



Food and Agriculture  
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United Nations



World Health  
Organization



# 2019 REPORT

## Pesticide residues in food

Joint FAO/WHO Meeting  
on Pesticide Residues



# **Pesticide residues in food 2019**

## **Joint FAO/WHO Meeting on Pesticide Residues**

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 Geneva, Switzerland, 17–26 September 2019.

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R, residue and analytical aspects; T, toxicological evaluation

\* New compound

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

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## Abbreviations and acronyms

ADI	Acceptable Daily Intake
ADME	Absorption, distribution, metabolism and excretion
AR	Applied Radioactivity
ARfD	acute reference dose
ATP	Adenosine triphosphate
AUC	Area under the curve
AUC <sub>0-∞</sub>	Area under the concentration–time curve from time zero to infinity
BBCH	Biologische Bundesanstalt, Bundessortenamt Und Chemische Industrie
BMD	Benchmark dose
BMDL <sub>10</sub>	Lower confidence limit on the benchmark dose for a 10% response
BMDL <sub>20</sub>	Lower confidence limit on the benchmark dose for a 20% response
bw	body weight
CAN	Canada
CAS	Chemical Abstracts Service
CCPR	Codex Committee on Pesticide Residues
cGAP	Critical GAP
DALA	Days after Last Application
DALT	Days After Last Treatment
DAT	Days after Treatment
DM	dry matter
DNA	Deoxyribonucleic acid
<i>dSPE</i>	Dispersive Solid Phase Extraction
DT <sub>50</sub>	Time Required For 50% Dissipation of the Initial Concentration
DT <sub>90</sub>	Time Required For 90% Dissipation of the Initial Concentration
Dw	dry weight
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC-ECD	Gas Chromatography – Electron Capture Detector
GECDE	Global Estimate of Chronic Dietary Exposure
GC-FPD	Gas Chromatography – Flame Photometric Detector
GC-NPD	Gas Chromatography – Nitrogen Phosphorous Detector
GD	Gestation day
GEMS	Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme

GI	gastrointestinal
GLP	good laboratory practice
HPLC	High performance liquid chromatography
HR	Highest Residue Level in the Edible Portion of A Commodity
HR-P	Highest Residue Level in a Processed Commodity
IEDI	International Estimated Daily Intake
IESTI	International Estimate of Short-Term Dietary Intake
IUPAC	International Union of Pure and Applied Chemistry
IC <sub>50</sub>	Median inhibitory concentration
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 <sub>50</sub>	Median lethal concentration
LC-MS/MS	Liquid Chromatography-Tandem Mass Spectrometry
LD <sub>50</sub>	Median lethal dose
LOAEL	lowest-observed-adverse-effect level
LOD	Limit of Detection
LOQ	Limit of Quantification
MOA	Mode of action
MRL	Maximum Residue Limit
NOAEL	no-observed-adverse-effect level
OECD	Organisation for Economic Co-Operation and Development
PBI	Plant-Back Interval
PES	Post Extraction Solid
Pf	Processing Factor
PHI	Pre-Harvest Interval
PND	Postnatal day
Po	Post-harvest
ppm	parts per million
RAC	Raw Agricultural Commodity
RBC	Red blood cell
RNA	Ribonucleic acid
RTI	Re-Treatment Interval
SC	suspension concentrate
SFO	Single first order model
SPE	Solid phase extraction

STMR	Supervised Trials Median Residue
STMR-P	Supervised Trials Median Residue in a processed commodity
$T_{\max}$	time to reach maximum concentration
TRR	Total Radioactive Residues
TTC	threshold of toxicological concern
UK	United Kingdom
USA	United States of America
USEPA	USA Environmental Protection Agency
WHO	World Health Organisation



## **Use of JMPR reports and evaluations by registration authorities**

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





## Pesticide residues in food

### Report of the 2019 Joint FAO/WHO Meeting on Pesticide Residues

## 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 in Geneva, Switzerland, from 17 to 26 September 2019. The FAO Panel Members met in preparatory sessions from 12 to 16 September.

The WHO Director of Food Safety and Zoonoses, Dr Kazuaki Miyagishima, welcomed all the experts and colleagues from FAO. Dr Miyagishima remarked that the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is an excellent example of how WHO and FAO can jointly mobilise some of the best expertise from around the world, in this case, in the interest of protecting public health from adverse effects of pesticide residues in food.

Dr Miyagishima reflected on the fact that the JMPR has met on an annual basis since 1963 to provide scientific advice to the Codex Alimentarius Commission and the Codex Committee on Pesticide Residues (CCPR). The high demand for scientific advice on pesticide residues had resulted in an extraordinary JMPR meeting earlier this year that was held in Ottawa in May. The ordinary JMPR meeting is now about to begin with a full agenda.

Dr Miyagishima appreciated the hard work of the experts prior to the meeting and intensive discussion and critical review during the meeting. This engagement assures that the scientific output from the meeting will meet the highest possible standard. This way of working is essential in maintaining the consistent high quality of the scientific advice provided by FAO and WHO to the Codex – and to the countries of the world. As a result, the advice from the JMPR is respected and widely used around the world through application of Codex standards for food in international trade and directly by national authorities.

On behalf of WHO and FAO, Dr Miyagishima conveyed a deep appreciation for the efforts and commitment to the JMPR by the experts. Without these expert inputs, the organisations would not be able to deliver this necessary expert advice and – consequently – the safety of food around the world would suffer. Finally, Dr Miyagishima wished all the participants a fruitful meeting over the next two weeks.

During the meeting, the FAO Panel of Experts on Pesticide Residues in Food was responsible for reviewing residue and analytical aspects of the pesticides under consideration, including data on their metabolism, fate in the environment and use patterns, and for estimating the maximum levels of residues that might occur as a result of use of the pesticides according to good agricultural practice. The methodologies are described in detail in the FAO Manual on the submission and evaluation of pesticide residue data for the estimation of maximum residue levels in food and feed (2016) hereafter referred to as the FAO manual. The WHO Core Assessment Group on Pesticide Residues was responsible for reviewing toxicological and related data in order to establish acceptable daily intakes (ADIs) and acute reference doses (ARfDs), where necessary and possible.

The Meeting evaluated 30 pesticides, including eight new compounds and three compounds that were re-evaluated for toxicity or residues, or both, within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting established ADIs and ARfDs, estimated maximum residue levels and recommended them for use by CCPR, and estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimating dietary exposures.

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

The Meeting considered a number of general issues addressing procedures for the evaluation and risk assessment of pesticide residues.

### **1.1 Declaration of interests**

The Secretariat informed the Meeting that all experts participating in the 2019 Extra JMPR had completed declaration of interest forms and that no conflicts had been identified.

## 2. General considerations

### 2.1 *Update to Chapter 5 of the Environmental Health Criteria (EHC) 240: Dose–response assessment and derivation of health-based guidance values*

Although the benchmark dose (BMD) was introduced some years ago as an alternative to the NOAEL as the point of departure (POD) in toxicity studies, only relatively recently has it seen broad adoption by a number of authorities. However, the number of options that can be used in determining a BMD has resulted in a lack of harmonization of the resulting PODs. For this reason, together with advances in hazard assessment practice led to the Eighty-third Joint FAO/WHO Expert Committee on Food Additives (JECFA 2017) recommending that Chapter 5 of EHC 240 should be updated. The Meeting was informed on the progress made on this update. WHO convened a working group, consisting of international experts on benchmark dose modelling and toxicologists to prepare a draft update of the guidance in Chapter 5. The draft was discussed by experts from various countries and organizations, including members of JECFA and JMPR, at a workshop held 25–29 March 2019 in Geneva. Participants approved the general outline of the Chapter, with subsections for dose-response assessment, determining the point of departure and establishing health based guidance values. The draft document was discussed and necessary changes and additions were agreed upon.

Main changes in the update of the guidance:

- In the section on dose-response modelling detailed information is provided on the principles of dose-response modelling with descriptions of mathematical functions for modelling various types of data (continuous, quantal, counts, etc.), model uncertainty, model parameter constraints, model averaging, benchmark dose (BMD) software (BMDS, PROAST) and modelling of epidemiological data.

An Annex provides specialist information about BMD analysis, and gives worked out examples of the use of the BMD software programs BMDS and PROAST.

- The section on determining the point of departure (NOAEL and BMDL) provides guidance on the determination of the benchmark response (BMR) for BMD modelling using a tiered approach, and on the reporting of BMD results (e.g. size of BMR, software used, models used for averaging, BMDL and BMDU, etc).
- The section on establishing health-based guidance values has been updated, among others, with information on International Programme on Chemical Safety (IPCS) guidance on the Mode of Action Human Relevance Framework, guidance on the use of epidemiological data, and on the consideration of the need for establishing a microbiological ADI or ARfD.

A decision tree provides guidance for a structured approach to the process of selecting critical endpoints, dose-response modelling, identification of the POD and establishing a health based guidance value (HBGV).

The guidance is being revised in line with the feedback from experts, and should be ready for public consultation in late 2019 or early 2020. Once finalized, it will replace Chapter 5 in EHC 240.

## 2.2 Combined exposure to multiple chemicals

Regulatory authorities are increasingly including consideration of exposure to multiple chemicals in their risk assessments of substances in food. In Europe, this resulted in the Euromix project, funded by Horizon 2020, which ran from 2015–2019, developing approaches and methods for the assessment of risks posed by combined exposures to multiple chemicals. A key objective of Euromix was to identify and promote opportunities to harmonize different approaches taken to such assessments, to which end Euromix arranged four international workshops on harmonization. A EuroMix web-based toolbox and handbook were developed to provide databases and methods for the tiered assessment of combined exposure to chemicals whatever the level of data available on each substance. Both exposure and hazard can be addressed using the tool. Details can be found at [www.euromixproject.eu](http://www.euromixproject.eu).

Complementary to Euromix, a joint FAO/WHO expert consultation was convened in Geneva, 16–18 April 2019. This involved 15 experts from European Union (EU) and non-EU countries, to develop guidance for the risk assessment of combined exposure to multiple chemicals. The ultimate objective is to publish guidance for consideration by FAO/WHO expert committees, such as JECFA and JMPR, and other experts who may find it valuable. A report on the consultation can be found at [www.who.int/foodsafety/areas\\_work/chemical-risks/Euromix\\_Report.pdf](http://www.who.int/foodsafety/areas_work/chemical-risks/Euromix_Report.pdf).

Participants agreed to restrict their recommendations to substances that are not DNA-reactive mutagens, which they suggested should instead be addressed by the WHO working group on Guidance for the Evaluation of Genotoxicity of Chemical Substances in Food. Participants then developed a suggested approach for the assessment of risk resulting from combined exposure to multiple chemicals in food. It was intended that this might be piloted by JMPR and JECFA at future meetings. The approach proposed for assessment of food chemicals is as follows:

- If the estimated dietary exposure for an individual substance exceeds the relevant HBGV or the margin of exposure (MoE) is considered low and of concern, the substance should be referred to risk managers (Codex Committee on Food Additives (CCFA), Codex Committee on Contaminants in Foods (CCCF), Codex Committee on Pesticide Residues (CCPR), Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) for appropriate consideration, as is current practice.
- If the substance belongs to an established chemical group previously considered in a risk assessment of combined exposure to multiple chemicals, it should be assessed as part of that group. Such chemical groups might be based on structure (for example, organophosphates), toxicological effects or mode of action (MOA).
- If the substance is not part of an established assessment group, to the best knowledge of the experts, the need to include it in a risk assessment of combined exposure to multiple chemicals should be determined.
- As a pragmatic cut-off, if estimated dietary exposure for the chemical is  $\leq 10\%$  of the relevant HBGV for all populations, there is no need to consider the compound further for an assessment of combined exposure.
- If estimated dietary exposure for the chemical is  $> 10\%$  of the relevant HBGV for at least one population, the need to include the compound in a risk assessment of combined exposure to multiple chemicals should be considered.
- For chemicals in a risk assessment group, standard procedures for hazard identification and characterization should be followed, including deriving relative potency factors where appropriate.
- For dietary exposure assessment, probabilistic approaches are recommended, ideally using individual food consumption and concentration data for each country. Different approaches will be necessary for acute and chronic exposure.
- Mean chronic dietary exposure for the general population (consumers and non-consumers) should be calculated assuming mean/median concentration and mean food consumption levels

for individual countries, or mean amounts of food available for consumption using the WHO cluster diets.

- For those chemicals for which combined exposure may be of concern, dose additivity should be assumed, unless there is evidence to the contrary. Combined risk should be assessed using standard approaches, such as the (adjusted) hazard index or relative potency factors.
- The key risk drivers should be identified, including the chemicals contributing most to the overall risk, those contributing most to total estimated dietary exposure and/or foods contributing to exposure from each chemical.
- For pesticide residues, JMPR experts should determine using weight of evidence, whether there is toxicological evidence for combined effects of the substance with other pesticides. This should be based on structural similarities, toxicological profiles for MOAs/adverse outcome pathways (AOPs), and shared adverse effects, referring to previous assessments at a national or regional level as necessary. The possibility of synergistic interactions between chemicals should be considered on a case-by-case basis.
- If it is concluded that the substance does belong to a chemical group, the potential for co-exposure (from co-occurrence or internal exposure) should be assessed. Information that could be useful for this purpose for pesticide residues includes good agricultural practice, use profiles, existing data on mean dietary exposure, toxicokinetics (internal exposure), and biomonitoring data.
- When considering which chemicals might be grouped, consideration will also need to be given to dual/multiple use compounds (e.g. used as a veterinary drug and as a pesticide) and discontinued persistent pesticides that occur as contaminants (POPs).

Participants recommended that the approach should be evaluated at forthcoming meetings of JECFA and JMPR and that after its application for 2–3 years, it should be evaluated and revised as necessary, including the pragmatic cut-off point. Once agreed, and if appropriate, the approach to risk assessment for combined exposure to chemical mixtures should be included in the updated FAO/WHO EHC 240, in Chapter 6 Dietary exposure assessments and Chapter 7 Risk characterization.

The Meeting agreed to pilot the approach based on chronic dietary exposure for compounds being evaluated for the first time at the present meeting. The only relevant compound for which the estimated dietary exposure exceeded 10% of the upper bound of the ADI was pyflubumide, which does not belong to an established assessment group for combined exposure to multiple pesticides.

### **2.3 Guidance for the evaluation of genotoxicity of chemical substances in food**

Following recent meetings of JECFA and JMPR (JMPR May 2016, 2018, JECFA 2017, 2019), it had been agreed that the guidance on the evaluation of genotoxicity of chemicals in food provided in subchapter 4.5 of the EHC 240 needed to be updated and expanded. WHO therefore convened an electronic working group to prepare a draft update of the guidance in subchapter 4.5. This was discussed at a workshop held 8–10 October, 2018 in Ann Arbor, Michigan, USA. Experts from a number of countries and organisations participated, including several members of JMPR.

Participants agreed on the general outline of the guidance, including a decision tree, and identified sections that required further discussion. The guidance was revised in line with the feedback from experts, and should be ready for public consultation late this year or early next year. Once finalized, it will replace subchapter 4.5 in EHC 240.

Main sections of the guidance comprise:

- an introduction, comprising risk analysis context and problem formulation, including a decision tree illustrating issues to be considered in assessing the genotoxic potential of different types of substances that can be found in food;

- a description of the available tests for different types of genetic toxicity;
- guidance on the interpretation of test results, including identification of relevant studies, weighting and integration of results, adequacy of the genotoxicity database, integration of carcinogenicity and genotoxicity;
- special considerations, including in silico approaches, the threshold of toxicological concern, and grouping and read-across approaches;
- considerations for specific situations, including mixtures, flavouring agents, minor constituents, and secondary metabolites in enzyme preparations;
- recent developments and future directions, including novel in vitro and in vivo tests, adverse outcome pathways, and quantitative assessment.

#### **2.4 Results for probabilistic modelling of acute dietary exposure to evaluate the IESTI equations**

As part of the process to review the International Estimate of Short-term Dietary Intake (IESTI) equations, the acute dietary exposure assessment for 47 pesticide residues in food for different populations/countries was performed by WHO based on a probabilistic approach combining data from national food consumption surveys and reported concentrations of pesticide residues from official monitoring programmes.

A presentation of the assessment, including results for Australia, Brazil, Canada, four European countries (Czech Republic, France, Italy and the Netherlands) and the United States of America (USA) was made to the Meeting. An assessment of acute dietary exposure estimates exceeding the ARfD, expressed as a proportion of the ARfD, based on two different modelling exercises was reported.

In the first exercise, the acute dietary exposure estimates from the probabilistic models were compared to the IESTI results, using the same residue definition for each approach. In the probabilistic models, two scenarios were tested: 10% use of the pesticide, i.e., only 10% of non-quantifiable samples were assumed to contain the pesticide (90% concentrations assigned a zero value; 10%, the LOQ) and 100% use (all commodities are treated and 100% of the non-quantifiable were assigned the LOQ). Conversion factors were applied to national food consumption data to convert foods reported as consumed to raw commodities, where appropriate. Results were reported for adults ( $\geq 16$  years) and children ( $\leq 6$  years).

From the probabilistic models there was a zero risk of exceeding the relevant ARfD in all countries for all populations tested. For adults, the 97.5<sup>th</sup> percentile of acute dietary exposure was  $< 10\%$  ARfD, for children  $< 50\%$  ARfD. From comparison with the IESTI results, the IESTI equation was considered protective for acute risk.

In the second exercise, the level of protection (LoP) of Codex MRLs was assessed by using the relevant MRL as the concentration value for each commodity in a survey individual's diet, rather than the distribution of actual results as above. The LoP is expressed as the proportion of individuals in a national survey with an acute dietary exposure estimate that exceeds the ARfD. For this exercise, the acute dietary exposure estimate describes a worst-case scenario where all commodities are assumed to contain the pesticide residue at the MRL and food consumption is the reported amounts consumed of each food with an MRL. If no acute dietary exposure estimates exceeded the ARfD, the LoP would be 100%. For any given dietary survey from which commodity consumption values are taken, LoPs can be calculated for the overall population or any specific subgroup.

The highly conservative acute dietary exposure estimates for each pesticide residue obtained for individuals in the national dietary surveys included were compared with the relevant ARfD to assess the LoP. From this scenario, the LoP for 14 pesticides was 100%; none of the calculated acute exposures exceeded the ARfD for these pesticides. For another 22 pesticides  $> 99\%$  were below the ARfD and seven were between 90% and 99%. For the remaining four pesticides, the LoP was less than 90% in at least one population tested. The IESTI equation is not designed to assess the LoP.

Based on the information presented, the JMPR concluded that given the extremely conservative estimates produced when assuming all commodities have residues present at the MRL, a LoP of less than 100% does not necessarily indicate that approved uses will lead to an exceedance of the ARfD in practice. The JMPR suggests that a more realistic assessment of the LoP could be made by assuming residues at the MRL for a single commodity and residues from monitoring data for other commodities in the assessment.

The Meeting agreed that a probabilistic approach to acute dietary exposure assessments should be considered in the future when adequate data and appropriate tools are available.

## **2.5 Need for a guidance on toxicological interpretation due to the shift from maximum tolerated dose (MTD)-based to kinetically-derived maximum dose (KMD)-based evaluation of pesticide residues**

In guideline studies of the toxicity of pesticides, the chemicals are evaluated using a dose-selection protocol that includes a maximum tolerated dose (MTD), designed to maximize the detection of any toxicity in experimental animals by the treatment. The introduction of concurrent in-life toxicokinetics into repeat-dose studies has revealed that in a number of such studies absorption is highly non-linear, and that in some cases there is no additional systemic exposure above a certain dose. Not only does this complicate interpretation of dose-response relationships, but it also results in the unnecessary use of animals, as no useful information is obtained from those dose groups above the point of saturation.

But non-linear toxicokinetics may be manifest not only in saturation of absorption but also in saturation of distribution, metabolism and/or elimination of the parent and/or its metabolites. This confounds toxicological interpretation of the studies.

Most pesticides are toxic at high doses when people are directly exposed to pesticides (Factsheet, WHO 2018<sup>1</sup>), however people are not exposed to pesticides at saturated blood levels through residues in the diet. Thus, consideration of internal exposure to pesticides and/or their metabolites is key to effective dietary risk assessment of pesticide residues with extrapolation to humans.

A top dose for use in animal toxicity testing based on evidence of dose non-proportionality has been termed the kinetically-derived maximum dose (KMD). If sufficient data are available for KMD-based evaluation, it is considered appropriate that the toxicological evaluation of pesticide residues shifts from MTD-based to KMD-based, both from the perspective of dietary risk assessment of pesticide residues with extrapolation to humans and from the viewpoint of scientific progress. In particular, the KMD-based toxicological interpretations are likely to contribute to evaluation on the carcinogenicity observed at high doses and on the results of teratogenicity studies conducted by oral gavage.

However, in order to increase the consistency and transparency of such toxicity assessments, guidance on KMD-based toxicity interpretation is needed.

It is recommended that the Joint Secretariat convene a group of experts to prepare guidance on the KMD-based evaluation of pesticide residues.

## **2.6 Comments on chlorpyrifos**

The Meeting is aware of new information from the European Food Safety Authority (EFSA) statement on the available outcomes of the human health assessment in the context of the peer review of chlorpyrifos.

The EFSA stated that an in vivo Comet assay, proposed in order to clarify the positive findings observed in an in vitro chromosome aberration test and in two studies on unscheduled DNA synthesis, was not provided.

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<sup>1</sup> WHO Fact Sheet 2018. Pesticide Residues in Food. <https://www.who.int/news-room/fact-sheets/detail/pesticide-residues-in-food>

According to EFSA's opinion, chlorpyrifos can produce DNA damage through topoisomerase II inhibition, which might be involved as a molecular initiating event for infant leukaemia that has also been associated with pesticide exposure in some epidemiological studies.

EFSA also stated that a Comet assay study might not be sufficient to rule out this concern, supporting the need for additional data to address the concerns regarding chromosome aberration and DNA damage caused by oxidative stress or through topoisomerase II inhibition.

An additional concern highlighted by EFSA was neurodevelopmental toxicity, based on the effects (decrease in cerebellum height corrected by brain weight) observed in rats and also supported by the available epidemiological evidence related to developmental neurological outcomes in children.

Given the 20-year gap since chlorpyrifos was last reviewed by the JMPR and the magnitude of potential concerns identified by the EU, the Meeting strongly recommends chlorpyrifos be prioritized for periodic re-evaluation. It was noted that aspects of epidemiology should be included.

### **2.7 Possible need for amendments to the Environmental Health Criteria (EHC) 240 guidance on appropriate use of toxicological historical control data (HCD)**

The Meeting noted a certain degree of recurring inconsistencies in the use of HCD. Although there is guidance in EHC 240 on the role of historical control data in the overall evaluation of toxicological data some points might need amendment. The Joint Secretariat was asked to set up an electronic working group that will identify and, if necessary, propose amendments to relevant paragraphs in EHC 240.

### **2.8 Use of monitoring data for the estimation of maximum residue levels**

The JMPR estimates maximum residue levels primarily based on supervised residue trial data conducted according to good agricultural practice GAP. They are recommended to the Codex Alimentarius Commission as MRLs. However, monitoring data were used as a basis of estimating extraneous maximum residue levels.

For a number of years, the CCPR had considered possibilities of setting MRLs for commodities of importance to developing countries. The Thirty-sixth Session of CCPR in 2004 agreed that MRLs for spices should be set on the basis of monitoring data because of the diverse production practices with spices and as GAP information was not available for spices. Noting that there had already been Codex MRLs for a number of pesticides in/on sweet/chili peppers and tea, the CCPR also agreed that chili peppers, tea and herbs fell outside of the definition of "spices" for the purposes of setting MRLs on the basis of monitoring data (irrespective of the Codex Classification). For these commodities, GAP and corresponding supervised trial data should be used for the estimation of maximum residue levels. The Thirty-sixth CCPR also requested JMPR to review existing MRLs on peppers with the view of setting MRLs for dried chili peppers using processing/dehydration factors as appropriate. (ALINORM 04/27/24, paras. 235-247)

The 2002 JMPR elaborated guidelines for selective surveys to provide residue data for estimating maximum residue levels in spices (JMPR Report 2002, Section 2.7). The 2004 JMPR, in response to the request of the Thirty-sixth CCPR above, developed principles and methodology for evaluating monitoring data on spices and estimated a number of maximum residue levels for spices based on monitoring data (JMPR Report 2004, Section 2.6 and 4.27). The principles and methodologies were refined by the 2015 JMPR (JMPR Report 2015, Section 5.30) (FAO Manual, 3<sup>rd</sup> Ed., 2016; Sections 3.9, 5.11, and 11.1)

The current Meeting received monitoring data on a number of spice commodities including dried chili peppers (HS 0444 in the Spice Group) and fresh curry, leaves (HH 0729, in the Herb Group).

The Meeting stressed that it prefers supervised trials conducted according to GAP as the basis of estimating maximum residue levels and confirmed its previous decisions to use monitoring data only



for estimation of extraneous residue levels and of maximum residue levels for spices. It further confirmed that for estimation of maximum residue levels for dried chili peppers, supervised residue trials on peppers conducted according to GAP should be the basis. Noting also the decision of the Thirty-sixth CCPR, the Meeting did not use the monitoring data on dried chili peppers or curry, leaves for estimating maximum residue levels.



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

#### 3.1 *Buprofezin (173)*

A public health concern was raised by the European Union (EU) about the potential for the formation of aniline from residues of buprofezin in commodities which are subject to processing. According to a communication from the European Food Safety Authority (EFSA), the concern form was triggered not by new toxicological studies that would require a revision of the health-based guidance values for buprofezin, but because aniline was considered a genotoxic carcinogen and a threshold could not be determined.

The Meeting received a new *in vivo* genotoxicity study in transgenic rats on aniline and a proposal for a mode of action for the splenic tumours seen in rats exposed to aniline.

The Meeting evaluated data on aniline and concluded that based on the absence of gene mutations in the spleen and a clear threshold for splenic tumours by the established mode of action aniline is unlikely to be carcinogenic to humans at estimated dietary exposure levels.

The Meeting established an ADI for aniline of 0–0.02 mg/kg bw based on the NOAEL of 0.2 mg/kg bw per day for increases in methaemoglobin levels in a human volunteer study. As this observation was made in humans no interspecies safety factor was necessary, and a safety factor of 10 was applied. There is a margin of 1100 between the upper bound of the ADI and the LOAEL for spleen tumours in the rat.

An ARfD of 0.02 mg/kg bw was established on the same basis as the ADI.

The Meeting concluded that the predicted exposures to aniline from residues of buprofezin in commodities, which are subsequently processed, did not represent a public health concern (see 5.5 of the 2019 JMPR Report).

#### 3.2 *Diflubenzuron (130)*

A public health concern was raised by the European Union (EU) about a plant metabolite of diflubenzuron, 4-chloroaniline. According to a communication from the European Food Safety Authority (EFSA), the concern form was triggered not by new toxicological studies that would require a revision of the health-based guidance values for diflubenzuron, but because 4-chloroaniline was considered a genotoxic carcinogen and a threshold could not be determined.

The Meeting did not receive any new data on 4-chloroaniline but was aware that the JECFA veterinary drugs meeting scheduled for October 2019 was reviewing diflubenzuron

#### 3.3 *Fluxapyroxad (256)*

##### *Background*

Fluxapyroxad was evaluated for new maximum residue levels by the 2018 JMPR. In evaluating fluxapyroxad residues in citrus fruits, the 2018 Meeting noted that the median residues from lemon (0.38 mg/kg), grapefruit (0.15 mg/kg), and orange (0.375 mg/kg) are within a 5-fold range, and that the single residue from mandarin (0.33 mg/kg) is encompassed by the residue data for the other citrus subgroups. Noting the overall similarity in the residues across citrus fruits and in an effort to provide a recommendation that covered the subgroup of mandarins, the 2018 Meeting estimated a maximum residue level, STMR, and HR for the Group of Citrus Fruit.

At the Fifty-first Session of the CCPR a concern was raised to the advancement of the proposed draft MRLs for citrus fruits. It was noted that the residue populations from oranges, lemons, and grapefruit are significantly different and the approach taken by JMPR in making its recommendation was not supported. Furthermore, only one trial was submitted for mandarin.

### *Comments by the current Meeting*

#### *Mandarins*

Regarding the general issue of lack of field trials for mandarins, the Meeting recalled the guiding principles and the criteria for crop group of the Codex Classification (CL 2017/22-PR) and noted that the characteristics for commodity grouping are:

1. Commodity's similar potential for pesticide residues;
2. Similar morphology;
3. Similar production practices, growth habits, etc;
4. Edible portion;
5. Similar GAP for pesticide uses;
6. Similar residue behaviour;
7. To provide flexibility for setting (sub) group tolerances.

A review was conducted of the residue potential of the commodities in the citrus subgroups. Residues of foliar applied pesticides are to a large extent governed by the initial spray deposits which in turn depend on a number of plant parameters including the relative surface area of the fruit compared to leaves and stems, the wettability of the fruit and leaf surfaces, as well as crop morphology.

Residues on the day of application of foliar sprays provide a good indication of relative residue potential for different commodities, with the ranking of residue potential largely preserved with increasing time after application.

A measure of the initial spray deposits can be gained by collating residue levels in the commodities on the day of application following a single spray. To expand the database, the Meeting considered data from trials where more than one spray had been applied could be used provided there was sufficient evidence to conclude that the earlier spray did not contribute more than 25% to the observed residue. The Meeting utilized JMPR evaluations in the period 1993 to 2017 and supplemented these with other publically available information such as published scientific papers and EU draft Assessment Reports to assemble a database of initial residue levels normalised to an application rate of 1 kg ai/ha.

A summary of the initial residue deposits for the different commodities is shown in Figure 1 in the form of box-plots. The boxes cover 50% of values (25<sup>th</sup> to 75<sup>th</sup> percentiles) while the whiskers cover 95% of values with the median represented by the dark horizontal lines.

Median residues were 0.74 mg/kg (n = 55) for lemons and limes, 0.62 (n = 102) for mandarins, 0.47 (n = 177) for oranges and 0.37 (n = 27) for grapefruit.

Therefore, the Meeting decided that for foliar uses, extrapolation of residue estimates from lemon or limes to mandarins is reasonable.

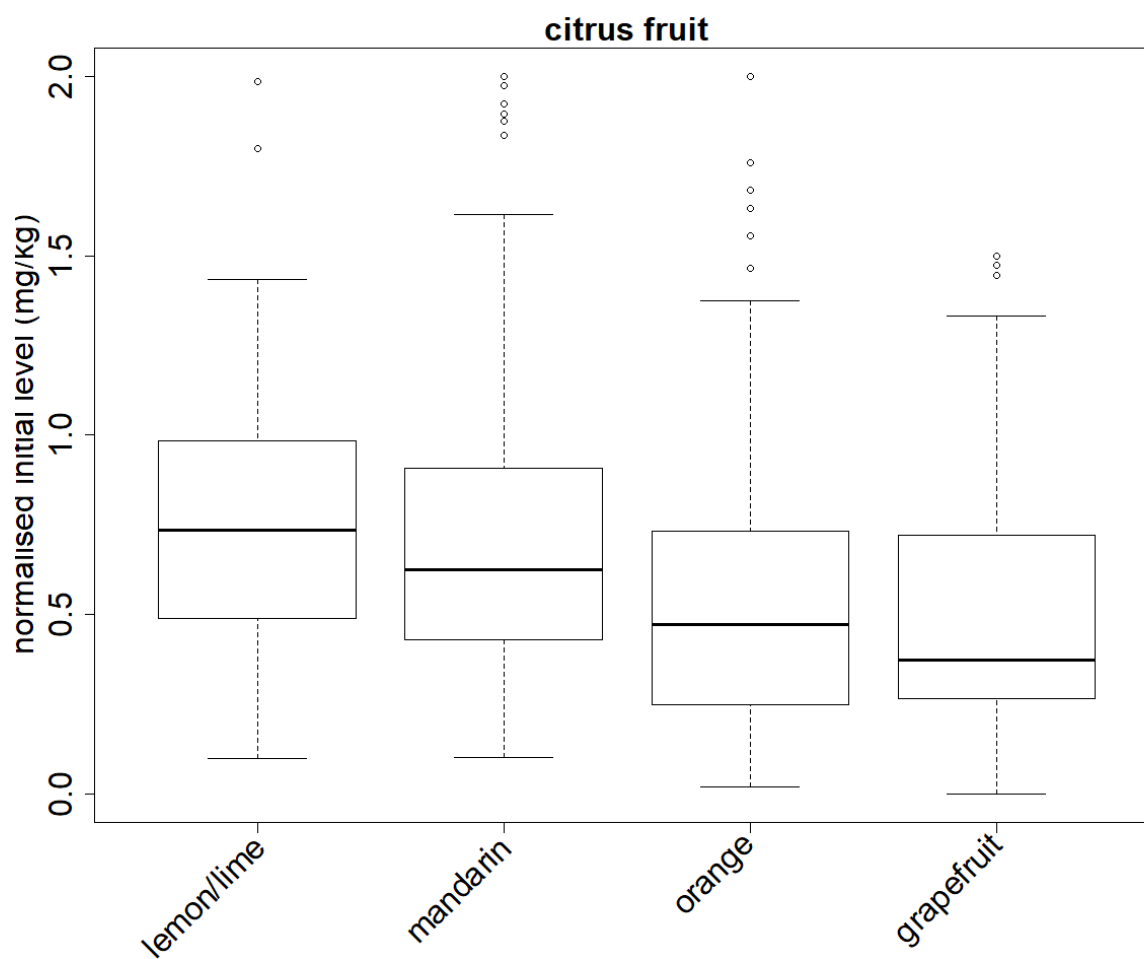


Figure 1 Box-plots of initial spray deposits for foliar treatments close to harvest (normalised to an application rate of 1 kg ai/ha) for citrus.

#### *Fluxapyroxad in citrus*

As to the specific concern regarding fluxapyroxad, the 2019 JMPR has re-examined the data for residues of fluxapyroxad in citrus. Noting that it is not standard practice to use combined data to estimate residue levels when they are shown to be from different populations, the Meeting considered making a recommendation for the citrus subgroups based on the data for the representative commodities.

Residues of **fluxapyroxad, *per se***, were:

Lemon (n = 7): 0.15, 0.16, 0.37, 0.38, 0.40 (2), and 0.45 mg/kg;

Mandarin (n = 1): 0.33 mg/kg;

Orange (n = 10): 0.16, 0.18, 0.32, 0.33, 0.37, 0.38, 0.44, 0.50, 0.52, and 0.58 mg/kg; and

Grapefruit (n = 5): 0.10, 0.15 (2), 0.24, and 0.27 mg/kg.

Residues of **total fluxapyroxad** were:

Lemon (n = 7): 0.15, 0.16, 0.37, 0.38, 0.40, 0.41, and 0.46 mg/kg;

Mandarin (n = 1): 0.33 mg/kg;

Orange (n = 10): 0.16, 0.18, 0.32, 0.33, 0.39, 0.40, 0.44, 0.50, 0.52, and 0.59 mg/kg; and

Grapefruit (n = 5): 0.10, 0.15 (2), 0.24, and 0.27 mg/kg.

The current Meeting estimated maximum residue levels, STMR values, and HR values applicable to citrus subgroups as follows:

Subgroup of Lemons and Limes: 1, 0.38, and 0.46 mg/kg

Subgroup of Oranges, Sweet, Sour: 1.5, 0.395, and 0.59 mg/kg, and

Subgroup of Pummelo and Grapefruits: 0.6, 0.15, and 0.27 mg/kg.

On the basis of the analysis discussed above for mandarins, the Meeting agreed to extrapolate the data from lemon to the Subgroup of Mandarins.

The 2018 Meeting derived processing factors from studies with orange. The Meeting agreed to extrapolate those factors to citrus fruits (Table 2).

Table 2 Processing factors derived by the 2018 JMPR for fluxapyroxad, per se, and total fluxapyroxad in citrus

Commodity	Fluxapyroxad	Total fluxapyroxad
	Processing factors [best estimate]	Processing factors [best estimate]
Wet pomace	1.2, 1.15 [1.2]	1.2, 1.15 [1.2]
Dried pulp	6.2, 3.48 [4.8]	6.2, 3.48 [4.8]
Peel	2.5, 1.23 [1.9]	2.5, 1.23 [1.9]
Juice	0.12, 0.018 [0.12]	0.032, 0.048 [0.040]
Marmalade	0.045, 0.039 [0.042]	0.065, 0.069 [0.067]
Oil	65, 53 [59]	65, 53 [59]

Table 3 Residues of fluxapyroxad (maximum residue level) and total fluxapyroxad (STMR-P, HR-P) in processed citrus commodities.

Crop	Processed Commodity	mg/kg		
		Maximum residue level	STMR-P	HR-P
Lemon and mandarin Max. res. level = 1 mg/kg STMR = 0.38 mg/kg HR = 0.46 mg/kg	Peel	--	0.72	0.87
	Juice (raw)	--	0.015	--
	Oil	60	22	--
Orange Max. res. level = 1.5 mg/kg STMR = 0.395 mg/kg HR = 0.59 mg/kg	Wet pomace	--	0.47	0.71
	Dried pulp	8	1.9	--
	Peel	--	0.75	1.1
	Juice (raw)	--	0.016	--
	Marmalade	--	0.026	--
	Oil	90	23	--
Grapefruit Max. res. level = 0.6 mg/kg STMR = 0.15 mg/kg HR = 0.27 mg/kg	Juice (raw)	--	0.006	--
	Oil	--	8.9	--

The Meeting estimated a maximum residue level for fluxapyroxad in citrus oil of 90 mg/kg to replace its previous estimate of 60 mg/kg, with an STMR of 23 mg/kg.

The Meeting estimated a maximum residue level for fluxapyroxad in citrus pulp, dry of 8 mg/kg and an STMR of 1.9 mg/kg.

### Recommendations

On the basis of the available data, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for dietary risk assessment.

The definition of the residue for compliance with the MRL for plant and animal commodities: *fluxapyroxad*.

The definition of the residue for estimating dietary risk from plant commodities: *Sum of fluxapyroxad and 3-(difluoromethyl)-N-(3',4',5'-trifluoro[1,1'- biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)-1-(β-D-glucopyranosyl)-N-(3',4',5'-trifluorobiphenyl-2-yl)-1H-pyrazole-4-carboxamide (M700F048), expressed as parent equivalents.*

The definition of the residue for estimating dietary risk from animal commodities: *Sum of fluxapyroxad and 3-(difluoromethyl)-N-(3',4',5'-trifluoro[1,1'- biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008), expressed as parent equivalents.*

The residue is fat soluble.

Table 4 Residue levels (for fluxapyroxad) suitable for establishing maximum residue limits and for IEDI and IESTI assessments

Commodity		Recommended MRL, mg/kg		STMR or STMR-P, mg/kg	HR or HR-P, mg/kg
CCN	Name	New	Previous		
FC 0001	Group of citrus fruit	W	1		
FC 0002	Subgroup of Lemons and Limes (including Citron)	1		0.38	0.46
FC 0003	Subgroup of Mandarins	1		0.38	0.46
FC 0004	Subgroup of Oranges, Sweet, Sour (including Orange-like hybrids)	1.5		0.395	0.59
FC 0005	Subgroup of Pummelo and Grapefruits (including Shaddock-like hybrids, among other Grapefruit)	0.6		0.15	0.27
OR 0001	Citrus oil, edible	90	60	23	
AB 0001	Citrus pulp, dry	8		1.9	
For dietary burdens and risk assessment					
	Lemon/lime/mandarin juice (raw)			0.015	
	Orange juice (raw)			0.016	
	Grapefruit juice (raw)			0.006	
	Grapefruit oil			8.9	
	Lemon/lime peel (fresh)			0.72	0.87
	Orange peel (fresh)			0.75	1.1
	Citrus wet pomace			0.47	0.71
	Marmalade			0.026	

The new recommendations do not result in changes to the dietary exposure estimates (up to 20% of the maximum ADI, up to 10% of the ARfD) or conclusions provided by the 2018 Meeting.

### 3.4 Iprodione (111)

A public health concern was raised by the European Union (EU) about the safety of iprodione residues. According to a communication from the European Food Safety Authority (EFSA), the concern form related to estimated intakes exceeding the EU ADI and ARfD by 2.7 and 17 fold respectively.

The EU ADI of 0.02 mg/kg bw is based on a LOAEL for adrenal vacuolation of 6 mg/kg bw per day and a safety factor of 300. The 1995 JMPR established an ADI of 0.06 mg/kg bw based on the same study and end-point but used a 100 fold safety factor as it considered that 6 mg/kg bw per day was a NOAEL.

The EU ARfD of 0.06 mg/kg bw is based on a LOAEL for umbilical hernia of 20 mg/kg bw per day in a rabbit developmental study and a safety factor of 300. The JMPR was not routinely establishing ARfDs at the time of the last review in 1995. The toxicology monograph for the 1995 JMPR includes an evaluation of the same rabbit developmental study but does not mention the umbilical hernia as a critical effect.

The current Meeting did not have access to the iprodione toxicology database and therefore could not assess if it agreed with the EU ADI and ARfD values.

Given the 24-year gap since iprodione was last reviewed by JMPR and the magnitude of potential concerns for acute intakes identified by the EU, the Meeting strongly recommends iprodione be prioritized for periodic re-evaluation. It was noted that aspects of epidemiology should be included.

### 3.5 Isofetamid (290) – Reconsideration of the maximum residue levels for bush berries, dry beans and dry peas

#### *Background*

At the Fifty-first Session of the CCPR, the EU, Norway and Switzerland stated that the MRL for bush berries, the MRL for the subgroup of dry beans, except soya bean and the MRL for the subgroup of dry peas needed to be revised.

For bush berries the EU, Norway and Switzerland stated the MRL should be 4 mg/kg and not 5 mg/kg as recommended by the 2018 JMPR.

For dry beans and dry peas the EU, Norway and Switzerland highlighted that the HR observed in the trials was 0.08 mg/kg and based on the residue trials data set the MRL proposal should be 0.09 mg/kg and not 0.05 mg/kg as recommended by the 2018 JMPR.

#### *Comments by the current Meeting*

The scaled residues in bush berries in rank order were (n = 10): 0.14, 0.19, 0.20, 0.23, 0.27, 0.35, 0.59, 0.68, 0.77 and 3.0 mg/kg.

The current Meeting estimated a maximum residue level of 4 mg/kg, an STMR of 0.31 mg/kg and a HR of 3 mg/kg for bush berries. Therefore, the Meeting recommended that the MRL of 4 mg/kg replace the previous recommendation of 5 mg/kg.

For dry beans and dry peas the residues in rank order were (n = 19): < 0.01 (16), 0.020, 0.036 and 0.080 mg/kg.

The current Meeting estimated a maximum residue level of 0.09 mg/kg and an STMR of 0.01 mg/kg for the subgroup of dry beans, except soya beans and for the subgroup of dry peas. Therefore, the Meeting recommended that the MRL of 0.09 mg/kg replace the previous recommendation of 0.05 mg/kg for the subgroup dry beans, except soya bean, and for the subgroup of dry peas.



The IEDIs and the IESTIs undertaken by the JMPR in 2018 are still applicable to this re-consideration of the maximum residue levels for bush berries and the subgroup of dry beans, except soya bean and the subgroup of dry peas. The Meeting concluded that the long-term and acute dietary exposures to residues of isofetamid resulting from the uses on bush berries, dry beans and dry peas are unlikely to present a public health concern.

Table 5 Residue levels (for isofetamid) suitable for establishing maximum residue limits and for IEDI and IESTI assessments

CNN	Commodity name	Recommended maximum residue level (mg/kg)		STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)
		New	Previous		
FB 2006	Bush berries, Subgroup of	4	5	0.31	3
VD 2065	Dry beans (except soya beans), Subgroup of	0.09	0.05	0.01	
VD 2066	Dry peas, Subgroup of	0.09	0.05	0.01	

### 3.6 Picoxystrobin (258)

A public health concern was raised by the European Union (EU) about a number of aspects of picoxystrobin, which had resulted in no reference doses being established in the EU. According to a communication from the European Food Safety Authority (EFSA), the concern form related to:

- genotoxicity of picoxystrobin
- clastogenicity/aneugenicity of a metabolite of picoxystrobin, IN-H8612
- uncertainty regarding whether the specification of the material tested in the toxicity studies was equivalent to that sold commercially
- the absence of information relating to EU-specific requirements such as “endocrine disruption”.

JMPR reviewed picoxystrobin in 2012, establishing an ADI of 0–0.09 mg/kg bw and ARfD of 0.09 mg/kg bw, both based on a combined NOAEL from 90-day and one year dog studies. The 2012 JMPR noted the weakly positive response in the mammalian cell gene mutation assay with metabolic activation, identified as a concern of EFSA, but concluded that picoxystrobin was unlikely to be genotoxic.

In 2013 JMPR evaluated a new in vivo micronucleus study on IN-8612, performed to investigate the positive response in one of two in vitro mammalian cell chromosome aberration assays. JMPR concluded that the results of the new study were negative and that IN-8612 could be assessed using the TTC as not genotoxic. EFSA concluded that the same study was equivocal.

JMPR and EFSA differ in their interpretations of the genotoxicity data for picoxystrobin and IN-H8612. At the 2012 and 2013 Meetings, the WHO panel of JMPR included a specialist genotoxicity expert.

The specification issue is outside the remit of the JMPR, is considered to be of questionable relevance to residues in treated commodities, but could be referred to the JMPS.

The meeting noted the lack of information on EU specific requirements such as “endocrine disruption”. Within the EU framework, endocrine disruption is a hazard identification process but JMPR includes these aspects as part of their risk assessments.

The Meeting concluded that the concerns identified about dietary exposures to picoxystrobin were unlikely to represent a public health concern

### **3.7 Propiconazole (160) – Reconsideration of the maximum residue level for peach**

#### ***Background***

At the Fifty-first Session of the CCPR, it was requested that the maximum residue level of 5 mg/kg (Po) for propiconazole in peach be retained as the GAP considered by the 2013 JMPR was still authorized in the USA.

The 2017 and 2018 JMPR had considered a new GAP authorized in the USA on peaches and plums and recommended replacement of the previous recommendation of 5 mg/kg (Po) with a maximum residue level of 0.7 mg/kg (Po) for peach.

#### ***Comments by the current Meeting***

The current Meeting received confirmation that the GAP considered for peach by the 2013 JMPR was still authorized in the USA. The GAP is a post-harvest in-line dip/drench treatment to peach and involves one application of 0.014 kg ai/hL.

The Meeting noted that the maximum residue level of 5 mg/kg (Po) recommended by the 2013 JMPR was based on  $3 \times$  mean in the OECD MRL calculator. In accordance with the decision of the 2018 JMPR, for post-harvest uses when homogenous residues are expected the “mean + 4\*SD” should be used as the basis for the maximum residue level.

Residues of propiconazole in peach in rank order were (n = 4): 1.2, 1.4, 1.7 and 2.1 mg/kg with the highest analytical result reported as 2.2 mg/kg.

Total residues (propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid) in peach in rank order were (n = 4): 0.73, 1.1, 2.3 and 2.5 mg/kg.

The Meeting recommended a maximum residue level of 4 mg/kg (Po) for peach, an STMR of 1.7 mg/kg and a HR of 2.5 mg/kg to replace the previous recommendation.

#### ***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 values estimated by the 2017 JMPR and the STMR considered in this Meeting for peaches. The results are shown in Annex 3 of the 2019 JMPR Report.

The IEDIs ranged from 1–7% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of propiconazole from uses considered by the JMPR is unlikely to present a public health concern.

#### ***Acute dietary exposure***

The ARfD for propiconazole is 0.3 mg/kg bw. The IESTIs for propiconazole were calculated for peaches. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs varied from 0–40% of the ARfD for children and 2–20 % of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of propiconazole from the use considered by the present Meeting on peach is unlikely to present a public health concern.

### **3.8 Pyraclostrobin (210)**

#### ***Background***

At the Fifty-first Session of the CCPR (2019), it was noted that there was an incorrect HR value in the 2018 JMPR report for spinach and that for root and tuber vegetables the maximum residue level recommendation should exclude sugar beet.

*Comment by the JMPR*

The current Meeting revisited the pyraclostrobin residue data for spinach and agreed that a residue in a trial from Italy had been incorrectly recorded by the 2018 JMPR as 0.91 mg/kg when the correct value is 0.091 mg/kg.

As noted by the 2018 JMPR, the critical GAPs for pyraclostrobin on spinach in European countries is that of Germany ( $2 \times 0.1$  kg ai/ha, a RTI of 8 days and a 14-day PHI) and Italy ( $2 \times 0.1$  kg ai/ha, a RTI of 7 days and a 14-day PHI).

