poultry)	
	T-despyridyl-quinazolinone (poultry)	0.00014 µg/kg bw	T-despyridyl-quinazolinone (poultry)	0.00014 µg/kg bw
	T-pyrazole-5-N-methyl-amide-hydroxy (poultry)	0.000094 µg/kg bw	T-pyrazole-5-N-methyl-amide-hydroxy (poultry)	0.000094 µg/kg bw
	T--deschloro-desmethyl-amide	0.00015 µg/kg bw	T--deschloro-desmethyl-amide	0.00015 µg/kg bw
			T-despyridyl-N-methyl-quinazolinone (poultry)	0.00083 µg/kg bw

The annual Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR) was held at the the Environmental Protection Agency of the United States, in Washington, D.C., from 19 to 28 September 2023. The FAO panel of experts had met in preparatory sessions from 14 to 18 September 2023. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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