In 10 trials conducted in France, Germany and Italy, and matching cGAP, residues in spinach were  $< 0.01$ , 0.02 (2), 0.05 (2), 0.091, 0.13 (2), 0.28 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg, a STMR of 0.071 mg/kg and a HR of 0.31 mg/kg for pyraclostrobin in spinach.

The meeting withdrew its previous maximum residue level recommendation of 1.5 mg/kg for spinach.

Regarding root and tuber vegetables, the Meeting noted that the registration in the USA is for the US Crop Subgroup 1B (Root vegetables, except sugar beet) and also separately for sugar beet. Members of the US Crop Subgroup 1B (except sugar beet) include: Garden beet, burdock, carrot, celeriac, turnip-rooted chervil, chicory, ginseng, horseradish, turnip-rooted parsley, parsnip, radish, oriental radish, rutabaga, salsify, black salsify, Spanish salsify, skirret, and turnip.

As the US Crop subgroup 1B closely matches the new Codex Subgroup 16A Root vegetables, and the GAPs in the USA for root and tuber vegetables and sugar beet are different, the Meeting decided to revise its previous recommendation for root vegetables, Subgroup of (includes all commodities in the subgroup) to be replaced by a recommendation for Root vegetables, Subgroup of (includes all commodities in the subgroup except sugar beet).

Table 6 Residue levels (for pyraclostrobin) suitable for establishing maximum residue limits and for IEDI and IESTI assessments

CNN	Commodity name	Recommended maximum residue level (mg/kg)		STMR or STMR-P (mg/kg)	HR or HR-P (mg/kg)
		New	Previous		
VR 2070	Root vegetables, Subgroup of (includes all commodities in the subgroup)	W	0.5	0.12	0.3
VR 2070	Root vegetables, Subgroup of (includes all commodities in the subgroup except sugar beet)	0.5	-	0.12	0.3
VL 0502	Spinach	0.6	1.5	0.071	0.31

### 3.9 Request from CCPR concerning okra

#### *Background*

At the Fifty-first Session of the CCPR (2019), some member countries expressed concerns at the JMPR's recommendations for the subgroup peppers (i.e. that the exclusion of okra from MRLs for the subgroup Peppers could impact trade). They requested that JMPR find more suitable commodity groups for which an MRL could be extrapolated to okra.

CCPR was informed that monitoring data for okra showed non-compliances for okra were low when compared to peppers, even when both were covered by a group MRL.

CCPR noted the need to find a solution for extrapolation of an MRL to okra and encouraged member countries and interested organisations to submit data from residue field trials as well as monitoring data for consideration by the JMPR as follows:

- In the absence of specific data for okra, what scientific evidence would JMPR consider in the extrapolation to facilitate the elaboration of an MRL that can ensure the protection of public health while facilitating trade.
- That a comparison of monitoring data for okra and other fruiting vegetables be done to determine if differences in residues observed in trade between these commodities are similar to the difference observed in supervised trials and hence confirm extrapolation principles.

#### *Comment by the JMPR*

The current Meeting received monitoring data from Canada for tomatoes (domestic and import), non-bell peppers and okra imported into Canada from the USA.

Focusing on just the US samples (where it was suggested that the use pattern on all three fruiting vegetables is similar), the data included analyses for 383 compounds. The current Meeting reviewed the data and noted:

- Residues were detected for eight compounds in both okra and non-bell peppers. The average ratio of maximum residues in okra to non-bell peppers was 4.
- Residues were detected for ten compounds in both okra and tomatoes. The average ratio of maximum residues in okra to tomatoes was close to 7.

The average ratios from the Canadian monitoring data are consistent with the results observed from supervised field trials (previously provided to CCPR) where residues in okra are higher than in both non-bell peppers (where median normalized initial residues were 4–7× higher in okra vs. non-bell peppers/chili peppers) and tomatoes (where median normalized initial residues were 14× higher in okra vs. tomatoes).

The Canadian monitoring data provides further evidence that residues of pesticides in okra are significantly higher than residues in other fruiting vegetable commodities such as non-bell peppers and tomatoes. As such, the Meeting concluded that the Canadian monitoring data confirms residues in peppers and tomatoes are not representative of residues in okra and should not be used to extrapolate an MRL to okra given that the use of these data would likely result in MRL recommendations that would be too low for this commodity.

The current Meeting considered other commodity groups for extrapolation to okra but were unable to identify one with an appropriate representative crop. One of the criteria for the selection of representative commodities is that it is most likely to contain the highest residues. Given okra's unique crop morphology (ridged and slight hairy surface) and its potential for higher residues, the Meeting is unable to suggest a commodity group/subgroup to extrapolate an MRL to okra. One option would be to include okra in Group 012 (Fruiting Vegetables other than Cucurbits) in a separate "Others" subgroup.

## 4 Dietary exposure assessment for pesticides residues in food

### 4.1 Chronic dietary exposure

At the present 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 from supervised trials median residues [STMRs] and/or supervised trials median residues in a processed commodity [STMR-Ps]). The food consumptions were estimated using the 17 Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) consumption cluster diets. A detailed description of the method is included in the Environmental Health Criteria 240 (EHC 240) monograph.<sup>2</sup>

These IEDIs are expressed as a percentage of the upper bound of the ADIs for a 55 kg or 60 kg person, depending on the cluster diet (Table 1). The spreadsheet application is available at [http://www.who.int/foodsafety/areas\\_work/chemical-risks/gems-food/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/). The detailed calculations of the chronic dietary exposure assessments are given in Annex 3.

CCPR code	Compound name	ADI (mg/kg bw)	Range of IEDI, as % of the upper bound of the ADI
312	Afidopyropen*	0–0.08	0–4
261	Benzovindiflupyr	0–0.05	0–2
178	Bifenthrin	0–0.01	10–40
173	Buprofezin	0–0.009	4–40 <sup>c</sup>
296	Cyclaniliprole	0–0.04	1–10
118	Cypermethrin	0–0.02	0
283	Fluazifop-P-butyl	0–0.004	30–160 (G16 diet 160) 20–90 <sup>a</sup>
265	Fluensulfone	0–0.001	1–3
199	Kresoxim-methyl	0–0.3	0
307	Mandestrobin*	0–0.02	0–2
313	Metconazole*	0–0.04	0–2
253	Penthiopyrad	0–0.1	1–8
258	Picoxystrobin	0–0.09	0
160	Propiconazole	0–0.07	1–7
314	Pyflubumide	0–0.007	3–20
200	Pyriproxyfen	0–0.1	0–1
317	Tolclofos-Methyl	0–0.07	0–1
269	Tolfenpyrad	0–0.006	1–20
319	Valifenalate*	0–0.2	0
246	Acetamiprid-spices	0–0.07	0 <sup>b</sup>
72	Carbendazim-spices	0–0.03	0 <sup>b</sup>

\*New chemicals; ADI: acceptable daily intake; bw: body weight; CCPR: Codex Committee on Pesticide Residues; IEDI: international estimated daily intake

<sup>a</sup> Based on the decision of CCPR 2017 (REP17/PR) to withdraw the draft MRLs for sweet potato and yam;

<sup>b</sup> based on median values derived from monitoring data for the Subgroup of spices, seeds only;

<sup>c</sup> The Meeting concluded that the long-term dietary risk assessment for buprofezin would adequately address long-term dietary risk to residues of aniline (ADI: 0-0.02 mg/kg bw) that may arise from the uses of buprofezin considered by the JMPR

<sup>2</sup> 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; <http://www.who.int/foodsafety/publications/chemical-food/en/>).

The Meeting was unable to derive a residue definition for dietary risk assessment for clethodim, dimethoate, pyrifluquinazon and triflumuron. A toxicological evaluation for carbosulfan and carbofuran was unable to be completed because of missing critical information. Chronic dietary risk assessments were not conducted for these compounds.

Mandestrobin was evaluated at the previous meeting for toxicology and an ADI established, but it was not possible to complete the evaluation for residues due to late submission of critical information. A residue evaluation and chronic dietary risk assessment were completed at this meeting.

Pyriofenone and cypermethrins were evaluated but did not lead to changes in the IEDI, so there were no changes to the chronic dietary exposure estimate from the previous meeting. There was insufficient information to propose MRLs for lambda-cyhalothrin.

### ***Chronic dietary exposure estimates using national dietary survey data***

The Meeting currently calculates the IEDI i.e. mean dietary exposure for the general population, based on the GEMS/Food cluster diets. These estimates are compared with the ADI to characterize the risk for each pesticide residue. The GEMS/Food cluster diets consist of multi-annual FAO supply utilization account data averaged over the general population for each country; the data have been grouped into 17 clusters that capture, for each, the amount of food available for consumption per capita (apparent food consumption), expressed in grams per day. The IEDI approach is therefore not suitable for assessing shorter-than-lifetime exposure for specific age/sex groups identified as being of toxicological concern.

As part of a trial exercise, food consumption data from national dietary surveys were used as the basis for estimating mean and high consumer chronic dietary exposure to pesticide residues for the general population and different age/sex groups. The global estimate of chronic dietary exposure (GECDE) model, developed by JECFA (veterinary drugs) in 2011<sup>3</sup>, was used for estimating potential high consumer dietary exposure to pesticide residues for population subgroups of toxicological concern, such as women of childbearing age, infants and young children (0–6 years). The GECDE model is based on summary statistics derived from individual food 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. This model is intended to be used when raw individual dietary records are not available for use in risk assessments, which is often the case for evaluations undertaken by JMPR .i.e. the GECDE serves as a proxy for deriving a high percentile dietary exposure value from a distribution of dietary exposures obtained by using the raw data.

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 food consumption data derived from national surveys that have two or more records per survey participant (for us in chronic dietary exposure assessments, results for each individual are averaged over the number of days of the survey prior to deriving summary statistics). For many countries, different population groups are surveyed at different times, for example there may be a separate adult and children's survey. In this case it is not possible to estimate dietary exposure for the general population for that country. The STMR residue levels were assigned to each food with an existing or proposed MRL for the pesticide. In some cases, factors were required to correct the STMR for the raw commodity (e.g. level in tea leaves) to a level relevant to the food reported as consumed in the dietary survey (e.g. STMR-P in tea beverage).

For each new pesticide evaluated at this Meeting and one other pesticide under periodic review (Clethodim) estimated dietary exposures for the mean for the general population and the GECDE for population groups of toxicological concern were derived using CIFOCoss survey data for each country

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<sup>3</sup> 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 ([http://www.fao.org/fileadmin/user\\_upload/agns/pdf/jecfa/Dietary\\_Exposure\\_Assessment\\_Methodologies\\_for\\_Residues\\_of\\_Veterinary\\_Drugs.pdf](http://www.fao.org/fileadmin/user_upload/agns/pdf/jecfa/Dietary_Exposure_Assessment_Methodologies_for_Residues_of_Veterinary_Drugs.pdf)).

in the database. An exception was for countries in the European Union, where the EFSA individual record files were used directly rather than the CIFOCCOs summary data to estimate the mean and high consumer's chronic dietary exposure for the general population and subgroups. A 95<sup>th</sup> percentile exposure from the distribution of exposures for each population was derived for each pesticide residue instead of using the GECDE high consumer model.

The results are summarized in Table 2, for illustrative purposes only. Generally, the results using national survey data to estimate mean dietary exposure to a specified residue for the general population were similar to the IEDI results. As expected, dietary exposure estimates for the high consumer (GECDE model or 95<sup>th</sup> percentile exposures for European Union countries) were all higher than the corresponding IEDI for the pesticides considered in this exercise, up to a factor of 5. None of the high consumer estimates exceeded the ADI.

Estimated chronic dietary exposure for Pyflubumide was the highest of the chemicals assessed in this exercise. MRLs are proposed for Pyflubumide for a limited number of commodities (apple and tea). For infants and toddlers estimated dietary exposure to Pyflubumide was 100% of the ADI for high consumers, with apples being the main food contributor.

The Meeting agreed it would be useful to report estimated dietary exposures based on national dietary survey data in addition to the IEDI results at future JMPR meetings because these data give a more realistic estimate of actual exposure for different populations around the world. Where there is an identified concern about shorter-than-lifetime exposures for the mean or high consumer, additional information on subpopulation groups are provided that is of use to risk assessors and risk managers. This level of information is not available using the IEDI.

Work is also required to improve the consistency of coding of foods in each country survey as submitted to WHO for inclusion in the CIFOCCOs database. The Meeting noted that WHO updated this database in 2019 using the EFSA FoodEx2 food classification system for foods reported as consumed, which is expected to improve consistency in the future. A file linking the Codex food classification codes and FoodEx2 codes would also be very useful and would need to be updated each year prior to the JMPR meeting.

The Meeting noted use of the GECDE model for estimating dietary exposure for high consumers for population subgroups will harmonize approaches for the risk assessments of pesticides and veterinary drugs and will be particularly useful for assessing those chemicals with dual use.

Table 2 Chronic dietary exposure estimates using national dietary survey data <sup>b</sup>, for illustrative purposes only

Pesticide	ADI (mg/kg bw)	IEDI (% ADI)	Mean dietary exposure General population (% ADI)	High consumer dietary exposure (GECDE <sup>a</sup> or 95 <sup>th</sup> percentile for European Union countries) (% ADI)
Afidopyropen	0-0.08	0-4 All	0-5 All 0-4 All adults 0-4 Adults, female 0-4 Children & adolescents 0-12 Infants & toddlers	0-23 All 0-22 All adults 0-22 Adults, female 0-19 Children & adolescents 0-82 Infants & toddlers
Mandestrobin	0-0.2	0-2 All	0 All 0-2 All adults 0-2 Adults, female 0-6 Children & adolescents 0-3 Infants & toddlers	0-4 All 0-5 All adults 0-5 Adults, female 0-16 Children & adolescents 0-14 Infants & toddlers

Pesticide	ADI (mg/kg bw)	IEDI (% ADI)	Mean dietary exposure General population (% ADI)	High consumer dietary exposure (GECDE <sup>a</sup> or 95 <sup>th</sup> percentile for European Union countries) (% ADI)
Metconazole	0-0.04	0-2 All	0-3 All 0-2 All adults 0-2 Adults, female 0-2 Children & adolescents 0-2 Infants & toddlers	1-13 All 0-9 All adults 0-9 Adults, female 0-7 Children & adolescents 0-8 Infants & toddlers
Pyflubumide	0-0.007	3-20 All	0-6 All 0-30 All adults 0-31 Adults, female 0-24 Children & adolescents 1-35 Infants & toddlers	0-66 All 1-68 All adults 0-70 Adults, female 0-85 Children & adolescents 4-100 Infants & toddlers
Valifenalate	0-0.2	0	0 All 0 All adults 0 Adults, female 0 Children & adolescents 0 Infants & toddlers	0 All 0 All adults 0 Adults, female 0 Children & adolescents 0-1 Infants & toddlers

ADI: acceptable daily intake; bw: body weight; CIFOcOss: Chronic Individual Food Consumption summary statistics; GECDE: global estimate of chronic dietary exposure; IEDI: international estimated daily intake

<sup>a</sup> For each national survey in the CIFOcOss database, for the GECDE model for a specified age group, a high percentile dietary exposure was first calculated for each commodity with an assigned supervised trials median residue (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 the whole population was derived for that Codex commodity code.

<sup>b</sup> The CIFOcOss database has the following numbers of national surveys in the database: whole population, 11 surveys; adults, 79 surveys; adult women, 74 surveys; children and adolescents (aged 3-17 years), 89 surveys; infants (aged 0-11 months) and toddlers (aged 1-3 years), 55 surveys.

## 4.2 Acute dietary exposure

At the present 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) data 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 national dietary survey data by WHO. For mixed commodities the STMR is used as the residue level in the IESTI calculation. In the case where a separate ARfD was established for women of childbearing age, the IESTI was calculated for this population group only. A description of the method is included in EHC 240.

These IESTI results are expressed as a percentage of the ARfD (Table 3). The spreadsheet application is available at [http://www.who.int/foodsafety/areas\\_work/chemical-risks/gems-food/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/).

The Meeting was unable to derive a residue definition for dietary risk assessment for clethodim, dimethoate, pyrifluquinazon and triflumuron. A toxicological evaluation for carbosulfan and carbofuran was unable to be completed because of missing critical information. Acute dietary risk assessments were not conducted for these compounds.

Mandestrobin was evaluated at the previous meeting for toxicology and an ARfD established, but it was not possible to complete the evaluation for residues due to late submission of critical information. An acute dietary risk assessment was completed at this meeting.



Pyriofenone was evaluated but no new MRLs were proposed, so there were no changes to the acute dietary exposure estimate from the previous meeting.

The present or previous Meetings agreed that ARfDs for kresoxim-methyl, cyclaniliprole, pyriproxyfen, tolclofos-methyl, valifenalate were unnecessary. For these compounds, an acute dietary exposure assessment was not conducted.

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

Table 3 Summary of acute dietary exposure assessments (IESTI)

CCPR <sup>a</sup> code	Compound name	ARfD (mg/kg bw)	Commodity (maximum % of ARfD)	Exceeding: population, (country)
312	Afidopyropen*	0.2 WCBA 0.3 All except WCBA	80 100	
261	Benzovindiflupyr	0.1	2	
178	Bifenthrin	0.01	380 Strawberry total 380	Toddlers 8-20m (Netherlands)
173	Buprofezin Aniline	0.5 0.02	10 0 <sup>b</sup>	
118	Cypermethrin	0.04	0	
283	Fluazifop-p-butyl	0.4	6	
265	Fluensulfone	0.3	1	
307	Mandestrobin*	3.0 WCBA	4	
313	Metconazole*	0.04	20	
253	Penthiopyrad	1	5	
258	Picoxystrobin	0.09	2	
160	Propiconazole	0.3	40	
309	Pydiflumetofen	0.3	350 Lettuce leaf total 350 Lettuce leaf raw 120 Lettuce head 130 Cos lettuce total 130 Cos lettuce raw 130 Endive total 140 Endive cooked 230  Endive raw 120 Spinach total 130 Spinach frozen 140	Child 1-6 (China) Child 2-6 yr (Netherlands) Child 2-6 yr (Netherlands) Child 2-6 yr (Netherlands) Child 2-6 yr (Netherlands) Toddler (PRIMo-Belgium) Toddler (PRIMo- Netherlands) Child 2-6 yr (Netherlands) Toddler (Primo-Belgium) Toddler (Primo- Netherlands)
314	Pyflubumide*	0.008	390 Apple total 350 Apple raw with peel 390 Tea total 250 Tea raw dried 230	Child 2-6 (Australia) Child 1-6 (China) Child (Primo-Ireland) General pop > 1 yr (China)

CCPR <sup>a</sup> code	Compound name	ARfD (mg/kg bw)	Commodity (maximum % of ARfD)	Exceeding: population, (country)
269	Tolfenpyrad	0.01	240 Tomatoes total 180 Tomatoes raw with peel 190 Tomatoes cooked with peel 120  Tomato canned, preserved 110 Aubergine raw with skin 240	Children <6 yr (Canada) Children 1-6 yr (China) Toddler 8-20 m (Netherlands) Children 2-6 yr (Australia) Children 1-6 yr (China)
246	Acetamiprid <sup>c</sup>	0.1	0 <sup>c</sup>	
72	Carbendazim <sup>c</sup>	0.1 WCBA 0.5 All except WCBA	0 <sup>c</sup> 0 <sup>c</sup>	

\*New chemicals;

<sup>a</sup> ARfD: acute reference dose; bw: body weight; CCPR: Codex Committee on Pesticide Residues; IESTI: international estimate of short-term intake; WCBA: women of childbearing age; PRIMo: Pesticide Residue Intake Model (EFSA);

<sup>b</sup> based on residues of aniline that may arise from the uses of buprofezin considered by the current Meeting.

<sup>c</sup> based on median values derived from monitoring data for the Subgroup of spices, seeds only;

#### **Possible refinement when the IESTI exceeds the ARfD**

As no alternative GAP data were available to the Meeting to estimate lower HR values for bifenthrin (strawberry), pydiflumetofen (lettuce, endive, spinach), pyflubumide (apple, tea leaf) or tolfenpyrad (tomato, aubergine), no refinement of the acute dietary exposure estimate for these pesticide residues was possible.

The Meeting recognized that the IESTI for these pesticides may be refined if new data become available in the future.

## 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 2, 4-D (020)

#### RESIDUE AND ANALYTICAL ASPECTS

The herbicide 2,4-D (2,4-dichlorophenoxyacetic acid) is currently registered for use in a variety of salt, amine, and ester formulations. It was first evaluated by the JMPR in 1970 and has undergone numerous subsequent evaluations.

The 1998 JMPR evaluated 2,4-D under the Periodic Re-evaluation Programme and established an ADI of 0–0.01 mg/kg bw for the sum of 2,4-D and its salts and esters expressed as 2,4-D and decided an ARfD was unnecessary. The residue definition established by the 1998 JMPR is 2,4-D for enforcement of MRLs and for dietary risk assessment for plant and animal commodities. The residue is not fat soluble.

The 2017 JMPR evaluated data to support the use of 2,4-D on genetically modified (GM) cotton. Due to questionable storage stability data for both 2,4-D and 2,4-DCP in GM cotton seed, it was not possible for the Meeting to recommend an MRL.

At the Fifty-first Session of the CCPR, 2,4-D was scheduled for evaluation of additional storage stability data by the 2019 JMPR.

The new data and the 2017 JMPR evaluation consider GM cotton in which expression of the aryloxyalkanoate dioxygenase-12 (AAD-12) protein confers tolerance to 2,4-D and associated increased metabolism of 2,4-D (hereafter referred to as AAD-12 cotton).

#### ***Stability of residues in stored analytical samples***

The new storage stability study supports the stability of 2,4-D and 2,4-DCP in AAD-12 cotton seed for 8 months of freezer storage at  $\leq -18$  °C.

The Meeting noted that the study designs, the analytical procedures and conduct of the study considered by the 2017 JMPR and the study considered by this Meeting, were identical. Based on all the data at each time point 2,4-D and 2,4-DCP were found to be stable on storage in AAD-12 cotton seeds stored at  $\leq -18$  °C. The Meeting also noted that the data evaluated by the 2017 JMPR demonstrated that 2,4-D and 2,4-DCP were stable on storage in other AAD-12 cotton fractions (at least 6 months for gin by-products and at least 3 months for hulls, untoasted meal, toasted meal and crude oil). No decline was observed over the storage intervals investigated. In addition, the 1998 JMPR concluded that 2,4-D was stable in conventional soya bean.

The Meeting concluded that based on the weight of evidence, 2,4-D and 2,4-DCP can be regarded as stable in AAD-12 cotton seeds for the 5 months of storage of the residue trial samples.

#### ***Definition of the residue***

The 2017 Meeting concluded that the residue definition for compliance with the MRL for cotton should be 2,4-D. The 2017 JMPR did not conclude on the residue definition for dietary risk assessment as no maximum residue level could be estimated.

In deciding which additional compounds should be included in the residue definition for dietary risk assessment for AAD-12 cotton the Meeting considered the likely occurrence of the compounds and the toxicological properties of the candidates.

In AAD-12 cotton seed 2,4-DCP was found at 3.2% TRR and conjugates of 2,4-DCP were found at 23% TRR (approximately 5 fold higher than 2,4-D). In AAD-12 cotton gin trash, 2,4-DCP

accounted for 2.6% TRR and its conjugates accounted for 38% TRR (approximately equal to the levels of 2,4-D).

The residue trials and processing studies confirm that residues of 2,4-DCP may occur in human foods. Therefore, the Meeting decided based on its occurrence, 2,4-DCP and its conjugates should be included in the residue definition for dietary risk assessment. A toxicological data package was not submitted for 2,4-DCP and the WHO Core Assessment Group recommended a full toxicological evaluation for 2,4-DCP.

As the WHO Core Assessment Group could not conclude on the toxicity of 2,4-DCP, the Meeting was unable to conclude on the residue definition for dietary risk assessment for AAD-12 cotton seed.

### ***Results of supervised residue trials on crops***

#### ***AAD-12 cotton***

The critical GAP provided to the 2017 JMPR for AAD-12 cotton was for the USA.

The GAP is 1 application made pre-emergence/pre-planting at a rate of 1060 g ae/ha followed by 1–2 applications post-emergence at a rate of 1060 g ae/ha. The interval between the post-emergence applications is 12 days with the latest application at growth stage BBCH 65.

A total of 16 trials from the USA approximating the GAP were evaluated by the 2017 Meeting.

Residues of 2, 4-D in rank order in undelinted AAD-12 cotton seeds were (n = 16): < 0.01(13), 0.014, 0.016 and 0.070 mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg for cotton seeds. As the Meeting could not conclude on the residue definition for dietary risk assessment, an STMR and HR could not be estimated.

### ***Animal feeds***

#### ***Cotton gin trash/ cotton gin by-products***

The critical GAP provided to the 2017 JMPR for AAD-12 cotton was for the USA.

The 2017 Meeting considered residues data for 2,4-D in cotton gin by-products. A total of five trials included the analysis of cotton gin by-products.

Residues of 2, 4-D in AAD-12 cotton gin by-products in rank order were (n = 5): < 0.01, 0.039, 0.11, 0.28, 0.56 mg/kg

The Meeting was unable to estimate a median and highest residue for cotton gin by-products as a conclusion on the residue definition for dietary risk assessment could not be reached.

### ***Fate of residues on processing***

The 2017 JMPR evaluated information on the fate of 2, 4-D residues during processing of AAD-12 cotton. Four processing trials were undertaken. No residues of 2, 4-D were detected in the RAC or the processed fractions. 2,4-DCP residues were found in the RAC and processed fractions. The best estimate processing factors derived by the 2017 JMPR for 2, 4-DCP were 1.16 (hulls), 2.96 (untoasted meal), 1.96 (toasted meal), 0.55 (crude oil) and 0.07 (refined oil).

The Meeting decided that as no residues of 2,4-D were detected in the RAC, in contrast to the positive residues found in field trials, it was not possible to estimate maximum residue levels for processed cotton fractions.

As the Meeting could not conclude on the residue definition for dietary risk assessment for AAD-12 cotton, STMR-P and HR-P were not estimated for processed cotton fractions.

***Residues in animal commodities***

As the Meeting could not conclude on the residue definition for dietary risk assessment for AAD-12 cotton, it was not possible to calculate dietary burdens for livestock.

**RECOMMENDATIONS**

The Meeting was unable to conclude on the residue definition for dietary risk assessment for AAD-12 cotton seed

**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 dietary risk assessment for AAD-12 cotton.



## 5.2 Afidopyropen (312)

### TOXICOLOGY

Afidopyropen is the ISO-approved common name for [(1*S*,2*S*,5*S*,6*R*,7*R*,9*S*,10*S*,18*R*)-5-(cyclopropanecarbonyloxy)-9,18-dihydroxy-2,6,10-trimethyl-16-oxo-14-pyridin-3-yl]-11,15-dioxatetracyclo[8.8.0.0<sup>2,7</sup>.0<sup>12,17</sup>]octadeca-12(17),13-dien-6-yl]methyl cyclopropanecarboxylate, with the CAS number 915972-17-7.

Afidopyropen is a pyripyropene-derivative insecticide and represents a novel class of pesticides. The proposed pesticidal MOA for afidopyropen is gate disruption of transient receptor potential vanilloid (TRPV) channel complexes in insect chordotonal stretch receptor organs. In insects, these organs are critical for hearing, balance, and proprioception, among other functions. The TRP channels play an important role in cilia-dependent function. Although humans lack these organs, there are human homologues of proteins that make up these channels.

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

All critical studies contained statements of compliance with GLP 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**

In ADME studies conducted in rats using afidopyropen labelled with <sup>14</sup>C at the nicotinic acid, <sup>13</sup>C at the pyranone-4 and pyranone-6 positions, and <sup>14</sup>C at the pyranone-6 position, the absorption of afidopyropen was rapid ( $T_{max} < 1-4$  hours), approximately 70% based on urine and bile and radioactivity was widely distributed to tissues. Area under the concentration-time curve for the interval 0-168 h ( $AUC_{0-168}$ ) values indicated a saturation of the elimination pathways with high-dose (300 mg/kg bw) values more than 300 times those of the low dose groups (3 mg/kg bw). Elimination half-life ( $t_{1/2}$ ) was rapid at 2-5 hours at low doses (3 mg/kg bw) but 6-12 hours at high doses (300 mg/kg bw).

Radioactivity was readily excreted within 96-120 hours with the majority of radioactivity (up to 86% of administered dose) excreted via the faeces and lower amounts (up to 21% of administered dose) excreted via the urine. Biliary excretion is the predominant route of elimination for afidopyropen, accounting for approximately half of the radioactivity in faeces based on the findings from studies with bile duct-cannulated rats. Generally, levels of radioactivity in urine increased with dose, whereas those in bile and faeces decreased with dose, indicating saturation of excretion. Bioavailability was not significantly different between the sexes and was not impacted by the dose level administered.

There were no changes following repeat-dose treatment in absorption, distribution and excretion studies.

Highest levels of radioactivity were observed in the GI tract, liver, adrenal glands, ovaries and kidney, at one hour and four hours following low- and high-dose administration, respectively. Very low levels of radioactivity were observed in the ovaries, testes and brain 36 hours following administration of high-doses. No sex differences were noted in the above parameters.

Afidopyropen was extensively metabolized in the rat with no significant sex differences identified. Most metabolites were structurally similar to the parent compound, with changes in one or two functional groups, and in some cases, loss of one or two cyclopropane carboxylic acid (CPCA) ester moieties. Following single or repeat dosing with low or high levels of C<sup>14</sup>-radiolabelled test material a range of metabolites were identified in the urine, faeces and bile, including M440I001 (urine, 2-11%; faeces, 3-23%; bile 2-4%) and M440I002 (urine, 0.4-5%; faeces, 2-10%) and bile (0.1-0.4%). Significant levels of unchanged afidopyropen were detected only in the faeces; 21-37% of the administered dose (AD) in single low-dose assays and 5-21% of AD in single and repeat high-dose

assays). The proposed metabolic pathway involves hydrolytic loss of one or both CPCA moieties, *N*-oxidation at the pyridine ring, hydroxylation of one of the methyl groups, and conjugation of hydroxyl groups of the metabolites.

### **Toxicological data**

In rats, afidopyropen had an acute oral LD<sub>50</sub> greater than 2000 mg/kg bw, an acute dermal LD<sub>50</sub> of greater than 2000 mg/kg bw and an acute inhalation median LC<sub>50</sub> greater than 5.48 mg/L. Afidopyropen was non-irritating to the skin and transiently irritating to the eyes of rabbits. It was not a dermal sensitizer in guinea pigs in a maximization test.

The main toxic effects of afidopyropen observed in short- and long-term studies were changes to the liver in mice, liver, heart and female reproductive system in rats, and the brain and kidney in dogs.

In a 90-day study, mice received a dietary concentration of afidopyropen of 0, 150, 500, 2000 or 6000 ppm (equal to 0, 21, 69, 285 and 819 mg/kg bw per day for males, 0, 25, 83, 327 and 919 mg/kg bw per day for females). The NOAEL was 500 ppm (equal to 69 mg/kg bw per day), based on increased blood bilirubin in males and females and increased blood triglycerides and spleen weights in females at the LOAEL of 2000 ppm (equal to 285 mg/kg bw per day).

In a 90-day toxicity study, rats received a dietary concentration of afidopyropen of 0, 150, 300, 1000 or 3000 ppm (equal to 0, 8.9, 18, 61 and 182 mg/kg bw per day for males, 0, 10.2, 20, 68 and 197 mg/kg bw per day for females). The NOAEL was 300 ppm (equal to 18 mg/kg bw per day), based on increased relative liver weights in females, increased urobilinogen in males and increased blood urea, nitrogen and potassium, and increased vacuolar change (fatty change) of the liver and myocardium in females at the LOAEL of 1000 ppm (equal to 61 mg/kg bw per day).

In a 90-day toxicity study, dogs received afidopyropen in capsules at a dose of 0, 15, 30 or 90→60 mg/kg bw per day. The high dose was reduced from 90 to 60 mg/kg bw per day and suspended at various points due to excessive toxicity. At 90→60 mg/kg bw per day, there was an increase in vomiting within the first week of treatment. At 30 mg/kg bw per day, increased vomiting occurred at week 3. The NOAEL was 15 mg/kg bw per day based on increased vomiting and hyaline droplet deposition in the hepatocytes of males and females and increased haematuria in males at the LOAEL of 30 mg/kg bw per day.

In a one-year toxicity study, dogs received afidopyropen in capsules at a dose of 0, 8, 20 or 50→40 mg/kg bw per day. The high dose was reduced from 50 to 40 mg/kg bw per day and suspended at various points due to excessive toxicity. The NOAEL was 8 mg/kg bw per day, based on decreased neutrophils and hyaline droplet deposition of the hepatocytes in males and females, vacuolation of the white matter and neuropil of the cerebrum in males at the LOAEL of 20 mg/kg bw per day.

In an 18-month carcinogenicity study, mice received a dietary concentration of afidopyropen of 0, 120, 700 or 4000 ppm for males (equal to 0, 13, 79 and 445 mg/kg bw per day) and 0, 120, 700 or 4000→3000→2000 mg ppm for females (equal to 0, 13, 76 and 333 mg/kg bw per day for females). In females, the dose was changed to 3000 ppm at week 24 and then to 2000 ppm at week 44 due to death or moribundity. The NOAEL was 700 ppm (equal to 76 mg/kg bw per day), based on clinical signs of toxicity culminating in mortality, decreased body weight, decreased feed consumption, increased white blood cell (WBC) counts, increased spleen and ovarian weights, increased pale coloured livers, decreased haematopoiesis in the bone marrow, atrophy of the spleen, myocardial fibrosis, apoptosis of lymphocytes of the thymus and lymph nodes and vacuolation of various tissues at the LOAEL of 2000 ppm (equal to 333 mg/kg bw per day). The NOAEL for carcinogenicity was 2000 ppm (equal to 333 mg/kg bw per day) in females and 4000 ppm (equal to 445 mg/kg bw per day) in males, the highest doses tested.

Two 1-year chronic toxicity studies and two 2-year oncogenicity studies were submitted on rats.



In a one-year toxicity study, rats received a dietary concentration of afidopyropen of 0, 75, 150, 300 or 1000 ppm (equal to 0, 3.7, 7.3, 15 and 48 mg/kg bw per day in males, 0, 4.4, 8.9, 18 and 56 mg/kg bw per day in females). The NOAEL was 300 ppm (equal to 15 mg/kg bw per day) based on increased platelets and decreased triglycerides in males and females and increased vacuolar change in the liver and myocardium of females at the LOAEL of 1000 ppm (equal to 48 mg/kg bw per day).

A second study was performed to investigate the effects at higher doses. The findings at 3000 ppm were consistent with those of the high dose in the main study.

In a two-year toxicity study, rats received a dietary concentration of afidopyropen of 0, 100, 300 or 1000 ppm (equal to 0, 4.4, 13, and 43 mg/kg bw per day in males, 0, 5.3, 16 and 51 mg/kg bw per day in females). The NOAEL for chronic toxicity was 300 ppm (equal to 13 mg/kg bw per day) based on increased kidney, liver and adrenal weights in males and increased uterine weights and hyperplasia of the bile duct of the liver at the LOAEL of 1000 ppm (equal to 43 mg/kg bw per day). The NOAEL for carcinogenicity was 300 ppm (equal to 16 mg/kg bw per day) based on an increased incidence of uterine adenocarcinomas in females at the LOAEL of 1000 ppm (equal to 51 mg/kg bw per day).

A second study was performed to investigate the effects at higher doses. The findings at 3000 ppm were consistent with those at the high dose of the main study.

A number of studies were performed in order to investigate a proposed dopamine agonist MOA for uterine tumours in rats. Inadequacies in the measurement of endpoints meant the MOA study failed to give support to all of the key events described.

The Meeting concluded that afidopyropen is carcinogenic in female rats, but not in mice or male rats. Based on the weight of evidence, the Meeting was unable to establish an MOA for the tumours and, therefore, human relevance could not be ruled out.

Afidopyropen 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 afidopyropen is unlikely to be genotoxic.

As afidopyropen is unlikely to be genotoxic and the uterine tumours in rats occurred by a mechanism that will exhibit a threshold, the Meeting concluded that afidopyropen is unlikely to pose a carcinogenic risk to humans via the diet.

Multiple reproductive toxicity studies were submitted. Following a range-finding one-generation study, a two-generation main study was performed. A subsequent one-generation study was performed to compare toxicity resulting from different purity levels, and a cross-fostering study performed to determine whether pup mortality in the first two-generation study was related to maternal care. A final two-generation study was performed with slightly higher dose levels and a higher purity of the active ingredient.

In a two-generation reproductive toxicity study rats received a dietary concentration of afidopyropen (purity 95.74%) of 0, 100, 300 or 1000 ppm (equal to 0, 7.7, 22 and 75 mg/kg bw per day in males, 0, 9.0, 27 and 85 mg/kg bw per day in females). The NOAEL for parental toxicity was 1000 ppm (equal to 75 mg/kg bw per day), the highest dose tested. The NOAEL for reproductive toxicity was 300 ppm (equal to 22 mg/kg bw per day), based on altered sex ratios at the LOAEL of 1000 ppm (75 mg/kg bw per day). The NOAEL for offspring toxicity was 300 ppm (equal to 27 mg/kg bw per day), based on increased pup deaths and decreased body weights at PND 21 in F<sub>1</sub> and F<sub>2</sub> offspring, decreased spleen weight in F<sub>1</sub> males and females and delayed sexual maturation and decreased prostate weights in F<sub>1</sub> males at the LOAEL of 1000 ppm (equal to 85 mg/kg bw per day).

There were no effects on parental toxicity when the lower (94.54%) and higher (99.0%) purity batches of afidopyropen were compared. Prostate weights were decreased in both treatment groups, however, an equivocal decrease in sperm counts in the testes and skewing of the sex ratios towards males was noted in the lower purity batch only. In the offspring, body weight, body weight gain and

spleen weights were decreased in both treatment groups. Pup deaths were increased only in the lower purity group.

In the cross-fostering study, pup death was determined to be related to in utero exposure, while reduced body weights were directly related to exposure whether in utero or through lactation.

In a two-generation reproductive toxicity study rats received a dietary concentration of afidopyropen (purity 97.2%) of 0, 100, 500 or 2000 ppm (equal to 0, 7.8, 39 and 150 mg/kg bw per day in males, 0, 8.4, 41 and 155 mg/kg bw per day in females). The NOAEL for parental toxicity was 100 ppm (equal to 8.4 mg/kg bw per day), decreased glucose in F<sub>0</sub> females and increased cholesterol in F<sub>0</sub> females at the LOAEL of 500 ppm (equal to 41 mg/kg bw per day). The NOAEL for reproductive toxicity was 500 ppm (equal to 39 mg/kg bw per day), based on improper nursing, altered sex ratios, decreased prostate weights and decreased ovarian weights in F<sub>0</sub> and F<sub>1</sub> generations, decreased sperm counts in F<sub>0</sub> males and decreased implantation sites, mean number of pups per dam, mean litter size at PND 0, increased infiltration of the prostate gland and decreased uterus weights in the F<sub>1</sub> generation adults at the LOAEL of 2000 ppm (equal to 150 mg/kg bw per day). The NOAEL for offspring toxicity was 100 ppm (equal to 8.4 mg/kg bw per day) based on decreased thymus weights in F<sub>1</sub> females and F<sub>2</sub> males and decreased spleen weights in F<sub>2</sub> males and females, and delayed preputial separation at the LOAEL of 500 ppm (equal to 41 mg/kg bw per day).

In a developmental toxicity study female rats received a gavage dose of afidopyropen at dose levels of 0, 10, 30 or 100 mg/kg bw per day from days six through 19 of gestation. The NOAEL for maternal toxicity was 30 mg/kg bw per day, based on increased adrenal weights at the LOAEL of 100 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 30 mg/kg bw per day, based on increased lumbar rib variations and altered sex ratios at the LOAEL of 100 mg/kg bw per day.

In a developmental toxicity study, female rats received a gavage dose of afidopyropen at dose levels of 0, 50, 100 or 200 mg/kg bw per day from days six through 19 of gestation. The NOAEL for maternal toxicity was 100 mg/kg bw per day, based on decreased body weight gain and feed consumption at the LOAEL of 200 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was not identified, based on increased skeletal variations and supernumerary ribs at the lowest dose tested of 50 mg/kg bw per day.

In a developmental toxicity study, female rabbits received a gavage dose of afidopyropen at 0, 8, 16 or 32 mg/kg bw per day from GD 6–27. The maternal NOAEL was 16 mg/kg bw per day based on increased early and late resorptions and post-implantation losses at the LOAEL of 32 mg/kg bw per day. The embryo/fetal NOAEL was 8 mg/kg bw per day based on altered sex ratios at the LOAEL of 16 mg/kg bw per day.

The Meeting concluded that afidopyropen was not teratogenic.

In an acute neurotoxicity study, rats were given gavage doses of afidopyropen at a concentration of 0, 200, 700 or 2000 mg/kg bw. The NOAEL was 700 mg/kg bw based on decreased motor activity in males and females and slight tremors and hypothermia in females at the LOAEL of 2000 mg/kg bw. These effects were considered secondary to generalized systemic toxicity and the NOAEL for acute neurotoxicity was 2000 mg/kg bw, the highest dose tested.

In a subchronic neurotoxicity study rats received a dietary concentration of afidopyropen of 0, 300, 1000 or 4000 ppm (equal to 0, 20, 73 and 396 mg/kg bw per day in males, 0, 24, 92 and 438 mg/kg bw per day in females). The NOAEL was 1000 ppm (equal to 73 mg/kg bw per day) based on decreased body weight and body weight gain in males at the LOAEL of 4000 ppm (equal to 396 mg/kg bw per day). The NOAEL for subchronic neurotoxicity was 4000 ppm (equal to 396 mg/kg bw per day), the highest dose tested.

The Meeting concluded that afidopyropen was not neurotoxic in rats, but produced brain vacuolation in dogs.

In an immunotoxicity study, rats were given a dietary concentration of afidopyropen at 0, 300, 1000 or 4000 ppm (equivalent to 0, 25, 69 and 278 mg/kg bw per day). The NOAEL for systemic toxicity was 1000 ppm (equal to 69 mg/kg bw per day) based on decreased body weight gain and

increased liver and thymus weights at the LOAEL of 4000 ppm (equal to 278 mg/kg bw per day). No specific indications of immunotoxicity were noted, therefore, the NOAEL for immunotoxicity was 4000 ppm (equal to 278 mg/kg bw per day), the highest dose tested.

The Meeting concluded that afidopyropen was not immunotoxic.

### ***Toxicological data on metabolites and/or degradates***

The acute oral LD<sub>50</sub> of M440I007, a plant metabolite, is > 2000 mg/kg bw and it tested negative for in vitro reverse mutation, forward mutation and micronucleus assays and in vivo micronucleus assay. A 90-day oral toxicity study was performed with dietary concentrations of M440I007 of 0, 600, 4000 or 10 000 ppm (equal to 0, 42, 277 and 708 mg/kg bw per day for males, 0, 47, 317 and 797 mg/kg bw per day for females). Effects were seen in the myocardium at the high dose that were consistent with the short- and long-term studies of the parent compound, however, histopathological investigations at lower doses were not adequate to identify a NOAEL/LOAEL. The data indicate M440I07 is likely to be of similar toxicity to its parent.

The acute oral LD<sub>50</sub> of CPCA, a rat and plant metabolite, is between 300 and 500 mg/kg bw. A 90-day oral toxicity study in the rat was performed with gavage doses of CPCA of 0, 2, 10, 30 or 60 mg/kg bw per day. The NOAEL was 10 mg/kg bw per day based on increased effects on the myocardium and decreased zymogen within acinar cells of the pancreas in males and females, decreased globulin in males and increased bile acids, blood urea nitrogen and inorganic phosphorus and decreased cholesterol, increased liver and kidney weights, increased discolouration of the liver and increased myocardial vacuolation, periportal fatty change and mononuclear cell infiltrate in the liver and lymphoid necrosis of the thymus in females at the LOAEL of 30 mg/kg bw per day. Although CPCA was not detected in rat metabolism studies due to the position of the radiolabel, it is likely to be present at more than 10% of the administered dose, based on the metabolic pathway. Therefore CPCA, is considered of similar toxicity to the parent compound.

### ***Microbiological data***

No data for antimicrobial activity or impact of afidopyropen on the human gut microbiome are available.

### ***Human data***

In reports on manufacturing plant personnel, no adverse health effects were noted.

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

## **Toxicological evaluation**

The Meeting established an ADI for afidopyropen of 0–0.08 mg/kg bw, on the one-year study on dogs and the rabbit developmental study, both having NOAELs of 8 mg/kg bw per day. Findings at the LOAEL consisted of vacuolation of the white matter of the cerebrum at 16 mg/kg bw per day in dogs and altered sex ratio (more males) and increased resorptions at 16 mg/kg bw per day in rabbits. A safety factor of 100 was applied. There was a margin of 540 to the uterine tumours in rats.

The Meeting established, for afidopyropen, an ARfD for women of childbearing age of 0.2 mg/kg bw, on the basis of the NOAEL of 16 mg/kg bw per day from the rabbit developmental toxicity study for increased early resorptions at 32 mg/kg bw per day. A safety factor of 100 was applied.

The Meeting established an ARfD for afidopyropen, for the general population, of 0.3 mg/kg bw, on the basis of increased vomiting in the first days of treatment at 60 mg/kg bw per day in the 90-day dog toxicity study. A safety factor of 100 was applied.

A toxicological monograph was prepared.

**Levels relevant to risk assessment of afidopyropen**

Species	Study	Effect	NOAEL	LOAEL
Mouse	90-day oral toxicity study <sup>a</sup>	Toxicity	500 ppm, equal to 69 mg/kg bw per day	2000 ppm, equal to 285 mg/kg bw per day
	Eighteen-month study of carcinogenicity <sup>a</sup>	Toxicity	700 ppm, equal to 76 mg/kg bw per day	2000 ppm, equal to 333 mg/kg bw per day
Carcinogenicity		2000 ppm, equal to 333 mg/kg bw per day <sup>e</sup>	-	
Rat	90-day oral toxicity study <sup>a</sup>	Toxicity	300 ppm equal to 18 mg/kg bw per day	1000 ppm equal to 61 mg/kg bw
	One-year study of toxicity <sup>a</sup>	Toxicity	300 ppm, equal to 15 mg/kg bw per day	1000 ppm, equal to 48 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	300 ppm, equal to 13 mg/kg bw per day	1000 ppm, equal to 43 mg/kg bw per day
		Carcinogenicity	300 ppm, equal to 13 mg/kg bw per day	1000 ppm, equal to 43 mg/kg bw per day
	Two-generation study of reproductive toxicity <sup>a, b</sup>	Reproductive toxicity	300 ppm, equal to 22 mg/kg bw per day	1000 ppm, equal to 75 mg/kg bw per day
		Parental toxicity	100 ppm, equal to 8.4 mg/kg bw per day	500 ppm, equal to 41 mg/kg bw per day
Offspring toxicity		100 ppm, equal to 8.4 mg/kg bw per day <sup>c</sup>	500 ppm, equal to 41 mg/kg bw per day	
Developmental toxicity study <sup>b, c</sup>	Maternal toxicity	30 mg/kg bw per day	100 mg/kg bw per day	
	Embryo and fetal toxicity	-	50 mg/kg bw per day	
Rabbit	Developmental toxicity study <sup>c</sup>	Maternal toxicity	16 mg/kg bw per day	32 mg/kg bw per day
		Embryo and fetal toxicity	8 mg/kg bw per day	16 mg/kg bw per day
Dog	90-day study of toxicity <sup>d</sup>	Toxicity	15 mg/kg bw per day	30 mg/kg bw per day
	One-year study of toxicity <sup>d</sup>	Toxicity	8 mg/kg bw per day	20 mg/kg bw per day
Metabolite M440I007				
Rat	13-week study of toxicity <sup>a</sup>	Toxicity	-	10 000 ppm equal to 708 mg/kg bw <sup>f</sup>
Metabolite CPCA				
Rat	13-week study of toxicity <sup>a</sup>	Toxicity	10 mg/kg bw per day	30 mg/kg bw per day

<sup>a</sup> Dietary administration.<sup>b</sup> Two studies combined<sup>c</sup> Gavage administration

<sup>d</sup> Capsule administration

<sup>e</sup> Highest dose tested.

<sup>f</sup> Limited examination at lower dose levels.

*Acceptable daily intake (ADI), applies to afidopyropen, M440I001, M440I007 and CPCA, expressed as afidopyropen*

0–0.08 mg/kg bw

*Acute reference dose for women of childbearing age (ARfD), applies to afidopyropen, M440I001, M440I007 and CPCA, expressed as afidopyropen*

0.2 mg/kg bw

*Acute reference dose for the general population (ARfD), applies to afidopyropen, M440I001, M440I007 and CPCA, expressed as afidopyropen*

0.3 mg/kg bw

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

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

### **Critical end-points for setting guidance values for exposure to afidopyropen**

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#### **Absorption, distribution, excretion and metabolism in mammals**

Rate and extent of oral absorption	Rapid ( $T_{max}$ 1–4 h depending on dose (3–300 mg/kg bw); and oral absorption of 70% based on urine and bile (rats))
Dermal absorption	1–6%, depending on concentration (rat, 50 g/L product)
Distribution	Extensive; highest concentrations in liver, adrenals and ovaries
Potential for accumulation	Low
Rate and extent of excretion	Relatively rapid (80% within 48 h in rats, mainly in faeces)
Metabolism in animals	Major metabolic reactions: cleavage of cyclopropylcarboxylic acid, <i>N</i> -oxidation and hydroxylation (rat)
Toxicologically significant compounds in animals and plants	Afidopyropen, M440I001, M440I007, CPCA

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#### **Acute toxicity**

Rat, LD <sub>50</sub> , oral	> 2000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	> 2000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	> 5.5 mg/L
Rabbit, dermal irritation	Non-irritating
Rabbit, ocular irritation	Transiently irritating (resolved within 24 h)
Guinea pig, dermal sensitization	Not sensitizing (maximization)

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#### **Short-term studies of toxicity**

Target/critical effect	Vacuolation, fibrosis, necrosis of myocardium; decreased ovary and uterus weight (rat) vacuolation of the brain white matter (dog)
Lowest relevant oral NOAEL	8 mg/kg bw per day (dog)

Lowest relevant dermal NOAEL	1000 mg/kg bw, the highest dose tested.
Lowest relevant inhalation NOAEC	No data
<b><i>Long-term studies of toxicity and carcinogenicity</i></b>	
Target/critical effect	Uterine adenocarcinoma, increased liver, kidney, adrenal weight (rat)
Lowest relevant NOAEL	13 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in female rats, not carcinogenic in mice or male rats <sup>a</sup>
<b><i>Genotoxicity</i></b>	No evidence of genotoxicity <sup>a</sup>
<b><i>Reproductive toxicity</i></b>	
Target/critical effect	Altered sex ratio (more males)
Lowest relevant parental NOAEL	8.4 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	8.4 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	22 mg/kg bw per day (rat)
<b><i>Developmental toxicity</i></b>	
Target/critical effect	Altered sex ratio (more males) (rats and rabbits) increased resorptions (rabbit)
Lowest relevant maternal NOAEL	16 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	8 mg/kg bw per day (rabbit)
<b><i>Neurotoxicity</i></b>	
Target/critical effect	Not neurotoxic (rats); brain vacuolation (dogs)
Lowest relevant oral NOAEL	8 mg/kg bw (1-year dogs)
Developmental neurotoxicity	No data
<b><i>Immunotoxicity</i></b>	
Immunotoxicity	Not immunotoxic (rats)
Lowest relevant oral NOAEL	> 278 mg/kg bw (rats)
<b><i>Human data</i></b>	No data
<b><i>Studies on toxicologically relevant metabolites</i></b>	
<b><i>Acute toxicity</i></b>	
<b>M440I007</b> , rat, oral	LD <sub>50</sub> > 2000 mg/kg bw
<b>CPCA</b> , rat, oral	300 < LD <sub>50</sub> < 500 mg/kg bw
<b><i>Short-term toxicity</i></b>	
<b>M440I007</b>	
Target/critical effect	Necrosis / fibrosis of myocardium
Lowest relevant oral NOAEL	< 708 mg/kg bw per day (rat; limited examination)
<b>CPCA</b>	
Target/critical effect	Cardiomyopathy/myocardial vacuolation, decreased zymogen in pancreas, liver and kidney effects
Lowest relevant oral NOAEL	10 mg/kg bw per day (rat)
<b><i>Genotoxicity</i></b>	
<b>M440I007</b>	Unlikely to be genotoxic <sup>a</sup>

<sup>a</sup> Unlikely to pose a carcinogenic threat to humans via exposure from the diet

### Summary

	Value	Study	Safety factor
ADI	0–0.08 mg/kg bw <sup>c</sup>	One-year toxicity (dog) and developmental toxicity study (rabbit)	100
ARfD <sup>a</sup>	0.2 mg/kg bw <sup>c</sup>	Developmental toxicity study (rabbit)	100
ARfD <sup>b</sup>	0.3 mg/kg bw <sup>c</sup>	90-day toxicity study (dog)	100

<sup>a</sup> Women of childbearing age

<sup>b</sup> General population

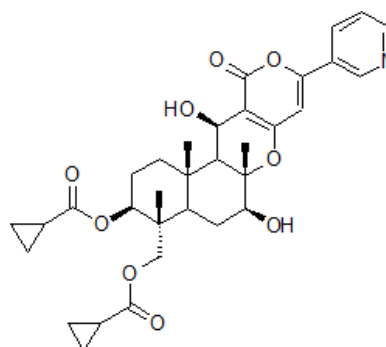
<sup>c</sup> Applies to afidopyropen, M440I001, M440I007 and CPCA, expressed as afidopyropen

### RESIDUE AND ANALYTICAL ASPECTS

Afidopyropen is an insecticide which acts by disrupting the gating of the vanilloid-type transient receptor (TRPV) channel complexes in chordotonal organs of insects. This causes a cessation of feeding and other behaviours in the target insects leading to death by starvation.

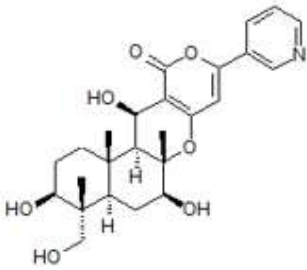
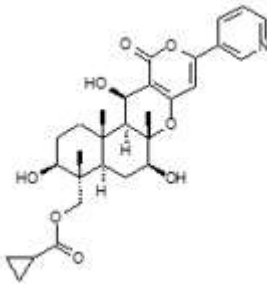
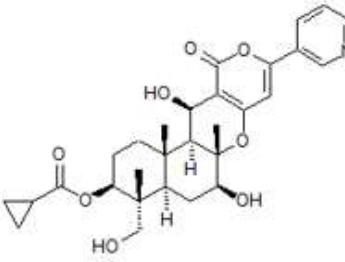
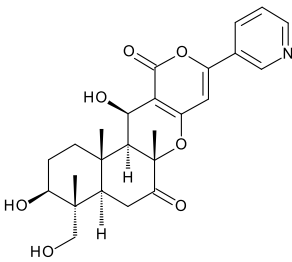
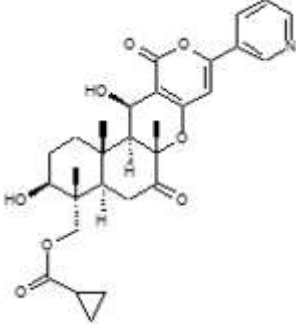
Afidopyropen was scheduled at the Fifty-first Session of the CCPR (2018), for toxicology and residue evaluation as a new compound by the 2019 JMPR. The Meeting received information on identity, physical-chemical properties, plant and animal metabolism, analytical methods, storage stability, use patterns, residues resulting from supervised trials, fate of residues during processing, and livestock feeding studies.

Afidopyropen is ((3*S*,4*R*,4*aR*,6*S*, 6*aS*, 12*R*,12*aS*,12*bS*)-3-(cyclopropanecarbonyloxy)-6,12-dihydroxy-4,6*a*, 12*b*-trimethyl-11-oxo-9-(pyridin-3-yl)-1,2,3,4,4*a*,5,6,6*a*,12*a*,12*b*-decahydro-11*H*,12*H*-benzo- [*f*] pyrano[4,3-*b*]chromen-4-yl)methyl cyclopropanecarboxylate with a molecular weight of 593.7 g/mol.

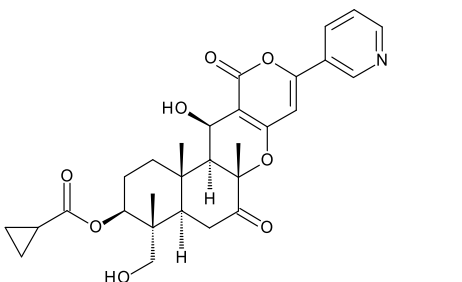
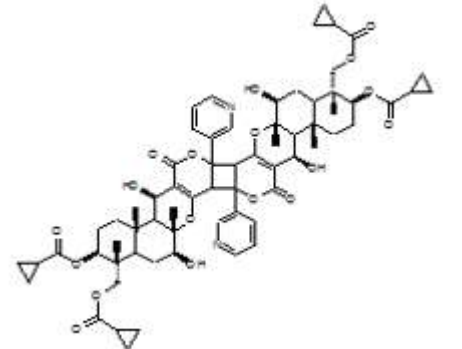
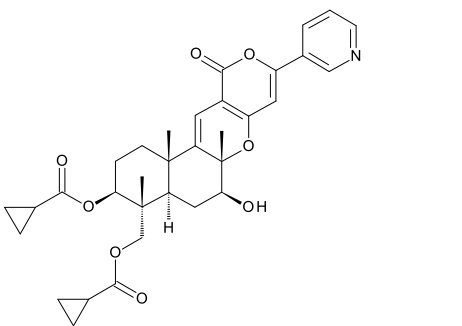
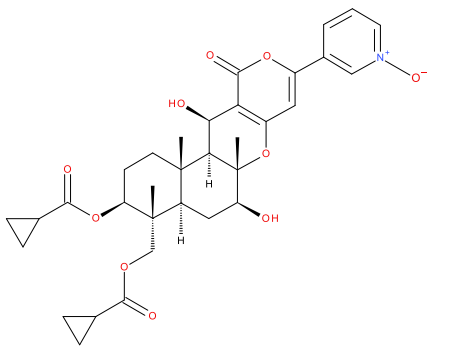
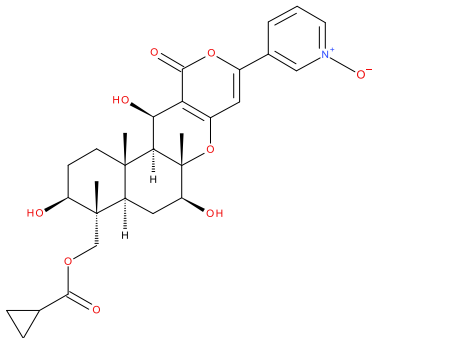


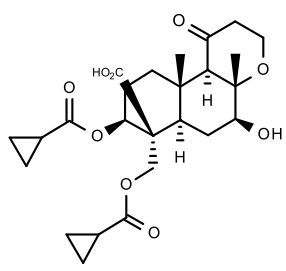
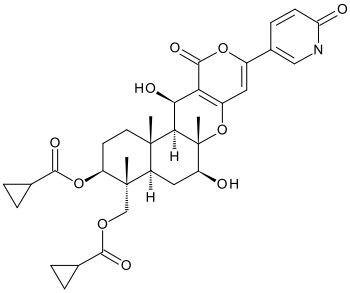
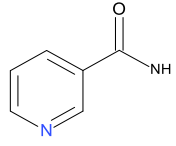
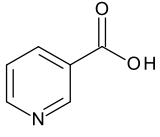
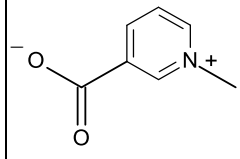
The abbreviations, chemical names, and structures discussed in the appraisal are summarized in Table 1.

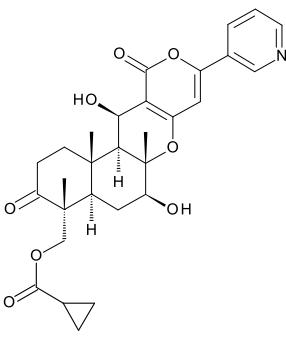
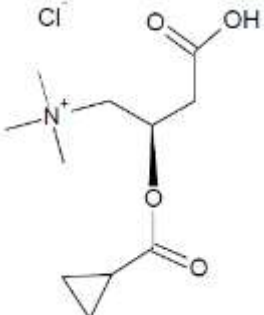
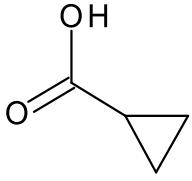
Table 1 Abbreviations for the relevant compounds referred to in this document.

Code	Name and Matrix	Structure
M440I001 ME5343-T1 Reg. No.: 5741530 <b>M001</b>	(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a,12b-trimethyl-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-11-one  Found in : rat, plants (tomato), animals (goat), soil, water MW= 457.5 g/mol	
M440I002 ME5343-T2 Reg. No.: 5741532 <b>M002</b>	[(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-3,6,12-trihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropanecarboxylate  Found in: rat, plants (tomato), animals (goat), soil, water	
M440I003 ME5343-T3 Reg. No.: 5741533 <b>M003</b>	(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-6,12-dihydroxy-4-(hydroxymethyl)-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-3-yl cyclopropanecarboxylate  Found in: rat, animals (goat), rotational crops (trace), soil, water	
M440I004 ME5343-T4 Reg. No.: 5824381 <b>M004</b>	(3S,4R,4aR,6aS,12R,12aS,12bS)-3,12-dihydroxy-4-(hydroxymethyl)-4,6a,12b-trimethyl-9-(pyridin-3-yl)-1,3,4,4a,5,12,12a,12b-octahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-6,11(6aH)-dione  Found in: animals (goat)	
M440I005 ME5343-T5 Reg. No.: 5824382 <b>M005</b>	[(3S,4R,4aR,6aS,12R,12aS,12bS)-3,12-dihydroxy-4,6a,12b-trimethyl-6,11-dioxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropanecarboxylate  Found in: animals (goat), soil, water	



Code	Name and Matrix	Structure
M440I006 ME5343-T6 Reg. No.: 5824383 <b>M006</b>	(3S,4R,4aR,6aS,12R,12aS,12bS)-12-hydroxy-4-(hydroxymethyl)-4,6a,12b-trimethyl-6,11-dioxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-3-yl cyclopropanecarboxylate Found in: animals (goat), water	
M440I007 ME5343-T7 Reg. No.: 5824749 <b>M007 (dimer)</b>	Dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl rac-cyclopropanecarboxylate Found in: plants (tomato, cabbage, soya bean), water MW= 1187.3 g/mol	
M440I014 Reg. No.: 5741536 <b>M014</b>	[(3S,4R,4aR,6S,6aS,12bS)-3-[(cyclopropylcarbonyl)oxy]-6-hydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12b-octahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropanecarboxylate Found in: plants (soya bean), soil	
M440I017 ME5343-T17 Reg No.: 6045738 <b>M017 (N-oxide of afidopyropen)</b>	[(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-3-(cyclopropylcarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-9-(1-oxidopyridin-3-yl)-11-oxo-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropanecarboxylate Found in: rat, plants (tomato leaves, cabbage), animals (goat, hen) MW= 609.7 g/mol	
M440I019 <b>M019 (N-oxide of M002)</b>	[(3S,4aR,6S,6aS,12R,12aS,12bS)-3,6,12-trihydroxy-4,6a,12b-trimethyl-11-oxo-9-(1-oxo-1lambda~5~-pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl cyclopropanecarboxylate Found in: rat, plants (tomato leaves)	

Code	Name and Matrix	Structure
M440I022 <b>M022</b>	IUPAC name: rac-(4aR,5R,6aS,8R,10aR,10bS)-8-[(cyclopropanecarbonyl)oxy]-7-[[cyclopropanecarbonyl]oxy]methyl)-3,5-dihydroxy-4a,10a-dimethyl-1-oxododecahydro-1H-naphtho[2,1-b]pyran-7-carboxylic acid Found in: soya bean	
M440I024 Reg. No.: 5886215 <b>M024</b>	IUPAC: [(3S,4a,4aR,6S,6aS,12R,12aS,12bS)-3-[(cyclopropylcarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(6-oxo-1,6-dihydropyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropanecarboxylate Found in: aerobic soil, soil photolysis (dark)	
M440I044 Reg. No.: 59878 <b>nicotinamide (M044)</b>	IUPAC name: pyridine-3-carboxamide Found in: head cabbage	
M440I045 Reg. No.: 14673 <b>nicotinic acid (M045)</b>	IUPAC name: pyridine-3-carboxylic acid Found in: head cabbage, tomato (trace), aqueous photolysis	
M440I031 Reg. No.: 68482 <b>trigonelline (M031)</b>	IUPAC name: 1-methylpyridin-1-ium-3-carboxylate Found in: soya bean	

Code	Name and Matrix	Structure
M440I057 Reg. No.: 6010129 <b>M057</b>	UPAC name: [(4R,4aR,6S,6aS,12R,12aS,12bS)-6,12-dihydroxy-4,6a,12b-trimethyl-3,11-dioxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropanecarboxylate Found in: aerobic soil	
M440I060 Reg. No.: 6009307 <b>CPCA-carnitine (M060)</b>	(2R)-3-carboxy-2-[(cyclopropylcarbonyl)oxy]-N,N,N-trimethylpropan-1-aminium chloride Found in: rat, goat, hen MW= 265.7 g/mol	
M440I061 Reg. No.: 53128 <b>CPCA (M061)</b>	Cyclopropanecarboxylic acid Found in: rat, goat, hen MW= 86.1 g/mol	

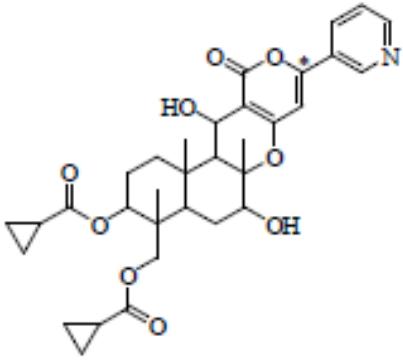
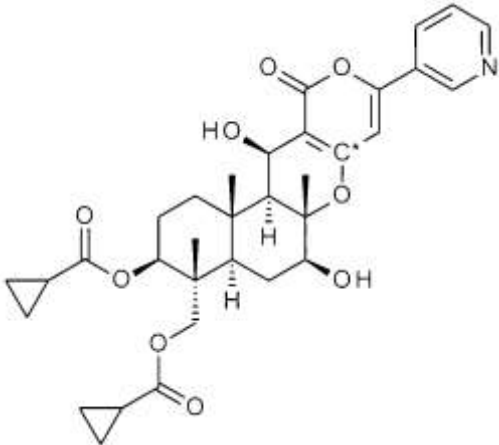
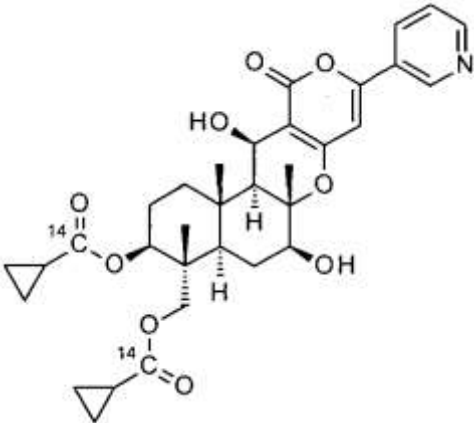
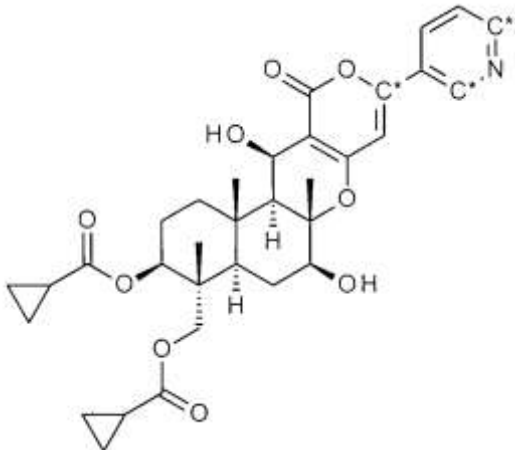
### Physical chemical properties

Afidopyropen is not soluble in water (25.1 mg/L), but is soluble in acetone, methanol and ethyl acetate (> 500 g/L). The compound has a  $\text{LogP}_{\text{o/w}}$  of 3.45 and a low vapour pressure of  $< 9.9 \times 10^{-6}$  Pa at 25 °C.

### Plant metabolism

The Meeting received plant metabolism studies for afidopyropen after soil and/or foliar applications on tomatoes (fruiting vegetables), cabbage (leafy crops) and soya bean (pulses and oil seeds). Afidopyropen was applied using either [ $^{14}\text{C}$ ]-9-nicotinic acid, [ $^{14}\text{C}$ ]-4-pyranone, [ $^{14}\text{C}$ ]-6-pyranone, or [ $^{14}\text{C}$ ]-cyclopropanecarboxylic acid carbonyl-label.

Table 2 Overview of the different labels used in the plant metabolism studies

	
<p>[<sup>14</sup>C]-9-nicotinic acid = [NCA-<sup>14</sup>C]-afidopyropen = [<sup>14</sup>C]-6-pyranone = [6-PYRA-<sup>14</sup>C]-afidopyropen used in primary metabolism studies on cabbage and tomato and in confined rotation crop studies.</p>	<p>[<sup>14</sup>C]-4-pyranone = [4-PYRA-<sup>14</sup>C]-afidopyropen used in primary metabolism studies in tomato, cabbage, and soya bean and confined rotational crops study</p>
	
<p>[<sup>14</sup>C]-cyclopropanecarboxylic acid carbonyl = [CPCA-<sup>14</sup>C]-afidopyropen used in primary metabolism study in soya bean</p>	<p>[<sup>14</sup>C]-6-pyranone, [<sup>14</sup>C]-2,6-pyridine = [6-PYRA/2,6-PYRI-<sup>14</sup>C]-afidopyropen used in primary metabolism study in soya bean</p>

### Tomato

The metabolic fate of [NCA-<sup>14</sup>C]-afidopyropen in greenhouse grown tomato plants, following a soil drench application at planting at an actual rate of 406 g ai/ha and two sequential foliar applications at an actual rate each of 144–157 g ai/ha, was studied. Plants were sampled seven (fruits) and 14 (fruits and leaves) days after the last treatment. Total radioactive residues were 0.30–0.34 mg eq/kg in fruits and 4.3 mg eq/kg in leaves. Fruit and leaves were surface rinsed with acetonitrile and extracted with acetone/water (8:2, v/v). Surface rinse removed 12–28% TRR of the fruits and 22% TRR of the leaves, indicating uptake in the plant. The sum of surface rinse and extracts ranged from 77 to 81% TRR in fruits and was 77% TRR in leaves. Residues in post extraction solids (PES) ranged from 19–23% TRR.

A total of 23–42% TRR could be identified in fruits and leaves. The major compound was identified as parent: 32% TRR (0.11 mg/kg) and 16% TRR (0.048 mg/kg), followed by M007, the dimer metabolite, accounting for 10% TRR (0.034 mg eq/kg) and 6.7% TRR (0.020 mg eq/kg) in fruits at PHI 7 and 14, respectively. Parent accounted for 25% TRR (1.0 mg/kg) in leaves and the dimer for 15% TRR (0.63 mg eq/kg). Various unidentified metabolites accounted for < 3% TRR (< 0.009 mg eq/kg) in fruit and leaves and in PES metabolites were associated with natural components such as pectin, lignin, hemicellulose and cellulose.

The metabolic fate of [4-PYRA-<sup>14</sup>C]-afidopyropen was studied in greenhouse grown tomato plants. Plants were treated with two sequential foliar applications at an actual rate each of 62.1 g ai/ha per application (retreatment interval (RTI) of 7 days). Plants were harvested 1 day after the last treatment (mature fruits and leaves).

Total radioactive residues were 0.048 mg eq/kg in fruits and 2.5 mg eq/kg in leaves. Samples were not surface rinsed. Fruit and leaves were extracted with methanol and water resulting in 86% TRR and 82% TRR in fruit and leaves, respectively. A total of 81% TRR could be identified in fruits and 50% TRR in leaves.

In fruit the major compound identified was parent with 61% TRR (0.033 mg/kg), followed by M007, the dimer metabolite, which accounted 14% TRR (0.0085 mg eq/kg). Various unidentified peaks were found in fruit accounting for < 3% TRR (0.001 mg eq/kg).

In leaves parent was the major compound (27% TRR, 0.62 mg/kg). Other identified metabolites, all accounting for less than 10% TRR were M001 (2.3% TRR, 0.053 mg eq/kg), M019 (3.1% TRR, 0.071 mg eq/kg), M002 (3.6% TRR, 0.082 mg eq/kg), M017 (8.4% TRR, < 0.19 mg eq/kg), and M007 (2.1% TRR, 0.048 mg eq/kg). Various unidentified metabolites accounted for < 3% TRR (< 0.064 mg eq/kg) in leaves.

### *Head cabbage*

The metabolic fate of [4-PYRA-<sup>14</sup>C]-afidopyropen was studied in greenhouse grown head cabbage plants. Plants received two foliar applications (RTI 7 days) at a rate of 144–151 g ai/ha at BBCH 44/45. Plants were collected at 1 DALA. Total radioactive residues in wrapper leaves and heads were 1.7 and 0.43 mg eq/kg, respectively. Total radioactive residues in heads + wrapper leaves were not determined. A high proportion of the residue (83 and 86% TRR in heads and wrapper leaves) could be extracted with methanol and water.

A total of 53–55% TRR could be identified in both heads and wrapper leaves at 1 DALA. Afidopyropen was the predominant compound accounting for a total of 22% TRR (0.094 mg/kg) in heads and 23% TRR (0.40 mg/kg) in wrapper leaves. M007, the dimer of afidopyropen, was the major metabolite accounting for a total of 14 and 17% TRR (0.30 and 0.060 mg eq/kg) in heads and wrapper leaves, respectively. A minor metabolite identified in heads and wrapper leaves was M017 (2.1–2.8% TRR, 0.012–0.037 mg eq/kg). Various unidentified metabolites (31–40 different peaks) each accounted for < 5% TRR (< 0.082 mg eq/kg). Furthermore, 6.3–7.2% TRR (0.027–0.13 mg eq/kg) that was characterized in PES was associated with natural sugars.

The metabolic fate of [NCA-<sup>14</sup>C]-afidopyropen was studied in outdoor grown head cabbage plants. At transplanting soils were treated with 844 g ai/ha, followed by two foliar spray applications at an actual rate of 62.5 g ai/ha, with intervals of 163 and 14 days. Plants were collected at intermediate (7 DALA) and final harvest (14 DALA). Total radioactive residues were 1.5 and 1.1 mg eq/kg at 7 and 14 DALA, respectively, with 44–47% TRR in surface wash, 44–49% TRR in washed wrapper leaves and 7.8–9.6% TRR in heads.

Residues could be extracted with acetonitrile/water (1:1, v/v) with an extraction efficiency of 91–97% TRR for heads and 85% TRR for washed wrapper leaves, including surface wash.

At 7 DALA, parent afidopyropen accounted for a total of 14% TRR (0.20 mg/kg). M007, the dimer of afidopyropen, accounted for a total of 17% TRR (0.24 mg eq/kg). Nicotinamide represented 9.8% TRR (0.14 mg eq/kg) and nicotinic acid 3.7% TRR (0.053 mg eq/kg). Various polar and unidentified metabolites accounted for ≤3.4% TRR (≤0.050 mg eq/kg) in heads + washed wrapper leaves.

At 14 DALA, parent afidopyropen accounted for a total of 6.9% TRR (0.073 mg/kg). M007, the dimer of afidopyropen, accounted for a total of 9.9% TRR (0.10 mg eq/kg). Nicotinamide represented 8.1% TRR (0.087 mg eq/kg) and nicotinic acid 2.5% TRR (0.027 mg eq/kg). Various polar and unidentified metabolites accounted for ≤9.0% TRR (≤0.096 mg eq/kg) in heads + washed wrapper leaves.

Remaining solids (wrapper leaves only) were characterized as natural products, such as pectin, lignin, hemicellulose and cellulose and accounted for 11% (0.16 mg eq/kg) and 14% (0.15 mg eq/kg) of the TRR in cabbage harvested at 7 DALA and 14 DALA, respectively.

The samples of this outdoor metabolism study in cabbage were re-analysed using different extraction techniques. In the polar fraction of the methanol extract of the cabbage wrapper leaves trigonelline (M031) was identified (7% TRR), a naturally occurring alkaloid.

### *Soya bean*

The metabolic fate of either [6-PYRA-/2,6-PYRI-<sup>14</sup>C]-afidopyropen or [4-PYRA-<sup>14</sup>C]-afidopyropen, in greenhouse grown soya bean following two sequential foliar applications at an actual rate each of 61–62 g ai/ha per application (RTI 7 days) was studied. Where two values are given divided by “/”, they account for the results of the plants treated with the [6-PYRA-/2,6-PYRI-<sup>14</sup>C]-label or the plants treated with the [4-PYRA-<sup>14</sup>C]-label, respectively. Plants were treated at maturity (BBCH 95–97) and harvested 14 days after the last treatment. Total radioactive residues were 0.41/0.17 mg eq/kg in dry soya bean seeds, 1.6/1.7 mg eq/kg in soya bean hulls, 18/20 mg eq/kg in soya bean leaves, and 0.42/0.34 mg eq/kg in stems (rest of plants) for both labels.

Extraction with methanol and water resulted in 75/74% TRR in soya bean leaves, 85/48% TRR in dry soya bean seeds, 75/75 % TRR in soya bean hulls, and 85/82% TRR in soya bean rest of plants. Extraction of the PES after exhaustive enzyme treatment resulted in a release of another 6.3–32% TRR.

For the [6-PYRA/2,6-PYRI-<sup>14</sup>C] label a total of 60% TRR (dry seeds), 72% TRR (pods/hulls), 61% TRR (leaves), and 82% TRR (rest of plants) could be identified in soya bean matrices at 14 DALA after simple extraction. Parent was not observed in soya bean seeds, but accounted for 13, 18, and 8.2% TRR in hulls, leaves, and rest of plant, respectively. M031, or trigonelline, was the only identified compound in soya bean seeds (47% TRR or 0.18 mg eq/kg) and the major compound found in the other matrices with 23% TRR in soya bean leaves, 34% TRR in soya bean hulls, and 60% TRR in rest of plants. Another major metabolite was M007, the dimer of afidopyropen, which accounted for 26% TRR in hulls, 14% TRR in leaves, and 14% TRR in rest of plants.

For the [4-PYRA-<sup>14</sup>C]-label, a total of 27% TRR (dry soya bean seed), 47% TRR (leaves), 72% TRR, (pods/hulls) and 70% TRR (rest of plants) could be identified after simple extraction. Parent was found at levels of 19, 18 and 18% TRR in soya bean leaves, soya bean hulls, and the rest of the plants, respectively. In these three matrices, the M007 accounted for the majority of the identified residue (50, 18, and 38% TRR, respectively in green pods with seeds, green and dry leaves, and the rest of the plants). In dry soya bean seeds parent and M007 were identified at trace levels only (0.4% TRR and 1.0% TRR, corresponding with 0.001 and 0.002 mg eq/kg, respectively). The radioactivity in the dry soya bean seeds consisted mainly of plant sugars (25% TRR or 0.042 mg/kg in the extract and another 16% TRR in the PES.

Minor metabolites identified with both labels were M014/M022 (2.1/3.5% TRR, 0.36/0.70 mg eq/kg) and M033 (0.7–1.3% TRR, 0.15–0.22 mg eq/kg) in soya bean leaves only. Other unidentified metabolites were below 10% TRR.

The metabolic fate of [CPCA-<sup>14</sup>C]-afidopyropen was studied in soya bean plants grown under greenhouse conditions. Soya bean plants received two sequential foliar applications each at a rate of 62 g ai/ha per application (RTI 7 days). BBCH growth stage was not reported. Plants were harvested 14 days after the last treatment. Total radioactive residues were 0.015 mg eq/kg in dry soya bean seeds, 0.18 mg eq/kg in soya bean green pods with seeds, 5.2 mg eq/kg in soya bean leaves, and 2.5 mg eq/kg in soya bean hulls.

Extraction with methanol and water released 57% TRR (0.008 mg eq/kg) in soya bean seeds, 68% TRR (0.12 mg eq/kg) in soya bean green pods, 75% TRR (3.7 mg eq/kg) in soya bean leaves, and 70% TRR (1.8 mg eq/kg) in soya bean hulls. Extraction of the PES after exhaustive treatment resulted in a release of another 5.7–30% TRR in the various matrices. Remaining solid was 5.9% TRR (0.001 mg eq/kg) in soya bean dry seeds, 17% TRR (0.029 mg eq/kg) in soya bean green pods with

seeds, 13% TRR (0.64 mg eq/kg) in soya bean leaves, and 16% TRR (0.42 mg eq/kg) in soya bean hulls.

After simple extraction a total of 12% TRR (soya bean dry seed), 50% TRR (soya bean green pods with seeds), 46% TRR (soya bean leaf), and 36% TRR (soya bean hulls) could be identified at 14 DALA. Parent accounted for the majority of the identified residues in green pods with seeds (18% TRR or 0.031 mg/kg), leaf (27% TRR or 1.3 mg/kg), and hulls (12% TRR or 0.32 mg/kg), but was not observed in soya bean dry seeds. M007 was the only compound found in dry soya bean seeds (12% TRR or 0.002 mg eq/kg) and the major compound found in the other three matrices with 32% TRR (0.056 mg eq/kg) in green pods with seeds, 9.2% TRR (0.46 mg eq/kg) in leaf, and 24% TRR (0.61 mg eq/kg) in hulls. Other minor metabolites, identified in soya bean leaves only, were M033 (1.5% TRR or 0.074 mg eq/kg), M014 (2.8% TRR or 0.14 mg eq/kg) and the isomer of afidopyropen (4.1% TRR or 0.20 mg eq/kg).

### ***Summary and conclusion of metabolism in crops***

The metabolism of afidopyropen includes dimerization via cycloaddition of two 2-pyrone rings to form M007 in cabbage, soya bean leaves, tomato, and to a very minor extent in soya bean seed. Cleavage of the CPCA unit(s) (formation of M001 and M002) and N-oxidation (formation of M017 from the parent and M019 from M002) are two minor pathways. Cleavage of the ring system also occurred to form nicotinic acid, nicotinamide and numerous unidentified minor metabolites with a range of polarities and incorporation into natural products (lignin, hemicellulose, carbohydrates and proteins). In soya bean and cabbage a methylation product of the proposed intermediate nicotinic acid yielded M031, trigonelline, which could be identified as the only major metabolite in dry soya bean seed. Trigonelline is a naturally occurring plant alkaloid. Several minor metabolites in soya bean matrices included a glucoside of parent (M033), a dehydration product (M014) of parent, a cleavage product of the nicotinic acid and 2-pyrone moiety (M022).

### ***Environmental fate***

The Meeting received information on the environmental fate and behaviour of afidopyropen, including hydrolytic stability, photochemical degradation in water and soil, and aerobic soil degradation studies.

#### ***Hydrolysis***

[NCA]-labelled afidopyropen was shown to be stable to hydrolysis, with a  $DT_{50} > 1$  year at pH 4 and pH 7 and a  $DT_{50}$  of 133 days at 25 °C and pH 9. The Meeting concluded that hydrolysis will not form a significant route of degradation in the aquatic environment under normal environmental conditions.

#### ***Photochemical degradation***

In a photolysis study in water [NCA]-labelled afidopyropen degraded under simulated sunlight with  $DT_{50}$  values ranging from 12 summer days in natural water to 28 summer days at pH 7 (40 °N), equal to 34 to 78 days of Tokyo spring sunlight. The major degradation product identified was nicotinic acid (8.4–26%). A minor degradation product observed was M007. In a photolysis study using [PYRA]-labelled afidopyropen  $DT_{50}$  values were 10 days in natural water and 17 days in pH 7 buffer (40°N, equivalent to 28 and 58 days, respectively of Tokyo spring sunlight. No major degradation products were observed (max 7% TAR). The Meeting concluded that aqueous photolysis of afidopyropen is moderate to slow.

With  $DT_{50}$  values ranging from 31–556 days photolysis was not considered to be a significant route of degradation.

#### ***Aerobic soil degradation***

The estimated  $DT_{50}$  for afidopyropen in aerobic soils ( $n = 3$ ) ranged from 2.7 to 19 days. A number of metabolites were formed, but only three reached levels  $> 10\%$  TAR, being M003 (7.5–14% TAR), M002 (up to 11% TAR), and M024 (combined label in study 1 only). In another study metabolite M057 was

also observed at relevant concentrations, with a maximum of 36% TAR in one soil at day 7. Half-lives were estimated for M002 (0.3–5.5 days), M003 (9.5–36 days), M057 (3.5–9.9 days), and M024 (28 days).

The results of the soil degradation studies show that afidopyropen and its soil metabolites are not persistent in soil.

### ***Rotational crop studies***

The Meeting received three confined rotational crop studies with information on the metabolism of afidopyropen in spinach, white radish, and spring wheat grown in rotation.

In one study [NCA-<sup>14</sup>C]- or [4-PYRA-<sup>14</sup>C]-labelled afidopyropen was applied once to bare soil at 125 g ai/ha. Rotational crops (spinach, radish and spring wheat) were sown at intervals (PBI) approximating 30, 120 and 365 days after application. In a second study [NCA-<sup>14</sup>C]-labelled afidopyropen was applied once to bare soil at a single rate of 20 g ai/ha. Spring wheat was sown at intervals (PBI) of 30, 61 and 90 days after application. Spinach (mature and immature foliage), radish (foliage and root), and wheat forage, hay, grain and straw were harvested at appropriate growth stages. In the third study [CPCA]-labelled afidopyropen was applied once to bare soil with a single application rate of 125 g ai/ha (spinach and radish) or 20 g ai/ha (wheat). Rotational crops were sown at plant intervals (PBI) 31 and 90 days (spinach and radish), or 30 and 61 days (wheat).

The application rates used in two of the confined metabolism studies are similar to the highest maximum seasonal rate (125 g ai/ha/season) of the currently submitted labels.

Residues of afidopyropen above 0.01 mg eq/kg were found only in wheat matrices (TRR ranging from 0.010 to 0.10 mg eq/kg at PBIs 30–365 days) and in spinach and radish roots and tops at PBI 30 days (up to 0.014 mg eq/kg). Extraction of the residues ranged from 12% TRR to 70% TRR depending on the matrix and label. Analysis of the TRR of the wheat samples showed a number of low level polar and non-polar metabolites all occurring  $\leq 0.008$  mg eq/kg. One metabolite, M003, was identified in wheat straw (PBI 31 days) at 0.9% TRR and absolute level of 0.001 mg eq/kg. Afidopyropen was not detected in any sample. The Meeting concluded that uptake from soil is low and afidopyropen is metabolized to low levels of metabolites.

### ***Animal metabolism***

The Meeting received information on the fate of orally-dosed afidopyropen in rat, lactating goats and laying hens.

#### ***Rats***

The metabolism in rats was reviewed by the WHO Core Assessment Group of the JMPR in 2019.

#### ***Lactating goat***

A single lactating goat was orally dosed with [4-PYRA-<sup>14</sup>C]-labelled afidopyropen by capsule at a dose rate equivalent to a mean of 17.3 ppm in the feed (0.38–0.41 mg/kg bw per day) for 7 consecutive days. The goat was sacrificed 8 hrs after the last dose. The majority of the cumulative administered dose was recovered in faeces (66.5% of applied radioactivity) with lower levels in the GI (21%) tract and urine (2.5% of applied radioactivity). The radioactivity recovered in tissues (liver, kidney, muscle and fat) accounted for a total of 0.27–0.33% of the applied radioactivity. Radioactivity associated with edible portions (milk and tissues) accounted for  $\leq 0.1\%$ , each, of the applied radioactivity

Steady state conditions in milk were achieved within 4–7 day of the first dose. TRR levels in milk ranged from 0.004 mg eq/kg on day 0 to 0.006 mg eq/kg on days 5 and 6. The ratio of the total residues (no parent identified in the individual fractions) in the cream to skimmed milk was 1.3:1.

Highest TRR levels were found in liver (0.19 mg eq/kg) followed by kidneys (0.037 mg eq/kg). In muscle and fat TRR levels were  $\leq 0.008$  mg eq/kg.



Extractability of the radioactive residues with neutral solvents (methanol and/or methanol/water and using dichloromethane as a precursory step in fat matrices) was high in milk (96% TRR) and in edible tissues: 78% TRR (muscle) to 98% TRR (fat). An additional 16% TRR (muscle only) was released with protease digest. A total of 78% TRR (milk), 91% TRR (liver), 94% TRR (kidney), 78% TRR (muscle), and 67% TRR (fat) was identified.

Parent was a major compound identified in liver (35% TRR), muscle (26% TRR) and fat (49% TRR) and to a lesser extent also in kidney (16% TRR) and milk (6.8% TRR). Metabolite M001 was the major compound observed in milk (45% TRR, 0.002 mg eq/kg), liver (46% TRR, 0.089 mg eq/kg), kidney (66% TRR, 0.025 mg eq/kg), and muscle (24% TRR, 0.002 mg eq/kg) and to a lesser extent in fat (4.6% TRR, 0.001 mg eq/kg). Metabolite M003 was identified as a major metabolite in muscle (22% TRR, 0.002 mg eq/kg) and kidney (12% TRR, 0.005 mg eq/kg) and represented a minor metabolite in milk (3.6% TRR, < 0.001 mg eq/kg), liver (4.4% TRR, 0.009 mg eq/kg) and fat (8.1% TRR, < 0.001 mg eq/kg). M005 was found to be a major compound in milk (17% TRR, 0.001 mg eq/kg). Other minor metabolites (< 10% TRR and below 0.01 mg eq/kg) identified were M002 (2.1% TRR, 0.004 mg eq/kg in liver only) and M006 (5.2–5.4% TRR, < 0.001 mg eq/kg) in milk, muscle and fat.

In a second lactating goat study, a single goat was orally dosed with [CPCA-<sup>14</sup>C]-labelled afidopyropen by capsule at a dose rate equivalent to a mean of 12 ppm in the feed (0.197 mg ai/kg bw per day) for 9 consecutive days. The goat was sacrificed 10 hrs after the last dose. The majority of the cumulative administered dose was recovered in faeces (50% of applied radioactivity), with lower levels in the GI (7.3%) tract and urine (13% of applied radioactivity). Radioactivity recovered in tissues (liver, kidney, muscle and fat) accounted for < 0.01–0.5% of the applied radioactivity. Radioactivity recovered in milk accounted for 1.9% of the applied radioactivity. The highest recovery from edible tissues was in composite muscle (0.5% of applied radioactivity).

Steady state conditions in milk were achieved 7 days after the first dose. TRR levels in milk ranged from 0.051 mg eq/kg on day 1 to 0.38 mg eq/kg on day 9. The ratio of total residues (no parent identified and consisting mainly of CPCA-carnitine) associated with cream and skimmed milk was determined in a representative 24 h composite sample from the plateau and shown to be 14:1 (2.6 mg eq/kg to 0.18 mg eq/kg).

Total radioactive residues were 0.22 mg eq/kg in liver, 0.47 mg eq/kg in kidneys, 0.33 mg eq/kg in muscle, 0.010 mg eq/kg in fat, 0.24 mg eq/kg in milk and 2.0 mg eq/kg in cream.

Extractability of the radioactive residues with neutral solvents (methanol and/or methanol/water and using dichloromethane as a precursory step in fat matrices) was high in milk (77% TRR) and in edible tissues: 84% TRR (liver) to 98% TRR (muscle). An additional 6.0 and 5.0% TRR was released in liver and kidney after protease digestion. Because of the low level of radioactivity observed in fat (0.009 mg eq/kg, 2.9% TRR), this matrix was not further analysed.

A total of 71% TRR (liver), 71% TRR (kidney), 94% TRR (muscle) was identified. Parent was only detected in liver (18% TRR, 0.038 mg/kg). Metabolite M060 (CPCA-carnitine) was the major compound in muscle (91% TRR, 0.28 mg eq/kg) and a minor compound in liver and kidney (5.8–6.9% TRR, 0.014–0.028 mg eq/kg). Metabolite M061 (CPCA) was the major compound in liver (28% TRR, 0.057 mg eq/kg) and kidney (64% TRR, 0.31 mg eq/kg). Minor metabolites identified were M003 (12% TRR, 0.026 mg eq/kg in liver, 1.4% TRR, 0.007 mg eq/kg in kidney and 0.20% TRR, 0.001 mg eq/kg in muscle) and M017 (3.7% TRR, 0.008 mg eq/kg) in liver only. The radioactivity in milk (92% TRR) was identified as M060 (CPCA-carnitine).

### *Laying hens*

A group of laying hens was orally dosed [<sup>14</sup>C-CPCA]-afidopyropen once daily for 14 consecutive days at 12 ppm in the feed (mean daily dose level 0.83 mg/kg bw per day). Hens were sacrificed 10 hrs after dosing. The majority of the administered dose was recovered in excreta (93% TAR). A minor part of the total applied radioactivity was recovered in eggs (0.2% TAR in egg yolk and 0.4% TAR in egg white), and tissues (< 0.01–0.01% TAR). The highest TRR in tissues was found in the liver (0.40 mg eq/kg) followed by high concentrations in egg (yolk: 0.38 mg eq/kg; white: 0.16 mg eq/kg)

and peritoneal fat (0.12 mg eq/kg). Lower levels were found in skin with fat (0.089 mg eq/kg), and muscle (0.033–0.061 mg eq/kg). Radioactive residues in eggs increased from 0.094 mg eq/kg on day 1 to 0.27 mg eq/kg on day 8. Residues in eggs reached a plateau within 5–9 days.

The extractability of the radioactive residues with neutral solvents (methanol and/or methanol/water and using dichloromethane as a precursory step in fat matrices) was high in all tissues accounting for 85–99% TRR. Protease treatment of the liver PES released an additional 7.1% TRR. A total of 84% TRR in liver to 97% TRR in egg yolk could be identified.

Parent was the major component in all tissues and egg fractions, ranging from 46% TRR (0.021 mg/kg) in muscle, 59% TRR in liver and 90–97% TRR (0.36 mg/kg) in fat and eggs. Metabolite M017 was observed in liver as a major metabolite (21% TRR, 0.085 mg eq/kg) and as minor metabolite in egg white (5.4% TRR, 0.007 mg eq/kg). Metabolite M060 or CPCA (38% TRR, 0.017 mg eq/kg) was a major metabolite found in muscle and not found in any other matrix. Minor metabolite M061 (CPCA-carnitine) was observed in liver only (4.1% TRR, 0.017 mg eq/kg). Two unknown metabolites were present at trace levels (< 9.0% TRR and < 0.01 mg eq/kg) in hen muscle.

### *Summary and conclusion of metabolism in livestock*

In summary, the primary metabolic process observed in lactating goats and laying hens included cleavage of one or two cyclopropyl carboxylic ester units leading to the formation of M001, M002, and M003 as well as to formation of cyclopropanecarboxylic acid (CPCA=M061). CPCA (M061) interacts with carnitine to form CPCA-carnitine (M060). A minor pathway is oxidation of the pyridine ring to form the N-oxide, M017, which can subsequently also form CPCA (M061) and CPCA-carnitine (M060). As a second minor pathway, oxidation of an alcohol group can give rise to the ketone metabolites M005, M006 and to a very minor extent M004.

The metabolic profile of afidopyropen in ruminants and poultry is very similar to that of rats. Metabolites M001, M002, M003, M017 are also observed in rats. CPCA and CPCA-carnitine were not analysed for in rat metabolism studies, but are assumed to be part of the residue, since CPCA is a cleavage product in the formation of the other metabolites (M001, M002 and M003, which are major metabolites in rats).

### *Methods of Analysis*

The Meeting received description and validation data for analytical methods of plant and animal commodities for the determination of afidopyropen and M007 in plant matrices as a well as data on afidopyropen, and metabolites M001, M003, M005, M017, and M060 (= CPCA-carnitine) in animal matrices.

Multi-residue HPLC-MS/MS methods were available for plant commodities based on the multi-residue method QuEChERS and AOAC Official method 2007.01. The methods are valid for the determination of afidopyropen and the dimer M007 in crops with high acid content (citrus/orange), high oil content (cotton seed and rape seed), high protein content (dry bean), high starch content (potato) and high water content (tomato and apple). The limit of quantification (LOQ) was 0.01 mg/kg for each analyte in each commodity for both methods.

A radio-validation study comparing the extraction efficiency of the extraction procedure of the analytical method D1103, commonly used in multi-residue methods for enforcement (QuEChERS, DFG S19 and SweEt) was verified against the extraction efficiency found in the metabolism studies. The results based on the three plant metabolism studies showed a relative extraction efficiency of 74–118% for parent and 63–96% for the dimer M007 when using method D1103/01, which was used in the supervised residue trials.

Analytical methods used in the study reports used acetone/water (25/10, v/v) for extraction of residues from various plant commodities. After clean-up residues were determined by HPLC-MS/MS. For all methods, final quantification is achieved with an LOQ of 0.01 mg/kg for each analyte. All methods for plant commodities were successfully validated for afidopyropen and the dimer M007, demonstrating good reproducibility in the concentration range of 0.1–1.0 mg/kg per analyte.

The analytical methods for enforcement of animal commodities and the study reports on animal commodities generally used methanol for extraction followed by dilution in water and clean up by SPE diluted with acetonitrile/water. Fat samples were extracted using dichloromethane and water. Analytes were determined by HPLC-MS/MS with an LOQ of 0.01 mg/kg for afidopyropen, M001, M003 in liver, muscle, fat, and eggs, and for M017 in liver only. For CPCA-carnitine an LOQ of 0.05 mg/kg was established. The LOQs for parent and metabolites M001, M005 in milk were 0.001 mg/kg and 0.005 mg/kg for CPCA-carnitine. The methods were successfully validated for parent afidopyropen, M001, M003, and CPCA-carnitine in all tissues, and eggs, except for M003 in milk. The methods were considered valid for M017 in liver and for M005 in milk.

### ***Stability of pesticide residues in stored analytical samples***

The Meeting received information on the storage stability of parent and metabolite M007 in raw plant commodities. In addition the Meeting received information on the storage stability of parent afidopyropen, M001 and M003 in tissues and milk and CPCA-carnitine in liver.

The data indicate that residues of afidopyropen and the dimer M007 are stable when stored frozen (-20 °C) for at least 24 months in high starch (barley grain), high water (lettuce), high protein (dry bean), high oil (soya bean seed, soya bean oil), high acid (orange), and dry (soya bean hay) matrices.

Storage stability studies with spiked animal matrices demonstrated that afidopyropen, metabolite M001, M003 (not in milk), M005 (in milk only), and CPCA-carnitine were stable for at least 80 days (fat), 90 days (muscle), 96 days (liver), and 99 days (milk) at < 10 °C. Storage stability of kidney was not investigated. No storage stability data on eggs were submitted, but samples were stored for a maximum of 42 days.

### ***Definition of the residue***

#### ***Plant commodities***

Parent (8.2–61% TRR) was the major compound in the majority of primary crop commodities (tomato fruit, cabbage heads, soya bean hulls, soya bean fodder/forage and soya bean hulls). Parent was detected at very low concentrations in soya bean dry seed (0.4% TRR, 0.001 mg/kg). The dimer metabolite M007, was a major compound (6.7–26% TRR) in the majority of the edible parts of primary crops, again with the exception of soya bean dry seed (1.0% TRR, 0.002 mg eq/kg, with the [PYRA]-label), but reaching 12% TRR (0.002 mg eq/kg) when using the CPCA-label. Trigonelline (M031) was the only metabolite identified in soya bean seed (47% TRR, 0.18 mg eq/kg). Trigonelline is a naturally occurring plant alkaloid and is therefore not considered suitable for enforcement purposes.

Suitable analytical methods for enforcement are available for afidopyropen in plant matrices.

The Meeting concluded that afidopyropen only should be considered as a suitable marker compound for enforcement purposes and decided to define the residue for enforcement/monitoring as afidopyropen.

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 M007, M017, nicotinamide, nicotinic acid, trigonelline, found in edible portions of primary crops and M001, M002, M019, M033, and M014/M022.

Minor metabolites M001 (approximately 2.4% TRR), M002 (3.6% TRR), M019 (< 2.5%, tomato leaves only), M033 and M014/M022 (< 4% TRR, soya bean leaves only) are observed only in non-edible parts of crops and were therefore not included in the residue definition for dietary risk assessment.

Nicotinamide (9.8% TRR, 0.13 mg eq/kg) and nicotinic acid (3.7% TRR, < 0.053 mg eq/kg) observed in cabbage heads and wrapper leaves, are naturally occurring compounds related to vitamin B. Trigonelline, the only and major metabolite found in soya bean seeds, is a methylation product of

vitamin B3 and is also a naturally occurring alkaloid. It is present in several other plants at levels up to more than 1,000 ppm in coffee and fenugreek<sup>4</sup>. Use of afidopyropen is not anticipated to contribute significantly to daily natural exposure to nicotinamide, nicotinic acid, and trigonelline. These three compounds are not further considered for the residue definition for dietary risk assessment.

M017 was found in head cabbages and tomato leaves (2.8% TRR, 0.012 mg eq/kg) and is a major rat metabolite. Its toxicity is therefore covered by the toxicological properties of the parent compound. However, since M017 comprises < 8% relative to the total residue (assuming parent + dimer) it was not included in the residue definition for dietary risk assessment.

M007 was found to be a metabolite of significance in metabolism studies and primary crop studies. Relative to parent it comprises 23–91% of the residue, based on the ratios found in the metabolism studies. Even higher levels of M007 relative to parent were found in field residue trials.

The toxicity of the dimer M007 was evaluated by the current Meeting. The dimer was not considered to be of greater toxicity than the parent. The ADI and ARfD cover both parent and the dimer metabolite M007.

In summary, the Meeting agreed that the residue definition for dietary risk assessment should be the sum of afidopyropen + M007, expressed as afidopyropen.

### *Animal commodities*

Parent was identified in all animal matrices with levels ranging from 18–35% TRR in goat liver, 17% TRR in goat kidney, 26% TRR in goat muscle, 49% TRR in goat fat, 59% TRR in hen liver, 46% TRR in hen muscle, 96% TRR in fat, 90% TRR in egg white and 97% TRR in egg yolk and up to 6.8% TRR in milk. In feeding studies parent was also found in bovine liver and milk at realistic feeding levels and in hen liver, fat and eggs at exaggerated feeding levels.

A suitable analytical method for determining afidopyropen in animal tissues, eggs and milk is available.

The Meeting concluded that afidopyropen is a suitable marker compound for enforcement purposes for all animal matrices and decided to define the residue for enforcement/monitoring as afidopyropen,

The Meeting assessed the behaviour of afidopyropen in fat. The log  $K_{ow}$  for afidopyropen is 3.45. In the metabolism studies, the fat:muscle ratio was approximately 1.9:1 in goat. The ratio for hen fat:muscle was 2.1:1 and 1.1:1 for egg yolk:egg white. The Meeting concluded that the residue is not fat-soluble.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the compounds and their toxicological properties. The metabolites M001, M003, M005, M017, M060, and M061 were the major compounds found in the various matrices. The Meeting also considered the relevance of two minor metabolites M002 and M006. Noting that the goats were sacrificed within 8–10 hours after last dosing in the metabolism studies, the Meeting concluded that for a realistic quantification of the residues the livestock feeding studies should be given greater weight, since they cover more realistic exposure and slaughter conditions.

Metabolite M001 was a major metabolite observed in milk, liver, kidney, and muscle (24–66% TRR) and a minor metabolite in fat (4.6% TRR, 0.001 mg eq/kg). M001 is a major metabolite found in rats and as such its toxicity is covered by the toxicity of the parent. In the animal feeding studies M001 was observed in bovine liver only at levels up to 12.5% relative to parent, but was not observed in any of the hen tissues or eggs. The Meeting concluded that M001 should be included in the residue definition for risk assessment for bovine commodities.

M017 was a major metabolite in hen liver (21% TRR, 0.085 mg eq/kg) and was also found in egg white (5.4% TRR, 0.007 mg eq/kg) and goat liver (3.7% TRR, 0.008 mg eq/kg) comprising 35%, 6% and 20% of the residue relative to parent, respectively. M017 is a major metabolite observed in rats

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<sup>4</sup> Garg, R. C. 2016. Fenugreek: Multiple health benefits. in *Nutraceuticals: Efficacy, Safety and Toxicity*. Elsevier

and as such its toxicity is covered by the toxicity of the parent. In feeding studies M017 was detected in hen liver (comprising 25–63% relative to parent), but was not analysed for in the dairy feeding study. The Meeting concluded that M017 should be included in the residue definition for risk assessment for liver only.

M061 (CPCA) was a major metabolite in goat liver (28% TRR) and kidney (64% TRR) and a minor metabolite in goat muscle and hen liver (2.3–4.1% TRR). It was not found in the hen metabolism study, nor was it analysed for in the feeding studies. M060, the subsequent carnitine conjugate of CPCA (CPCA-carnitine) was found in goat muscle (91% TRR) and hen muscle (38–91% TRR), in goat milk (92% TRR) and in goat liver and kidney at 5.8–6.9% TRR. It was not observed in any of the hen matrices, but it was the main metabolite in bovine milk and the only metabolite observed muscle in the dairy feeding study.

CPCA and CPCA-carnitine were not analysed for in rat metabolism studies, but are assumed to part of the residue, since CPCA is a cleavage product in the formation of the other metabolites (M001, M002 and M003, which are major metabolites in rats). The WHO Panel concluded that CPCA and its carnitine conjugate should be considered major metabolites, whose toxicity is covered by the toxicity of the parent. The Meeting concluded that M060 and M061 should be included in the residue definition for risk assessment for bovine tissues and milk.

Depending on the label, metabolite M003 was identified as major metabolite in liver (4.4–12% TRR), muscle (0.20–22% TRR), kidney (1.4–12% TRR) and represented a minor metabolite in milk (3.6% TRR) and fat (8.1% TRR). M003 is a metabolite observed in rats and as such its toxicity is covered by the toxicity of the parent. However, absolute values were  $\leq 0.009$  mg eq/kg and M003 was not observed in any of the matrices in the animal feeding studies. M003 was therefore not included in the residue definition for dietary risk assessment.

M005 is a major component found only in milk (17% TRR). M005 is not a rat metabolite, but since it reached absolute levels of only 0.001 mg eq/kg and it was not observed in the dairy feeding study the Meeting concluded that M005 does not need to be included in the residue definition for dietary risk assessment.

M002 was a minor metabolite observed only in liver (1.5–2.1% TRR, 0.003–0.004 mg eq/kg). M002 is a major metabolite in rats and as such its toxicity is covered by the toxicity of the parent. However, since it comprises < 8.3% of the residue relative to parent and a lower percentage to the total residue of toxicological concern the Meeting concluded that M002 does not need to be included in the residue definition for dietary risk assessment.

M006 is a minor metabolite found in milk, muscle and fat, observed at levels of 5.1–5.2% TRR. M006 is not a rat metabolite. However, since absolute levels were < 0.001 mg eq/kg, the Meeting concluded that M006 does not need not be included in the residue definition for dietary risk assessment.

The Meeting concluded that afidopyropen, M001, M017 (liver only) and CPCA and its conjugate CPCA-carnitine should be included in the residue definition for dietary risk assessment for animal tissues, milk and eggs.

The Meeting decided to define two different residue definitions for dietary risk assessment for animal commodities, one for liver and one for the other animal matrices including milk and eggs:

Liver: afidopyropen + M001 + M017 + M061 (CPCA) + its carnitine conjugate (M060), expressed as afidopyropen

Other animal commodities: afidopyropen + M001 + CPCA and its carnitine conjugate (M060), expressed as afidopyropen

#### **Summary of the residue definitions:**

The Meeting recommended the following residue definitions for afidopyropen:

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

Definition of the residue for dietary risk assessment for plant commodities: sum of *afidopyropen* + M007, expressed as *afidopyropen*.

Definition of the residue for compliance with the MRL for animal commodities: *afidopyropen*

Definition of the residue for dietary risk assessment for animal commodities, except liver: *afidopyropen* + M001 + CPCA and its carnitine conjugate, expressed as *afidopyropen*

Definition of the residue for dietary risk assessment for liver: *afidopyropen* + M001 + M017 + CPCA and its carnitine conjugate, expressed as *afidopyropen*

The Meeting considers the residue not fat-soluble.

### Results of supervised residue trials on crops

The Meeting received supervised trial data for the foliar application of *afidopyropen* on a broad range of crops. Product labels were available from Australia, Canada, India and the USA.

When calculating the sum of *afidopyropen* and the dimer M007, values below the LOQ were assumed to be at the LOQ. Examples are shown below.

Table 4 Examples of the addition of LOQs

afidopyropen (mg/kg)		M007 (mg/kg)		Sum (mg/kg)
Reported	Assumed	Reported	Assumed	
< 0.01	< 0.01	< 0.01	< 0.01	< 0.02
< 0.01	0.01	0.02	0.02	0.03
0.02	0.02	0.02	0.02	0.04

### Citrus fruit

The critical GAP for *afidopyropen* on citrus fruit is from the USA consisting a maximum individual foliar treatment rate of 51 g ai/ha and a seasonal maximum rate of 103 g ai/ha, leading to a maximum of 2 applications at the maximum rate per season, with a retreatment interval (RTI) of 7 days and a PHI of 0 days.

The Meeting received residue trials data, performed in the USA, on oranges, grapefruits and lemons. None of the trials matched the critical GAP precisely, consisting of 3 applications, i.e. 1 application of 25 g ai/ha, followed by 2 applications of 50 g ai/ha each, with a mean RTI of 7 days. Since 1 × 25 g ai/ha applied 14 days before harvest was not considered to contribute more than 25% to the total residue at harvest, the Meeting concluded that the trials were suitable for maximum residue level estimation.

In the trials from the USA approximating the critical GAP residue levels in ranked order were:

Oranges (n = 12): < 0.01, 0.025, 0.036, 0.040, 0.046, 0.051, 0.063, 0.064, 0.069, 0.070, 0.072, and 0.072 mg/kg.

Grapefruits (n = 6): < 0.01, 0.014, 0.020, 0.035, 0.054, and 0.062 mg/kg.

Lemons (n = 8): < 0.01, < 0.01, 0.023, 0.035, 0.041, 0.050, 0.055, and 0.070 mg/kg.

The Meeting noted that the GAP covers the citrus crop groups and that median residues are within a 5-fold difference. Although trials were not provided for mandarins, the Meeting noted that residues in lemons/limes have been shown to be similar to or greater than residues in mandarins. Therefore, the Meeting decided to combine the three datasets for estimation of a maximum residue level in citrus fruit. Residues of the combined datasets in ranked order were (n = 26): < 0.01 (4), 0.014, 0.020, 0.023, 0.025, 0.035, 0.035, 0.036, 0.040, 0.041, 0.046, 0.050, 0.051, 0.054, 0.055, 0.062, 0.063, 0.064, 0.069, 0.070, 0.070, 0.072, and 0.072 mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) of the combined datasets in ranked order were (n = 26): < 0.02 (4), 0.024, 0.030, 0.033, 0.035, 0.045, 0.045, 0.046, 0.050, 0.051, 0.056, 0.060, 0.061, 0.064, 0.065, 0.072, 0.073, 0.074, 0.079, 0.080, 0.080, 0.082, and 0.086 mg/kg.

Based on the combined datasets from the USA trials for oranges, grapefruits and lemons, the Meeting estimated a maximum residue level of 0.15 mg/kg (parent only) for the Group of Citrus Fruit. The Meeting estimated an STMR and HR of 0.0535 and 0.086 mg/kg, respectively, for whole fruit for the Group of Citrus Fruit.

### *Pome fruit*

The critical GAP for afidopyropen on pome fruit, not including Japanese persimmon, was from the USA consists of a foliar application at a rate of 25 g ai/ha, with a maximum seasonal rate of 51 g ai/ha, leading to a maximum of 2 applications/season, with a RTI of 7 days and a PHI of 7 days.

Residue trials, performed in the USA and Canada, matching this critical GAP, were provided on apples and pears. Residues levels (parent only) in ranked order were:

Apples (n = 13): < 0.01 (12) and 0.010 mg/kg.

Pears (n = 7): < 0.01 (3), 0.011, 0.012, 0.014, and 0.014 mg/kg.

STMRs are within 5× difference. Statistical analysis (Kruskal-Wallis) showed that the datasets are not of the same population. For estimating STMRs and HRs total residues (parent + dimer) in ranked order were:

Apples (n = 13): < 0.02 (12) and 0.020, mg/kg

Pears (n = 7): < 0.02 (3), 0.021, 0.022, 0.024, and 0.024 mg/kg (highest individual value: 0.029 mg/kg).

Noting that pears are a representative crop for the pome fruit crop group, based on the dataset for pears, the Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR and HR of 0.021 and 0.029 mg/kg, respectively, for the Group of Pome Fruit, except Japanese persimmon.

### *Stone fruit*

The critical GAP for afidopyropen on stone fruit was from Canada and the USA consisting of two foliar applications at a maximum rate of 11 g ai/ha, a RTI of 7 days and a PHI of 7 days.

Residue trials, performed in Canada and the USA, matching the critical GAP, were provided on cherries, plums, and peaches.

#### *Cherries*

Residue levels (parent only) for cherries in ranked order were (n = 8): < 0.01 (5), 0.010, 0.014, and 0.020 mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 8): < 0.02 (5), 0.020, 0.024, and 0.030 mg/kg (highest individual value: 0.031 mg/kg).

The Meeting estimated a maximum residue level of 0.03 mg/kg, and an STMR and HR of 0.02 and 0.031 mg/kg, respectively, for the Subgroup of Cherries.

#### *Plums*

Residue levels (parent only) for plums in ranked order were (n = 9): < 0.01 (9) mg/kg. For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 9): < 0.02 (9) mg/kg.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg, and an STMR and HR of 0.02 mg/kg, each, for the Subgroup of Plums.

*Peaches*

Residue levels (parent only) for peaches in ranked order were (n = 11): < 0.01 (10) and 0.011 mg/kg. For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 11): < 0.02 (10) and 0.021 mg/kg (highest individual value: 0.022 mg/kg)

The Meeting estimated a maximum residue level of 0.015 mg/kg, and an STMR and HR of 0.02 and 0.022 mg/kg, respectively, for the Subgroup of Peaches.

*Brassica vegetables*

The GAP for afidopyropen on brassica vegetables, except brassica leafy vegetables from Canada consisted of up to four foliar applications at a maximum rate of 50 g ai/ha per application, a seasonal maximum rate of 125 g ai/ha, a RTI of 7 days and a PHI of 0 days. The Meeting assumed that 1 application at 25 g ai/ha, followed by 2 applications at 50 g ai/ha each was the critical GAP. Trials using two foliar applications each at 12.5 g ai/ha, followed by two applications each at 50 g ai/ha, an RTI of 7 days and a PHI of 0 days, were provided and were considered to approximate GAP, as the first applications applied 21 to 14 days before harvest would not contribute more than 25% to the residues at harvest. The Meeting concluded that the residue trials were within 25% of the GAP.

*Broccoli*

Residue trials, performed in Australia and the USA, approximating the critical GAP, were submitted on broccoli. Residue levels (parent only) in ranked order were (n = 10): 0.046, 0.064, 0.084, 0.089, 0.10, 0.11, 0.12, 0.16, 0.17, and 0.21 mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 10): 0.066, 0.079, 0.11, 0.13, 0.13, 0.14, 0.15, 0.26, 0.26, and 0.30 (highest individual value 0.34) mg/kg.

Noting that broccoli is a representative crop for Flowerhead brassicas, the Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR and HR of 0.135 and 0.34 mg/kg, respectively, for the Subgroup of Flowerhead brassicas, based on the dataset for broccoli.

*Cabbages, head*

Residue trials, performed in Australia and the USA, approximating the critical GAP, were submitted on head cabbage and Brussels sprouts. Residue levels (parent only) in ranked order were:

Head cabbage (with wrapper leaves=WWL) (n = 10): 0.010, 0.012, 0.034, 0.038, 0.041, 0.042, 0.049, 0.14, 0.27, and 0.28 mg/kg. Brussels sprouts (n = 1): 0.012 mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were:

Cabbage (without wrapper leaves = WOWLs) (n = 12): < 0.02 (8), 0.034, 0.038, 0.039, and 0.10 mg/kg.

Cabbage (WWLs) (n = 10) for animal dietary burden calculation: < 0.02, 0.026, 0.052, 0.060, 0.085, 0.088, 0.096, 0.16, 0.30, 0.39 mg/kg (highest individual value: 0.43 mg/kg).

Brussels sprouts (n = 1): 0.022 mg/kg

The Meeting noted that insufficient trials for Brussels sprouts were available to combine the data for extrapolation to the Subgroup of Head brassicas. Based on the dataset for head cabbage the Meeting estimated a maximum residue level of 0.5 mg/kg (parent only) and an STMR and HR of 0.02 and 0.10 mg/kg, respectively, (parent + dimer) for Cabbages, Head.

The Meeting estimated a median and highest residue for animal dietary burden calculation of 0.0865 mg/kg and 0.43 mg/kg, respectively.

*Fruiting vegetables, cucurbits*

The critical GAP for afidopyropen on fruiting vegetables, cucurbits, is from Canada consisting of up to



four foliar applications at a maximum rate of 50 g ai/ha per application, but with a maximum seasonal rate of 125 g ai/ha, a RTI of 7 days and a PHI of 0 days. The Meeting assumed that one application at 25 g ai/ha, followed by 2 applications each at 50 g ai/ha is the critical GAP. Trials using two foliar applications each at 12.5 g ai/ha, followed by two applications each at 50 g ai/ha, a RTI of 7 days and a PHI of 0 days, were considered to approximate GAP, since the first applications applied 21 to 14 days before harvest do not contribute more than 25% to the residues at harvest. The Meeting concluded that the residue trials are within 25% of the GAP.

#### *Cucumbers and summer squashes*

Residue trials, performed in the USA on cucumber and summer squash were submitted. Residue levels (parent only) approximating the critical GAP in ranked order were:

Cucumber (n = 9): 0.053, 0.076, 0.081, 0.11, 0.11, 0.15, 0.15, 0.32, and 0.41 mg/kg.

Summer squash (n = 5): < 0.01, 0.012, 0.018, 0.029, and 0.033 mg/kg.

Medians are not within 5× difference. The Meeting decided to make individual estimations for cucumber and for summer squashes.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were:

Cucumber (n = 9): 0.063, 0.088, 0.11, 0.14, 0.17, 0.17, 0.18, 0.42, and 0.57 mg/kg (highest individual value: 0.60 mg/kg).

Summer squash (n = 5): < 0.02, 0.022, 0.028, 0.039, and 0.044 mg/kg (highest individual value: 0.050 mg/kg).

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR and HR of 0.17 and 0.60 mg/kg, respectively, for Cucumbers.

The Meeting estimated a maximum residue level of 0.07 mg/kg and an STMR and HR of 0.039 and 0.050 mg/kg, respectively, for Summer squashes.

#### *Melons, pumpkins and winter squashes*

Residue trials, performed in Brazil (melon) and the USA (melon and winter squash) were submitted. Residue levels (parent only) approximating the critical GAP in ranked order were:

Melon (n = 8): < 0.01, 0.012, 0.017, 0.017, 0.019, 0.021, 0.022, and 0.024 mg/kg mg/kg.

Winter squash (n = 5): < 0.01, < 0.01, 0.011, 0.022, and 0.037 mg/kg.

Medians are within 5× difference. Statistical analysis (Kruskal-Wallis) shows that datasets in melon and winter squash are of the same population. The Meeting decide to combine the datasets of melon and winter squash.

Residues of the combined datasets of melons and winter squash in ranked order were (n = 13): < 0.01 (3), 0.011, 0.012, 0.017, 0.017, 0.019, 0.021, 0.022, 0.022, 0.024, and 0.037 mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 13): < 0.02 (2), 0.020, 0.022, 0.022, 0.027, 0.027, 0.029, 0.031, 0.032, 0.032, 0.034, and 0.047 mg/kg (highest individual value: 0.048 mg/kg). No data were submitted on flesh only.

Melon is a representative crop for the Subgroup of Melons, Pumpkins, and Winter squashes. Based on the combined dataset of melon and winter squash (whole fruit) the Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR and HR of 0.027 and 0.048 mg/kg, respectively, for the Subgroup of Fruiting vegetables, Cucurbits – Melons, Pumpkins and Winter squashes.

#### *Fruiting vegetables, other than cucurbits*

The Canadian GAP for afidopyropen on fruiting vegetables, other than cucurbits is for up to four foliar applications at a maximum rate of 50 g ai/ha per application, but with a maximum seasonal rate of 125

g ai/ha, with an interval of 7 days and a PHI of 0 days. The Meeting assumed that 1 application at 25 g ai/ha, followed by 2 applications at 50 g ai/ha each is the critical GAP. Trials using two foliar applications each at 12.5 g ai/ha, followed by two applications each at 50 g ai/ha, an RTI of 7 days and a PHI of 0 days, were considered to approximate GAP, since the first applications applied 21 to 14 days before harvest do not contribute more than 25% to the final residues at harvest. The Meeting concluded that the residue trials are within 25% of the GAP.

### *Tomatoes*

Residue trials, performed in Brazil and the USA approximating the Canadian GAP, were submitted on tomatoes. Residue levels (parent only) in tomatoes, including cherry tomatoes [CT] in ranked order were (n = 28): < 0.01 (3), 0.011, 0.012, 0.012, 0.013, 0.014, 0.014, 0.014, 0.018<sup>[CT]</sup>, 0.018, 0.019, 0.020, 0.020, 0.020, 0.020, 0.023, 0.024, 0.035, 0.038, 0.040<sup>[CT]</sup>, 0.040, 0.046, 0.068, 0.071<sup>[CT]</sup>, and 0.097 mg/kg (MRL: 0.15 mg/kg).

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 28): < 0.02 (3), 0.021, 0.022, 0.022, 0.023, 0.024, 0.024, 0.024, 0.028, 0.028<sup>[CT]</sup>, 0.029, 0.030, 0.030, 0.030, 0.030, 0.030, 0.033, 0.034, 0.045, 0.048, 0.050, 0.050<sup>[CT]</sup>, 0.056, 0.078, 0.091<sup>[CT]</sup>, and 0.11 mg/kg (highest individual value: 0.12 mg/kg)

Based on the dataset of tomato, the Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR and HR of 0.030 and 0.12 mg/kg, respectively, for the Subgroup of Tomatoes.

### *Peppers*

Residue trials, performed in Australia, Brazil and the USA approximating the Canadian GAP, were submitted on peppers, including chili peppers. Residue levels (parent only) in peppers, including chili peppers [CP] in ranked order were (n = 11): < 0.01, < 0.01, 0.011, 0.016, 0.022, 0.026, 0.028, 0.046, 0.046<sup>[CP]</sup>, and 0.055<sup>[CP]</sup>, and 0.059<sup>[CP]</sup> mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 11): < 0.02, < 0.02, 0.021, 0.026, 0.032, 0.036, 0.038, 0.056<sup>[CP]</sup>, 0.059, 0.073<sup>[CP]</sup> and 0.10<sup>[CP]</sup> mg/kg (highest individual value: 0.11 mg/kg)

Based on the dataset of sweet and chili peppers the Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR and HR of 0.036 and 0.11 mg/kg, respectively, for the Subgroup of Peppers, excluding martynia, okra and roselle.

Based on a drying factor of 10 the Meeting estimated a maximum residue level of 1 mg/kg and an STMR and HR 0.36 and 1.1 mg/kg, respectively, for peppers chili, dried.

### *Eggplants, Subgroup of*

The Canadian critical GAP for fruiting vegetables, other than cucurbits, also covers eggplants. The Meeting decided the data could be used to extrapolate the maximum residue level of 0.15 mg/kg and STMR and HR of 0.030 and 0.12 mg/kg, respectively, for tomatoes to the Subgroup of Eggplants.

### *Leafy vegetables*

The Canadian GAP for afidopyropen on leafy vegetables, including brassica leafy vegetables, is for up to four foliar applications at a maximum rate of 50 g ai/ha per application, but with a maximum seasonal rate of 125 g ai/ha, a RTI of 7 days and a PHI of 0 days. The Meeting assumed that 1 application at 25 g ai/ha, followed by 2 applications at 50 g ai/ha each is the critical GAP. Trials using two foliar applications each at 12.5 g ai/ha, followed by two applications each at 50 g ai/ha, an RTI of 7 days and a PHI of 0 days, were considered to approximate GAP, since the first applications applied 21 to 14 days before harvest do not contribute more than 25% to the residues at harvest. The Meeting concluded that the residue trials are within 25% of the GAP.

*Leafy greens*

Residue trials, performed in Australia and the USA, approximating the critical GAP, were submitted on lettuce (head, leaf, and cos) and on spinach. Residue levels (parent only) in ranked order were:

Lettuce, head (WWL) (n = 9): 0.014, 0.086, 0.12, 0.12, 0.16, 0.17, 0.20, 0.28, and 1.1 mg/kg.

Lettuce, leaf (n = 7): 0.17, 0.25, 0.47, 0.52, 0.70, 0.77, and 0.94 mg/kg.

Cos lettuce (n = 1): 0.42 mg/kg.

Spinach (n = 8): 0.042, 0.40, 0.42, 0.62, 0.64, 0.82, 1.0, and 1.1 mg/kg.

Medians were within 5× difference. Statistical analysis (Kruskal-Wallis) indicates that the datasets for head lettuce, leafy lettuce and cos lettuce are of the same population and that the combined lettuce data set is similar to the spinach dataset. The Meeting decided to combine the data for all lettuces and spinach. The combined residues in lettuces and spinach in ranked order were (n = 25): 0.014, 0.042, 0.042, 0.086, 0.12, 0.12, 0.16, 0.17, 0.17, 0.20, 0.25, 0.28, 0.40, 0.42, 0.47, 0.52, 0.62, 0.64, 0.70, 0.77, 0.82, 0.94, 1.0, 1.1, and 1.1 mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 25): 0.036, 0.054, 0.11, 0.15, 0.26, 0.35, 0.37, 0.43, 0.53, 0.56, 0.66, 0.68, 0.88, 1.0, 1.1, 1.2, 1.3, 1.4, 1.6, 1.8, 1.8, 1.8, 1.9, 2.0, and 2.6 mg/kg.

Head and/or leafy lettuce and spinach are representative crops for the Subgroup of Leafy greens. Based on the combined dataset for lettuce and spinach, the Meeting estimated a maximum residue level of 2 mg/kg and an STMR and HR of 0.88 and 2.6 mg/kg, respectively, for the Subgroup of Leafy greens.

*Leaves of Brassicaceae*

Residue trials, performed in Australia and the USA, approximating the critical GAP were submitted on mustard greens. Residues levels (parent only) in ranked order were (n = 7): 0.67, 1.1, 1.1, 1.3, 1.8, 1.8, and 2.7 mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 7): 1.3, 2.0, 2.4, 2.5, 2.8, 3.3 and 4.2 mg/kg (highest individual value: 4.8 mg/kg)

Noting that mustard greens is a representative crop for the Subgroup of Leaves of Brassicaceae, the Meeting estimated a maximum residue level for the Subgroup of Leaves of Brassicaceae of 5 mg/kg and an STMR and HR of 2.5 and 4.8 mg/kg, respectively.

*Soya bean, dry*

The critical GAP of afidopyropen on soya bean in the USA is two foliar applications each at a rate of 11 g ai/ha with an interval of 7 days and a PHI of 7 days.

Residue trials, performed in Canada and the USA, matched this critical GAP. Residues levels (parent only) in ranked order were (n = 23): < 0.01 (23) mg/kg.

For estimating an STMR total residues (parent + dimer) in ranked order were (n = 23): < 0.02 (23) mg/kg.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg and an STMR of 0.02 mg/kg for Soya bean (dry).

*Tuberous and corm vegetables*

The Canadian GAP for afidopyropen on tuberous and corm vegetables is for up to four foliar applications at a maximum rate of 50 g ai/ha per application, but with a maximum seasonal rate of 125 g ai/ha, an interval of 7 days and a PHI of 7 days. The Meeting assumed that 1 application at 25 g ai/ha, followed by 2 applications at 50 g ai/ha is the critical GAP. Trials using two foliar applications each at 12.5 g ai/ha, followed by two applications each at 50 g ai/ha, an RTI of 7 days and a PHI of 0 days, were considered to approximate GAP, since the first applications applied 28 to 21 days before harvest

do not contribute more than 25% to the residues at harvest. The Meeting concluded that the residue trials are within 25% of the GAP.

Field residue trials in potatoes, performed in Canada and the USA, approximated the critical GAP. Residue levels (parent only) in ranked order were (n = 23): < 0.01 (23) mg/kg.

For estimating STMRs and HRs total residues (parent + dimer) in ranked order were (n = 23): < 0.02 (23) mg/kg. In three trials using exaggerated application rates (5×GAP) residues were < 0.02 mg/kg.

Noting that potato is a representative crop for the Subgroup of Tuberous and corm vegetables, the Meeting estimated a maximum residue level of 0.01(\*) mg/kg and an STMR and HR of 0 and 0 mg/kg, respectively, for the Subgroup of Tuberous and corm vegetables.

### *Stems and petioles subgroup*

The critical GAP for afidopyropen for the subgroup of stems and petioles is from Canada which allows up to four foliar applications at a maximum rate of 50 g ai/ha per application, and with a seasonal maximum of 125 g ai/ha, a retreatment interval of 7 days and a PHI of 0 days. The Meeting assumed that 1 application at 25 g ai/ha, followed by 2 applications at 50 g ai/ha is the critical GAP. Trials using two foliar applications each at 12.5 g ai/ha, followed by two applications each at 50 g ai/ha, an RTI of 7 days and a PHI of 0 days, were considered to approximate GAP, since the first applications applied 21 to 14 days before harvest do not contribute more than 25% to the residues at harvest. The Meeting concluded that the residue trials are within 25% of the GAP.

In the trials on celery from the USA approximating this GAP residue levels (parent only) in ranked order were (n = 9): 0.027, 0.13, 0.13, 0.28, 0.42, 0.52, 0.92, 1.0, and 1.6 mg/kg.

When assessing the total residue (parent + dimer) for estimating STMR and HR residues in ranked order were (n = 9): 0.064, 0.22, 0.24, 0.31, 0.54, 0.57, 0.97, 1.1, and 1.9 mg/kg (highest individual value: 2.2 mg/kg).

Noting that celery is a representative commodity for the Subgroup of Stems and Petioles, the Meeting estimated a maximum residue level of 3 mg/kg (parent only) and an STMR and HR of 0.54 and 2.2 mg/kg, respectively, (parent + dimer) for the Subgroup of Stems and Petioles.

### *Tree nuts*

The critical GAP for afidopyropen on tree nuts is the US GAP with two foliar applications each at a maximum rate of 11 g ai/ha, with an interval of 7 days and a PHI of 7 days.

A total of 13 field residue trials (almonds (5), pecan (5) and pistachio (3)), performed in Canada and the USA, matched this GAP. Residue levels (parent only) in ranked order were:

Almond nutmeat (n = 5): < 0.01 (5) mg/kg

Pecan nutmeat (n = 5): < 0.01 (5) mg/kg

Pistachio nutmeat (n = 3): < 0.01 (3) mg/kg

The Meeting considered the combined dataset for almond, pecan and pistachio as representative for the tree nut group. Residues of the combined dataset is (n = 13) were: < 0.01 mg/kg. For assessing the total residue (parent + dimer) for estimation STMR and HR, residues in the combined dataset in ranked order were (n = 13): < 0.02 mg/kg

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg and an STMR and HR of 0.02 and 0.02 mg/kg, respectively, for the Group of Tree nuts.

### *Cottonseed*

The critical GAP for afidopyropen on cotton is from the US GAP with two foliar applications each at a maximum rate of 51 g ai/ha, with an interval of 7 days and a PHI of 7 days.

Field residue trials on cotton, performed in Australia and the USA, approximated the critical GAP. Residue levels (parent only) in ranked order were (n = 15): < 0.01 (10), 0.01, 0.02, 0.03, 0.03, and 0.06 mg/kg.

Residues levels (parent + dimer) for estimating STMR and HR in ranked order were (n = 15): < 0.02 (10), 0.02, 0.03, 0.04, 0.04, and 0.11 mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.02 mg/kg for Cotton seeds.

### *Herbs*

The critical GAP of afidopyropen on several leafy herbs (cilantro/coriander, dill, and parsley) is the Canadian GAP which allows up to four foliar applications at a maximum rate of 50 g ai/ha per application, but with a maximum seasonal rate of 125 g ai/ha, an interval of 7 days and a PHI of 0 days.

No field residue trials with herbs were submitted. The critical GAP for herbs is similar to the GAP for leafy vegetables from Canada. Data were available for leaf lettuce, spinach, and mustard greens. Residues are expected to be high in herbs and the Meeting considered mustard greens to be more representative for herbs. The Meeting therefore decided to extrapolate the maximum residue level of 5 mg/kg and an STMR and HR of 2.5 and 4.8 mg/kg, respectively, for the Subgroup of Leaves of Brassicaceae based on the dataset of mustard greens to Coriander, leaves, Dill, leaves, and Parsley, leaves.

### *Spices, Root or rhizome*

The critical GAP for afidopyropen on ginger rhizome and turmeric root is from the US GAP consisting of two foliar applications at a maximum rate of 50 g ai/ha per application, a RTI of 7 days and a PHI of 7 days.

No field residue trials with ginger rhizome or turmeric root were submitted. Potato is a representative of the group of Root and tuber vegetables, but is not a very suitable crop for extrapolation to ginger rhizome or turmeric root. However, the information available suggests that afidopyropen is not prone to systemic uptake and the levels observed in potato tubers are below LOQ. Since residue trials on potatoes with exaggerated applications rates ( $6.25 \times$  GAP of ginger rhizome and turmeric root) did not lead to residues in potato tuber, the Meeting decided to extrapolate the maximum residue level of 0.01\* mg/kg, and STMR and HR of 0 mg/kg each of potato to Ginger, rhizome and Turmeric root.

### *Animal feeds*

The Meeting received data on animal feeds, including field residue data on soya bean forage and hay, almond hulls and cotton gin by-products. Since all labels on soya bean include feeding restrictions, these data were not further considered.

#### *Almond hulls*

The same trials as for almond (nutmeat) were considered for almond hulls. Five trials on almonds matched the critical US GAP on tree nuts (2 foliar applications each at 11 ga i/ha, RTI 7 days and PHI 7 days).

Residue levels (parent only) in ranked order were (n = 5): 0.030, 0.039, 0.054, 0.058, and 0.072 mg/kg.

Residue levels (parent only) corrected for percentage dry matter in ranked order were (n = 5): 0.089, 0.11, 0.19, 0.20, 0.34 mg/kg.

Total residue levels (parent + dimer) in ranked order were (n = 5): 0.040, 0.049, 0.064, 0.068, and 0.082 mg/kg. Corrected for percentage dry weight, residues in ranked order were (n = 5): 0.11, 0.15, 0.23, 0.24, and 0.38 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg (dry weight) and a median residue of 0.064 mg/kg (as received) for afidopyropen in almond hulls, respectively.

### *Cotton gin trash*

The same trials as for cotton seed were considered for cotton gin by-products. Six trials approximated the critical US GAP on oilseeds (2 foliar applications each at 51 g ai/ha, RTI 7 days and PHI 7 days).

Residues (parent only) in ranked order were (n = 6): 0.15, 0.31, 0.46, 0.54, 0.60, and 0.69 mg/kg.

Total residues levels (parent + dimer) in ranked order were (n = 6): 0.21, 0.33, 0.63, 0.67, 0.91, and 1.0 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg and a median and highest residue of 0.65 mg/kg and 1.0 mg/kg (parent + dimer), respectively, in cotton gin trash.

### ***Fate of residues during processing***

#### *High temperature hydrolysis*

The Meeting noted that in an environmental hydrolysis study afidopyropen was shown to degrade at pH 9 with a DT<sub>50</sub> of 9.8 days at 50 °C. Three major (> 10% AR) degradation products were identified, being nicotinic acid (22% AR), and the metabolites M001 (47% AR) and M002 (14% AR).

The degradation of [CPCA-<sup>14</sup>C]-labelled afidopyropen was studied under hydrolytic conditions at high temperatures in sterile aqueous buffers at pH 4, 5 and 6 for periods up to 60 minutes (20 minutes for pH 4 and 6) so as to simulate common processing practice (pasteurisation, baking/brewing/boiling and sterilisation). No degradation was observed at any of the investigated pH and temperature ranges.

The Meeting concluded that afidopyropen is stable under hydrolytic conditions at pH 4–6, but may degrade at pH 9.

#### *Residues in processed commodities*

The fate of total afidopyropen residues after processing has been examined in oranges, apples, plums, tomatoes, potatoes, soya bean and cotton. For soya bean, potato and plum processed fractions no reliable PFs can be calculated, since the RAC contained residues <LOQ. The estimated processing factors derived from processing studies with incurred residues in combination with the estimated maximum residue levels and STMRs from supervised trials proposed STMR-Ps and median-P residues are summarized in the table below. MRLs in processed commodities are only proposed where they are higher than the MRL in the raw commodity. For estimation of the STMR-P the processing factors are based on parent + dimer. For MRL derivation the processing factors are based on parent only. The Meeting concluded that the processing factors based on orange data can be extrapolated to other processed citrus commodities (citrus juice, citrus oil, citrus pulp and peel of lemon).

Table 5 Estimated processing factors for the commodities considered at this Meeting

Commodities	PF <sub>ENF</sub> (parent only) individual results <sup>a</sup>	PF <sub>ENF</sub> (parent only) median or best estimate <sub>a, b</sub>	PF <sub>DRA</sub> (parent + dimer) individual results <sup>a</sup>	PF <sub>DRA</sub> (parent + dimer) median or best estimate <sub>a, b</sub>	STMR-P (STMR × PF <sub>DRA</sub> )	HR-P (HR × PF <sub>DRA</sub> )
<b>Citrus (based on oranges): STMR (parent + dimer): 0.0535 mg/kg (citrus); HR (parent + dimer): 0.086 mg/kg</b>						
- raw citrus juice	< 0.01, < 0.01, < 0.12	< 0.01	< 0.13, < 0.22, 0.23	0.23	0.012	
- citrus wet pomace	0.44, 0.53, 0.58	0.53	0.40, 0.58, 0.62	0.58	0.031	
- citrus dried pomace	1.9, 2.5, 2.9	2.5	1.7, 2.4, 2.7	2.4	0.13	
- citrus peel, fresh	1.0, 1.9, 2.0	1.9	0.92, 1.8, 1.9	1.8	0.096	0.15
- citrus oil	4.2, 4.6, 7.7	4.6	3.96, 4.2, 6.4	4.2	0.22	
- citrus marmalade	0.1, < 0.12,	0.1	0.14, 0.22, < 0.23	0.22	0.012	

Commodities	PF <sub>ENF</sub> (parent only) individual results <sup>a</sup>	PF <sub>ENF</sub> (parent only) median or best estimate <sub>a, b</sub>	PF <sub>DRA</sub> (parent + dimer) individual results <sup>a</sup>	PF <sub>DRA</sub> (parent + dimer) median or best estimate <sub>a, b</sub>	STMR-P (STMR × PF <sub>DRA</sub> )	HR-P (HR × PF <sub>DRA</sub> )
	< 0.13					
<b>Apples (STMR (parent + dimer): 0.021 mg/kg) and HR (Parent + dimer): 0.029 mg/kg</b>						
- apple sauce	< 0.46, < 0.95	< 0.46	< 0.64, < 0.80	< 0.64	0.013	
- dried apple (peeled)	< 0.46, < 0.95	< 0.46	< 0.64, < 0.80	< 0.64	0.013	0.019
- canned apple	< 0.46, < 0.95	< 0.46	< 0.64, < 0.80	< 0.64	0.013	
- apple wet pomace	3.9, 4.84	4.8	3.8, 4.0	4.0	0.084	
- pasteurized apple juice	< 0.46, < 0.95	< 0.46	< 0.64, < 0.80	< 0.64	0.013	
- dried apple pomace	6.4, 7.0	7.0	5.2, 5.2	5.2	0.11	
<b>Tomatoes: STMR (parent + dimer): 0.030 mg/kg and HR (Parent + dimer): 0.12 mg/kg</b>						
- canned, peeled tomato	0.075, < 0.099, 0.48	0.48	0.094, < 0.15, 0.54	0.54	0.016	0.065
- dried tomatoes	4.2, 4.3, 6.6	4.3	3.3, 5.8, 7.6	5.8	0.17	0.70
- tomato paste	0.21, 0.63, 0.67	0.63	0.26, 0.53, 0.69	0.53	0.016	
- tomato puree	0.13, < 0.22, 0.28	0.28	0.17, 0.24, < 0.34	0.24	0.0072	
- raw tomato juice (without peel)	0.062, < 0.099	0.062	0.085, < 0.15	0.085	0.0026	
- raw tomato juice (with peel)	< 0.22	-	< 0.34	-	-	
- tomato wet pomace	1.5, 1.8, 2.9	1.8	1.4, 1.5, 2.6	1.5	0.045	
- tomato dry pomace	13, 18, 21	18	11, 16, 19	16	0.48	
<b>Cotton (STMR (parent + dimer): 0.02 mg/kg)</b>						
- cotton seed hulls	0.14, 0.77	0.77	0.19, 0.92	0.92	0.018	
- cotton seed meal	< 0.14, 0.23	0.23	< 0.19, 0.26	0.26	0.0052	
- oil (refined cotton oil)	< 0.076, < 0.14	< 0.076	< 0.063, < 0.19	< 0.063	0.0013	

<sup>a</sup> PFs based on afidopyropen are used for maximum residue level estimation; HR-P and STMR-Ps are used for the long-term and short-term dietary exposure estimates and for dietary burden calculations and are based on the residue definition for dietary risk assessment.

<sup>b</sup> For setting the PF either the median was used if  $n \geq 3$ , or the best estimate if  $n = 2$ . Where finite values were available, they were given preference over “< values”.

Using the maximum residue level estimate for the raw agricultural commodity (RAC) and the processing factors based on parent only, the Meeting estimated maximum residue levels of:

0.7 mg/kg (maximum residue levels <sub>tomatoes</sub> of  $0.15 \text{ mg/kg} \times 4.3 = 0.64 \text{ mg/kg}$ ) for Tomatoes, dried,

0.7 mg/kg (maximum residue levels <sub>citrus</sub>  $0.15 \text{ mg/kg} \times 4.6 = 0.69 \text{ mg/kg}$ ) for Citrus oil, edible,

0.4 mg/kg (maximum residue levels <sub>citrus</sub>  $0.15 \text{ mg/kg} \times 2.5 = 0.375 \text{ mg/kg}$ ) for Citrus pulp, dry

0.02 mg/kg (maximum residue levels <sub>pome fruit</sub> of  $0.03 \text{ mg/kg} \times 0.46 = 0.014 \text{ mg/kg}$ ) for Apple, dried

## Residues in animal commodities

### Farm animal feeding studies

The Meeting received feeding studies involving afidopyropen in lactating cows and laying hens.

Afidopyropen was fed via the diet to three to six lactating cows per dose group for 29 consecutive days. The animals received equivalents of 1.54, 4.61, or 15.34 ppm of afidopyropen in the diet (dry feed). Residues of parent, M001, M003 (tissues only), M005 (milk only) and CPCA-carnitine were determined. Tissues and milk were not analysed for M017. Total residues were calculated as indicated in the table below.

Table 6 Example of addition of residues for total residue calculations in the livestock feeding studies

Parent		M001		CPCA(-carnitine)		Sum
reported	corrected <sup>a</sup>	reported	corrected <sup>a</sup>	reported	corrected <sup>a</sup>	
Tissues						
< 0.01	< 0.01	< 0.01	< 0.012	< 0.05	< 0.11	< 0.13
0.01	0.01	< 0.01	0.012	< 0.05	0.11	0.13
0.01	0.01 0.012 liver <sup>b</sup>	< 0.01	0.012	0.05	0.11 × 5.1 liver <sup>c</sup> × 12 kidney <sup>c</sup>	0.13 <sup>d</sup> 0.58 liver 1.3 kidney
Milk						
< 0.001	< 0.001	< 0.001	< 0.0012	< 0.005	< 0.011	< 0.013
0.001	0.001	< 0.001	0.0012	< 0.005	0.011	0.013

<sup>a</sup> Corrections based on the molecular weight differences (parent = 593.67, M001 = 457.52, M017 = 609.7; CPCA-carnitine = 265.74)

<sup>b</sup> M017 was not measured in the dairy feeding study. Detectable levels of parent in liver in the dairy feeding study they were corrected using a correction factor of 1.2 applied to parent (based on metabolism study (3.7% TRR M017 versus 18% TRR of parent).

<sup>c</sup> CPCA is a major compound in liver and kidney, rather than CPCA-carnitine that is found in muscle and milk. A correction factor should be applied to account for that (6.9% TRR of CPCA-carnitine versus 28%. TRR of CPCA in liver and 5.8% TRR CPCA-carnitine versus 64% TRR of CPCA in kidney)

<sup>d</sup> All tissues and eggs, except liver and kidney.

M003 and M005 were not observed in any of the samples. Parent and metabolite M001 were found in liver samples only. CPCA-carnitine was detected only in muscle and milk at the mid- and high-dose levels. CPCA-carnitine levels in milk from the 4.6 and 14.5 ppm feeding level reached plateau levels within 4–7 days of consecutive dosing and declined rapidly, from 0.020 mg/kg to < 0.005 mg/kg (14.5 ppm group) after cessation of the dosing.

The residue pattern observed in the different tissues and milk are summarized in the table below.

Table 7 Overview of mean and highest residue levels observed in the dietary feeding study with lactating cows

	1.54 ppm		4.61 ppm		15.3 ppm	
	parent	Total <sup>a</sup>	parent	Total <sup>a</sup>	parent	Total <sup>a</sup>
Liver	0.017 (0.019)	0.15 (0.15)	0.046 (0.056)	0.18 (0.19)	0.19 (0.20)	0.36 (0.37)
Kidney	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)
Muscle	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	0.15 (0.17)	< 0.01 (< 0.01)	0.29 (0.29)



	1.54 ppm		4.61 ppm		15.3 ppm	
	parent	Total <sup>a</sup>	parent	Total <sup>a</sup>	parent	Total <sup>a</sup>
Fat	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)
Milk	< 0.001 (< 0.001)	< 0.013 (< 0.013)	< 0.001 (< 0.001)	0.016 (0.020)	< 0.001 (< 0.001)	0.035 (0.044)

<sup>a</sup> Total residues include parent+M001+CPCA-carnitine, corrected for their respective molecular weights (parent = 593.67, M001 = 457.52, CPCA-carnitine =265.74). In liver residue levels of parent were corrected for M017 using a correction factor of 1.2.

In a feeding study in laying hens three to six hens/treatment group were dosed with afidopyropen for 29 days, at feeding levels equivalent to 0.20, 0.62, and 2.0 ppm afidopyropen in the diet. Residues of parent and metabolites M001, M003, M017 (liver only), and CPCA-carnitine were determined.

Residues established in the feeding study include parent (for maximum residue level estimation) or total residues including parent + M001 + CPCA-carnitine + M017 (liver) for STMR and HR estimation. Mean and highest levels of parent and total residues are given in Table 8.

Residues of afidopyropen in all tissues and eggs were <LOQ within 5 days of cessation of the dosing.

Table 8 Overview of mean (and highest) residue levels observed in the dietary feeding study with laying hens

	0.20 ppm		0.62 ppm		2.0 ppm	
	parent	Total <sup>a</sup>	parent	Total <sup>a</sup>	parent	Total <sup>a</sup>
Liver	0.010 (0.011)	0.14 (0.15)	0.025 (0.027)	0.16 (0.17)	0.085 (0.095)	0.24 (0.28)
Muscle	< 0.01 (< 0.01)	< 0.13 (< 0.13)	< 0.01 (< 0.01)	< 0.13 (< 0.13)	0.011 (0.012)	0.14 (0.13)
Fat	< 0.01 (< 0.01)	< 0.13 (< 0.13)	0.011 (0.012)	0.14 (0.14)	0.036 (0.042)	0.16 (0.17)
Eggs	< 0.01 (< 0.01)	< 0.13 (< 0.13)	0.011 (0.018) <sup>b</sup>	0.14 (0.14)	0.026 (0.036)	0.15 (0.16)

<sup>a</sup> Total residues include parent+ M001+CPCA-carnitine (+ M017 in liver) corrected for molecular weight differences (parent = 593.67, M001 = 457.52, M017 = 609.7; CPCA-carnitine =265.74)

<sup>b</sup> Results from day 28 and 32 only.

### 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 in 2019. 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 input was based on the intake of parent + dimer M007.

Table 8 Processed and forage commodities used in estimating livestock dietary burdens

Codex classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
AM 0660	Almond hulls	0.064 (as received)	n.a.
AB 0226	Apple pomace, wet (STMR 0.021 mg/kg × PF 4.0 (n = 2))	0.084	n.a.
AM/AV	Cabbage, head (heads, leaves)	0.0865	0.43

Codex classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
AB	Citrus pulp, dry	0.13	n.a.
SM	Cotton, meal	0.0052	n.a.
SO	Cotton, undelinted seed	0.02	n.a.
SM	Cotton hulls	0.018	n.a.
AM/AV	Cotton gin trash	0.65	1.0
AV 0480	Kale forage (leaves) – based on the STMR and HR for The Subgroup of Leaves of Brassicaceae	2.5	4.8
VR	Potato culls	0	0
AB	Potato, process waste	0	n.a.
AB	Potato pulp, dry	0	n.a.
SM	Soya bean, aspirated grain fraction	0.02	n.a.
SM	Soya bean meal	0.02	n.a.
SM	Soya bean hulls	0.02	n.a.
SM	Soya bean okara	0.02	n.a.
SO	Soya bean seeds	0.02	n.a.
AB	Tomato pomace, wet (STMR of 0.030 × PF 1.5 (n = 3))	0.045	n.a.

n.a. = not applicable

The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual<sup>5</sup>, are presented in Annex 6 and summarized below.

<sup>5</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

Table 9 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: parent + dimer, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	0.054	0.073	6.45	3.38	0.076	0.076	0.014	0.014
Dairy cattle	0.033	0.033	6.44	3.34	12.9 <sup>a</sup>	6.7 <sup>b</sup>	0.013	0.013
Poultry – broiler	0.005	0.005	0.009	0.009	0.005	0.005	0.008	0.008
Poultry – layer	0.005	0.005	0.15 <sup>c</sup>	0.034 <sup>d</sup>	0.005	0.005	0.007	0.007

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues and milk.

<sup>b</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues and milk.

<sup>c</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues and poultry eggs.

<sup>d</sup> 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 12.9 ppm and 6.7 ppm for estimating residue levels in milk and ruminant tissues.

For poultry commodities, the calculated dry weight maximum dietary burden is 0.15 and the calculated mean dietary burden is 0.034 ppm dry weight in feed.

### Animal commodity maximum residue levels

#### Cattle

The calculations used to estimate maximum residue levels, STMR and HR values for cattle matrices are shown below.

Table 10 Anticipated residues of afidopyropen 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 + M001+ CPCA-carnitine + M017 (liver only)							
Feeding Study	4.61	0.016	4.61	0.17	0.19	< 0.13	< 0.13
	15.3	0.035	15.3	0.29	0.38	< 0.13	< 0.13
Dietary burden and estimate of highest residue	12.9	0.031	12.9	0.26	0.34	< 0.13	< 0.13
STMR Determination (beef or dairy cattle) - Parent + M001 + CPCA-carnitine + M017 (liver only)							
Feeding Study	4.61	0.016	4.61	0.15	0.18	< 0.13	< 0.13
	15.3	0.035	15.3	0.29	0.36	< 0.13	< 0.13
Dietary burden and estimate of median residue	6.7	0.020	6.7	0.18	0.22	< 0.13	< 0.13
MRL Determination (beef or dairy cattle) - Parent							
Feeding Study	4.61	< 0.001	4.61	< 0.01	0.056	< 0.01	< 0.01
	15.3	< 0.001	15.3	< 0.01	0.20	< 0.01	< 0.01
Dietary burden and estimate of highest residue	12.9	< 0.001	12.9	< 0.01	0.17	< 0.01	< 0.01

The Meeting estimated maximum residue levels of 0.001(\*) mg/kg in milk, 0.01(\*) mg/kg in meat (mammalian except marine mammals) and mammalian fats, and 0.2 mg/kg in edible offal (based on liver).

For estimating dietary exposure calculated HR values are: 0.34 mg/kg for edible offal (based on liver), 0.26 mg/kg for muscle, and 0.13 mg/kg for kidney and fat. Calculated STMRs are: 0.22 mg/kg

edible offal (based on liver), 0.18 mg/kg for muscle, 0.13 mg/kg for kidney and fat, and 0.020 mg/kg for milk.

### Poultry

The calculations used to estimate maximum residue levels, STMR and HR values for poultry matrices are shown below.

Table 11 Anticipated residues of afidopyropen in poultry commodities

	Feed Level (ppm) for egg residues	Total residues (mg eq/kg) in egg	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)		
				Muscle	Liver	Fat
HR Determination (poultry broiler or layer) - Parent + M001+ CPCA-carnitine + M017 (liver only)						
Feeding Study	0.2	< 0.13	0.2	< 0.13	0.15	< 0.13
Dietary burden and estimate of highest residue	0.15	0.098	0.15	0.098	0.11	0.098
STMR Determination (poultry broiler or layer) – Parent + M001+ CPCA-carnitine + M017 (liver only)						
Feeding Study	0.2	< 0.13	0.2	< 0.13	0.14	< 0.13
Dietary burden and estimate of median residue	0.034	0.022	0.034	0.022	0.024	0.022
MRL Estimation (poultry broiler of layer) – Parent only						
Feeding Study	0.2	< 0.01	0.2	< 0.01	0.011	< 0.01
Dietary burden and estimate of highest residue	0.15	0.0075	0.15	0.0075	0.0083	0.0075

The Meeting estimated maximum residue levels of 0.01(\*) mg/kg in poultry meat (muscle), poultry fat, poultry edible offal, and eggs.

For estimating dietary exposure calculated HR values are: 0.11 mg/kg for poultry edible offal (based on liver), and 0.098 mg/kg for muscle, fat and eggs. Calculated STMRs are: 0.024 mg/kg for liver and poultry edible offal (based on liver), and 0.022 mg/kg for muscle, fat, and eggs.

## 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 levels and for IEDI and IESTI assessment.

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

Definition of the residue for dietary risk assessment for plant commodities: sum of afidopyropen + dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyran[3,4-e]pyran-4-yl]methyl rac-cyclopropanecarboxylate (M007), expressed as afidopyropen.

Definition of the residue for compliance with the MRL for animal commodities: afidopyropen

Definition of the residue for dietary risk assessment for animal commodities, excluding liver: afidopyropen + (3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a, 12b-trimethyl--9-(pyridin-3-yl)-1, 3,4,4a,5,6,6a,12, 12a,12b-decahydro-2H,11H-benzo- [f] pyrano[4,3-b]chromen-11-one (M001) + Cyclopropane carboxylic acid (CPCA/M061) and (2R)-3-carboxy-2-[(cyclopropylcarbonyl)oxy]- N, N, N-trimethylpropan-1- aminium chloride (CPCA-carnitine conjugate/M060) , expressed as afidopyropen

Definition of the residue for dietary risk assessment for animal commodities, liver: afidopyropen + (3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a, 12b-

*trimethyl-9-(pyridin-3-yl)-1, 3,4,4a,5,6,6a,12, 12a,12b-decahydro-2H,11H-benzo- [f] pyrano[4,3-b]chromen-11-one (M001) + Cyclopropane carboxylic acid (CPCA/M061) and (2R)-3-carboxy-2-[(cyclopropylcarbonyl)oxy]- N, N, N-trimethylpropan-1- aminium chloride (CPCA-carnitine conjugate/M060) + [(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-3-(cyclopropylcarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-9-(1-oxidopyridin-3-yl)-11-oxo-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H, 11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropane-carboxylate (M017) , expressed as afidopyropen.*

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

### **Long-term dietary exposure**

The ADI for afidopyropen is 0–0.08 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for afidopyropen 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 2019 JMPR Report.

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

### **Acute dietary exposure**

The ARfD for afidopyropen is 0.2 mg/kg bw for women of childbearing age and 0.3 mg/kg bw for adults and children. The International Estimate of Short Term Intakes (IESTIs) for afidopyropen 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 2019 JMPR Report.

The IESTIs were 0–80% of the ARfD for women of childbearing age and 0–100% of the ARfD for children and 0–50% of the ARfD for adults. The Meeting concluded that acute dietary exposure to residues of afidopyropen from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.3 Benzovindiflupyr (261)

### RESIDUE AND ANALYTICAL ASPECTS

Benzovindiflupyr is a broad-spectrum fungicide first evaluated by JMPR in 2013 (Toxicology) and 2014 (Residues). The toxicological review established an acceptable daily intake (ADI) of 0–0.05 mg/kg bw and an acute reference dose (ARfD) of 0.1 mg/kg bw. The definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities is *benzovindiflupyr*. The residue is fat-soluble.

In 2016 the JMPR evaluated the compound for residues and recommended a number of maximum residue levels.

At the Fiftieth Session of the CCPR, benzovindiflupyr was scheduled for evaluation of additional uses by the 2019 JMPR

The current Meeting received additional analytical methods, GAP information and residue trial data from uses on bulb onion, green onion and sugar cane and processing data for sugar cane

#### **Analytical methods**

The Meeting received additional validation information on analytical methods evaluated by the 2014 JMPR for benzovindiflupyr and metabolite SYN546039 in bulb and green onion, as well as in sugar cane, refined sugar and molasses.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure benzovindiflupyr and metabolite SYN546039 in bulb and green onion, as well as in sugar cane, refined sugar and molasses.

#### **Results of supervised residue trials on crops**

Supervised trials were available for the use of benzovindiflupyr on bulb and green onion and sugar cane.

#### **Bulb vegetables**

The critical GAP for the use on bulb vegetables in the USA allows for 4 foliar applications at a rate of 76 g ai/ha with a 7 day interval between applications and a 7 day PHI.

##### ***Bulb onion***

In independent field trials with bulb onion from Canada and the USA, residues of benzovindiflupyr following GAP treatment ( $\pm 25\%$ ) were (n = 8): < 0.01(5), 0.011, 0.012 and 0.015 mg/kg.

The Meeting estimated a maximum residue level of 0.02 mg/kg, a STMR of 0.01 mg/kg and a HR of 0.015 mg/kg for benzovindiflupyr in bulb onion (extrapolated to subgroup 009A).

##### ***Green onion***

In independent field trials on green onion from Canada and the USA, residues of benzovindiflupyr following GAP treatment ( $\pm 25\%$ ) were (n = 3): 0.11, 0.16 and 0.20 mg/kg.

The Meeting noted that green onions fall under category 3 of the minor crop classification, requiring a minimum of five supervised field trials to estimate maximum residue levels. Hence, the Meeting concluded that no maximum residue level could be estimated for benzovindiflupyr in green onion.

### *Grasses for sugar or syrup production*

#### *Sugar cane*

Sugar cane was previously evaluated by the 2016 JMPR when a maximum residue level of 0.04 mg/kg was recommended based on a GAP from Brazil.

The Meeting received a more critical GAP for the use of benzovindiflupyr on sugar cane in the USA, allowing for 3 foliar applications at a rate of 76 g ai/ha with a 14 day interval between applications and a 30 day PHI.

In field trials on sugar cane from the USA, residues of benzovindiflupyr following GAP treatment ( $\pm 25\%$ ) were (n = 8): 0.013, 0.031, 0.062, 0.068, 0.070, 0.13, 0.14 and 0.21 mg/kg (highest individual value: 0.25 mg/kg).

The Meeting estimated a maximum residue level of 0.4 mg/kg, a STMR of 0.069 mg/kg and a HR of 0.25 mg/kg for benzovindiflupyr in sugar cane, to replace the previous recommendation of 0.04 mg/kg.

#### *Fate of residues during processing*

The Meeting received new information on the fate of benzovindiflupyr residues during processing in sugar cane.

Table 1 Estimated processing factors for the commodities considered at this Meeting according to the residue definition (benzovindiflupyr)

Raw commodity [STMR/HR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)
Sugar cane	Refined sugar	< 0.04, < 0.09	0.04	0.003
	Molasses	< 0.09, 0.09,	0.09	0.006

### *Residues in animal commodities*

#### *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 in 2014, 2016 and the current Meeting. The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO manual<sup>6</sup>, are presented in Annex 6.

Previous evaluations included the following potential feed items: cereal (barley, oat, rye, triticale, wheat) forage, straw and grain, pea vines and seeds, peanut hay and meal, sugar cane tops, molasses and bagasse, potatoes, beans seeds, soya bean seeds and processing fractions (aspirated grain fraction, meal, hulls, okara, pollard), apple pomace, canola meal, grape pomace and tomato pomace. Additionally, the current Meeting considered higher STMRs for sugar cane tops and molasses.

Residues of benzovindiflupyr in the crops considered by the current Meeting do not significantly increase the livestock dietary burden of a maximum of 15 ppm for beef cattle, 14 ppm for dairy cattle and 2.1 ppm for laying hens using the 2018 update of the OECD Feed Calculator, and do not have an impact on the previous recommendations for residues in animal commodities made by the 2016 JMPR.

<sup>6</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>



## 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 and for dietary risk assessment for plant and animal commodities: *benzovindiflupyr*.

The residue is fat soluble

## DIETARY RISK ASSESSMENT

### ***Long-term dietary exposure***

The ADI for benzovindiflupyr is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for benzovindiflupyr 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 2019 JMPR Report.

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

### ***Acute dietary exposure***

The ARfD for benzovindiflupyr is 0.1 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for benzovindiflupyr 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 2019 JMPR Report.

The IESTIs varied from 0–1% of the ARfD for children and 0–2% of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of benzovindiflupyr from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.4 Bifenthrin (178)

### RESIDUE AND ANALYTICAL ASPECTS

Bifenthrin is a pyrethroid insecticide and miticide. It was first evaluated for residues and toxicology by the JMPR in 1992 and re-evaluated in 2009 (T), 2010 (R) and 2015 (R).

An ADI of 0–0.01 mg/kg bw and an ARfD of 0.01 mg/kg bw was established by the 2009 JMPR. The residue definition for compliance with MRLs and for estimation of dietary intake (for animal and plant commodities) is bifenthrin (sum of isomers). The residue is fat-soluble.

At the Fiftieth Session of the CCPR (2018), bifenthrin was scheduled for evaluation of additional uses. The current Meeting received new residues data and GAP information for mango, cucumber, okra and barley. In addition, new GAP information was provided for strawberry.

#### **Methods of Analysis**

Residues were determined in the crops using several different analytical methods. In general, the data generation methods considered by this Meeting involved extraction with either acetone or ethyl acetate. Final determination was achieved using GC-MS, GC-MS/MS or GC-ECD. The validated LOQs for okra and barley grain were 0.01 mg/kg. For cucumber the validated LOQ was 0.1 mg/kg. For mango the validated LOQs for the different methods used ranged from 0.02–0.1 mg/kg.

The meeting concluded that suitable methods are available for the determination of bifenthrin in mango, cucumber, okra and barley.

#### **Stability of residues in stored analytical samples**

The 2010 and 2015 JMPR concluded that residues of bifenthrin were stable for at least 18 months when stored at  $\leq -18$  °C (high acid), 49 months (high water), 36 months (high oil), 36 months (high starch) and 15 months (high protein).

The Meeting agreed that the new storage stability data for head cabbage, barley grain and barley straw confirms the stability of bifenthrin when stored at  $\leq -18$  °C. The Meeting concluded that the new storage data for cucumber and okra were of limited use owing to missing information in the studies.

The overall data were sufficient to support the storage intervals in the residue trials.

#### **Results of supervised residue trials on crops**

The meeting received residue trial data and GAP information for strawberry, mango, cucumber, okra and barley.

##### **Strawberry**

A new GAP was provided for strawberry. The GAP is for the USA and involves four applications of 0.11 kg ai/ha with a PHI of 3 days.

The Meeting received information that confirmed that the more critical use considered by the 2010 JMPR is still authorized in the USA. The application rate is 0.045–0.22 kg ai/ha per application with a total dose not exceeding 0.56 kg ai/ha. No PHI was defined.

The Meeting confirmed its previous recommendation of a maximum residue level of 3 mg/kg, STMR of 0.46 mg/kg and a HR of 2.3 mg/kg.

The Meeting noted that the ARfD was exceeded for children (380% of the ARfD) and the general population (210% of the ARfD).

No alternative GAP was available from another country.

### *Mango*

The critical GAP for mango is in Brazil with 1 application of 0.003 kg ai/hL with a PHI of 7 days.

Trials were available from Brazil, Mali, the Philippines and Senegal. The three trials conducted in Brazil matched the GAP.

Residues in mango at a PHI of 7 days were (n = 3): < 0.02 (2) and < 0.04 mg/kg.

The Meeting concluded that three trials were insufficient to estimate a maximum residue level for mango.

### *Cucumber*

The critical GAP for cucurbits is in the USA with three applications at 110 g ai/ha with a minimum interval between applications of 7 days and a PHI of 3 days.

One trial supports the GAP.

Residues in cucumber at a PHI of 3 days from trials approximating the GAP were (n = 1): < 0.1 mg/kg.

The Meeting concluded that one trial is insufficient to estimate a maximum residue level for cucumber.

### *Okra*

The critical GAP for okra is in the USA with two applications at 110 g ai/ha, an interval between applications of 7 days and a PHI of 7 days.

The residue trials evaluated by the 2010 JMPR do not reflect the GAP. However, the Meeting agreed that three of the trials could be scaled to the GAP using the proportionality principle.

The unscaled residues in okra at a PHI of 7 days were (n = 3): 0.01, 0.02 and 0.04 mg/kg.

The scaled residues (scaling factor of 2.75) in okra at a PHI of 7 days (in rank order) were (n = 3): 0.028, 0.055, 0.11 mg/kg

The Meeting agreed that three trials were insufficient to estimate a maximum residue level for okra.

The GAP in India is one application of 59 g ai/ha followed by a second application of 62 g ai/ha. The retreatment interval is not stated. The PHI is 5 days.

This Meeting received trials from India approximating the GAP.

Residues in okra at a PHI of 5 days in rank order were (n = 4): < 0.01 (2), 0.014, 0.018 mg/kg.

The Meeting concluded that four trials were insufficient to estimate a maximum residue level for okra.

### *Cereals*

The critical GAP for cereals is in Switzerland with two applications at 0.016 kg ai/ha and a PHI of 42 days.

#### *Barley*

The Meeting noted that the residue trials considered by the 2010 JMPR and the trials considered by this Meeting were conducted at a lower application rate compared to the GAP. However, the trials could be scaled using the proportionality principle, except where residues were reported as < 0.01 mg/kg. It was also noted that the PHI varied within the trials. The Meeting agreed that only trials with samples taken 40–44 DALA could be used to support the GAP. Four trials were considered to support the GAP.

The unscaled residues in barley (in rank order) were (n = 4): 0.01 and 0.02 (3) mg/kg

The scaled residues (scaling factors of 1.45–2.13) in barley were (n = 4): 0.02, 0.03 and 0.04 (2) mg/kg.

The Meeting concluded that four trials were insufficient to estimate a maximum residue level for barley.

#### *Oats, triticale and wheat*

The 2010 JMPR evaluated residue trial data on oats, triticale and wheat. Although the trials were all conducted at lower application rates compared to the GAP, the number of applications and the PHI matched the GAP for some of the trials. However, as residues were < 0.01 mg/kg scaling of the residues using the proportionality principle was not possible.

The Meeting concluded that the trials were not suitable for estimating maximum residue levels for oats, triticale and wheat.

#### *Residues in animal feed*

##### *Cereal forage*

The critical GAP for cereals is in Switzerland. Grazing of forage from cereal grain crops is not common practice in Europe and is precluded in conjunction with agricultural chemical use unless specifically allowed by label instructions. Median and highest residues for barley forage have therefore not been estimated.

##### *Cereal Straw*

The critical GAP for cereals is in Switzerland with two applications at 0.016 kg ai/ha and a PHI of 42 days.

Residue trials on barley, oats, triticale and wheat were evaluated by the 2010 JMPR. None of the trials matched the GAP. However, the Meeting agreed that the trials could be scaled using the proportionality principle. The Meeting noted that the DALA varied and the Meeting agreed that only trials with 40–44 DALA could be used to support the GAP.

Thirteen trials conducted on cereal straws support the GAP when the proportionality principle is applied.

The unscaled residues in cereal straw were (n = 13): 0.059, 0.074, 0.09, 0.11 (3), 0.12, 0.18 (2), 0.19, 0.2, 0.21 and 0.24 mg/kg (as received).

The scaled residues (scaling factors of 1.45–2.13) in cereal straw were (n = 13): 0.12, 0.15, 0.19, 0.22, 0.23 (2), 0.26, 0.28, 0.38 (2), 0.39, 0.42 and 0.45 mg/kg (as received).

The Meeting estimated a highest residue of 0.45 mg/kg (as received), a median residue of 0.26 mg/kg (as received) and a maximum residue level of 1 mg/kg (dw), using a correction factor of 90% for dry matter, for straw and fodder (dry) of cereal grains.

#### *Residues in animal commodities*

##### *Straw can be fed to livestock.*

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR. The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO manual<sup>7</sup>, are presented in Annex 6.

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<sup>7</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

The maximum total dietary burdens calculated in 2010 were 8.3 ppm (beef cattle), 7.4 ppm (dairy cattle), 0.59 ppm (poultry broiler) and 2.0 ppm (poultry layer). The maximum total dietary burdens calculated by the current Meeting using the OECD diets were 8.5 ppm (beef cattle), 7.6 ppm (dairy cattle), 0.59 (poultry broiler) and 1.5 ppm (poultry layer).

The Meeting noted that the contribution of straw to the dietary burden was less than 10% of the maximum total dietary burden estimated by the 2010 JMPR and did not change the estimated residues in milk, eggs and tissues. The Meeting therefore confirmed its previous recommendations for maximum residue levels in animal products.

### RECOMMENDATIONS

On the basis of the data 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 dietary risk assessment for plant and animal commodities: bifenthrin (sum of isomers).

The residue is fat-soluble.

### DIETARY RISK ASSESSMENT

#### ***Long-term dietary exposure***

The ADI for bifenthrin is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) of bifenthrin were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR values estimated by the JMPR in this Meeting and in 2010 and 2015. The results are shown in Annex 3 of the 2019 JMPR Report.

The IEDIs ranged from 10–40% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of bifenthrin resulting from the uses considered by the current and previous Meetings are unlikely to present a public health concern.

#### ***Acute dietary exposure***

The ARfD for bifenthrin is 0.01 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for bifenthrin were calculated for the food commodities and their processed commodities for which HRs and STMRs were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs varied from 2–380% of the ARfD for children and 1–210% of the ARfD for the general population.

The Meeting concluded that acute dietary exposure to residues of bifenthrin from the consumption of strawberry may present a public health concern.

## 5.5 Buprofezin (173)

### TOXICOLOGY

Buprofezin is the ISO-approved name for (*Z*)-2-*tert*-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one (IUPAC), CAS number 69327-76-0. Buprofezin is an insecticide that acts by the inhibition of chitin synthesis.

Buprofezin was previously evaluated by JMPR in 1991, 1999 and 2008. In 1991 an ADI of 0–0.01 mg/kg bw was established based on a NOAEL of 0.9 mg/kg bw per day identified in a two-year study in rats and with a safety factor of 100. In 1999 JMPR considered that the establishment of an ARfD was unnecessary. In 2008 the JMPR Meeting concluded on an ADI of 0–0.009 mg/kg bw, based on the same study and NOAEL as the 1991 evaluation. The 2008 JMPR established an ARfD of 0.5 mg/kg bw based on the NOAEL of 50 mg/kg bw per day for ataxia in a 13-week dog study.

Buprofezin was re-evaluated at the present Meeting at the request of CCPR to support additional MRLs and in response to a concern raised by a Codex member. This concern related to the production of aniline from residues of buprofezin during the processing of commodities. New information, not previously evaluated, included an *in vivo* gene mutation study of aniline in transgenic rats and published literature on the toxicity and carcinogenic mode of action of aniline. There were no new data submitted on buprofezin. This evaluation focuses on the available data for aniline, in particular that for carcinogenicity, genotoxicity and relevance to human exposures.

The new gene mutation study contained a statement of compliance with GLP and complied with the applicable OECD test guideline. The review used both primary sources of information and reviews from national/international organizations. The papers from the published literature did not provide evidence that they complied with GLP or national or international test guidelines.

#### ***Toxicology data on metabolites and/or degradates.***

##### ***Biochemical aspects***

Aniline is extensively absorbed when administered orally to rats (ca 90% at 50 or 250 mg/kg bw) and mice (ca 70% at 100 or 500 mg/kg bw), based on 0–24 h urine samples.

Peak plasma radioactivity levels in rats dosed with <sup>14</sup>C-aniline at 10, 30 or 100 mg/kg bw were 0.5, 1 and 2 h respectively. Following oral dosing of <sup>14</sup>C-aniline to rats, at 100 mg/kg bw for one day, the highest concentration of radiolabel was detected in erythrocytes (25 µg equiv./g), with lower levels (0.4– 4 µg equiv./g) in plasma, liver, spleen, kidney, lung and heart. Following 10 days dosing at 100 mg/kg bw per day, radioactivity in spleen was 12 times higher than after one day, other tissues had increases of 1.8- to 3.8-fold. Covalent binding of radioactivity to proteins was six times higher in the spleen than in the liver.

Excretion is rapid in rats and humans with a half-life of approximately three hours.

The metabolism of aniline is via *N*-hydroxylation, *N*-acetylation and/or hydroxylation of the phenyl ring, followed by conjugation with glucuronic acid or sulfate. The excretory pathway in rats relies extensively on sulfate conjugation, which is reported to become saturated at doses above 50 mg/kg bw. In mice, conjugation is with glucuronic acid and this pathway is reported not to become saturated. The proportion of *N*-hydroxylation or *N*-acetylation is reported to vary with species, sex and, in humans, acetylation phenotype. The *N*-hydroxy metabolite, *N*-hydroxyaniline (phenylhydroxylamine), is reported to be oxidized to nitrosobenzene in erythrocytes, leading to the production of methaemoglobin (MetHb) and a sulfuric acid amide adduct of haemoglobin.

##### ***Toxicological data***

Aniline has an LD<sub>50</sub> of 442 mg/kg bw in rats and an LC<sub>50</sub> of 1 mg/L in rats. Aniline is slightly irritating to the skin, severely irritating to the eye and exhibits skin sensitizing potential in guinea pigs and

humans.

In an eight-week range-finding study, mice received aniline hydrochloride at 0, 100, 300, 3000 or 10 000 ppm in the diet weeks (equivalent to aniline exposures of 11, 32, 324 or 1080 mg/kg bw per day). At 3000 ppm (equivalent to 324 mg/kg bw per day) and above, all mice had dark, granular and enlarged spleens. There is insufficient information to determine a NOAEL.

In an eight-week range-finding study, rats received aniline hydrochloride at 0, 100, 300, 3000 or 10 000 ppm in the diet (equivalent to aniline exposures of 7, 21, 210 or 700 mg/kg bw per day). At 3000 ppm (equivalent to 210 mg/kg bw per day) and above, all rats had dark, granular and enlarged spleens. There is insufficient information to determine a NOAEL.

In a repeat dose toxicity study, male rats received aniline hydrochloride at variable concentrations in the diet for one or four weeks to provide nominal aniline exposures of 0, 4, 12 or 40 mg/kg bw per day. The LOAEL in this study was 4 mg/kg bw per day, the lowest dose tested, based on vascular congestion of the spleen and haemoglobin (Hb) adducts.

Aspects of the repeat dose toxicity of aniline were investigated in a 28-day study of genotoxicity. Groups of transgenic Fischer 344 Big Blue<sup>®</sup> male rats were administered aniline at doses of 0, 25, 50 or 100 mg/kg bw per day, once daily via oral gavage. A NOAEL could not be determined from this study as changes in blood (increased MetHb and reticulocytes) and spleen (increased weight and iron deposition) were noted at all dose levels. The LOAEL was 25 mg/kg bw per day.

In a long-term toxicity and carcinogenicity study, mice received aniline hydrochloride at 0, 6000 or 12 000 ppm in the diet for 103 weeks followed by a four-week observation period. Doses were equivalent to aniline exposures of 600 or 1200 mg/kg bw per day. Investigation of general toxicity was limited, and a NOAEL for general toxicity could not be derived. The NOAEL for carcinogenicity was 12 000 ppm (equivalent to 1200 mg/kg bw per day), the highest dose tested.

In a long-term toxicity and carcinogenicity study, rats received aniline hydrochloride at 0, 3000 or 6000 ppm in the diet for 103 weeks followed by a four-week observation period. Doses were equivalent to aniline exposures of 105 or 210 mg/kg bw per day. Tumours of the spleen (fibrosarcoma, stromal sarcoma, haemangiosarcoma, osteogenic sarcoma) were increased in both male groups and high-dose females. The LOAEL for carcinogenicity was 3000 ppm (equivalent to 105 mg/kg bw per day) the lowest dose tested, based on increases in tumours of the spleen in males at this dose level. The LOAEL for toxicity is 3000 ppm (equivalent to 105 mg/kg bw per day) the lowest dose tested, based on papillary hyperplasia of the spleen in females. A review of the histopathology slides confirmed the carcinogenicity and general toxicity to the spleen.

In a second long-term toxicity and carcinogenicity study, in the same strain, rats received aniline hydrochloride in the diet at variable concentrations, for two years to give nominal exposures of 7, 22 or 72 mg/kg bw per day. Tumours of the spleen were increased in males in the mid- and high-dose groups, but not in females. The LOAEL for general toxicity was 7 mg/kg bw per day, based on reduced erythrocyte counts, and pathological changes in the spleen at this dose level. The NOAEL for carcinogenicity is 7 mg/kg bw per day. The Meeting calculated BMDL<sub>10</sub> values for all spleen tumours of 38.6 mg/kg bw per day and 43.4 mg/kg bw per day for stromal sarcoma of the spleen.

The Meeting concluded that aniline is not carcinogenic in mice but carcinogenic in rats.

Aniline has been investigated in a wide range of in vitro and in vivo genotoxicity studies of varying quality. It was negative in bacterial mutation assays but some positive results, with and without metabolic activation, have been reported in in vitro mammalian cell gene mutation assays and clastogenicity studies in vitro and in vivo. The most consistent finding was of clastogenicity, which was supported by colony size analysis in the mouse lymphoma gene mutation assays. Low levels of aniline-derived radioactivity binding to DNA in some organs were seen at high doses of aniline (500 mg/kg bw), possibly via the production of reactive intermediates such as *N*-hydroxyphenylamine and *p*-hydroxyacetanilide. In a 28-day study of genotoxicity, groups of transgenic Fischer 344 Big Blue<sup>®</sup> male rats were administered aniline at doses of 0, 25, 50 or 100 mg/kg bw per day, via oral gavage. A dose-related increase in micronucleated erythrocytes from the peripheral blood was seen at



four and 29 days, together with increases in erythropoiesis and numbers of reticulocytes. There was no increase in *cII* mutants in the spleen, liver or bone marrow at any dose level.

There is evidence that aniline is clastogenic in vitro and in vivo but not mutagenic in vivo.

The Meeting considered that the clastogenicity of aniline was due to a mechanism secondary to reactive oxygen production and that a threshold would apply. The Meeting concluded therefore that aniline is unlikely to be genotoxic at estimated dietary exposure levels.

### ***The mode of action for formation of spleen tumours***

The MOA behind the spleen tumours has been investigated. The meeting considered that the low level of DNA binding of aniline metabolites was unlikely to be the cause for the significant increase of spleen tumours in male rats observed at moderate doses. This is supported by absence of tumour response in other organs. A range of studies support the proposed mode of action based on redox-associated damage to erythrocytes, increase in Heinz bodies, and stimulation of erythropoiesis. The damaged erythrocytes are removed by the spleen, which leads to an increase in free iron deposition in the spleen, production of reactive oxygen species, protein oxidation and lipid peroxidation. These changes result in a progression of pathological lesions in the spleen from congestion, capsulitis, to hyperplasia and tumours. Although the available studies do not address all the tumour findings (e.g. sensitivity of male rats versus females and no splenic tumours in mice), the proposed mode of action is plausible and taken with the absence of mutations in the spleen in the in vivo gene mutation study, it supports a threshold mode of action secondary to erythrocyte damage. Humans exposed to aniline produce significant levels of MetHb (a biomarker of redox damage) therefore the mode of action is of relevance to humans.

The Meeting concluded that, based on the absence of gene mutations in the spleen and a clear threshold for splenic tumours by the established mode of action, aniline is unlikely to be carcinogenic to humans at estimated dietary exposure levels.

In a study of developmental and postnatal toxicity, rats were dosed with aniline hydrochloride by gavage at 0, 7, 21 or 70 mg/kg bw per day (as aniline) on days 7–20 of gestation. Dams were allowed to deliver naturally (up to day 24 of gestation) and then nurse the pups until PND 30. The NOAEL for maternal toxicity was 21 mg/kg bw per day, based on increases in MetHb and relative spleen weights at 70 mg/kg bw per day. The NOAEL for offspring toxicity was 7 mg/kg bw per day, based on increased pup mortality at 21 mg/kg bw per day.

In a study of developmental toxicity, rats were dosed with aniline hydrochloride by gavage at 0, 7, 21 or 70 mg/kg bw per day on days 7–20 of gestation. The LOAEL for maternal toxicity was 7 mg/kg bw per day, the lowest dose tested, based on increased relative spleen weights at this dose level. The NOAEL for embryo/fetal toxicity was 70 mg/kg bw per day, the highest dose tested.

The Meeting concluded that aniline is not teratogenic in rats.

### ***Microbiological data***

No data available.

### ***Human data***

Human volunteers received an oral dose of aniline of 5, 15, 25, 35, 45, 55 or 65 mg/person per day on three consecutive days. Volunteers exposed to 5 or 15 mg of aniline had small, not statistically significant, increases in MetHb levels (< 2%). Volunteers receiving 25 mg to 55 mg aniline had statistically significant increases in MetHb (2.5% to 7%). The volunteer receiving 65 mg of aniline had a peak MetHb level of 16% at 2 h post-dose but this had returned to normal at the 3 h sample, showing rapid recovery. The NOAEL was 15 mg/person (equivalent to 0.2 mg/kg bw per day) based on significant increases in MetHb at 25 mg/person (equivalent to 0.35 mg/kg bw per day).

The excess of bladder cancer deaths observed in clusters of cases of workers in the aniline-based dye industry has been attributed to exposure to chemicals other than aniline. Epidemiological studies of workers exposed to aniline, but not to other known bladder carcinogens, have shown little

evidence of increased risk. A mortality study of 342 men employed in the manufacture of organic dyes, in which two of the three processes involved aniline as a raw material, showed no death from bladder cancer.

### Toxicological evaluation

The Meeting established an ADI of 0–0.02 mg/kg bw on the NOAEL of 0.2 mg/kg bw per day for increases in methaemoglobin levels in a human volunteer study. As this observation was made in humans no interspecies safety factor was necessary and a safety factor of 10 was applied. There is a margin of 1100 between the upper bound of the ADI and the LOAEL for spleen tumours in the rat.

An ARfD of 0.02 mg/kg bw was established on the same basis as the ADI.

A toxicological monograph addendum was prepared.

#### Levels relevant to risk assessment of aniline

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	– <sup>b</sup>	– <sup>b</sup>
		Carcinogenicity	12 000 ppm, equivalent to 1200 mg/kg bw per day <sup>c</sup>	–
Rat	28-day oral toxicity study <sup>a</sup>	Toxicity	–	Variable ppm to give 4 mg/kg bw per day <sup>d</sup>
	Two-year studies of toxicity and carcinogenicity <sup>a</sup> ,	Toxicity	–	Variable ppm to give 7 mg/kg bw per day <sup>d</sup>
		Carcinogenicity	Variable ppm to give 7 mg/kg bw per day	Variable ppm to give 22 mg/kg bw per day
	One-generation study of developmental and post-natal toxicity	Reproductive toxicity	– <sup>b</sup>	– <sup>b</sup>
Parental toxicity		21 mg/kg bw per day	70 mg/kg bw per day	
Offspring toxicity		7 mg/kg bw per day	21 mg/kg bw per day	
Developmental toxicity study <sup>b</sup>	Maternal toxicity	–	7 mg/kg bw per day <sup>d</sup>	
	Embryo and fetal toxicity	70 mg/kg bw per day <sup>c</sup>	–	
Rabbit	No data			
Dog	No data			
Human	Three-day study of toxicity <sup>e</sup>	MetHb production	0.2 mg/kg bw per day	0.35 mg/kg bw per day

<sup>a</sup> Dietary administration

<sup>b</sup> Inadequate investigation

<sup>c</sup> Highest dose tested

<sup>d</sup> Lowest dose tested

<sup>e</sup> Gavage administration

*Acceptable daily intake (ADI) for aniline*

0–0.02 mg/kg bw

*Acute reference dose (ARfD) for aniline*

0.02 mg/kg bw

### ***Information that would be useful for the continued evaluation of aniline***

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

### ***Critical end-points for setting guidance values for exposure to aniline***

<b><i>Absorption, distribution, excretion and metabolism in mammals</i></b>	
Rate and extent of absorption	Rapid ( $T_{\max}$ 2 h) and extensive (70–90% based on urine)
Dermal absorption	No data
Distribution	Extensive; highest concentrations in RBC, liver, kidney, spleen
Potential for accumulation	High in spleen
Rate and extent of excretion	Rapid (half-life 3 h in rats, mainly in urine)
Metabolism	<i>N</i> -acetylation, <i>N</i> -hydroxylation, <i>C</i> -hydroxylation; conjugation with glucuronic acid or sulfate.
Toxicologically significant compounds in animals and plants	Aniline
<b><i>Acute toxicity</i></b>	
Rat, LD <sub>50</sub> , oral	442 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	1 mg/L
Rabbit, dermal irritation	Slight irritant
Rabbit, ocular irritation	Severe irritant
Guinea pig/human, dermal sensitization	Evidence of sensitization
<b><i>Short-term studies of toxicity</i></b>	
Target/critical effect	MetHb formation, erythrocyte damage, toxicity to spleen
Lowest relevant oral LOAEL	4 mg/kg bw per day (rats)
Lowest relevant oral NOAEL	0.2 mg/kg bw per day (humans)
<b><i>Long-term studies of toxicity and carcinogenicity</i></b>	
Target/critical effect	Carcinogenic to the spleen of rats MetHb formation, erythrocyte damage, toxicity to spleen
Lowest relevant LOAEL (toxicity)	7 mg/kg bw per day, lowest dose tested (rats)
Carcinogenicity	Unlikely to pose a carcinogenic risk to humans at estimated dietary exposure levels.
Carcinogenicity lowest NOAEL <sup>a</sup>	7 mg/kg bw per day (rats)
<b><i>Genotoxicity <sup>a</sup></i></b>	
	Clastogenic in vitro and in vivo. Not mutagenic in vivo in the spleen, liver or bone marrow. Unlikely to be genotoxic at estimated dietary exposure levels.
<b><i>Reproductive toxicity</i></b>	

Target/critical effect	Reduction of pup survival
Lowest relevant reproductive NOAEL	7 mg/kg bw per day (rats)
<b><i>Developmental toxicity</i></b>	
Target/critical effect	None
Lowest relevant NOAEL	70 mg/kg bw per day, highest dose tested (rats)
<b><i>Neurotoxicity</i></b>	
No data	
<b><i>Immunotoxicity</i></b>	
No data	
<b><i>Studies on toxicologically relevant metabolites</i></b>	
No data	
<b><i>Human data</i></b>	
NOAEL for MetHb in a three-day gavage study in volunteers is 0.2 mg/kg bw per day	
Reports of bladder cancer in workers exposed to multiple aromatic amines considered not to be related to aniline; no reports of spleen tumours	

<sup>a</sup> 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	Human volunteer	10
ARfD	0.02 mg/kg bw	Human volunteer	10

## RESIDUE AND ANALYTICAL ASPECTS

The insecticide buprofezin was first evaluated by the JMPR in 1991. It was evaluated under the Periodic Review Programme in 2008 when an ADI of 0–0.009 mg/kg bw and an ARfD of 0.5 mg/kg bw were established. Numerous residue reviews have been completed since then; the last was done in 2016. The residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities is buprofezin. The residue is not fat soluble.

Buprofezin was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 JMPR. Residue data on analytical methods, storage stability (aniline), supervised trials (tree nuts), and processed commodities (citrus, grape, apple, olive, tomato (aniline only)) were submitted to the present Meeting.

The buprofezin metabolites BF-9, BF-11, BF-12, BF-25, and BF-26 are not included in the residue definitions and, as such, results for those compounds are not further discussed.

Aniline is a breakdown product of buprofezin. However, aniline is not specific to buprofezin breakdown and exposure may come from many sources. Nevertheless, the Meeting evaluated information to assess the dietary risk from exposure to aniline coming from buprofezin.

### Methods of analysis

New information on analytical methods was provided to the Meeting for analysis of buprofezin residues in pecans as well as raw and processed orange, grape, apple, olive, and tomato commodities.

Method 52004A003 was used for the analysis of buprofezin in pecan nutmeats. Residues are extracted using acetonitrile and determined by LC-MS/MS. The Meeting concluded, based on similarity with other methods already deemed acceptable by the JMPR and on mean concurrent recovery (90% at

0.01 mg/kg and 93% at 0.1 mg/kg), that the method is suitable for the analysis of buprofezin in pecan nutmeats, with a validated LOQ of 0.01 mg/kg.

Methods used in the processing studies were LMS0022, GE-04, and NIHON/GLP/0801-1. Extraction solvents were dioxane:HCl for LMS0022, acetonitrile for GE-04, and acetonitrile, acetonitrile:water, or hexane:HCl (citrus oil only) for NIHON/GLP/0801-1. For all methods, residues were determined by LC-MS/MS. The methods were validated for analysis of buprofezin in all matrices tested to an LOQ of 0.01 mg/kg, except Method GE-04 for orange wet pomace (0.5 mg/kg) and orange oil (1 mg/kg).

The methods described for the analysis of aniline were based on the same principles. Concurrent recoveries demonstrated that the methods were suitable for the analysis of aniline in processed apple, grape, olive, and tomato commodities.

### ***Stability of residues in stored samples***

The 2009 Meeting concluded that buprofezin was stable for up to 28 months in almond nutmeat and 2.5 months in almond hulls. In residue trials evaluated by the 2009 Meeting, samples of almond nutmeats and hulls were stored frozen for up to 11 months. In studies submitted to the current Meeting, samples of pecans were stored for up to 2.8 months. The Meeting noted that almond hulls are a dry, fibrous commodity and that buprofezin was shown to be stable for at least 28 months in cereal straws. Based on the available storage stability data from almond nutmeats and cereal straws, the Meeting considered the residues in the stored analytical samples of almond and pecan nutmeat and almond hulls to be stable for the storage period incurred during the residue trials.

Residues of aniline were shown to be stable for at least 7 months in apple and grape processed commodities and at least 9 months in olive commodities.

### ***Residues in supervised residue trials on crops***

The Meeting received supervised residue trials for application of buprofezin to almonds and pecans.

#### ***Tree nuts***

The critical GAP is from the USA for tree nuts and consists of a single, broadcast application at 2.24 kg ai/ha and a PHI of 60 days.

In trials in almond approximating the US GAP, residues in nutmeats were: < 0.05 (6) mg/kg.

In trials in pecan approximating the US GAP, residues in nutmeats were: < 0.05 (5) mg/kg.

Noting that the GAP is for the tree nut group and that almonds and pecans are representative commodities, 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 residues of buprofezin in the group of tree nuts. The Meeting withdrew its previous recommendation of 0.05(\*) mg/kg for almond.

### ***Animal feeds***

#### ***Almond hulls***

The critical GAP is from the registration on tree nuts in the USA and consists of a single, broadcast application at 2.24 kg ai/ha and a PHI of 60 days.

In trials approximating the US GAP, residues in almond hulls were (n = 7): 0.06, 0.08, 0.15, 0.22 (2), 0.51, and 1.5 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg and a median residue of 0.22 mg/kg for buprofezin in almond hulls. This replaced the previous recommendation of 2 mg/kg.

### ***Residues in processed commodities***

Processing factors based on data reviewed by the 2008, 2009, and the 2019 Meetings are summarized

below, as well as estimates of maximum residue levels, STMR-P and HR-P, as needed. The Meeting decided to extrapolate the processing factors from orange to citrus fruits.

Table 1 Summary of processing factors, maximum residue levels, STMRs and HRs for buprofezin. Values are from 2019 JMPR unless otherwise indicated

Crop	Commodity	Processing factors		Residue, mg/kg		
		Individual values	Best estimate	Max. residue level	Median/STMR/STMR-P	Highest residue/HR/HR-P
Orange	Whole fruit	--	--	1	0.23 (median)	0.46 (highest residue)
	Flesh	< 0.015, < 0.022, 0.054, 0.066, 0.093, 0.21, 0.23, 0.25, 0.38, 0.40	0.17	--	0.039	0.078
	Peel (fresh)	1.1, 1.4, 2.0, 2.3, 2.4, 2.8, 3.0, 3.3, 3.4, 4.1, 4.3, 4.8	2.9	--	0.67	1.3
	Dried pulp	1.1, 1.4, 2.4, 2.7 (3), 2.8, 2.9, 4.1, 4.5 <sup>a</sup> , 4.6, 5.1, 6.0 <sup>a</sup> , 16	4.2	5	0.97	1.9
	Juice (2008=pasteurised; 2019=boiled 15 min.)	0.06, 0.07, 0.13, 0.24, 0.31, 0.31, 0.56, 0.56 <sup>a</sup> , 0.58 <sup>a</sup> , 0.60, 0.63, 0.92, 1.0, 1.3	0.52	--	0.12	--
	Marmalade	0.14, 0.17, 0.44, 0.88, 0.94, 0.99, 1.1, 1.4, 2.1, 2.6	1.1	--	0.25	--
	Oil	0.88, 2.2, 2.5, 4.2, 5.6, 6.4, 6.9, 8.1, 8.4, 8.9	5.4	6	1.2	--
Apple	Whole fruit	--	--	3	0.28	0.99
	Dried	0.43, 0.77	0.60	--	0.17	0.59
	Canned	< 0.055, < 0.063	< 0.055	--	0.015	--
	Puree	< 0.055, 0.069	0.069	--	0.019	--
	Jelly	< 0.055, < 0.063	< 0.055	--	0.015	--
	Juice (raw)	0.56 <sup>b</sup> , 0.58 <sup>b</sup>	0.57	--	0.16	--
	Pomace (wet)	1.9 <sup>b</sup> , 2.1 <sup>b</sup>	2.0	--	0.56	--
Grape	Berry	--	--	1	0.17	0.74
	Raisins	0.20, 0.62, 1.0 <sup>a</sup> , 1.1, 1.5 <sup>b</sup> , 1.7 <sup>a</sup> , 1.9, 2.0 <sup>b</sup> , 2.4 <sup>b</sup> , 3.4 <sup>b</sup>	1.6	2	0.27	1.2
	Juice (pasteurised)	< 0.037, 0.068, 0.14 <sup>b</sup> , < 0.24, 0.31 <sup>a</sup> , 0.35 <sup>a</sup> , 0.53 <sup>b</sup> , 0.63 <sup>b</sup> , 0.64 <sup>b</sup> , 0.75	0.43	--	0.073	--
	Wine	0.16, 0.39, 2.0, 5.1, 0.51 <sup>a</sup> , 0.52 <sup>a</sup> , 0.56 <sup>a</sup> , 0.68 <sup>b</sup> , 0.69 <sup>a</sup> , 0.78 <sup>a</sup> , 1.2 <sup>b</sup> , 1.4 <sup>b</sup>	1.2	--	0.2	--
Olive	Whole fruit	--	--	5	1.125	1.7
	Canned (pickled, fermented)	0.57, 0.63, 0.85	0.68	--	0.76	1.2
	Oil (crude)	0.90, 3.1 <sup>b</sup> , 3.3, 3.6, 4.1	3.5 <sup>c</sup>	20	3.9	--

<sup>a</sup> from JMPR 2008,

<sup>b</sup> from JMPR 2009

<sup>c</sup> Best estimate calculated without the value of 0.9 based on the log KOW of 4.9 at pH 7, which suggests a high fat solubility.

The Meeting decided to extrapolate the processing factors from orange to citrus fruits.

For citrus, dried pulp, the Meeting estimated a maximum residue level of 5 mg/kg to replace the previous recommendation (2 mg/kg), a median residue of 0.97 mg/kg and a highest residue of 1.9 mg/kg

For citrus oil, the Meeting estimated a maximum residue level of 6 mg/kg and an STMR-P of 1.2 mg/kg.

For processed apple and grape commodities, the Meeting confirmed previous recommendations.

For olive oil, raw the Meeting estimated a maximum residue level of 20 mg/kg and an STMR-P of 3.9 mg/kg.

The Meeting evaluated residues of aniline in processed commodities of orange, apple, grape, and olive. In raw and processed commodities of apple, grape, and olive, residues of aniline were either not detected or were <LOQ; therefore, the Meeting decided that those commodities did not contribute significantly to the dietary exposure to aniline from the use of buprofezin. In the orange study, a quantifiable residue of aniline was observed in one sample of orange as well as in peel, juice, marmalade, and oil. The Meeting used the ratio of aniline to buprofezin in whole fruit from that study (0.00093) to convert the STMR and HR for buprofezin in citrus (0.23 and 0.46, respectively (2008 JMPR)) to an aniline-equivalent STMR (0.00021 mg/kg) and HR (0.00043 mg/kg). The Meeting used the aniline-equivalent STMR and HR and the processing factors for aniline in orange (Table 2) to estimate STMR-Ps and HR-Ps for aniline in orange. The Meeting agreed to extrapolate to the group of citrus fruits. As aniline exposure may come from many sources and is not unique to buprofezin, the Meeting did not estimate maximum residue levels for aniline.

Table 2 Summary of processing factors and estimated residues of aniline in raw and processed citrus commodities

Commodity	Processing factors	Best estimate processing factor	STMR-P, mg/kg	HR-P, mg/kg
Whole fruit	--	--	0.00021 (STMR)	0.00043 (HR)
Flesh	n.c., < 0.77	0.77	0.00016	0.00033
Peel (fresh)	> 1, 1.77	1.77	0.00037	0.00076
Dried pulp	n.c., < 0.77	0.77	0.00016	--
Juice	n.c., 0.85	0.85	0.00018	--
Marmalade	n.c., 2.3	2.3	0.00048	--
Oil	> 1.3, 10	10	0.0021	--

n.c. – not calculable

### **Residues in animal commodities**

The Meeting estimated dietary burdens for livestock based on residues in apple pomace, citrus dried pulp, almond hulls, and soya bean seed. The dietary burdens were estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO manual<sup>8</sup>. The burdens are summarized below.

Table 3 Summary of livestock dietary burdens, as ppm of dry matter, for buprofezin

Livestock	Canada and USA		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
<b>Beef cattle</b>	0.11	0.11	0.28	0.28	0.41 <sup>a</sup>	0.41 <sup>c</sup>	0.002	0.002
<b>Dairy cattle</b>	0.17	0.17	0.25	0.25	0.38 <sup>b</sup>	0.38 <sup>d</sup>	0.001	0.001
<b>Broiler chickens</b>	0.002	0.002	0.002	0.002	0.002	0.002	--	--

<sup>8</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

Livestock	Canada and USA		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
<b>Layer hens</b>	0.002 <sup>e</sup>	0.002 <sup>f</sup>	0.002	0.002	0.002	0.002	--	--

- <sup>a</sup> Highest maximum dietary burden for beef or dairy cattle; suitable for estimating the maximum residue levels for mammalian meat, fat, and offal.
- <sup>b</sup> Highest maximum dietary burden for dairy cattle; suitable for estimating the maximum residue levels for milk.
- <sup>c</sup> Highest mean dietary burden for beef or dairy cattle; suitable for estimating STMRs for mammalian meat, fat, and offal.
- <sup>d</sup> Highest mean dietary burden for dairy cattle; suitable for estimating the STMR for milk.
- <sup>e</sup> Highest maximum dietary burden for broiler chickens or laying hens; suitable for estimating the maximum residue levels for poultry meat, fat, offal, and eggs.
- <sup>f</sup> Highest mean dietary burden for laying hens; suitable for estimating the STMRs for poultry meat, fat, offal, and eggs.

In the lactating cattle feeding study conducted at 5 and 15 ppm buprofezin in dry feed, residues of buprofezin were not detected in any tissues or in milk. Based on the dietary burdens of 0.41 ppm for beef cattle, 0.38 ppm for dairy cattle, and 0.002 ppm for poultry, the Meeting confirmed its previous recommendations. Noting that recommendations had not been made previously for residues in mammalian fats or for residues in any poultry commodities, the Meeting decided to make maximum residue level estimates of 0.01(\*) mg/kg for those commodities, with STMRs and HRs of 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 and for dietary risk assessment for plant and animal commodities: buprofezin.

The residue is not fat-soluble.

### DIETARY RISK ASSESSMENT

#### **Long-term dietary exposure**

The ADI for buprofezin is 0–0.009 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for buprofezin 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 2019 JMPR Report.

The IEDIs ranged from 4–40% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of buprofezin from uses considered by the JMPR is unlikely to present a public health concern.

#### **Acute dietary exposure**

The ARfD for buprofezin is 0.5 mg/kg bw. The International Estimate of Short-Term Intakes (IESTIs) for buprofezin 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 2019 JMPR Report.

The IESTIs were up to 5% for the general population and up to 10% for children of the ARfD. The Meeting concluded that acute dietary exposure to residues of buprofezin from uses considered by the present Meeting is unlikely to present a public health concern.



**Aniline**

Aniline is a breakdown product of *inter alia* buprofezin. The current Meeting established a maximum ADI and ARfD for aniline, both at 0.02 mg/kg bw. Information available to the Meeting indicated that the dietary exposure to aniline via buprofezin is minor compared to the estimated dietary exposure to buprofezin itself.

Noting that the ADI for buprofezin is lower than that of aniline, the Meeting concluded that the long-term dietary risk assessment for buprofezin adequately addresses long-term dietary risk to residues of aniline from the use of buprofezin.

For acute dietary exposure, the Meeting estimated residues in commodities from crops evaluated by the Meeting. The estimated acute dietary risk to residues of aniline coming from buprofezin was 0% of the aniline ARfD for both the general population and for children.

Given the multiple sources of aniline, the Meeting recommended that FAO/WHO evaluate aniline as an environmental contaminant.



## 5.6 Carbofuran (096) and Carbosulfan (145)

### TOXICOLOGY

The Meeting identified concerns regarding the genotoxicity of carbofuran that required additional information.

In addition, the Meeting became aware that there was more information available on the genotoxicity testing of carbofuran which was not submitted in the dossier. As carbofuran is a major and toxic metabolite of carbosulfan and the dossier for carbofuran was incomplete, the Meeting was unable to proceed with the evaluation of either of the two compounds. The evaluations of carbofuran and carbosulfan were therefore postponed until additional information on genotoxicity for both compounds is provided.



## 5.7 Clethodim (187)

### TOXICOLOGY

Clethodim is the ISO-approved common name for (5*RS*)-2-[(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl]-5-[(2*RS*)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one (IUPAC), with the CAS number 99129-21-2. Clethodim is a selective cyclohexanedione herbicide and exhibits its pesticidal activity in plants by inhibiting acetyl coenzyme A carboxylase, an enzyme common to the pathways of fatty acid biosynthesis.

Clethodim was evaluated by JMPR in 1994 and 1999. An ADI of 0–0.01 mg/kg bw was established in 1994 on the basis of a NOAEL of 1 mg/kg bw per day in a one-year study in dogs and the establishment of an acute reference dose was considered unnecessary. In 1999 the toxicological monograph prepared in 1994 was reviewed and the previous conclusions were reaffirmed.

Clethodim was evaluated by the present Meeting within the periodic review program of CCPR. The present Meeting reviewed all previous studies, and new data comprising neurotoxicity (acute and short-term), immunotoxicity studies, and studies on metabolites (acute oral, repeated dose and genotoxicity) are included in the monograph currently in preparation.

All studies were conducted to internationally recognized guidelines, generally OECD, and GLP, or were otherwise quality audited, except where indicated. A literature search did not identify any further useful toxicological information for the current assessment.

#### **Biochemical aspects**

Male and female rats were given single oral doses of [propyl-1-<sup>14</sup>C]-clethodim at 4.4 or 468 mg/kg bw, or unlabelled test material at 4.5 mg/kg bw per day for 14 consecutive days before treatment with a single radiolabelled dose of 4.8 mg/kg bw. Oral absorption was 88–95% based on urine, tissue, expired CO<sub>2</sub>, cage wash and residual carcass. Seven days after treatment, the total amount of radiolabel recovered from organs and tissues was less than 1% of the administered dose. Elimination was rapid, with 94–98% of the administered dose excreted by 48 hours after administration. The principal route of excretion was the urine (87–93%), and a smaller percentage of the radioactivity (9–17%) was eliminated in the faeces. The amount of radioactivity excreted in expired air as carbon dioxide represented 0.5–1% of the administered dose. Although the elimination patterns were similar in all groups, the rate of elimination was somewhat faster in animals that were administered the single low dose of 4.4 mg/kg bw (84% eliminated within 24 hours) than in those given the single high dose of 468 mg/kg bw (53% within 24 hours), suggesting the tendency to saturation. No sex differences in elimination rate were seen in animals administered repeated low doses of clethodim. There were no significant dose-related or sex-specific differences in tissue distribution, when expressed as a proportion of the dose administered, and there was no evidence of bioaccumulation.

Clethodim was extensively metabolized in all dosed groups. Unchanged parent was detected in urine of females (0.4% of the administered dose) of the high-dose group only, in faeces of females and males of the low-dose and high-dose groups (0.3–1% of the administered dose). The primary routes of metabolism were by oxidation and subsequent hydroxylation or demethylation with subsequent oxidation. The major metabolite in excreta was clethodim sulfoxide, which accounted for 46–61% and 2–5% of the administered dose in urine and faeces, respectively. *S*-methyl sulfoxide, accounted for 6–11% and 0.4–1% of the administered dose in urine and faeces, respectively. Imine sulfoxide was 6–9% of the administered dose in urine, and 1–2% in faeces, in females and males. Other identified compounds ( $\leq$  5% of the administered dose), in urine and faeces of females and males were 5-OH sulfoxide (3–5%), oxazole sulfoxide (2–3%), trione sulfoxide (ca 1%), 5-OH sulfone (0.3–1%), clethodim sulfone (0.1–1%), aromatic sulfone (0.2–0.7%) and *S*-methyl sulfone (0.0–0.4%). No significant differences were noted in the pattern of metabolites between sexes and dose regimes.

#### **Toxicological data**

In rats, the acute oral LD<sub>50</sub> was 1133 mg/kg bw. In mice the acute oral LD<sub>50</sub> was 1688 mg/kg bw, and

the acute LC<sub>50</sub> was greater than 3.25 mg/L. In rabbits, the acute dermal LD<sub>50</sub> was greater than 4167 mg/kg bw. Clethodim was mildly irritating to eyes and skin, and was a skin sensitizer to the skin of guinea pigs.

The short-term toxicity of clethodim was tested in mice, rats and dogs, and the long-term toxicity and carcinogenicity was tested in mice and rats. In rodent short-term studies critical effects were observed on the liver (increased liver weight, hepatocyte hypertrophy and focal coagulative necrosis) and body weights. In dogs, toxicity effects on liver consisted of organ weight changes, associated with biochemical and histopathological changes. Sternum marrow hyperplasia and pigment in spleen were also observed in dogs.

In a 28-day study in mice in which clethodim was administered at dietary concentrations of 0, 100, 250, 625, 1500 and 4000 ppm (equivalent to 0, 11.9, 29.7, 74.4, 179 and 476 mg/kg bw per day), the NOAEL was 1500 ppm (equivalent to 179 mg/kg bw/day) based on increased liver weights, increased liver hypertrophy in both sexes and increased liver focal coagulative necrosis in males at the 4000 ppm (equivalent to 476 mg/kg bw per day) dose level.

In a 35-day study in rats in which clethodim was administered at dietary concentrations of 0, 5, 200, 1000, 4000 and 8000 ppm (equal to 0, 0.26, 12.5, 65.6, 216 and 515 mg/kg bw per day for males, 0, 0.29, 13.9, 70.6, 291 and 554 mg/kg bw per day for females), the NOAEL was 1000 ppm (equal to 65.6 mg/kg bw per day) based on decreased body weights and food consumption in both sexes at 4000 ppm (equal to 216 mg/kg bw per day).

In a 90-day study in rats in which clethodim was administered at dietary concentrations of 0, 50, 500, 2500 and 5000 ppm (equal to 0, 2.3, 25, 134 and 279 mg/kg bw per day for males, 0, 2.8, 30, 159 and 341 mg/kg bw per day for females), the NOAEL was 500 ppm (equal to 25 mg/kg bw per day) based on changes in body weight in males at 2500 ppm (equal to 134 mg/kg bw per day).

In a 90-day study in beagle dogs in which clethodim was administered by gelatine capsules at dose levels of 0, 1, 25, 75 and 125 mg/kg bw per day (equal to 0, 0.83, 21, 62 and 104 mg/kg bw per day after correction for purity), the NOAEL was 62 mg/kg bw per day based on elevated liver weights and liver histopathology lesions (centrilobular vacuoles) in both sexes, and increased serum cholesterol and alkaline phosphatase at 104 mg/kg bw per day.

In a one-year study in beagle dogs in which clethodim was administered by capsule at dose levels of 0, 1, 75 and 300 mg/kg bw per day (equal to 0, 0.83, 62 and 250 mg/kg bw per day after correction for purity), the NOAEL was 62 mg/kg bw per day, based on increased platelets, increased liver weights and associated increase of biochemical parameters (alkaline phosphatase and cholesterol) and histopathological effects (hypertrophy and pigment), hyperplasia in sternum marrow and pigments in the spleen in both sexes at 250 mg/kg bw per day.

In an 18-month toxicity and carcinogenicity study in mice, clethodim was administered at dietary concentrations of 0, 20, 200, 1000 and 3000 ppm (equivalent to 0, 2.4, 24, 119 and 238 mg/kg bw per day until week 15, the highest dose increasing thereafter to 357 mg/kg bw per day, after correction for purity), the systemic NOAEL was 200 ppm equivalent 24 mg/kg bw per day based on hepatic changes, notably centrilobular hypertrophy, increased pigmentation and bile duct hyperplasia, and an increased incidence of alveolar macrophages in the lungs of mice given 1000 ppm (equivalent to 119 mg/kg bw per day). No evidence for a carcinogenic potential in mice was observed with clethodim.

In a two-year toxicity and carcinogenicity study in rats, when clethodim was administered at dietary concentrations of 0, 5, 20, 500 and 2500 ppm (equal to 0, 0.15, 0.57, 16 and 86 mg/kg bw per day for males, 0, 0.20, 0.72, 21 and 113 mg/kg bw per day for females), the NOAEL for systemic toxicity was 500 ppm (equal to 16 mg/kg bw per day), based on decreased body weight gain, decreased food intake in both sexes, increased mortality in males and increased chronic pancreatitis in females at 2500 ppm (equal to 86 mg/kg bw per day). The NOAEL for carcinogenicity was 500 ppm (equal to 21 mg/kg bw per day), based on increased incidence of benign granulosa cell tumours in the ovary (2/63) at 2500 ppm (equal to 113 mg/kg bw per day).

The Meeting concluded that clethodim is carcinogenic in female rats, but not in mice or male rats.

Clethodim 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 clethodim is unlikely to be genotoxic.

In view of the lack of genotoxicity, and the fact that tumours were observed only at doses unlikely to occur in humans, by a mechanism that would exhibit a threshold, the Meeting concluded that clethodim is unlikely to pose a carcinogenic risk to humans due to exposure in the diet.

In a two-generation reproductive toxicity study in which rats were given clethodim at a dietary concentration of 0, 5, 20, 500 and 2500 ppm (equal to 0, 0.5, 1.2, 32.2 and 163 mg/kg bw per day for males, 0, 0.5, 1.5, 37.4 and 181 mg/kg bw per day for females, after correction for purity), the NOAEL for parental toxicity was 500 ppm (equal to 32.2 mg/kg bw per day), based on body weight changes and reduced food consumption in F<sub>0</sub> and F<sub>1</sub> generations at 2500 ppm (equal to 163 mg/kg bw per day). The NOAEL offspring toxicity was 2500 ppm (equal to 163 mg/kg bw per day). The NOAEL for reproductive toxicity was 2500 ppm (equal to 163 mg/kg bw per day).

In a developmental toxicity study in rats given clethodim by gavage at doses of 0, 10, 100, 300 and 700 mg/kg bw per day (equal to 0, 8.3, 83.3, 292 and 583 mg/kg bw per day, after correction for purity) the NOAEL for maternal toxicity was 83.3 mg/kg bw per day based on a reduction in body weight gain, reduced food consumption and clinical signs (excessive salivation, red/mucoid nasal discharged, alopecia, staining ano-genital area) at 292 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 83.3 mg/kg bw per day, based decreased fetal weight and delayed ossification at 292 mg/kg bw per day.

In a developmental toxicity study in rabbits given clethodim by gavage at 0, 25, 100 and 300 mg/kg bw per day (equal to 0, 20.8, 83.3 and 250 mg/kg bw per day after correction for purity), the NOAEL for maternal toxicity was 20.8 mg/kg bw per day, based on increased clinical signs (red substance in pan, dried faeces), decrease body weights and food consumption. The NOAEL for embryo and fetal toxicity was 250 mg/kg bw per day.

The Meeting concluded that clethodim is not teratogenic.

In an acute neurotoxicity study, clethodim was given to rats by gavage at a dose of 0, 10, 100 and 1000 mg/kg bw. The NOAEL for systemic toxicity was 100 mg/kg bw, based on transient decreased locomotor activity (total and/or ambulatory counts) at 1000 mg/kg bw. The NOAEL for neurotoxicity was 1000 mg/kg bw, the highest dose tested.

In a 90-day neurotoxicity study in rats given clethodim at a dietary concentration of 0, 500, 1500 and 5000 ppm (equal to 0, 31, 94 and 331 mg/kg bw per day for males, 0, 38, 115 and 380 mg/kg bw per day for females), the NOAEL for systemic toxicity was 1500 ppm (equal to 94 mg/kg bw per day) based on the treatment-related reductions in mean body weights, and food consumption in both sexes at 5000 ppm (equal to 331 mg/kg bw per day). The NOAEL for neurotoxicity was 5000 ppm (equal to 331 mg/kg bw per day), the highest dose tested.

The Meeting concluded that clethodim is not neurotoxic.

In a 28-day immunotoxicity study in female mice given clethodim at a dietary concentration of 0, 400, 2000 and 4000 ppm (equal to 0, 136, 603 and 1312 mg/kg bw per day), the NOAEL for immunotoxicity was 4000 ppm (equal to 1312 mg/kg bw per day), the highest dose tested.

The Meeting concluded that clethodim is not immunotoxic.

In a mechanistic study to investigate liver microsomal cytochrome P450 induction, groups of eight male rats were given clethodim (purity 83.8%) by gavage at 0 or 250 mg/kg bw per day for 21 consecutive days. Results indicated that microsomal cytochrome P450 was not increased, indicating that the increased liver weight was not due to cytochrome P450 induction.

### **Toxicological data on metabolites and/or degradates**

#### ***Metabolite Clethodim imine sulfone (RE-47719)***

Clethodim imine sulfone (5-(2-(ethylsulfinyl)propyl)-3-hydroxy-2-(1-iminopropyl) cyclohex-2-en-1-one) is a metabolite found in the leaves of soya bean, carrot and cotton, in rotational crops, and in goats.

The acute oral LD<sub>50</sub> of clethodim imine sulfone in rats was greater than 1400 mg/kg bw.

In a 35-day toxicity study in rats in which clethodim imine sulfone was administered at dietary concentrations of 0, 100, 1000 and 8000 ppm (equal to 0, 6.6, 70.9 and 604 mg/kg bw per day for males, 0, 7.8, 83.7 and 723 mg/kg bw per day for females), the NOAEL was 1000 ppm (equal to 70.9 mg/kg bw per day) based on increased reticulocytes, liver weights and higher serum cholesterol levels at 8000 ppm (equal to 604 mg/kg bw per day).

In a screening developmental toxicity study in which clethodim imine sulfone was administered to rats by gavage at dose levels of 0, 10, 100 and 700 mg/kg bw per day, the NOAEL for maternal toxicity was 10 mg/kg bw per day, based on reduction in body weight gain at 100 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 100 mg/kg bw per day, based on reduced fetal weight and increased incidence of skeletal findings (increase in cervical ribs and decrease of sternbrae ossification sites) at 700 mg/kg bw per day.

Clethodim imine sulfone was tested in a gene mutation assay in bacteria and an in vitro chromosomal aberration test. There was no evidence of genotoxicity.

The Meeting concluded that clethodim imine sulfone is of similar toxicity to clethodim, therefore is considered to be covered by the parent compound.

#### ***Metabolite clethodim imine sulfoxide***

Clethodim imine sulfoxide (5-(2-(ethylsulfinyl)propyl)-3-hydroxy-2-(1-iminopropyl) cyclohex-2-en-1-one) is a metabolite in rats (up to 9% in urine), plants (soya bean, carrot, cotton leaves, rotational crops) and animals (goat).

No specific toxicological data are available, but the Meeting noted that clethodim imine sulfoxide has a similar structure to clethodim imine sulfone, and concluded that clethodim imine sulfoxide is of no greater toxicity than clethodim, therefore is considered to be covered by the parent compound.

#### ***Metabolite clethodim 5-OH sulfone (RE-51228)***

Clethodim 5-OH sulfone, (2-((E)-1-(((E)-3-chloroallyl)oxy)imino)propyl)-5-(2-(ethylsulfonyl)propyl)-3,5-dihydroxycyclohex-2-en-1-one) is a metabolite in soya beans (seeds), carrots (roots), and also a minor rat metabolite (1% in urine).

The acute oral LD<sub>50</sub> of metabolite clethodim 5-OH sulfone in rats was greater than 1400 mg/kg bw.

In a 35-day toxicity study in rats in which clethodim 5-OH sulfone was administered at a dietary concentration of 0, 100, 1000 and 8000 ppm (equal to 0, 5.94, 67.7 and 588 mg/kg bw per day for males, 0, 6.43, 75.5 and 663 mg/kg bw per day for females), the NOAEL was 8000 ppm (equal to 588 mg/kg bw per day), the highest dose tested.

In a screening developmental toxicity study in rats in which clethodim 5-OH sulfone by gavage at dose levels of 0, 10, 100 and 700 mg/kg bw per day, the NOAEL for maternal toxicity was 100 mg/kg bw per day, based on clinical signs at 700 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 700 mg/kg bw per day, the highest dose tested.

Metabolite clethodim 5-OH sulfone was tested in a gene mutation assay in bacteria and an in vitro chromosomal aberration test. There was no evidence of genotoxicity.



The Meeting concluded that clethodim 5-OH sulfone is of lower toxicity than clethodim, and it would be covered by the parent compound.

***Metabolite clethodim sulfone (RE-47253), free and conjugated***

Clethodim sulfone (2-((E)-1-(((E)-3-chloroallyloxy)imino)propyl)-5-(2-(ethylsulfonyl)propyl)-3-hydroxycyclohex-2-en-1-one) is a metabolite in rats ( $\leq 1\%$  in urine), spinach, carrot (outdoor, roots & leaves), soil, goats and hens. The conjugate form is a plant (soya bean) metabolite. The submitted studies were performed with the free form of the metabolite only.

Clethodim sulfone was tested for genotoxicity in an adequate range of in vitro and in vivo assays. Positive or equivocal results were observed in gene mutation assays in bacteria or mammalian cells and in an in vitro chromosomal aberration assay. However, negative results were observed with the same genotoxicity assays, using a purer batch of clethodim sulfone. Equivocal results were observed in an in vivo micronucleus test.

The Meeting concluded that a TTC approach for genotoxicity could be applied to clethodim sulfone.

***Metabolite clethodim oxazole sulfone (RE-47797)***

Clethodim oxazole sulfone (2-ethyl-6-(2-(ethylsulfonyl)propyl)-6,7-dihydrobenzo[d]oxazol-4(5H)-one) is a soil and rotational crop metabolite.

Clethodim oxazole sulfone was tested for genotoxicity in an adequate range of in vitro and in vivo assays. Negative results were obtained in gene mutation assays in bacteria and mammalian cells. Positive results were obtained in an in vitro chromosomal aberration assay. Negative results were obtained in an in vivo micronucleus test.

For chronic toxicity of clethodim oxazole sulfone, the Meeting concluded that a TTC approach could be applied using Cramer class III.

***Metabolite clethodim oxazole sulfoxide***

Clethodim oxazole sulfoxide (2-ethyl-6-(2-(ethylsulfinyl)propyl)-6,7-dihydrobenzo[d]oxazol-4(5H)-one) is minor rat ( $\leq 3\%$  in urine), soil and rotational crop metabolite.

No specific toxicological data are available, but the Meeting concluded that clethodim oxazole sulfoxide has a similar structure to clethodim oxazole sulfone. Therefore, for chronic toxicity, the Meeting concluded that a TTC approach could be applied using Cramer class III.

***Metabolite DME sulfoxide acid (M17R)***

Metabolite DME sulfoxide acid (3-[(2-ethylsulfinyl)propyl]-pentanedioic acid) is a crop metabolite found in spinach, carrot roots and foliage.

The acute oral LD<sub>50</sub> of metabolite DME sulfoxide acid in rats was greater than 5000 mg/kg bw.

In a 28-day toxicity study in rats in which DME sulfoxide acid was administered at a dietary concentration of 0, 200, 1000 and 5000 ppm (equal to 0, 15, 80 and 396 mg/kg bw per day for males, 0, 16, 78, and 407 mg/kg bw per day for females), the NOAEL was 1000 ppm (equal to 80 mg/kg bw per day), based on thymus and adrenal weight changes in males at 5000 ppm (equal to 396 mg/kg bw per day).

Metabolite DME sulfoxide acid was tested in a gene mutation assay in bacteria and an in vitro chromosomal aberration test. There was no evidence of genotoxicity.

The Meeting concluded that metabolite DME sulfoxide acid is of no greater toxicity than clethodim, and is therefore considered to be covered by the parent compound.

***Metabolite DME sulfone acid (M18R)***

DME sulfone acid (3-[(2-ethylsulfonyl) propyl]-pentanedioic acid) is a metabolite of crops (spinach, carrot roots and foliage).

The acute oral LD<sub>50</sub> of metabolite DME sulfone acid in rats was greater than 5000 mg/kg bw.

DME sulfone acid was tested in a gene mutation assay in bacteria. There was no evidence of mutagenicity.

The Meeting noted that metabolite DME sulfone acid (M18R) has a similar structure to metabolite DME sulfoxide acid (M17R), which is of no greater toxicity than clethodim, and concluded that metabolite DME sulfone acid (M18R) would be covered by the parent compound.

***Metabolite M15R***

Metabolite M15R (hydroxy-3-[(2-ethylsulfinyl)propyl]-pentanedioic acid) is a plant metabolite (spinach, outdoor carrot roots).

No specific toxicological data are available, but the Meeting concluded that metabolite M15R has a similar structure to metabolite DME sulfoxide acid (M17R) and metabolite DME sulfone acid (M18R).

The Meeting concluded that metabolite M15R would be covered by the parent compound.

***Metabolite clethodim sulfoxide (free and conjugated)***

Clethodim sulfoxide (2-((E)-1-(((E)-3-chloroallyl)oxy)imino)propyl)-5-(2-(ethylsulfinyl) propyl)-3-hydroxycyclohex-2-en-1-one) is a major rat metabolite (up to 60% in urine), and a metabolite in plants (spinach, soya bean seeds, carrot roots and leaves, cotton seeds), soil and other animals (goat, hen).

No specific toxicological data are available, but the Meeting concluded that clethodim sulfoxide (free and conjugate) would be covered by toxicological studies on the parent.

***Metabolite M19R***

M19R (3-hydroxy-5-(2-hydroxypropyl)-2-(1-iminopropyl)cyclohex-2-en-1-one glucose conjugate) is a plant metabolite (carrots leaves).

No specific toxicological data are available. The Meeting concluded that a TTC approach for genotoxicity could be applied.

***Metabolite M15A***

M15A (3-chloroallyl alcohol glucoside) is a plant metabolite (spinach). No specific toxicological data are available. The Meeting noted that repeated-dose and in vitro and in vivo genotoxicity studies were available to another international authority, which had concluded that metabolite M15A appears to be more toxic than clethodim after repeated oral doses, and that no conclusion could be drawn as to its genotoxicity potential.

The Meeting concluded that a TTC approach for genotoxicity could be applied.

***Metabolite S-methyl sulfoxide***

Metabolite S-methyl sulfoxide (2-((E)-1-(((E)-3-chloroallyl)oxy)imino)propyl)-3-hydroxy-5-(2-(methylsulfinyl)propyl)cyclohex-2-en-1-one) is a metabolite in rats (up to 11% in urine), rotational crops, and animals (goat).

No specific toxicological data are available, but the Meeting concluded that S-methyl sulfoxide would be covered by toxicological studies on the parent.

**Human data**

No information was provided on the health of workers involved in the manufacture or use of clethodim. No information on accidental or intentional poisoning in humans was available.

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

**Toxicological evaluation**

The Meeting established an ADI for clethodim of 0–0.2 mg/kg bw, based on a NOAEL of 16 mg/kg bw per day on the basis of decreased body weight gain, decreased food intake in both sexes, marginally increased mortality in males and increased chronic pancreatitis in females, and using a safety factor of 100. The upper bound of this ADI provides a margin of about 565 times relative to the LOAEL for increased incidence of benign granulosa cell tumours in the ovary (2/63) of rats at the highest dose.

The Meeting concluded that it was not necessary to establish an ARfD for clethodim 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 clethodim**

Species	Study	Effect	NOAEL	LOAEL
Mouse	Four-week toxicity <sup>a</sup> study	Toxicity	1500 ppm, equal to 179 mg/kg bw per day	4000 ppm, equal to 476 mg/kg bw per day
	18-months carcinogenicity <sup>a</sup> study	Toxicity	200 ppm, equivalent to 24 mg/kg bw per day	1000 ppm, equivalent to 119 mg/kg bw per day
		Carcinogenicity	3000 ppm, equivalent to 357 mg/kg bw per day <sup>c</sup>	-
Rat	Five-week toxicity <sup>a</sup> study	Toxicity	1000 ppm, equal to 65.6 mg/kg bw per day	4000 ppm, equal to 216 mg/kg bw per day
	13-week toxicity study <sup>a</sup>	Toxicity	500 ppm, equal to 25 mg/kg bw per day	2500 ppm, equal to 134 mg/kg bw per day
	Two-year toxicity and carcinogenicity <sup>a</sup> study	Toxicity	500 ppm, equal to 16 mg/kg bw per day	2500 ppm, equal to 86 mg/kg bw per day
		Carcinogenicity	500 ppm, equal to 21 mg/kg bw per day	2500 ppm, equal to 113 mg/kg bw per day
	Two-generation reproductive toxicity <sup>a</sup> study	Reproduction/fertility	2500 ppm, equal to 163 mg/kg bw per day <sup>c</sup>	-
		Parental toxicity	500 ppm, equal to 32.2 mg/kg bw per day	2500 ppm, equal to 163 mg/kg bw per day
		Offspring toxicity	2500 ppm, equal to 163 mg/kg bw per day <sup>c</sup>	-
Developmental toxicity <sup>b</sup> study	Maternal toxicity	83.3 mg/kg bw per day	292 mg/kg bw/day	
	Fetal toxicity	83.3 mg/kg bw per day	292 mg/kg bw/day	
Rabbit	Developmental toxicity <sup>b</sup> study	Maternal toxicity	20.8 mg/kg bw per day	250 mg/kg bw per day

Species	Study	Effect	NOAEL	LOAEL
		Fetal toxicity	250 mg/kg bw per day <sup>c</sup>	-
Dog	90-day toxicity <sup>d</sup> study	Toxicity	62 mg/kg bw per day (males)	104 mg/kg bw per day
	One-year toxicity <sup>d</sup> study	Toxicity	62 mg/kg bw per day (males)	250 mg/kg bw per day
Clethodim imine sulfone (metabolite RE-47719)				
Rat	Five-week toxicity <sup>a</sup> study	Toxicity	1000 ppm, equal to 70.9 mg/kg bw per day	8000 ppm, equal to 604 mg/kg bw per day
	Developmental toxicity <sup>b</sup> study	Maternal toxicity	10 mg/kg bw per day	100 mg/kg bw per day
		Fetal toxicity	100 mg/kg bw per day	700 mg/kg bw per day
Clethodim 5-OH sulfone (metabolite RE-51228)				
Rat	Five-week toxicity <sup>a</sup> study	Toxicity	8000 ppm, equal to 588 mg/kg bw per day <sup>c</sup>	-
	Developmental toxicity <sup>b</sup> study	Maternal toxicity	100 mg/kg bw per day	700 mg/kg bw per day
		Fetal toxicity	700 mg/kg bw per day <sup>c</sup>	-
DME Sulfoxide acid (metabolite M17R)				
Rat	Five-week toxicity <sup>a</sup> study	Toxicity	1000 ppm, equal to 80 mg/kg bw per day	5000 ppm, equal to 396 mg/kg bw per day

<sup>a</sup> Dietary administration

<sup>b</sup> Gavage administration

<sup>c</sup> Highest dose tested

<sup>d</sup> Capsule administration

*Acceptable daily intake (ADI) for clethodim, clethodim sulfoxide (free and conjugated), 5-hydroxy sulfone, clethodim imine sulfoxide, clethodim imine sulfone, M15R, M17R, M18R and S-methyl sulfoxide, expressed as clethodim*

0–0.2 mg/kg bw

*Acute reference dose (ARfD) for clethodim, clethodim sulfoxide (free and conjugated), 5-hydroxy sulfone, clethodim imine sulfoxide, clethodim imine sulfone, M15R, M17R, M18R and S-methyl sulfoxide, expressed as clethodim*

Not necessary

### **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 clethodim**

<b><i>Absorption, distribution, excretion, and metabolism in mammals</i></b>	
Rate and extent of oral absorption	Approximately 90% based on urine, tissue, expired CO <sub>2</sub> , cage wash and residual carcass within 168 h
Distribution	Widely (0.2–0.7% in tissues); highest residues in adrenals, liver and kidneys
Rate and extent of excretion	Urinary: 80–86% in 24 h; faecal 8.5–14% in 24 h
Potential for accumulation	No evidence for accumulation
Metabolism in mammals	Extensively metabolized; primary routes of metabolism are oxidation and subsequent hydroxylation or demethylation with subsequent oxidation
Toxicologically significant compounds (animals, plants, and the environment)	Clethodim, clethodim sulfoxide (free and conjugate), clethodim imine sulfone, clethodim imine sulfoxide, clethodim oxazole sulfoxide, clethodim oxazole sulfone, clethodim sulfone (free and conjugate), 5-hydroxy sulfone, M15R, DME sulfoxide acid (M17R), DME sulfone acid (M18R), M19R, M15A, S-methyl sulfoxide.
<b><i>Acute toxicity</i></b>	
Rat LD <sub>50</sub> oral	1133 mg/kg bw
Rat LD <sub>50</sub> dermal	> 4167 mg/kg bw
Rat LC <sub>50</sub> inhalation	> 3.25 mg/L (4 h; whole body)
Rabbit, skin irritation	Mildly irritant
Rabbit, eye irritation	Mildly irritant
Guinea pig, skin sensitization	Sensitizing (Magnusson & Kligman test)
<b><i>Short-term studies of toxicity</i></b>	
Target/critical effect	Liver (increased weight and associated histopathological findings in all species, bone marrow and spleen in dog), red blood cells (rat, mouse, dog).
Lowest relevant oral NOAEL	25 mg/kg bw/day (90-day study in rat)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
<b><i>Long-term studies of toxicity and carcinogenicity</i></b>	
Target/critical effect	Decreased body weight and food consumption, mortality in males and chronic pancreatitis in females (rat) Liver: increased weights and associated histopathological findings (rat, mouse) Lungs: increased incidence of multiple foci of amphophilic alveolar macrophages (mouse)
Lowest relevant oral NOAEL	16 mg/kg bw per day (two-year study in rat)
Carcinogenicity	Carcinogenic in female rats, but not in male rats or mice <sup>a</sup>
<b><i>Genotoxicity</i></b>	No evidence of genotoxicity <sup>a</sup>
<b><i>Reproductive toxicity</i></b>	
Target/critical effect	Parental: decreased body weight and food consumption Offspring: no adverse effects Reproductive: no adverse effects
Lowest relevant parental NOAEL	32.2 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	163 mg/kg bw per day, highest dose tested (rat)

Lowest relevant reproductive NOAEL	163 mg/kg bw per day, highest dose tested (rat)
<b>Developmental toxicity</b>	
Target/critical effect	Maternal: clinical signs, decreased body weight and food consumption (rat, rabbit), increased mortality (rat) Developmental: reduced foetal weight and delayed ossification (rat)
Lowest relevant maternal NOAEL	20.8 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	83.3 mg/kg bw per day (rat)
<b>Neurotoxicity</b>	
Acute neurotoxicity NOAEL	1000 mg/kg bw, the highest dose tested (rat)
Subchronic neurotoxicity NOAEL	331 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity NOAEL	Not available
<b>Immunotoxicity</b>	1312 mg/kg bw per day, the highest dose tested (mice)
<b>Mechanism studies</b>	No in vivo evidence of liver cytochrome induction in male rats
<b>Studies on metabolites or impurities</b>	
<b>Clethodim imine sulfone</b>	Rat LD <sub>50</sub> oral, > 1400 mg/kg bw No genotoxic potential (Ames, chrom. aberr. in vitro) Subacute toxicity Oral NOAEL 70.9 mg/kg bw per day (rat) Developmental toxicity NOAEL maternal toxicity, 10 mg/kg bw per day (rat) NOAEL embryo/fetal toxicity, 100 mg/kg bw per day (rat) Not teratogenic.
<b>Clethodim 5-OH sulfone</b>	Rat LD <sub>50</sub> oral, > 1400 mg/kg bw No genotoxic potential (Ames, chrom. aberration in vitro) Subacute toxicity Oral NOAEL 588 mg/kg bw per day (rat) highest dose tested Developmental toxicity, oral, rat: NOAEL maternal toxicity, 100 mg/kg bw per day NOAEL for embryo/fetal toxicity, 700 mg/kg bw per day Not teratogenic.
<b>Clethodim oxazole sulfone</b>	Genotoxicity: unlikely to be genotoxic (in vitro: negative Ames test, positive chrom. aberration, negative gene mutation; in vivo: negative (mouse micronucleus)
<b>Clethodim sulfone</b>	Genotoxicity: in vitro some positive result (some Ames tests, some chrom. aberration and some mammalian gene mutation), in vivo negative (mouse liver UDS), in vivo equivocal (mouse micronucleus)
<b>DME sulfoxide acid M17R</b>	LD <sub>50</sub> oral > 5000 mg/kg bw (rat) Oral NOAEL, 80 mg/kg bw per day (rat) Ames test: negative
<b>DME sulfone acid M18R</b>	LD <sub>50</sub> oral > 5000 mg/kg bw (rat) Ames test: negative

**Human data**

No data

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet**Summary**

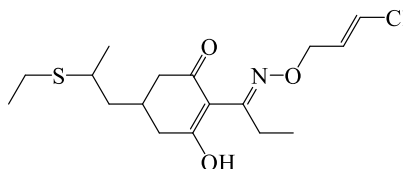
	Value	Study	Safety factor
ADI <sup>a</sup>	0–0.2 mg/kg bw <sup>a</sup>	Two-year toxicity and carcinogenicity (rat)	100
ARfD	Not necessary		

<sup>a</sup> Applies to clethodim, clethodim sulfoxide (free and conjugated), 5-hydroxy sulfone, clethodim imine sulfoxide, clethodim imine sulfone, M15R, M17R, M18R and *S*-methyl sulfoxide)**RESIDUE AND ANALYTICAL ASPECTS**

Clethodim is a fatty acid synthesis inhibitor herbicide, which interacts with acetyl CoA carboxylase. It stops new cell growth leading to the gradual death of the plant.

Clethodim was first evaluated for toxicology and residues by the JMPR in 1994. Clethodim was scheduled at the Fiftieth Session of the CCPR for periodic evaluation by the 2019 JMPR. The Meeting received information on identity, physical and chemical properties, animal and plant metabolism, rotational crop study, environmental fate, analytical methods, GAP information, storage stability, processing, supervised residue trials and farm animal feeding study.

The IUPAC name for clethodim is (5*RS*)-2-[(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl]-5-[(2*RS*)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one.



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

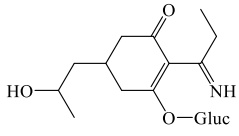
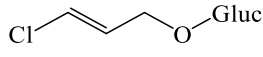
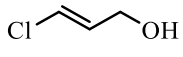
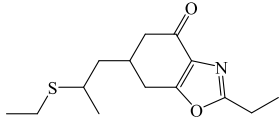
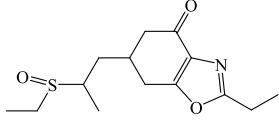
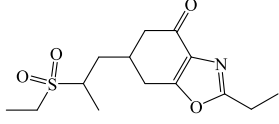
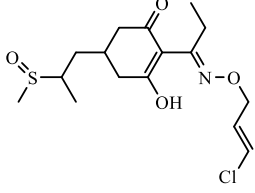
Metabolites converted to DME (3-[2-(ethylsulfonyl)propyl]-pentanedioic acid, dimethyl ester) or DME-OH (3-[2-(ethylsulfonyl)propyl]-3-hydroxy-pentanedioic acid, dimethyl ester) moieties by common moiety analytical methods are indicated in brackets.

Table 1 Metabolites referred to in this appraisal

Code	Name and Matrix	Structure
Clethodim sulfoxide (DME moiety)	2-((E)-1-(((E)-3-chloroallyl)oxy) imino)propyl)-5-(2-(ethylsulfinyl) propyl)-3-hydroxycyclohex-2-en-1-one  Spinach, Soya bean (seeds), Carrot (roots & leaves), Cotton (seeds), Soil, Goat, Hen	

Code	Name and Matrix	Structure
Clethodim sulfone (DME moiety)	2-((E)-1-(((E)-3-chloroallyl)oxy) imino)propyl)-5-(2-(ethylsulfonyl) propyl)-3-hydroxycyclohex-2-en-1-one  Spinach, Carrot (outdoor: roots & leaves), Soil, Goat, Hen	
5-hydroxy sulfone (DME-OH moiety)	2-((E)-1-(((E)-3-chloroallyl)oxy) imino)propyl)-5-(2-(ethylsulfonyl) propyl)-3,5-dihydroxycyclohex-2-en-1-one  Soya bean (seeds), Carrot (roots)	
Clethodim sulfoxide glucoside (DME moiety)	Conjugates of clethodim sulfoxide  Soya bean (seeds & leaves), Carrot (outdoor: leaves) Cotton (leaves)	
Clethodim sulfone glucoside (DME moiety)	Conjugates of clethodim sulfone  Soya bean (leaves)	
Clethodim imine sulfoxide (DME moiety)	5-(2-(ethylsulfinyl)propyl)-3-hydroxy-2-(1-iminopropyl)cyclohex-2-en-1-one  Soya bean (leaves), Carrot (leaves), Cotton (leaves), Goat	
Clethodim imine sulfone (DME moiety)	5-(2-(ethylsulfonyl)propyl)-3-hydroxy-2-(1-iminopropyl)cyclohex-2-en-1-one  Spinach	
M15R	Hydroxy 3-[(2-Ethylsulfinyl) propyl]-pentanedioic acid  Spinach, Carrot (outdoor: roots)	
M17R (DME moiety)	3-[(2-Ethylsulfinyl) propyl]- pentanedioic acid  Spinach, Carrot (outdoor: leaves & roots)	
M18R (DME moiety)	3-[(2-Ethylsulfonyl) propyl]- pentanedioic acid  Spinach, Carrot (outdoor: leaves & roots)	



Code	Name and Matrix	Structure
M19R	3-hydroxy-5-(2-hydroxypropyl)-2-iminopropyl)cyclohex-2-en-1-one glucose conjugate (1- Carrot (outdoor: leaves)	
M15A	3-Chloroallyl alcohol glucoside Spinach	
Chloroallyl alcohol	3-Chloroallyl alcohol Water (hydrolysis)	
Clethodim oxazole (DME moiety)	2-ethyl-6-(2-(ethylthio)propyl)-6,7-dihydrobenzo[d]oxazol-4(5H)-one High temperature hydrolysis	
Clethodim sulfoxide (DME moiety)	2-ethyl-6-(2-(ethylsulfinyl)propyl)-6,7-dihydrobenzo[d]oxazol-4(5H)-one Soil	
Clethodim oxazole sulfone (DME moiety)	2-ethyl-6-(2-(ethylsulfonyl)propyl)-6,7-dihydrobenzo[d]oxazol-4(5H)-one Soil	
S-methyl sulfoxide	2-((E)-1-(((E)-3-chloroallyl)oxy) imino)propyl)-3-hydroxy-5-(2-(methylsulfinyl)propyl)cyclohex-2-en-1-one Goat	

### Physical and chemical properties

Clethodim has a higher solubility in organic solvents in comparison to water and is not volatile. Clethodim was shown to be hydrolytically stable at neutral and basic conditions but photolytically unstable ( $DT_{50}$  of < 10 days).

### Plant metabolism

The Meeting received plant metabolism studies for clethodim after foliar application to spinach, soya bean, carrot and cotton with clethodim labelled at [Ring-4,6- $^{14}C$ ] and [Allyl-2- $^{14}C$ ].

### Spinach

Outdoor grown spinach received a single foliar application of [ $^{14}C$ ]-clethodim at a rate of 0.50 kg ai/ha. Treated spinach foliage was harvested 14 days after treatment (DAT) (immature) and 28 DAT (mature). The TRRs in the treated foliage measured by the extraction procedure were 3.4–6.9 mg eq/kg. The residues in immature leaves were greater than residues in the mature leaves. Total extractability was  $\geq$

81% TRR in immature and mature leaves extracted with acetonitrile/water, acetonitrile and acetonitrile/0.2 N HCl.

Parent clethodim was not detected in either immature or mature foliage. Ring opened metabolites made up the majority of the residues in both immature and mature leaves: M17R (33–35% TRR, 1.2–2.3 mg eq/kg), M15A (21–23% TRR, 0.79–1.1 mg eq/kg), M15R (13–14% TRR, 0.48–0.88 mg eq/kg) and M18R (9.7–13% TRR, 0.42–0.66 mg eq/kg). Clethodim imine sulfoxide was the major ring-intact metabolite in immature spinach leaves (14% TRR, 0.98 mg eq/kg); it was not detected in mature leaves. Clethodim imine sulfone was the major ring-intact metabolite in mature leaves (7.5% TRR, 0.25 mg eq/kg). Clethodim sulfoxide (free: 2.8–6.8% TRR, 0.12–0.35 mg eq/kg) and clethodim sulfone (free: 0.3–0.6% TRR, 0.01–0.03 mg eq/kg) were present in both immature and mature foliage. A multi-component fraction, M3/4A, was also present at 18–21% TRR (0.73–0.90 mg eq/kg) with no individual component greater than 3.6% TRR (0.018 mg eq/kg).

### *Soya bean*

Greenhouse grown soya bean received two foliar applications of [<sup>14</sup>C]-clethodim of 0.28 kg ai/ha with a 14-day retreatment interval (RTI). The first treatment was applied when the soya bean plants were at the 6–8 leaf stage. The soya bean plants were grown to maturity and harvested at 30 days after the last application (DALA). The TRRs in soya bean were 18–28 mg eq/kg for leaves, 1.6–1.8 mg eq/kg for pods and 3.9–4.3 mg eq/kg for seeds. Total extractability was ≥ 70% TRR in all commodities extracted with hexane, acetone, methanol, methanol/water and methanol/0.2 N HCl.

Parent clethodim was not detected in any of the plant parts. Major metabolites in seeds were clethodim sulfoxide (free: 32% TRR, 1.2–1.3 mg eq/kg; conjugated: 8.5–12% TRR, 0.33–0.49 mg eq/kg) and 5-OH sulfone (10–11% TRR, 0.41–0.43 mg eq/kg), and in leaves were clethodim imine sulfoxide (14% TRR, 3.9 mg eq/kg), conjugates of clethodim sulfoxide (25–27% TRR, 4.7–6.9 mg eq/kg) and conjugates of clethodim sulfone (2.0–12% TRR, 0.56–2.2 mg eq/kg).

### *Carrot*

Greenhouse grown carrots received two foliar applications of [<sup>14</sup>C]-clethodim at 0.28 kg ai/ha with a 14 day. The treated carrots were harvested at 20 DALA. The TRRs in carrot were 9.2–22 mg eq/kg for leaves and 0.40–0.62 mg eq/kg for carrot roots. Total extractability was ≥ 88% TRR in leaves and roots extracted with acetone, methanol, methanol/water and methanol/0.2 N HCl.

Parent clethodim was only detected in the roots (0.8–1.1% TRR, 0.003–0.007 mg eq/kg). Major metabolites were clethodim sulfoxide (29–34% TRR, 0.11–0.21 mg eq/kg) and 5-OH sulfone (10% TRR, 0.063 mg eq/kg) in roots, and clethodim sulfoxide (11–16% TRR, 0.97–3.5 mg eq/kg) and clethodim imine sulfoxide (22% TRR, 4.9 mg eq/kg) in leaves.

Field grown carrots received a dingle foliar application of [<sup>14</sup>C]-clethodim at a rate of 0.60 kg ai/ha. Carrot roots and foliage were harvested 21 DAT (immature) and 56 DAT (mature). The TRRs in immature carrots were 3.9–5.7 mg eq/kg for leaves and 0.74–0.82 mg eq/kg for roots. The TRRs in mature carrots were 0.75–0.84 mg eq/kg for leaves and 0.13–0.16 mg eq/kg for roots. Total extractability was ≥ 80% TRR in leaves and roots extracted with acetonitrile/water, acetonitrile and acetonitrile/0.2 N HCl.

Parent clethodim was detected at very low concentrations in immature leaves (0.004–0.005 mg eq/kg) but was not detected in mature leaves. Clethodim sulfoxide (free: 11–22% TRR, 0.095–0.16 mg eq/kg; glucoside: 9.3–15% TRR, 0.078–0.11 mg eq/kg) was the major residue in mature leaves. Metabolites M17R (8.9% TRR, 0.075 mg eq/kg), M18R (8.1% TRR, 0.068 mg eq/kg) and M19R (14% TRR, 0.12 mg eq/kg) were significant in mature leaves. A multi-component fraction, M3A (11–15% TRR, 0.020–0.081 mg eq/kg), was also detected as the major residue in immature and mature leaves with no individual component being greater than 2.4% TRR (0.018 mg eq/kg).

Parent clethodim was not detected in mature roots. Clethodim sulfoxide (18–24% TRR, 0.029–0.032 mg eq/kg), M17R (14% TRR, 0.022 mg eq/kg), M18R (13% TRR, 0.020 mg eq/kg) and M15R (12% TRR, 0.019 mg eq/kg) were present at > 10% TRR in mature roots.

The cyclohexene ring opened metabolites, M15R, M17R and M18R observed in the outdoor study were not observed in the study performed in a greenhouse.

### **Cotton**

Greenhouse grown cotton plants received two foliar applications of [<sup>14</sup>C]-clethodim at 0.28 kg ai/ha with a 14 day RTI. The first treatment was applied when the cotton plants were at the 8–12 leaf stage. Cotton plants were grown to maturity and harvested at 70 DALA. The TRRs in cotton were 6.7–14 mg eq/kg for leaves, 0.47–1.4 mg eq/kg for shell and 0.068–0.22 mg eq/kg for seeds. Total extractability was  $\geq 87\%$  TRR in leaves with acetone, methanol and methanol/water. Total extractability was 39–54% TRR in seeds extracted with hexane, acetone, methanol and methanol/water.

Parent clethodim was not detected in any of the plant parts. The metabolites  $\geq 10\%$  TRR in cotton leaves were conjugates of clethodim sulfoxide (10% TRR, 0.67 mg eq/kg) and clethodim imine sulfoxide (18% TRR, 2.4 mg eq/kg). Identified residues in cotton seed were  $\leq 0.007$  mg eq/kg, with the most abundant residue being clethodim sulfoxide (3.1% TRR).

### **Conclusions**

Parent clethodim is rapidly metabolized in plant commodities. The one major metabolic pathway in plants is sulfoxidation to clethodim sulfoxide followed by further oxidation to clethodim sulfone. Clethodim sulfoxide and clethodim sulfone conjugates were also identified as major or minor metabolites in all crops. Another pathway is elimination of the chloroallyl moiety, leading to the formation of clethodim imine and 3-chlorolallyl metabolites, including 3-chloroalcohol glucoside (M15A).

The studies in carrots and spinach were performed in outdoor conditions and suggest that the clethodim ring can be opened by a photolytic reaction (also from imine metabolites) to form pentanedioic acids. Metabolites M15R, M17R and M18R belong to the pentanedioic acids.

### **Environmental fate**

The Meeting received aqueous hydrolysis, soil photolysis, aerobic soil metabolism and soil degradation studies for clethodim.

In the aqueous hydrolysis study, clethodim was hydrolytically stable at pH 7 and 9 but degraded at pH 5 with a  $DT_{50}$  of 28–54 days at 25 °C. The major hydrolysis products were clethodim oxazole (51% applied residue (AR) after 32 days) and chloroallyl alcohol (31% AR after 30 days). Hydrolysis is unlikely to be a major route of environmental degradation.

In the soil photolysis studies, clethodim was rapidly degraded in irradiated soils ( $DT_{50}$  of 0.15–1.8 days) and in non-irradiated soils ( $DT_{50}$  of 1.9–3.6 days). Clethodim sulfoxide was the major degradation product on soil and was rapidly photodegraded in the irradiated soils. The major dissipation route of clethodim sulfoxide was degradation to trans-3-chloro-acrylic acid, 2-[3-chloroallyloxyimino] butanoic acid (CBA), formation of bound residues and CO<sub>2</sub>. Clethodim is susceptible to photolytic degradation.

In the aerobic soil metabolism studies, clethodim was rapidly degraded in a variety of soils with a  $DT_{50}$  of < 2.5 days at 25 °C. Clethodim sulfoxide was the most significant metabolite and other significant soil metabolites were clethodim sulfone, clethodim oxazole sulfoxide and clethodim oxazole sulfone.

The  $DT_{50}$ s of clethodim sulfoxide and clethodim sulfone were 1.6–2.5 days and 3.8–10 days, respectively.

The  $DT_{50}$  of clethodim oxazole sulfone was 20–68 days. The photolysis product CBA was degraded with a  $DT_{50}$  of 5.5 days.

Clethodim was rapidly degraded in the environmental fate studies, and the breakdown products also rapidly degraded to form bound residues and CO<sub>2</sub>. Clethodim is not persistent in soil.

### **Rotational crop metabolism**

The Meeting received a confined rotational crop study with <sup>14</sup>C-labeled clethodim.

Rotational crops (lettuce, carrots and wheat) were planted in sandy loam soil that had been treated at 1.1 kg ai/ha with [<sup>14</sup>C]-clethodim and then aged for 30, 120 and 365 days in a greenhouse.

In carrot leaf, lettuce leaf (30 days), and wheat straw and hulls, the radioactive residues were found at > 0.05 mg eq/kg (0.053–0.65 mg eq/kg).

Parent clethodim was not detected in any of the analysed extracts. Small amounts of clethodim imine sulfoxide (2.4–19% TRR, 0.006–0.040 mg eq/kg), clethodim oxazole sulfoxide (< 0.1–3.9 TRR, < 0.001–0.017 mg eq/kg) and clethodim oxazole sulfone (< 0.1–8.0% TRR, < 0.001–0.029 mg eq/kg) were detected.

The results show that the metabolism of clethodim in rotated crops was similar for all crop types. The metabolites in rotational crops, clethodim oxazole sulfoxide and clethodim oxazole sulfone were soil metabolites of clethodim. Their occurrence in rotational crops is due to the uptake by plant roots.

Residues related to clethodim are not expected to be significant in rotational crops as the treated rate in the study was 2 × GAP rate.

### **Animal metabolism**

The Meeting received animal metabolism studies on rats, lactating goats and laying hens where animals were dosed with [<sup>14</sup>C]-clethodim. The metabolism and distribution of clethodim in farm animals were investigated using the [Propyl-1-<sup>14</sup>C]-clethodim for lactating goats and the [Ring-4,6-<sup>14</sup>C]-clethodim for laying hens.

#### **Rats**

The metabolism of clethodim in rats was reviewed within the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2019 JMPR.

#### **Lactating goats**

Lactating goats received daily oral dosing of [<sup>14</sup>C]-clethodim at 1.2 mg/kg bw/day (equivalent to 24 ppm in the diet) for 4 consecutive days. The goats were sacrificed 4 hours after the last dose. Most of the total administered dose was found in the urine (56%) and faeces (34%).

Total radioactive residues (TRR) were highest in the liver (0.41 mg eq/kg) and kidney (0.38 mg eq/kg), followed by muscle (forequarter: 0.033 mg eq/kg, hindquarter: 0.034 mg eq/kg) and fat (subcutaneous: 0.079 mg eq/kg, peritoneal: 0.047 mg eq/kg). The concentration of radioactivity in the milk reached a plateau of about 0.035 mg eq/L by day 2.

The majority of the radioactive residues in liver (77% TRR), kidney (91% TRR), muscle (90–93% TRR) and subcutaneous fat (95% TRR) were extracted into organic solvents (acetone and methanol/water). Most of the milk radioactivity was not extracted by organic solvents and remained in the post-extraction solids (PES)(30–66% TRR).

Clethodim was found in liver (28% TRR, 0.11 mg/kg), kidney (1.3% TRR, 0.005 mg/kg), fat (2.8% TRR, 0.002 mg/kg) and milk on Day 4 (3.3% TRR, 0.001 mg/kg). No clethodim was found in muscle.

Clethodim sulfoxide was major metabolite in milk (15–29% TRR, 0.005–0.013 mg eq/kg) and tissues (33–52% TRR, 0.014–0.14 mg eq/kg).

S-methyl clethodim sulfoxide was also a major metabolite in kidney, muscle and fat (29–32% TRR, 0.009–0.12 mg eq/kg).

Significant residues of the radioactivity in milk were incorporated into natural products; [<sup>14</sup>C]-lactose was identified in milk (30–54% TRR, 0.014–0.017 mg eq/kg).

Other identified metabolites in milk and tissues, clethodim sulfone, clethodim imine sulfoxide and 5-OH clethodim sulfone were observed at levels below 5% TRR (< 0.016 mg eq/kg).

### *Laying hens*

Laying hens received daily oral doses of [<sup>14</sup>C]-clethodim for 5 consecutive days at a rate equivalent to 27 ppm in the diet as received (2.1 mg/kg bw per day). Another group of hens were treated identically, but received a higher dose (equivalent to 707 ppm in the diet as received, 51.3 mg/kg bw per day) to facilitate identification of unknown metabolites. The hens were sacrificed 4 hours after the last dose. After administration, 78–85% of the total dose was recovered in excreta.

In the 27 ppm dose group, radioactive residues in tissues were highest in kidney (1.2 mg eq/kg) and liver (0.7 mg eq/kg). Residue levels in skin, fat, thigh muscle and breast muscle were all within the range of 0.1–0.3 mg eq/kg. Residue levels in eggs were ≤ 0.22 mg eq/kg (maximum at day 4 in egg white). Radioactivity levels in egg yolk and egg white did not reach a plateau within the 4-day study period.

Liver, kidney, thigh and breast muscles were extracted with methanol and methanol/water. Skin, fat and egg yolks were extracted with acetone and methanol/water. Good extractability was achieved for all samples (≥ 84% TRR).

In kidney, liver, skin, breast and thigh muscle, major identified metabolites were clethodim sulfoxide (30–57% TRR) and clethodim sulfone (16–34% TRR). Clethodim was also detected (0.5–7.5% TRR). In fat, major components were clethodim (65% TRR), clethodim sulfoxide (15–41% TRR) and clethodim sulfone (10–16% TRR). No other metabolites were identified.

### *Conclusions*

The metabolic pathway of clethodim in rat is consistent with that in ruminants (goat) where clethodim, clethodim sulfoxide, clethodim sulfone and at lower levels 5-hydroxy sulfoxide, 5-hydroxy sulfone, imine sulfoxide, S-methyl clethodim and S-methyl sulfoxide were identified. In hen, the metabolic pathway was simpler than that observed in rat and goat. None of the imine analogues, 5-hydroxy analogues or S-methyl analogues identified in rat and goat were found in hens.

### *Methods of analysis*

The Meeting received information on analytical methods for clethodim and its metabolites in plant and animal matrices. There are two types of methods of plant matrices, one is a common moiety method and the other is a specific individual method.

In the common moiety methods of plant and animal matrices, samples were extracted with methanol/water. All compounds containing the 5-(2-ethylthiopropyl) cyclohexene-3-one moiety were converted into DME and all compounds containing the 5-(2-ethylthiopropyl)-5-hydroxy cyclohexene-3-one moiety were converted into DME-OH by alkaline precipitation, oxidation and methylation. The residues can be measured by GC-FPD. Representative compounds that are converted into DME (clethodim or clethodim sulfoxide) and DME-OH (5-OH clethodim sulfoxide) are used as reference materials for fortification and method validation. The methods of analysis were validated with an LOQ of 0.095 mg/kg expressed as clethodim equivalents for DME and 0.088 mg/kg expressed as clethodim equivalents for DME-OH.

In the specific individual methods of plant matrices, samples were extracted with methanol/water, and then clethodim, clethodim sulfoxide, clethodim sulfone, M17R and M18R (free form of all analytes) can be measured by LC-MS/MS with an LOQ of 0.005 mg/kg for each analyte.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure clethodim and its metabolites in plant (common-moiety and individual analyte methods) and animal (common-moiety method only) commodities.

### ***Stability of pesticide residues in stored analytical samples***

The Meeting received information on storage stability of clethodim and its metabolites in raw/processed plant and animal commodities.

Storage stability studies using the specific individual analytical method showed that clethodim was stable for at least 6 months at -18 °C in crop commodities representative of the high protein (dry pea) and high oil (oilseed rape) commodity groups, but it was degraded within 30 days in the high water (alfalfa) and high starch (potato) commodity groups.

Storage stability studies using the specific individual analytical method showed that clethodim sulfoxide was stable for at least 6 months at  $\leq -18$  °C in crop commodities representative of the high water (alfalfa), high acid (grape), high starch (potato), high protein (dry pea) and high oil (oilseed rape) commodity groups.

Storage stability studies using the specific individual analytical method showed that clethodim sulfone was stable at  $< -18$  °C for at least 6 months in crop commodities representative of the high acid (grape), high starch (potato), high protein (dry pea) and high oil (oilseed rape) commodity groups, and stable at least 3 months in the high water (alfalfa) commodity group.

Storage stability studies using the specific individual analytical method showed that M17R and M18R were stable for at least 9 months at  $\leq -18$  °C in crop commodities representative of the high acid (grape), high starch (potato), high protein (dry pea) and high oil (oilseed rape) commodity groups.

Storage stability studies fortified with 5-OH clethodim sulfone showed that residues analysed as DME-OH were stable for at least 5 months at -12 to -22 °C in crop commodities representative of the high water (peach, plum, lettuce, sugar beet leaves), high acid (blueberry, cranberry), high starch (carrot roots, sugar beet roots) and high protein (dry pea) commodity groups and hops.

Storage stability studies in animal commodities fortified with clethodim, 5-OH clethodim sulfone and S-methyl clethodim sulfoxide showed that residues analysed as DME, DME-OH and S-methyl DME were stable for at least 5 months at -20 °C in milk and bovine tissues (liver, kidney, muscle and fat), and for at least 1 month at -18 °C in chicken eggs and tissues (liver, muscle and fat).

The Meeting noted that clethodim was unstable in high water and high starch commodity groups during freezer storage. However, the residues analysed as DME by the common moiety analytical methods were stable for at least 5 months in raw/processed plant and animal commodities including the high water and high starch commodities. The Meeting agreed that the demonstrated storage stability on various representative plant and animal commodities using the common moiety analytical methods covered the residue sample storage intervals used in the field trials considered by the current Meeting.

### ***Definition of the residue***

#### ***Plant commodities***

In plant metabolism studies on clethodim in root crops (carrot), leafy crops (spinach) and pulses/oilseeds (soya bean/ cotton), clethodim was extensively metabolized and not detected or occurred in low amounts in mature crops at levels up to 1.1% TRR.

Clethodim sulfoxide (2.8–34% TRR) and clethodim sulfone (0.3–9.9% TRR) were found in all primary crop commodities. Conjugates of clethodim sulfoxide (2.7–27% TRR) and conjugates of clethodim sulfone (0.5–12% TRR) were also identified as metabolites in soya bean (leaves and seeds), carrot (leaves and roots) and cotton (leaves).

5-OH clethodim sulfone was identified in soya bean seeds (10–11% TRR) and carrot roots (7.6–10% TRR). Clethodim imine sulfoxide was found in leaves of immature spinach (14% TRR), soya bean (14% TRR), carrot (13–22% TRR) and cotton (18% TRR). Clethodim imine sulfoxide (2.4–19% TRR) was also determined in rotational crops (carrot, lettuce and wheat). Clethodim imine sulfoxide levels increased with exposure to sunlight.

The ring opened metabolites M15R (7.7–14% TRR), M17R (8.9–35% TRR) and M18R (7.3–13% TRR) belong to the pentanedioic acids and were identified as major metabolites in spinach and carrot grown outdoors. 3-Chloroallyl alcohol glucoside (M15A) was also a major metabolite found in spinach (21–23% TRR).

In rotational crops, the metabolites in soil, clethodim oxazole sulfoxide (< 0.1–3.9% TRR) and clethodim oxazole sulfone (< 0.1–8.0% TRR), were also detected.

In the high temperature hydrolysis study for processed commodities, the major metabolite of plant commodities, clethodim sulfoxide, degraded to clethodim oxazole sulfoxide (pH4: 89% AR, pH5: 94% AR, pH6: 98% AR). This metabolite was not observed in plant metabolism studies.

In a storage stability study conducted in alfalfa and potato tubers, clethodim was decomposed to compounds other than clethodim sulfoxide and clethodim sulfone during freezer storage. Therefore, the sum of clethodim, clethodim sulfoxide and clethodim sulfone would not be appropriate as a marker for monitoring.

Common moiety analytical methods that determined the common moiety DME and DME-OH are available. Parent clethodim, clethodim sulfoxide, clethodim sulfone, clethodim imine sulfoxide, clethodim oxazole sulfoxide, clethodim oxazole sulfone, M17R and M18R (including the free and conjugated forms) are converted into the DME. 5-OH clethodim sulfone and M15R (including the free and conjugated forms) are converted into the DME-OH.

The Meeting noted that the common moiety methods are not specific to monitor clethodim and residues may arise from sethoxydim, no other suitable marker compound and analytical method were available.

The Meeting decided to define the residue for compliance with the MRL for plant commodities as sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME) and dimethyl 3-[2-(ethylsulfonyl)propyl]-3-hydroxy-pentanedioate (DME-OH), expressed as clethodim.

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 clethodim sulfone, clethodim oxazole sulfoxide, M19R, M15A and 3-chloroallyl alcohol.

The Meeting concluded that the TTC approach for genotoxicity could be applied for clethodim sulfone, M19R and M15A and the TTC approach using Cramer Class III could be applied for clethodim oxazole sulfoxide.

Clethodim sulfone is measured as DME by the common moiety analytical method but the individual residue cannot be determined. Therefore, the field trial data analysed with a specific analytical method were used for the estimation of exposure. The chronic dietary exposure was estimated based on uses on head cabbage, dry peas, carrot and artichoke because the residue data for clethodim sulfone itself were available.

The Meeting noted that the estimated chronic dietary exposure to clethodim sulfone (0.028 µg/kg bw per day) exceeds the threshold of toxicological concern for genotoxicity (0.0025 µg/kg bw per day).

3-Chloroallyl alcohol was the major hydrolysis product (31% AR after 30 days) and is the free form of M15A (glucose conjugate). M15A was the major residue in spinach (21–23% TRR, 0.79–1.1 mg eq/kg) and M19R was the major residue in carrot mature leaves (14% TRR, 0.12 mg eq/kg) at a 2 × GAP rate of 0.50 kg ai/ha. Those three metabolites cannot be measured by the common moiety analytical method. The Meeting noted that M15A and M19R were not observed in the rat metabolism study and no information is available on their toxicity.

M19R and M15A are expected to occur in leaves with exposure to sunlight. Therefore, the chronic dietary exposure was estimated based on uses on leafy greens and head cabbage. The maximum residues of M19R and M15A in the plant metabolism studies, with adjustment to the GAP rate (50%

the rate used in the metabolism studies), were used to estimate the chronic dietary exposure. It was noted that 3-chloroallyl alcohol (free form of M15A) was only detected in the hydrolysis study. Estimated exposures were:

M19R: 0.091 µg/kg bw per day

M15A: 0.84 µg/kg bw per day

The Meeting noted that the estimated exposures to M19R and M15A exceeded the threshold of toxicological concern for genotoxicity (0.0025 µg/kg bw per day).

Clethodim oxazole sulfoxide is generated from clethodim sulfoxide during high temperature processing of plant commodities. This compound can be measured by a common moiety analytical method but individual residues of the compound cannot be determined. The Meeting could not estimate the chronic dietary exposure for clethodim oxazole sulfoxide.

Because the Meeting was unable to conclude on the toxicological relevance of the metabolites clethodim sulfone, M19R, M15A and clethodim oxazole sulfoxide the Meeting could not reach a conclusion on the residue definition for dietary risk assessment.

### *Animal commodities*

In animal metabolism studies, clethodim was rapidly metabolized and not detected or in low amounts in tissues (up to 7.5% TRR) except goat liver, hen fat and egg yolk. Clethodim was the major component of the residue in goat liver (28% TRR), hen fat (34–65% TRR) and egg yolk (15–34% TRR).

Clethodim sulfoxide and clethodim sulfone were identified in goat and hen. Clethodim sulfoxide was a major metabolite in all animal commodities (milk: 15–29% TRR, egg: 25–82% TRR, tissues: 15–57% TRR). Clethodim sulfone was a major metabolite identified in hen commodities (egg yolk: 11–29% TRR, egg white: 9.9–38% TRR, tissues: 10–34% TRR).

S-methyl clethodim sulfoxide, clethodim imine sulfoxide and 5-OH clethodim sulfone were found only in goat. S-methyl clethodim sulfoxide was identified as a major metabolite in kidney (31% TRR), muscle (29–32% TRR) and fat (29% TRR). Clethodim imine sulfoxide and 5-OH clethodim sulfone were present at < 5% TRR in milk and tissues.

In plant metabolism studies, clethodim sulfoxides and clethodim sulfones (free and conjugated) were found but no clethodim was observed. S-methyl clethodim is directly formed from parent clethodim and then oxidized to S-methyl sulfoxide. Therefore, S-methyl clethodim sulfoxide cannot be formed in the animal due to the absence of parent clethodim in feed.

In farm animal feeding studies the administered dose comprised 5% clethodim and 95% clethodim sulfoxide. No residue of 5-OH clethodim sulfone was found in any animal commodities. Therefore, residues that can be converted to the DME-OH moiety are unlikely to be found in animal commodities.

The Meeting decided to define the residue for compliance with the MRL for animal commodities as sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME), expressed as clethodim.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting considered the likely occurrence of the compound and the toxicological properties of the candidate clethodim sulfone.

Clethodim sulfone residues cannot be identified in animal commodities since no specific analytical method is available. However, the estimated chronic dietary exposure to clethodim sulfone from plant commodities exceeds the threshold of toxicological concern for genotoxicity.

Farm animal feeding studies show that DME residues in fat are two times higher than in muscle, and, in cream, more than four times higher than in skimmed milk. The Meeting considered the residue fat-soluble.



Because the Meeting was unable to conclude on the toxicological relevance of the metabolite clethodim sulfone the Meeting could not reach a conclusion on the residue definition for dietary risk assessment.

The Meeting recommended the following residue definitions for clethodim:

Definition of the residue for compliance with the MRL for plant commodities: *Sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME) and dimethyl 3-[2-(ethylsulfonyl)propyl]-3-hydroxy-pentanedioate (DME-OH), expressed as clethodim*

Definition of the residue for compliance with the MRL for animal commodities: *Sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME), expressed as clethodim*

The Meeting considers the residue to be fat-soluble.

Definition of the residue for dietary risk assessment for plant and animal commodities: *A conclusion could not be reached*

### **Results of supervised residue trials on crops**

Supervised trials were available for the use of clethodim on apple, pear, cherry, plum, peach, blueberry, cranberry, strawberry, onion, broccoli, cabbage, cucumber head lettuce, beans, peas, carrot, artichoke, oilseed rape and hops.

Product labels were available from Australia, European countries and the USA.

Since no residue data were provided for alfalfa fodder, beans (succulent), cotton seed, cotton seed oil, fodder beat, peanut, potato, soya bean, soya bean oil, sugar beet, sunflower seed, sunflower seed oil and tomato, the Meeting withdrew the previous recommendations for maximum residue levels for these commodities.

Total residues for estimation of maximum residue levels in plant commodities are calculated by summing up the concentrations of DME and DME-OH (expressed as clethodim equivalents) in common moiety methods. The method of calculation is illustrated below.

Example of the method for calculation of total residues

DME	DME-OH	Total
< 0.095	< 0.088	< 0.18
0.18	< 0.088	0.27

### **Pome fruits**

The critical GAP for pome fruit (not including persimmon, Japanese) in the USA allows four directed ground sprays of 0.14 kg ai/ha with a maximum seasonal rate of 0.54 kg ai/ha and a PHI of 14 days.

Data were available from supervised trials on apples and pears in the USA.

Total residues of DME and DME-OH in apples from independent trials in the USA with two applications of 0.27–0.29 kg ai/ha at a total application rate of 0.55–0.58 kg ai/ha with a PHI of 12–15 days were (n = 13): < 0.18 (13) mg/kg.

Total residues of DME and DME-OH in pears from independent trials in the USA with two applications of 0.27–0.30 kg ai/ha at a total application rate of 0.54–0.59 kg ai/ha with a PHI of 13–16 days were (n = 6): < 0.18 (6) mg/kg.

Since total residues of DME and DME-OH in apples and pears from the 2 × treated plots were all < 0.18 mg/kg, the Meeting agreed to estimate a maximum residue level of 0.2(\*) mg/kg for the group of pome fruits except persimmon, Japanese.

### *Stone fruits*

The critical GAP for stone fruit or peach in the USA allows four directed ground sprays of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 14 days.

Data were available from supervised trials on cherries (sweet and sour), plums and peaches in Canada and the USA.

Total residues of DME and DME-OH in cherries from independent trials in Canada and the USA with two applications of 0.27–0.30 kg ai/ha at a total application rate of 0.55–0.60 kg ai/ha with a PHI of 13–16 days were (n = 14): < 0.18 (14) mg/kg.

Total residues of DME and DME-OH in plums from independent trials in the USA with two applications of 0.27–0.29 kg ai/ha at a total application rate of 0.55–0.57 kg ai/ha with a PHI of 12–14 days were (n = 5): < 0.18 (5) mg/kg.

Total residues of DME and DME-OH in peaches from independent trials in the USA with two applications of 0.27–0.31 kg ai/ha at a total application rate of 0.54–0.61 kg ai/ha with a PHI of 12–15 days were (n = 7): < 0.18 (7) mg/kg.

Since total residues of DME and DME-OH in cherries, plums and peaches from the 2 × treated plots were all < 0.18 mg/kg, the Meeting agreed to estimate a maximum residue level of 0.2 (\*) mg/kg for the group of stone fruits.

### *Bush berries, Subgroup of*

The critical GAP for bush berries (high bush) in the USA allows four directed ground sprays of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 14 days.

Data were available from supervised trials on blueberries in Canada and the USA.

Total residues of DME and DME-OH in blueberries (high bush varieties) from independent trials in Canada and the USA with two applications of 0.27–0.30 kg ai/ha at a total application rate of 0.54–0.60 kg ai/ha with a PHI of 13–15 days were (n = 7): < 0.18 (7) mg/kg.

Since total residues of DME and DME-OH in blueberries (high bush varieties) from the 2 × treated plots were all < 0.18 mg/kg, the Meeting agreed to estimate a maximum residue level of 0.2 (\*) mg/kg for the subgroup of bush berries.

The Meeting noted that the US GAP also covered high bush cranberries and elderberry, listed in the Codex Classification as Guelder rose (*Viburnum opulus* L.) and elderberries (*Sambucus* spp.) in the subgroup of large shrub/tree berries, and agreed to extrapolate a maximum residue level of 0.2 (\*) mg/kg for Guelder rose and elderberries.

### *Low growing berries, Subgroup of*

#### *Cranberry*

Data were available from supervised trials on cranberries in the USA.

The critical GAP for cranberry in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 30 days.

The trials on cranberries in the USA did not match the GAP.

The Meeting could not estimate a maximum residue level for clethodim in cranberry.

#### *Strawberry*

Data were available from supervised trials on strawberries in Germany, the UK and the USA.

The critical GAP for strawberry in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 4 days.

The trials on strawberries in the USA did not match the GAP.

The critical GAP for strawberry in the Netherlands allows one spray application of 0.24 kg ai/ha with a PHI of 30 days.

Total residues of DME and DME-OH in strawberries from independent trials in Germany and the UK matching GAP in the Netherlands were (n = 8): 0.07, 0.09 (2), 0.13, 0.16, 0.19 and 0.22 (2) mg/kg.

Based on the residues in strawberries from trials in Germany and the UK, the Meeting estimated a maximum residue level of 0.5 mg/kg for strawberry.

#### ***Bulb onions, Subgroup of***

Data were available from supervised trials on onion in Norway.

The critical GAP for onions in the Netherlands allows one application of 0.24 kg ai/ha with a PHI of 56 days.

The trials on onions in Norway did not match the GAP.

The Meeting could not estimate a maximum residue level for clethodim in bulb onions.

The Meeting withdrew the previous recommendation for onion and garlic of 0.5 mg/kg.

#### ***Flowerhead Brassicas, Subgroup of***

##### ***Broccoli***

Data were available from supervised trials on broccoli in the USA.

The critical GAP for brassica head and stem vegetables in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 30 days.

The trials on broccoli in the USA did not match the GAP.

The Meeting could not estimate a maximum residue level for clethodim in broccoli.

#### ***Head Brassicas, Subgroup of***

##### ***Cabbage, Head***

Data were available from supervised trials on head cabbage in Australia and European countries.

The GAP for cabbages in Australia allows one spray application of 0.12 kg ai/ha with a PHI of 7 days.

Total residues of DME and DME-OH in head cabbage from independent trials in Australia matching the Australian GAP were (n = 1): 0.07 mg/kg and the total residues at two times the GAP rate were (n = 1): 0.20 mg/kg.

The critical GAP for head cabbage in the Netherlands allows one spray application of 0.24 kg ai/ha with a PHI of 28 days.

Since the methods of analysis in the European trials did not measure all analytes in the clethodim residue definition, the Meeting could not estimate a maximum residue level for clethodim in the Subgroup of head brassicas.

#### ***Fruiting vegetables, Cucurbits – Cucumber and Summer squashes, Subgroup of***

##### ***Cucumber***

Data were available from supervised trials on cucumber in the USA.

The critical GAP for cucurbits in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 14 days.

Total residues of DME and DME-OH in cucumber from independent trials in the USA with two applications of 0.28 kg ai/ha at a total application rate of 0.56 kg ai/ha with a PHI of 13–14 days were (n = 6): < 0.27 (6) mg/kg.

Since total residues of DME and DME-OH in cucumber from the 2 × treated plots were all < 0.27 mg/kg, the Meeting agreed to estimate a maximum residue level of 0.3 (\*) mg/kg for cucumber.

#### *Lettuce, Head*

Data were available from supervised trials on head lettuce in the USA.

The critical GAP for leafy greens in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 14 days.

The trials on head lettuce in the USA did not match the GAP.

The Meeting could not estimate a maximum residue level for clethodim in leafy greens.

#### *Dry beans, Subgroup of*

Data were available from supervised trials on dry beans in European countries.

The critical GAP for dry beans in Croatia allows one spray application of 0.25 kg ai/ha with a PHI of 42 days.

The trials on dry beans in France, Spain and the UK did not match the GAP and the methods of analysis in the European trials did not measure all analytes in the clethodim residue definition.

The Meeting could not estimate a maximum residue level for clethodim in the Subgroup of dry beans.

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

#### *Dry peas, Subgroup of*

Data were available from supervised trials on dry peas in European countries and the USA.

The GAP for dry peas in the USA allows 2–4 spray applications of up to 0.27 kg ai/ha at a maximum seasonal rate of 0.54 kg ai/ha with a PHI of 30 days, which leads to a critical GAP of 2 applications at 0.27 kg ai/ha.

The trials on dry peas in the USA did not match the GAP.

The critical GAP for dry peas in Slovakia allows one spray application of 0.26 kg ai/ha at application timing of BBCH 12–30.

The trials on dry peas in France did not match the GAP. The methods of analysis in the other European trials did not measure all analytes in the clethodim residue definition.

The Meeting could not estimate a maximum residue level for clethodim in the Subgroup of dry peas.

The Meeting withdrew the previous recommendation for field peas (dry) of 2 mg/kg.

#### *Root vegetables, Subgroup of*

##### *Carrot*

Data were available from supervised trials on carrot in European countries and the USA.

The critical GAP for carrot in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 30 days.

The trials on carrot in the USA did not match the GAP.

The critical GAP for carrot in Slovakia allows one spray application of 0.24 kg ai/ha with a PHI of 40 days.

The trials on carrot in European countries did not match the GAP and the methods of analysis in the European trials did not measure all analytes in the clethodim residue definition.

The Meeting could not estimate a maximum residue level for clethodim in carrot.

#### *Other stalk and stem vegetables, Subgroup of*

##### *Artichoke, globe*

Data were available from supervised trials on artichoke in Greece, Spain and the USA.

The critical GAP for artichoke in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 5 days.

The trials on artichoke in the USA did not match the GAP.

The critical GAP for artichoke in Spain allows one spray application of 0.18 kg ai/ha with a PHI of 40 days.

Since the methods of analysis in the trials conducted in Greece and Spain did not measure all analytes in the clethodim residue definition, the Meeting could not estimate a maximum residue level for clethodim in artichoke, globe.

#### *Small seed oilseeds, Subgroup of*

##### *Rape seed*

Data were available from supervised trials on rape seed in Canada, France, the UK, and the USA.

The critical GAP for rape seed (winter rape) in Slovakia allows one spray application of 0.26 kg ai/ha (for spring application) at an application timing of BBCH 12–30.

The trials on rape seeds in France and the UK did not match the GAP.

The critical GAP for rape seed in the USA allows an application rate of 0.11 kg ai/ha with a maximum seasonal rate of 0.28 kg ai/ha and a PHI of 70 days.

Total residues of DME and DME-OH in rape seeds from independent trials in Canada and the USA matching the US GAP were (n = 4): 0.25 (3) and 0.50 mg/kg. However, the trials for rape seeds in Canada and the USA were insufficient to estimate a maximum residue level for the commodity.

The Meeting could not estimate a maximum residue level for clethodim in rape seed.

The Meeting withdrew the previous recommendation for rape seed of 0.5 mg/kg, rape seed crude oil of 0.5 (\*) mg/kg and rape seed edible oil of 0.5 (\*) mg/kg.

##### *Hops, dry*

Data were available from supervised trials on dried hops in the USA.

The critical GAP for hops in the USA allows four spray applications of 0.14 kg ai/ha with a maximum seasonal rate of 0.56 kg ai/ha and a PHI of 21 days.

Since the methods of analysis in the US trials did not measure all analytes in the clethodim residue definition, the Meeting could not estimate a maximum residue level for clethodim in hops, dry.

## ***Residues in animal feeds***

### ***Legume animal feeds***

#### ***Bean fodder***

Data were available from supervised trials on bean fodder in France, Spain and the UK.

The critical GAP for beans in Croatia allows one spray application of 0.25 kg ai/ha with a PHI of 42 days.

The trials on bean fodder in France, Spain and the UK did not match the GAP.

The Meeting could not estimate a maximum residue level for clethodim in the Subgroup of bean fodder.

The Meeting withdrew the previous recommendation for bean fodder of 10 mg/kg.

#### ***Bean forage***

Data were available from supervised trials on bean forage in France, Spain and UK.

The critical GAP for beans in Croatia allows one spray application of 0.25 kg ai/ha and no instruction for feeding.

Since the methods of analysis in the trials conducted in France, Spain and the UK did not measure all analytes in the clethodim residue definition, the Meeting could not estimate a maximum residue level for clethodim in bean forage.

#### ***Pea fodder***

Data were available from supervised trials on pea fodder in European countries and the USA.

The critical GAP for peas in Slovakia allows one spray application of 0.26 kg ai/ha at application timing of BBCH 12–30.

The trials on pea fodder in France did not match the GAP.

The methods of analysis in the other European trials did not measure all analytes in the clethodim residue definition.

The Meeting could not estimate a maximum residue level for clethodim in pea fodder.

#### ***Pea vines***

Data were available from supervised trials on pea vines in European countries.

The critical GAP for peas in Slovakia allows one spray application of 0.26 kg ai/ha at application timing of BBCH 12–30.

Since the methods of analysis in the European trials did not measure all analytes in the clethodim residue definition, the Meeting could not estimate a maximum residue level for clethodim in pea vines.

## ***Fate of residues during processing***

### ***High temperature hydrolysis***

The hydrolytic stability of [<sup>14</sup>C]-clethodim and [<sup>14</sup>C]-clethodim sulfoxide was studied under conditions of high temperature in sterile aqueous buffers at pH 4, 5 and 6 for periods of up to 60 minutes to simulate common processing practices (pasteurization, baking/boiling, and sterilization).

At pH 4 with heating at 90 °C for 20 min, clethodim degraded to clethodim oxazole (14% AR). At pH 5 with heating at 100 °C for 60 min and at pH 6 at 120 °C for 20 min, clethodim oxazole was formed with amounts of 80% and 96% AR, respectively, and an additional degradation product, clethodim trione with amounts of 5.4% and 3.8% AR, respectively.

At pH 4, 5 and 6 with heating, clethodim sulfoxide degraded to clethodim oxazole sulfoxide (89, 94 and 98% AR), and an additional degradation product, clethodim trione sulfoxide with amounts of 6.9%, 5.5% and 2.7% AR, respectively.

### ***Residues in processed commodities***

The Meeting received information on the fate of clethodim residues during processing of apples, plums and oilseed rape.

Although the studies on apples and plums were conducted at an exaggerated application rate compared to GAP, residues of clethodim determined as DME and DME-OH in the RAC and the processed fractions (apple: juice and pomace, plum: dried) were all below the respective LOQs of 0.095 mg/kg for DME and 0.088 mg/kg for DME-OH. Processing factors for apple juice, apple pomace and dried plum could not be established.

Processing studies on rape seed did not indicate concentration of residues in the oil.

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

The Meeting received a lactating dairy cow and a laying hen feeding studies, which provided information on likely residues resulting in animal commodities, milk and eggs from clethodim and clethodim sulfoxide residues in the animal diet.

#### ***Lactating dairy cows***

Holstein/Friesian dairy cows were dosed with 5% clethodim and 95% clethodim sulfoxide for 28 days at the equivalent of 0.53, 1.7 and 5.7 ppm for clethodim and 10, 32 and 107 ppm for clethodim sulfoxide in the diet. Residues of DME-OH were below the LOQ in milk (< 0.013 mg eq/kg) and tissues (liver, kidney, muscle and fat: < 0.05 mg eq/kg) at all feeding levels. Residues of S-methyl DME were below the LOQ in milk (< 0.013 mg eq/kg) at the 0.53/10 ppm and 1.7/32 ppm feeding levels, below the LOQ in muscle and fat (< 0.05 mg eq/kg) at all feeding levels and were detected in milk (< 0.013–0.032 mg eq/kg), liver (< 0.05–0.087 mg eq/kg) and kidney (< 0.05–0.078 mg eq/kg) at the highest feeding level (5.7/107 ppm).

Residues of DME (expressed as clethodim) were below the LOQ (< 0.05 mg eq/kg) in muscle and fat at the 0.53/10 ppm and 1.7/32 ppm feeding levels. Whole milk contained no residue (< 0.013 mg eq/kg) of DME at the 0.53/10 ppm feeding level. Residues of DME in whole milk achieved a plateau concentration of < 0.013–0.033 mg eq/kg at the 1.7/32 ppm feeding level and 0.035–0.081 mg eq/kg at the 5.7/107 ppm feeding level.

Residues of DME in liver and kidney were < 0.05–0.059 mg eq/kg at the 0.53/10 ppm feeding level, 0.070–0.17 mg/kg at the 1.7/32 ppm feeding level and 0.22–0.54 mg/kg at the 5.7/107 ppm feeding level.

#### ***Laying hens***

Laying hens were dosed with 5% clethodim and 95% clethodim sulfoxide for 28 days at the equivalent of 0.74, 1.9 and 5.5 ppm for clethodim and 11, 34 and 108 ppm for clethodim sulfoxide in the diet. Residues of DME-OH and S-methyl DME were below the LOQ (0.1 mg/kg) in eggs, liver, muscle and fat at all feeding levels.

Residues of DME (expressed as clethodim) were below the LOQ (0.1 mg/kg) in liver, muscle and fat at all feeding levels. Eggs contained no residue (< 0.1 mg/kg) of DME at the 0.74/11 ppm and the 1.9/34 ppm feeding level. Residues of DME in eggs achieved a plateau concentration of 0.14–0.24 mg/kg at the 5.5/108 ppm feeding level.

#### ***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.

The only potential feed item was apple wet pomace. Total residues of DME and DME-OH in apple wet pomace are expected to be below the LOQ as residues in apple fruits are below the LOQ.

#### ***Animal commodity maximum residue levels***

The dietary burden for beef and dairy cattle is 0 ppm. No residues of DME are expected in any tissues or milk. No feed items for poultry were applicable.

The Meeting estimated maximum residue levels at the LOQ of 0.02 (\*) mg/kg for milk and 0.05 (\*) mg/kg for mammalian meat and mammalian edible offal to replace the previous recommendations for milk of 0.05 (\*) mg/kg, mammalian meat of 0.2 (\*) mg/kg and mammalian edible offal of 0.2 (\*) mg/kg. The Meeting estimated a maximum residue level of 0.05 (\*) mg/kg for mammalian fat.

The Meeting estimated maximum residue levels of 0.1 (\*) mg/kg for eggs, poultry meat and poultry, edible offal to replace the previous recommendations for eggs of 0.05 (\*) mg/kg, poultry meat of 0.2 (\*) mg/kg and edible offal of poultry of 0.2 (\*) mg/kg. The Meeting estimated a maximum residue level of 0.1 (\*) mg/kg for poultry fat.

### **RECOMMENDATIONS**

Definition of the residue for compliance with the MRL for plant commodities: Sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME) and dimethyl 3-[2-(ethylsulfonyl)propyl]-3-hydroxy-pentanedioate (DME-OH), expressed as clethodim.

Definition of the residue for compliance with the MRL for animal commodities: Sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME), expressed as clethodim.

The residue is fat-soluble.

Definition of the residue for dietary risk assessment for plant and animal commodities: *A conclusion could not be reached*

### **DIETARY RISK ASSESSMENT**

Because the Meeting was unable to conclude on the toxicological relevance of the metabolites clethodim sulfone, clethodim oxazole sulfoxide, M19R and M15A, the Meeting could not reach a conclusion on the residue definitions for dietary risk assessment for plant and animal commodities.

As a result, long-term and acute dietary risk assessments could not be conducted.



## 5.8 Cyclaniliprole (296)

### RESIDUE AND ANALYTICAL ASPECTS

Cyclaniliprole is an insecticide belonging to the chemical class of diamide insecticides which act at the ryanodine receptor, which is critical for muscle contraction.

Cyclaniliprole was first evaluated by the 2017 JMPR where an ADI of 0–0.04 mg/kg bw was established. An ARfD was determined to be unnecessary.

A residue definition of *cyclaniliprole* was determined for compliance with the MRL for plant and animal commodities and for dietary risk assessment for animal commodities.

For dietary risk assessment for plant commodities, the residue definition was determined to be *cyclaniliprole* + *3-bromo-2-((2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b]-[1,4]oxazin-4-ylidene)amino)-5-chloro-N(1-cyclopropylethyl)benzamide (NK-1375)*, expressed as cyclaniliprole equivalents.

The residue is fat-soluble.

Cyclaniliprole was scheduled by the Fiftieth Session of the CCPR for the reassessment of the trials reviewed in 2017 and the evaluation of additional new uses. The current Meeting received revised GAP information for several of the uses evaluated by the 2017 JMPR as well as new GAP information, supervised field trials on citrus fruits, berries and tuberous and corm vegetables, and orange and potato processing studies.

#### **Methods of analysis**

The LC-MS/MS analytical method (Report JSM 0269) used for analysis of residues of cyclaniliprole and NK-1375 in plant commodities, with LOQs of 0.01 mg/kg for each analyte, was reviewed by the 2017 JMPR. All samples collected from the supervised residue trials submitted to the current Meeting were analysed using the same method.

#### **Stability of residues in stored analytical samples**

The stability of residues of cyclaniliprole and NK-1375 during frozen storage was evaluated by the 2017 JMPR. Cyclaniliprole and NK-1375 were determined to be stable when stored frozen for at least 18 months at -20 °C in commodities representative of the high water, high acid, high starch, high protein and high oil commodity groups.

The periods of demonstrated stability adequately covered the frozen storage intervals of the samples in the supervised residue trials on crops considered by the current Meeting.

#### **Results of supervised residue trials on crops**

The current Meeting received supervised trial data for cyclaniliprole on lemons, oranges, grapefruits, raspberries, blueberries, strawberries, kiwifruit and potato. The Meeting also received revised use pattern information for pome fruits, stone fruits, *Brassica* head and stem vegetables, fruiting vegetables except cucurbits, fruiting vegetables, leafy vegetables, tree nuts and tea, previously assessed at the 2017 Meeting. Therefore, the supervised residue trials for these crops were reassessed in the framework of the revised use patterns.

Residues for maximum residue estimation are expressed in mg cyclaniliprole/kg. Residues for dietary risk assessment include parent cyclaniliprole and metabolite NK1375. The totals (sum of the mean of parent and NK-1375) are expressed as parent equivalents by applying a conversion factor of 1.064 to NK-1375.

For all crops, with the exception of tea, the number of applications, re-treatment interval and PHI approximated the critical GAPs from USA (citrus fruits only) or Canada, however, individual application rates were all greater than those of the critical GAPs. Therefore, the current Meeting agreed

to utilize the proportionality approach to estimate residues matching the critical GAP for estimation of the maximum residue levels and dietary exposures. For tea, all trials were conducted within 25% of the critical GAP in Japan.

### *Citrus fruits*

The critical GAP for citrus fruits is from the USA; 3×80 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from the USA on citrus fruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 7-day RTI and 1-day PHI.

#### *Lemons*

Cyclaniliprole residues in lemons in ranked order were (n = 5): 0.018, 0.048, 0.13, 0.14 and 0.17 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): 0.015, 0.038, 0.11 (2) and 0.14 mg/kg.

Total cyclaniliprole residues in lemons in ranked order were (n = 5): 0.029, 0.059, 0.14, 0.15 and 0.18 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): 0.023, 0.047, 0.12 (2) and 0.15 mg/kg.

#### *Orange*

Cyclaniliprole residues in oranges in ranked order were (n = 12): 0.033, 0.092, 0.093, 0.098, 0.11, 0.12 (2), 0.13, 0.14, 0.16, 0.19 and 0.36 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 12): 0.026, 0.074, 0.075, 0.078, 0.090, 0.094, 0.095, 0.10, 0.11, 0.13, 0.15 and 0.28 mg/kg.

Total cyclaniliprole residues in oranges in ranked order were (n = 12): 0.044, 0.10 (2), 0.11, 0.12, 0.13 (2), 0.14, 0.15, 0.17, 0.20 and 0.39 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 12): 0.035, 0.083 (2), 0.087, 0.099, 0.10 (2), 0.11, 0.12, 0.14, 0.16 and 0.31 mg/kg.

#### *Grapefruit*

Cyclaniliprole residues in grapefruits in ranked order were (n = 6): 0.024, 0.042, 0.059, 0.078, 0.082 and 0.096 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 6): 0.019, 0.034, 0.047, 0.061, 0.066 and 0.077 mg/kg.

Total cyclaniliprole residues in grapefruits in ranked order were (n = 6): 0.035, 0.053, 0.07, 0.089, 0.093 and 0.11 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 6): 0.028, 0.042, 0.056, 0.069, 0.075 and 0.085 mg/kg.

The Meeting noted that the GAP covers the group of citrus fruits and that median residues of lemons, oranges and grapefruits are within a 5-fold difference. Although trials were not provided for mandarins, the Meeting noted that residues in lemons/limes have been shown to be similar to or greater than residues in mandarins. The Kruskal-Wallis H-test also determined that the datasets were from the same population. Therefore, the Meeting decided to combine the three datasets of lemons, oranges and grapefruits.

Combined scaled cyclaniliprole residues in lemons, oranges and grapefruits were (n = 23): 0.015, 0.019, 0.026, 0.034, 0.038, 0.047, 0.061, 0.066, 0.074, 0.075, 0.077, 0.078, 0.090, 0.094, 0.095, 0.096, 0.11 (3), 0.13, 0.14, 0.15 and 0.28 mg/kg.

Total scaled cyclaniliprole residues in lemons, oranges and grapefruits in ranked order were (n = 23): 0.023, 0.028, 0.035, 0.042, 0.047, 0.056, 0.069, 0.075, 0.083 (2), 0.085, 0.087, 0.099, 0.10 (2), 0.11, 0.12 (3), 0.14, 0.15, 0.16 and 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.087 mg/kg for the Group of citrus fruits.

The Meeting estimated a median residue of 0.078 mg/kg (parent only) for animal dietary burden calculations.

### *Pome fruits*

The critical GAP for pome fruit is from Canada; 3×80 g ai/ha, 14-day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on pome fruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha/application, 14-day RTI and 1-day PHI.

#### *Apple*

Cyclaniliprole residues in apples in ranked order were (n = 16): 0.013, 0.023, 0.027, 0.035, 0.037, 0.046, 0.049, 0.054 (2), 0.055, 0.058, 0.068 (2), 0.10 (2) and 0.13 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 16): 0.01, 0.018, 0.021, 0.027, 0.030, 0.037, 0.039, 0.042, 0.043 (2), 0.046, 0.053, 0.054, 0.079 (2) and 0.10 mg/kg.

Total cyclaniliprole residues in apples in ranked order were (n = 16): 0.023, 0.033, 0.038, 0.046, 0.053, 0.056, 0.059, 0.065 (2), 0.067, 0.073, 0.079, 0.084, 0.12, 0.13 and 0.17 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 16): 0.018, 0.026, 0.030, 0.036, 0.043, 0.045, 0.047, 0.051, 0.052, 0.053, 0.058, 0.063, 0.065, 0.095, 0.10 and 0.14 mg/kg.

#### *Pear*

Cyclaniliprole residues in pears in ranked order were (n = 8): 0.037, 0.060, 0.069, 0.097, 0.11, 0.13 and 0.14 (2) mg/kg. Using scaling factors of 0.7–0.8, scaled residues in ranked order were (n = 8): 0.029, 0.048, 0.055, 0.078, 0.079, 0.10, 0.11 (2) mg/kg.

Total cyclaniliprole residues in pears in ranked order were (n = 8): 0.051, 0.070, 0.081, 0.12 (2), 0.14 and 0.16 (2) mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 8): 0.040, 0.056, 0.065, 0.085, 0.097, 0.11 and 0.13 (2) mg/kg.

The Meeting noted that the scaled median residues of cyclaniliprole in apples and pears were within five-fold and that the datasets were from the same population (Mann-Whitney U-test). The Meeting decided to combine the data to estimate a maximum residue level for pome fruits. The combined cyclaniliprole scaled residues in apples and pears were (n = 24): 0.01, 0.018, 0.021, 0.027, 0.029, 0.030, 0.037, 0.039, 0.042, 0.043 (2), 0.046, 0.048, 0.053, 0.054, 0.055, 0.078, 0.079 (3), 0.10 (2) and 0.11 (2) mg/kg.

Scaled total cyclaniliprole residues in apples and pears in ranked order were (n = 24): 0.018, 0.026, 0.030, 0.036, 0.040, 0.043, 0.045, 0.047, 0.051, 0.052, 0.053, 0.056, 0.058, 0.063, 0.065 (2), 0.085, 0.095, 0.097, 0.10, 0.11, 0.13 (2) and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.057 mg/kg for pome fruits, except Japanese persimmons, and withdraws its previous recommended maximum residue level of 0.3 mg/kg for the Group of pome fruits.

The Meeting estimated a median residue of 0.047 mg/kg (parent only) for animal dietary burden calculations.

### *Stone fruit*

The critical GAP for stone fruit is from Canada; 3×80 g ai/ha, 7-day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on stone fruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 7-day RTI and 7-day PHI.

#### *Cherries*

Cyclaniliprole residues in cherries in ranked order were (n = 15): 0.010, 0.016, 0.082, 0.097, 0.13 (2), 0.14 (2), 0.18, 0.24, 0.28, 0.30, 0.33, 0.44 and 0.56 mg/kg. Using scaling factors of 0.7–0.8, scaled residues in ranked order were (n = 15): 0.008, 0.013, 0.063, 0.075, 0.10, 0.11 (3), 0.14, 0.19 (2), 0.24,

0.26, 0.36 and 0.45 mg/kg.

Residue levels in the field trials from Canada and the USA were reported as flesh without stone. At the 2017 Meeting, it was concluded that, based on the Japanese trials on cherries, the contribution of the pit to the weight of the whole fruit is approximately 10%. Correcting the residue levels using this weight/weight ratio would lead to the same maximum residue level.

Total cyaniliprole residues in flesh in ranked order were (n = 15): 0.021, 0.027, 0.10, 0.11, 0.14 (2), 0.16, 0.17, 0.19, 0.26, 0.32, 0.34 (2), 0.48 and 0.61 mg/kg. Using the same scaling factors, scaled total cyaniliprole residues in ranked order were (n = 15): 0.017, 0.022, 0.077, 0.085, 0.11 (2), 0.12, 0.14, 0.15, 0.21, 0.23, 0.26, 0.27, 0.40 and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.14 mg/kg for the Subgroup of cherries, to replace its previous recommended maximum residue level of 0.9 mg/kg.

### *Plums*

Cyaniliprole residues in plums in ranked order were (n = 8): 0.019 (2), 0.024, 0.027, 0.056, 0.062, 0.065 and 0.091 mg/kg. Using scaling factors of 0.8–1.2, scaled residues in ranked order were (n = 8): 0.015 (2), 0.019, 0.033, 0.044, 0.049, 0.052 and 0.073 mg/kg.

Residue levels in the field trials from Canada and the USA were reported as flesh without stone. At the 2017 Meeting, it was concluded that, based on the ratio of the residue levels in flesh versus whole fruit which ranged between 0.86 and 0.97, an overestimation of residues of approximately 10% was anticipated. Correcting for this factor would lead to the same maximum residue level.

Total cyaniliprole residues in plums in ranked order were (n = 8): 0.030 (2), 0.035, 0.042, 0.067, 0.075, 0.076 and 0.11 mg/kg. Using the same scaling factors, scaled total cyaniliprole residues in ranked order were (n = 8): 0.024 (2), 0.028, 0.051, 0.053, 0.060, 0.061 and 0.089 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR value of 0.052 mg/kg for the Subgroup of plums, to replace its previous recommended maximum residue level of 0.2 mg/kg.

### *Peaches (including nectarines and apricots)*

Cyaniliprole residues in peaches in ranked order were (n = 13): 0.019, 0.023, 0.041, 0.045, 0.050, 0.051, 0.054, 0.064, 0.081, 0.094, 0.11, 0.16 and 0.19 mg/kg. Using scaling factors of 0.8–1.1, scaled residues in ranked order were (n = 13): 0.018, 0.021, 0.033, 0.036, 0.040, 0.041, 0.044, 0.051, 0.065, 0.073, 0.087, 0.13 and 0.15 mg/kg.

Residue levels in the field trials from Canada and the USA were reported as flesh without stone. At the 2017 Meeting, it was concluded that, based on the ratio of the residue levels in flesh versus whole fruit which ranged between 0.85 and 0.96, an overestimation of residues of approximately 10% was anticipated. Correcting for this factor would lead to the same maximum residue level.

Total cyaniliprole residues in peaches in ranked order were (n = 13): 0.030, 0.034, 0.056, 0.058, 0.061, 0.062, 0.065, 0.078, 0.092, 0.10, 0.12, 0.17 and 0.20 mg/kg. Using the same scaling factors, scaled total cyaniliprole residues were (n = 13): 0.027, 0.034, 0.045, 0.047, 0.049, 0.050, 0.053, 0.063, 0.074, 0.078, 0.095, 0.14 and 0.16 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.053 mg/kg for the Subgroup of peaches, and confirms its previous recommended maximum residue level of 0.3 mg/kg.

### *Cane berries*

The critical GAP for caneberrries is from Canada; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on raspberries where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 5–6 day RTI and 1-day PHI.

### *Raspberries*

Cyclaniliprole residues in raspberries in ranked order were (n = 5): 0.14, 0.24, 0.30, 0.31 and 0.53 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): 0.11, 0.18, 0.24, 0.25 and 0.42 mg/kg.

Total cyclaniliprole residues in raspberries in ranked order were (n = 5): 0.16, 0.27, 0.34, 0.36 and 0.58 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): 0.13, 0.21, 0.27, 0.30 and 0.47 mg/kg.

Noting that raspberries are the representative crop of the subgroup cane berries, the Meeting estimated a maximum residue level of 0.8 mg/kg and an STMR of 0.27 mg/kg for the Subgroup of cane berries.

### *Bush berries*

The critical GAP for bushberries is from Canada; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on blueberries where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 5-day RTI and 1-day PHI.

### *Blueberries*

Cyclaniliprole residues in blueberries in ranked order were (n = 10): 0.10, 0.14, 0.15, 0.20, 0.23, 0.29 (2), 0.42, 0.43 and 1.0 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 10): 0.079, 0.12 (2), 0.16, 0.19, 0.23 (2), 0.32, 0.34 and 0.81 mg/kg.

Total cyclaniliprole residues in blueberries in ranked order were (n = 10): 0.12, 0.20, 0.22, 0.24, 0.32, 0.37, 0.38, 0.50, 0.58 and 1.1 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): 0.092, 0.16, 0.19, 0.20, 0.25, 0.30(2), 0.39, 0.45, 0.89 mg/kg.

Noting that blueberries is the representative crop of the subgroup bush berries, the Meeting estimated a maximum residue level of 1.5 mg/kg and an STMR of 0.275 mg/kg for the Subgroup of bush berries and extrapolated these values to elderberries and Guelder rose.

### *Grapes*

The critical GAP for grapes is from Canada; 3×80 g ai/ha, 7-day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on grapes where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 6-day RTI and 6–7-day PHI.

Cyclaniliprole residues in grapes in ranked order were (n = 15): 0.025, 0.044, 0.048, 0.076, 0.11, 0.12 (2), 0.14 (2), 0.17, 0.21, 0.24, 0.33, 0.39 and 0.51 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 15): 0.020, 0.035, 0.038, 0.061, 0.088, 0.094, 0.096, 0.11(2), 0.14, 0.17, 0.19, 0.26, 0.31 and 0.41 mg/kg.

Total cyclaniliprole residues in grapes in ranked order were (n = 15): 0.036, 0.055, 0.059, 0.092, 0.13 (2), 0.15 (2), 0.17, 0.22, 0.25, 0.28, 0.44, 0.48 and 0.59 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 15): 0.029, 0.044, 0.047, 0.074, 0.10 (2), 0.12 (2), 0.14, 0.18, 0.20, 0.22, 0.34, 0.38 and 0.47 mg/kg.

The Meeting estimated a maximum residue level of 0.6 mg/kg and an STMR of 0.12 mg/kg for grapes to replace its previous recommended maximum residue level of 0.8 mg/kg.

The Meeting estimated a median residue of 0.11 mg/kg (parent only) for animal dietary burden calculations.

### *Low growing berries*

The critical GAP for low growing berries is from Canada; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on grapes where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 4–6 day RTI and 1-day PHI.

### *Strawberries*

Cyclaniliprole residues in strawberries in ranked order were (n = 9): 0.054, 0.091, 0.10, 0.23, 0.14, 0.15, 0.16, 0.21 and 0.34 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 9): 0.043, 0.074, 0.079, 0.099, 0.11, 0.12, 0.13, 0.17 and 0.28 mg/kg.

Total cyclaniliprole residues in strawberries in ranked order were (n = 9): 0.065, 0.10, 0.11, 0.14, 0.16 (2), 0.18, 0.25 and 0.36 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 9): 0.051, 0.083, 0.088, 0.12 (2), 0.13, 0.14, 0.20 and 0.29 mg/kg.

Noting that strawberries is the representative crop of the subgroup low growing berries but that the cultural practices for cranberries are significantly different from those of the other berries within the same crop subgroup, the Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR of 0.12 mg/kg for the Subgroup of low growing berries, except cranberries.

### *Kiwifruit*

The critical GAP is from Canada for “small fruits vine climbing, except grapes” including kiwifruit; 3×80 g ai/ha, 5-day RTI, 1-day PHI. The Meeting received trials from the USA on kiwifruits where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 5-day RTI and 1-day PHI.

Cyclaniliprole residues in kiwifruit in ranked order were (n = 3): 0.013, 0.24 and 0.49 mg/kg.

Total cyclaniliprole residues in kiwifruit in ranked order were (n = 3): 0.024, 0.25 and 0.50 mg/kg.

The Meeting noted that three trials are insufficient to estimate a maximum residue level and STMR for kiwifruit.

### *Brassica vegetables (except Brassica leafy vegetables)*

The critical GAP for flowerhead brassicas is from Canada for “Brassica head and stem vegetables”; 3 × 60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on Brassica vegetables where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha/application, 6–8 day RTI and 1-day PHI.

#### *Flowerhead Brassicas*

Cyclaniliprole residues in broccoli in ranked order were (n = 10): 0.11, 0.12, 0.18, 0.20, 0.34, 0.37, 0.41, 0.42, 0.47, and 0.66 mg/kg. Using scaling factors of 0.72–0.98, scaled residues in ranked order were (n = 10): 0.08, 0.12, 0.15, 0.18, 0.25, 0.28, 0.31, 0.32, 0.35 and 0.48 mg/kg.

Total cyclaniliprole residues in broccoli in ranked order were (n = 10): 0.12, 0.13, 0.19, 0.23, 0.38 (2), 0.42, 0.49, 0.54, and 0.71 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): 0.088, 0.13, 0.17, 0.19, 0.28 (2), 0.32, 0.38, 0.41 and 0.51 mg/kg.

Noting that broccoli is the representative crop of the flowerhead brassicas subgroup, the Meeting estimated a maximum residue level of 0.8 mg/kg and an STMR of 0.28 mg/kg for the Subgroup of flowerhead brassicas to replace its previous recommended maximum residue level of 1 mg/kg.

#### *Brussels sprouts*

Residue trials performed on Brussels sprouts in Europe, reviewed by the 2017 JMPR, did not match the critical GAP from Canada nor could the proportionality approach be used. Therefore, the Meeting could not estimate a maximum residue level for Brussels sprouts.

#### *Cabbages, head*

Cyclaniliprole residues in cabbage heads with wrapper leaves in ranked order were (n = 10): < 0.01 (2), 0.014, 0.025, 0.027, 0.040, 0.082, 0.15, 0.32 and 0.39 mg/kg. Using scaling factors of 0.60–0.98, scaled

residues in ranked order were (n = 10): < 0.01 (2), 0.01, 0.017, 0.024 (2), 0.063, 0.11, 0.31 and 0.38 mg/kg.

Total cyclaniliprole residues in cabbage heads with wrapper leaves in ranked order were (n = 10): < 0.01 (2), 0.025, 0.035, 0.038, 0.051, 0.094, 0.17, 0.34, and 0.42 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): < 0.01 (2), 0.018, 0.024, 0.031, 0.034, 0.072, 0.13, 0.33 and 0.41 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg and an STMR of 0.0325 mg/kg for cabbage heads and withdraws its previous recommendation of 0.7 mg/kg for the Subgroup of head Brassicas.

The Meeting estimated a median residue of 0.024 mg/kg and a highest residue of 0.38 mg/kg (parent only) for animal dietary burden calculations.

### *Fruiting vegetables – Cucurbits*

The critical GAP for fruiting vegetables-cucurbits is from Canada for “cucurbit vegetables”; 3×60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on fruiting vegetables - cucurbits where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 7-day RTI and 1-day PHI.

#### *Subgroup of cucumbers and summer squashes*

##### *Cucumbers*

Cyclaniliprole residues in cucumbers in ranked order were (n = 9): < 0.01 (2), 0.011, 0.013, 0.014, 0.018, 0.019, 0.024, and 0.025 mg/kg. Using scaling factors of approximately 0.74, scaled residues in ranked order were (n = 9): < 0.01 (3), 0.010, 0.011, 0.013, 0.014 and 0.018 (2) mg/kg.

Total cyclaniliprole residues in cucumbers in ranked order were (n = 9): < 0.01 (2), 0.022, 0.024, 0.025, 0.029, 0.030, 0.035 and 0.036 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 9): < 0.01 (2), 0.016, 0.018, 0.019, 0.021, 0.022 and 0.026 (2) mg/kg.

##### *Summer squashes*

Cyclaniliprole residues in summer squashes in ranked order were (n = 9): < 0.01(2), 0.014, 0.016, 0.026, 0.028(2), 0.033 and 0.046 mg/kg. Using scaling factors of approximately 0.75, scaled residues in ranked order were (n = 9): < 0.01 (2), 0.011, 0.012, 0.020, 0.021 (2), 0.024 and 0.034 mg/kg.

Total cyclaniliprole residues in summer squashes in ranked order were (n = 9): < 0.01 (2), 0.025, 0.027, 0.037, 0.039, 0.040, 0.043 and 0.057 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 9): < 0.01 (2), 0.019, 0.021, 0.028, 0.029, 0.030, 0.032 and 0.042 mg/kg.

The Meeting noted that the median residues of cucumbers and summer squashes were within 5-fold, and that the Mann-Whitney U-test determined the datasets of cucumbers and summer squashes were from the same population. Therefore, the Meeting decided to combine the two datasets of cucumbers and summer squashes.

The ranked order of the combined cyclaniliprole scaled residues in cucumbers and summer squashes were (n = 18): < 0.01(5), 0.010, 0.011 (2), 0.012, 0.013, 0.014, 0.018 (2), 0.020, 0.021 (2), 0.024 and 0.034 mg/kg.

The ranked order of total cyclaniliprole scaled residues in cucumbers and summer squashes were (n = 18): < 0.01 (4), 0.016, 0.018, 0.019 (2), 0.021 (2), 0.022, 0.026 (2), 0.028, 0.029, 0.030, 0.032 and 0.042 mg/kg.

Noting that cucumbers and summer squashes are the representative crops for the crop subgroup cucumbers and summer squashes, the Meeting estimated a maximum residue level of 0.05 mg/kg and

an STMR of 0.021 mg/kg for the Subgroup of cucumbers and summer squashes to replace its previous recommended maximum residue level of 0.06 mg/kg.

### *Melons, pumpkins and winter squashes*

#### *Melons*

The critical GAP for melons is from Canada for “cucurbit vegetables”: 3 × 60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on melons where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 6–8 day RTI and 1-day PHI.

Cyclaniliprole residues in melons in ranked order were (n = 10): 0.014, 0.017, 0.023, 0.039, 0.040, 0.042, 0.044, 0.051, 0.071 and 0.087 mg/kg. Using scaling factors of approximately 0.75, the scaled residues in ranked order were (n = 10): 0.010, 0.013, 0.017, 0.029, 0.030, 0.031, 0.033, 0.038, 0.052 and 0.064 mg/kg.

In the absence of data on melons without peel, residues used for the estimation of the STMR are based on whole fruit. Total cyclaniliprole residues in whole melon in ranked order were (n = 10): 0.024, 0.028, 0.033, 0.050, 0.055 (2), 0.058, 0.063, 0.081, and 0.099 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 10): 0.018, 0.021, 0.025, 0.037, 0.041 (2), 0.043, 0.047, 0.060 and 0.073 mg/kg for whole melon.

Noting that melons is the representative crop of the melons, pumpkins and winter squashes crop subgroup, the Meeting estimated a maximum residue level of 0.1 mg/kg and an STMR of 0.041 mg/kg for the Subgroup of melons, pumpkins and winter squashes to replace its previous recommended maximum residue level of 0.15 mg/kg.

### *Fruiting vegetables, other than Cucurbits*

The critical GAP for fruiting vegetables, other than cucurbits is from Canada for “fruiting vegetables”; 3 × 60 g ai/ha, 7-day RTI, 1-day PHI. The Meeting received trials from Canada and the USA on cherry tomatoes, tomatoes, sweet bell peppers and non-bell peppers where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 6–8 day RTI and 1-day PHI.

#### *Tomatoes*

Cyclaniliprole residues in field tomatoes (including cherry tomatoes) in ranked order were (n = 22): 0.011, 0.013, 0.017, 0.018, 0.019, 0.025 (2), 0.026 (2), 0.029, 0.030, 0.032 (2), 0.033, 0.034, 0.037, 0.038, 0.040, 0.042, 0.043, 0.070 and 0.076 mg/kg. Using scaling factors of 0.72–0.99, scaled residues in ranked order were (n = 22): 0.008, 0.010, 0.015, 0.017, 0.018, 0.019, 0.020, 0.021, 0.023, 0.024 (3), 0.025 (3), 0.027, 0.028, 0.029, 0.031, 0.032, 0.053, and 0.058 mg/kg.

Total cyclaniliprole residues in tomatoes (including cherry tomatoes) in ranked order were (n = 22): 0.019, 0.022, 0.028, 0.029 (2), 0.036 (3), 0.037, 0.040, 0.041, 0.042, 0.043, 0.045, 0.047, 0.048, 0.049, 0.051, 0.053 (2), 0.08 and 0.1 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 22): 0.014, 0.017, 0.022, 0.027 (2), 0.028, 0.029, 0.030, 0.031 (2), 0.032, 0.034, 0.035 (2), 0.036 (3), 0.037, 0.039 (2), 0.060 and 0.076 mg/kg.

The Meeting estimated a maximum residue level of 0.08 mg/kg and an STMR of 0.033 mg/kg for the Subgroup of tomatoes and withdraws its previous recommendations of 0.1 mg/kg for tomato and cherry tomato.

The Meeting estimated a median residue of 0.024 mg/kg (parent only) for animal dietary burden calculations.

#### *Peppers*

Cyclaniliprole residues in bell peppers and non-bell peppers [NB] in ranked order were (n = 12): 0.014,



0.019, 0.025, 0.041<sup>[NB]</sup>, 0.046, 0.048, 0.057<sup>[NB]</sup>, 0.068, 0.072, 0.077<sup>[NB]</sup>, 0.098, and 0.10 mg/kg. Using scaling factors of 0.74–0.99, scaled residues in ranked order were (n = 12): 0.011, 0.014, 0.018, 0.031<sup>[NB]</sup>, 0.036, 0.043<sup>[NB]</sup>, 0.045, 0.050, 0.054, 0.058<sup>[NB]</sup>, 0.073 and 0.099 mg/kg.

Total cyclaniliprole residues in sweet bell and non-bell peppers in ranked order were (n = 12): 0.025, 0.029, 0.035, 0.051<sup>[NB]</sup>, 0.056, 0.059, 0.067<sup>[NB]</sup>, 0.083, 0.094<sup>[NB]</sup>, 0.096, 0.11, and 0.12 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues were (n = 12): 0.020, 0.022, 0.026, 0.039<sup>[NB]</sup>, 0.044, 0.050<sup>[NB]</sup>, 0.055, 0.063, 0.071, 0.071<sup>[NB]</sup>, 0.082 and 0.119 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg and an STMR of 0.0525 mg/kg for the Subgroup of peppers (excluding martynia, okra and roselle), to replace its previous recommended maximum residue level of 0.2 mg/kg.

The Canadian critical GAP for fruiting vegetables, other than cucurbits, also covers eggplants. The Meeting decided the pepper data could be used to extrapolate the maximum residue level of 0.15 mg/kg and the STMR of 0.0525 mg/kg for peppers to the Subgroup of eggplants to replace its previous recommended maximum residue level of 0.1 mg/kg.

### *Chili peppers, dried*

Based on the estimated maximum residue level of 0.15 mg/kg for the Subgroup of peppers (excluding Martynia, okra and Roselle) and applying a default processing factor of 10, the Meeting estimated a maximum residue level of 1.5 mg/kg for peppers, chili, dried, together with an STMR of 0.525 mg/kg parent equivalents (0.0525 mg/kg × 10), to replace its previous recommended maximum residue level of 2.0 mg/kg.

### *Leafy vegetables (including Brassica leafy vegetables)*

The critical GAP for leafy vegetables (including Brassica leafy vegetables) is from Canada for “leafy vegetables”; 3 × 60 g ai/ha, 7 day-RTI, 1-day PHI. The Meeting received trials from Canada and the USA on leafy vegetables where 3 foliar spray applications were made at a nominal rate of 80 g ai/ha per application, 6–9 day RTI and 1-day PHI.

### *Head lettuce*

Cyclaniliprole residues in head lettuce with wrapper leaves, in ranked order were (n = 7): 0.067, 0.26, 0.32, 0.56, 1.2, 1.4 and 2.2 mg/kg. Using scaling factors of 0.74–0.97, scaled residues in head lettuce with wrapper leaves in ranked order were (n = 7): 0.051, 0.19, 0.28, 0.54, 0.87, 1.04 and 2.14 mg/kg.

Total cyclaniliprole residues in head lettuce with wrapper leaves were in ranked order (n = 7): 0.096, 0.31, 0.36, 0.61, 1.4, 1.6 and 2.3 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in head lettuce with wrapper leaves were in ranked order (n = 7): 0.074, 0.23, 0.32, 0.59, 1.02, 1.19 and 2.24 mg/kg.

### *Leaf lettuce*

Cyclaniliprole residues in leaf lettuce in ranked order were (n = 10): 0.094, 0.25, 0.77, 0.86, 1.2, 1.3, 2.0, 2.2, 2.4 and 3.0 mg/kg. Using scaling factors of 0.73–0.98, scaled residues in ranked order were (n = 10): 0.072, 0.18, 0.57, 0.63, 0.97, 1.18, 1.82, 1.68, 1.97 and 2.27 mg/kg.

Total cyclaniliprole residues in leaf lettuce in ranked order were (n = 10): 0.11, 0.27, 0.79, 1.0, 1.3, 1.4, 2.2, 2.6 (2) and 3.3 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues were in ranked order (n = 10): 0.084, 0.20, 0.58, 0.73, 1.05, 1.28, 1.98 (2), 2.16 and 2.50 mg/kg.

### *Cos lettuce*

In trials from the USA matching the critical GAP, cyclaniliprole residues in cos lettuce were (n = 3): 0.74, 0.76 and 0.94 mg/kg. Using scaling factors of 0.8–0.9, scaled residues were (n = 3): 0.57, 0.67 and 0.70 mg/kg.

Total cyclaniliprole residues in cos lettuce in ranked order were (n = 3): 0.84, 0.85 and 1.0 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues were (n = 3): 0.63, 0.75 and 0.77 mg/kg.

### *Spinach*

Cyclaniliprole residues in spinach in ranked order were (n = 8): 1.4, 2.0, 2.3, 2.4, 2.8, 2.9, 3.4 and 4.6 mg/kg. Using scaling factors of 0.73–0.99, scaled residues in ranked order were (n = 8): 1.4, 1.8, 1.9, 2.1, 2.2, 2.5, 2.9 and 3.5 mg/kg.

Total cyclaniliprole residues in spinach in ranked order were (n = 8): 1.5, 2.1, 2.5, 2.7, 3.3 (2), 4.1 and 5.5 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 8): 1.5, 2.0 (2), 2.4 (2), 3.0, 3.3 and 4.2 mg/kg.

The Meeting noted that the scaled median residues of cyclaniliprole in head lettuce (with wrapper leaves), leaf lettuce, cos lettuce and spinach were within a 5-fold range. From the Kruskal-Wallis H-test, the datasets of head lettuce (with wrapper leaves), leaf lettuce, cos lettuce and spinach were not from the same population. Therefore, using the spinach dataset, the Meeting estimated a maximum residue level of 7 mg/kg and an STMR of 2.4 mg/kg for the Subgroup of Leafy greens.

### *Subgroup of Leaves of Brassicaceae*

#### *Mustard greens*

Cyclaniliprole residues in mustard greens in ranked order were (n = 5): 1.4, 3.0, 4.0, 4.1, and 5.9 mg/kg. Using scaling factors of 0.75–0.98, scaled residues in ranked order were (n = 5): 1.4, 3.0 (2), 4.0 and 4.4 mg/kg.

Total cyclaniliprole residues in mustard greens in ranked order were (n = 5): 1.5, 3.5, 4.3, 4.4 and 6.2 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): 1.5, 3.2, 3.5, 4.3 and 4.6 mg/kg.

Noting that mustard greens is the representative crop of the leaves of brassicaceae subgroup, the Meeting estimated a maximum residue level of 10 mg/kg and an STMR of 3.5 mg/kg for the Subgroup of leaves of brassicaceae to replace its previous recommended maximum residue level of 15 mg/kg.

The Meeting estimated a median residue value of 3.0 mg/kg and a highest residue of 4.4 mg/kg, both for parent only, for the Subgroup of leaves of brassicaceae for livestock dietary burden calculations.

### *Tuberous and Corm Vegetables*

The critical GAP for tuberous and corm vegetables is from Canada; 3×60 g ai/ha, 5 day RTI, 7-day PHI. The Meeting received trials from Canada and the USA on potatoes where 3 foliar spray applications were made at a 100 g ai/ha per application, 4–6-day RTI and 6–7-day PHI.

Cyclaniliprole residues in potatoes were all < 0.01 mg/kg (n = 25) when treated at seasonal application rates of 214–308 g ai/ha, equivalent to 1.2–1.7-fold the critical GAP in Canada. Therefore, when treated in accordance with the critical GAP from Canada, residues of cyclaniliprole in potatoes are not expected to be quantifiable.

Total cyclaniliprole residues in potatoes were all < 0.01 mg/kg (n = 25) following treatment at exaggerated rates (1.2–1.7-fold the critical GAP in Canada). Therefore, when treated in accordance with the critical GAP from Canada, total residues of cyclaniliprole in potatoes are not expected to be quantifiable.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg and an STMR of 0 mg/kg parent equivalents for the Subgroup of Tuberous and corm vegetables.

The Meeting estimated a median residue value of 0 mg/kg (parent only) for potatoes for livestock dietary burden calculations.

### *Tree nuts*

The critical GAP for tree nuts is from Canada:  $3 \times 80$  g ai/ha, 14 day-RTI, 30-day PHI. The Meeting received trials from the USA on tree nuts where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha per application, 12–15 day RTI and 30-day PHI for almonds and 14–30 days for pecans.

#### *Almonds*

Cyclaniliprole residues in almond nutmeats in ranked order were (n = 5): < 0.01 (2), 0.013 (2) and 0.015 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): < 0.01 (2), 0.010 (2) and 0.012 mg/kg.

Total cyclaniliprole residues in almond nutmeats in ranked order were (n = 5): < 0.01 (2), 0.024 (2) and 0.026 mg/kg. Using the same scaling factors, scaled total cyclaniliprole residues in ranked order were (n = 5): < 0.01 (2), 0.019 (2) and 0.021 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR of 0.019 mg/kg for almonds.

#### *Pecans*

Two of the five pecan field trials from the USA differed from the critical GAP with regard to the pre-harvest interval. Therefore, due to the insufficient number of trials, conducted in accordance with the critical GAP, the Meeting did not estimate a maximum residue level and STMR for pecans.

### *Tea*

The critical GAP for tea is from Japan:  $1 \times 4.5$  g ai/hL and a 3-day PHI.

In trials from Japan matching the critical GAP, cyclaniliprole residues in dried tea leaves in ranked order were (n = 6): 4.8, 6.8, 8.4, 13, 16 and 28 mg/kg.

The total cyclaniliprole residues in dried tea leaves in ranked order were (n = 6): 4.9, 7.5, 11, 14, 17 and 30 mg/kg.

The Meeting estimated a maximum residue level of 50 mg/kg and an STMR of 12.5 mg/kg for tea, green, black (black, fermented and dried).

### *Miscellaneous fodder and forage*

#### *Almond hulls*

The critical GAP for tree nuts is from Canada:  $3 \times 80$  g ai/ha, 14 day-RTI, 30-day PHI. The Meeting received trials from the USA on almonds where 3 foliar spray applications were made at a nominal rate of 100 g ai/ha/application, 13–15 day RTI and 30–31 day PHI.

Cyclaniliprole residues in almond hulls, on a dry weight basis, in ranked order were (n = 5): 1.8, 2.0, 2.1, 2.5 and 3.3 mg/kg. Using scaling factors of approximately 0.8, scaled residues in ranked order were (n = 5): 1.4, 1.6, 1.7, 2.0 and 2.6 mg/kg.

The Meeting estimated a maximum residue level of 6 mg/kg and median residue of 1.7 mg/kg for almond hulls.

### *Residues in processed commodities*

At the current Meeting, processing studies were reviewed for oranges and potatoes, while at the 2017 Meeting processing studies were reviewed for apples, peaches, tomatoes, plums, grapes, and tea. Maximum residue levels in processed commodities are only proposed where they are higher than the maximum residue levels in the raw commodity. For maximum residue level derivation the processing factors are based on parent only. For estimation of the dietary exposure, STMR-P's were based on the processing factors for parent + metabolite NK-1375 (separate table).

Table 1 Maximum Residue Level Derivation for Processed Commodities

Raw Agricultural Commodity (RAC)	Processed Commodity	PF (parent only)	PF (best estimate)	MRL × PF (mg/kg)
Citrus fruit [MRL = 0.4 mg/kg]	Citrus, oil	116 <sup>a</sup>	116 (n = 1)	50
Plum [MRL = 0.15]	Prunes	3.7	3.7 (n = 1)	0.6
Tomato [MRL = 0.08]	Tomato, dried	3.33, 3.75, 3.8, 4, 5.5	3.8 (median, n = 5)	0.35

<sup>a</sup> Noting that the Meeting is recommending a maximum residue level for the Group of citrus fruits, the processing factor for orange was extrapolated to the entire citrus fruit crop group.

Cyclaniliprole residues were shown to concentrate in citrus oil, prunes, and tomato, dried.

The Meeting estimated a maximum residue level of 50 mg/kg (0.4 mg/kg × 116 = 46.4 mg/kg) for citrus oil. The Meeting also estimated maximum residue levels of 0.6 mg/kg (0.15 mg/kg × 3.7 = 0.56 mg/kg) for prunes and 0.35 mg/kg (0.08 mg/kg × 3.8 = 0.30 mg/kg) for tomato, dried to replace its previous recommended maximum residue levels of 0.8 mg/kg and 0.4 mg/kg, respectively, for these processed commodities.

Table 2 Derivation of STMR-Ps for dietary exposure estimation

Commodity	PF (parent + NK-1375)	PF (best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)
Citrus fruit			0.087	
- juice	0.12	0.12 (n = 1)		0.01
- oil	116	116 (n = 1)		10.1
Apples			0.057	
- juice, pasteurised	0.13, < 0.33, < 0.5	< 0.33 (median, n = 3)		0.019
Plums			0.052	
- dried	3.7 <sup>a</sup>	3.7 (n = 1)		0.19
Grapes			0.12	
- must	0.63, 0.63, 0.71, 0.86	0.67 (median n = 4)		0.08
- juice, pasteurised	0.20, 0.12, 0.33, 0.38, 0.50, 0.71	0.36 (median, n = 6)		0.04
- wine, stored	0.14, 0.20, < 0.33, 0.38, 0.040, 0.50	0.355 (median, n = 6)		0.04
Tomatoes			0.033	
- canned	< 0.14, < 0.17, < 0.2, < 0.5, < 0.5	0.14 (median, n = 5)		0.005
- paste	0.49, 0.50, 0.67, 1.57, 1.8, 2.5	1.12 (median, n = 6)		0.04
- juice, pasteurised	< 0.5, 0.17, 0.8, 1.14, 1.5	0.8 (median, n = 6)		0.03
- dried	3, 3.2, 3.3, 5, 6	3.3 (median, n = 5)		0.11
Potatoes			0	
-crisps	< 0.26	< 0.26 (n = 1)		0
-flakes/granules	< 0.26	< 0.26 (n = 1)		0

Commodity	PF (parent + NK-1375)	PF (best estimate)	RAC STMR (mg/kg)	STMR-P (mg/kg)
Tea			13	
-infusion	0.09 (3), 0.13 (2), 0.14, 0.17 (3), 0.19	0.14 (median)		1.8

PF based on total cyclaniliprole; cyclaniliprole + NK-1375 expressed as parent equivalents

STMR-P is used for the dietary exposure estimates and is based on the residue definition for dietary risk assessment: cyclaniliprole + NK-1375 expressed as parent equivalents

### Livestock dietary burden

The Meeting estimated the livestock dietary burden for cyclaniliprole on the basis of the diets (USA/Canada, EU, Australia and Japan) using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual<sup>9</sup>. Calculation from highest residue and median values (some bulk commodities) provide the levels in feed suitable for estimating maximum and highest residue levels while calculation from median values for feed is suitable for estimating STMR values for animal commodities.

The commodities used in estimating livestock dietary burdens are included in the table below and capture both the feed items assessed at the 2017 Meeting together with the new feed items assessed by the current Meeting. In the rotational crop studies, reviewed by the 2017 Meeting, residues of cyclaniliprole were detected in wheat straw and forage. For the dietary burden calculation, these levels were extrapolated to the straw/hay (dry feed commodities) and forage (wet feed commodities) of the whole group of cereal grain crops. The input was based on the intake of parent only.

Table 3 Commodities for consideration in dietary burden calculations

Codex Classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
AB 0001	Citrus pulp, dry (median 0.078 mg/kg x PF 1.27)	0.099	
AB 0226	Apple pomace, wet (median 0.047 mg/kg x PF 3.2)	0.15	-
AB 0269	Grape pomace, wet (median 0.11 mg/kg x PF 1.7)	0.19	-
VL 0054	Leaves of Brassicaceae, (based on mustard greens dataset)	3.0	4.4
VB 0041	Cabbages, head	0.024	0.38
AB – no code	Tomato pomace, wet (median of 0.024 x PF 0.67)	0.02	-
	Potato, wet peels (median of 0 x PF 4.25)	0	
AF – no code	Barley, forage (30% DM)	0.01	0.026
AS 0640	Barley, hay (88% DM)	0.0475	0.18
AS 0641	Barley, straw (89% DM)	0.0475	0.18
AF/AS – no code	Corn, field, forage/silage (40% DM)	0.01	0.026
AS 0645	Corn, field, stover (83% DM)	0.0475	0.18
AF – no code	Corn, pop, stover (83% DM)	0.0475	0.18
AF – no code	Corn, sweet, forage (48% DM)	0.01	0.026
AF – no code	Corn, sweet, stover (83% DM)	0.0475	0.18
AF – no code	Millet, forage (30% DM)	0.01	0.026
AF – no code	Millet, hay (85% DM)	0.0475	0.18
AF 0646	Millet, straw (90% DM)	0.0475	0.18
AF 0647	Oat, forage (30% DM)	0.01	0.026

<sup>9</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

Codex Classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
AS 0647	Oat, hay (90% DM)	0.0475	0.18
AF – no code	Oat, straw (90% DM)	0.0475	0.18
AS0469	Rice, straw (90% DM)	0.0475	0.18
AF0650	Rye, forage (30% DM)	0.01	0.026
AS0650	Rye, straw (88% DM)	0.0475	0.18
AF0651	Sorghum, grain, forage (35% DM)	0.01	0.026
AS – no code	Sorghum, grain, stover (88% DM)	0.0475	0.18
AF – no code	Triticale, forage (30% DM)	0.01	0.026
AF – no code	Triticale, hay (88% DM)	0.0475	0.18
AF – no code	Triticale, straw (90% DM)	0.0475	0.18
AF 0654	Wheat forage (25% DM)	0.01	0.026
AS 0654	Wheat, hay (88% DM)	0.0475	0.18
AS 0654	Wheat, straw (88% DM)	0.0475	0.18
AM 0660	Almond hulls	1.7	-

Note: levels for cereal straw, hay, and forage are presented on as received basis.

The dietary burden calculations for cyclaniliprole for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6 of the 2019 JMPR Report and summarized below.

Table 4 Livestock dietary burden for cyclaniliprole

		Livestock dietary burden for cyclaniliprole (based on cyclaniliprole parent only) ppm of dry matter diet			
		USA/Canada	EU	Australia	Japan
<b>Max</b>	<b>beef cattle</b>	0.06	9.0	14.7 <sup>a</sup>	0.11
	<b>dairy cattle</b>	4.52	6.0	12.1 <sup>b</sup>	0.07
	<b>poultry – broiler</b>	-	0.005	-	-
	<b>poultry – layer</b>	-	1.49 <sup>c</sup>	-	-
<b>Mean</b>	<b>beef cattle</b>	0.021	6.10	10.0 <sup>d</sup>	0.03
	<b>dairy cattle</b>	3.06	4.07	8.3 <sup>e</sup>	0.02
	<b>poultry – broiler</b>	-	-	-	-
	<b>poultry – layer</b>	-	1.00 <sup>f</sup>	-	-

<sup>a</sup> Highest maximum beef cattle dietary burden suitable for maximum residue level estimates for mammalian meat.

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for maximum residue level estimates for milk.

<sup>c</sup> Highest maximum poultry-layer dietary burden suitable for maximum residue level estimates for poultry meat and eggs.

<sup>d</sup> Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian meat.

<sup>e</sup> Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

<sup>f</sup> Highest mean poultry-layer dietary burden suitable for STMR estimates for poultry meat and eggs.

**Animal commodity maximum residue levels**

Table 5 Animal commodity residue levels for mammalian matrices

	Feeding level (ppm) for milk residues	Residues (mg/kg) in milk cream <sup>a</sup>	Feed level (ppm) for tissue residues	Residues (mg/kg) in			
				Muscle	Liver	Kidney	Fat
<b>MRL beef or dairy cattle</b>							
Feeding study <sup>b</sup>	3.5	0.02	3.5	< 0.01	0.040	0.045	0.045
	11.6	0.078	11.6	0.032	0.141	0.114	0.199
Dietary burden and high residue estimate	12.1	0.078	14.7	0.032	0.141	0.114	0.199
<b>STMR beef or dairy cattle</b>							
Feeding study <sup>c</sup>	3.5	0.02	3.5	< 0.01	0.021	0.022	0.023
	11.6	0.078	11.6	0.018	0.071	0.059	0.074
Dietary burden and mean residue estimate	8.3	0.054	10.0	0.016	0.061	0.052	0.064

<sup>a</sup> No residues were found in skimmed milk, all residues were detected in milk cream which contains 50% milk fat, therefore residues in milk fat are 0.156 mg/kg (0.078 mg/kg ÷ 0.50). Based on the default milk fat content of 4% for whole milk, the maximum residue level and STMR for mammalian milk were estimated at 0.01 mg/kg (0.156 x 0.04 = 0.006) and 0.004 mg/kg ((0.054 ÷ 0.5) x 0.04 = 0.004), respectively.

<sup>b</sup> Highest residue for tissues and milk cream

<sup>c</sup> Mean residues for tissues and milk cream

The Meeting estimated maximum residue levels of 0.01 mg/kg for milks, 0.2 mg/kg for milk fats, 0.25 mg/kg for meat, based on fat (from mammals other than marine mammals) and mammalian fats (except milk fats) and 0.2 mg/kg for edible offal (mammalian). The Meeting estimated STMRs of 0.004 mg/kg for milks, 0.108 mg/kg for milk fats, 0.016 mg/kg for meat (muscle), 0.061 mg/kg for liver, 0.052 mg/kg for kidney and 0.064 mg/kg for mammalian fat. These recommendations are intended to replace all previous recommendations for all ruminant matrices.

**Poultry**

In the absence of a poultry feeding study, the Meeting relied on the laying hen metabolism study to determine the maximum residue levels and STMRs in poultry commodities.

Table 6 Animal commodity residue levels for poultry matrices

	Dose level (ppm) for egg TRRs	Cyclaniliprole TRRs in eggs (mg eq/kg)	Dose level (ppm) for tissue TRRs	TRRs (mg eq/kg) in			
				Fat	Skin	Muscle	Liver
Dose level from metabolism study	10.8	0.156	10.8	0.158	0.09	0.006	0.17
Dietary burden and high residue estimate	1.49	0.0004	1.49	0.0004	0.0002	0.00001	0.0004
Dietary burden and mean residue estimate	1.0	0.00027	1.0	0.00027	0.00013	0.000007	0.00027

The Meeting estimated maximum residue levels of 0.01(\*) mg/kg for eggs and poultry fats, meat and edible offal and STMRs of 0 for these poultry commodities.

## RECOMMENDATIONS

On the basis of the data 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.

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

Definition of the residue for dietary risk assessment for plant commodities: *cyclaniliprole* + 3-bromo-2-((2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b]-[1,4]oxazin-4-ylidene)amino)-5-chloro-N-(1-cyclopropylethyl)benzamide (NK-1375), expressed as *cyclaniliprole equivalents*. The molecular weight conversion factor to express NK-1375 in *cyclaniliprole equivalents* = 1.064.

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

The residue is fat-soluble.

The Meeting maintained its previous recommendation for the maximum residue level of 0.45 mg/kg (dw) in straw and fodder, dry of cereal grains (AS 0081).

## DIETARY RISK ASSESSMENT

### ***Long-term dietary exposure***

The ADI for *cyclaniliprole* is 0–0.04 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for *cyclaniliprole* 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 2019 JMPR Report.

The IEDIs ranged from 1–10% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of *cyclaniliprole* from uses considered by the JMPR is unlikely to present a public health concern.

### ***Acute dietary exposure***

The 2017 JMPR decided that an ARfD for *cyclaniliprole* was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of *cyclaniliprole* from the uses considered is unlikely to present a public health concern.



## 5.9 Cypermethrins (including alpha- and zeta-cypermethrin) (118)

### RESIDUE AND ANALYTICAL ASPECTS

Cypermethrin is a non-systemic pyrethroid insecticide. The mode of action is non-systemic with contact and stomach action. Cypermethrin was first evaluated by JMPR in 1979 and periodic reviews were conducted in 2006 for toxicology and in 2008 for residues. Further evaluations for additional uses were conducted in 2009 and 2011.

The 2006 JMPR established an ADI of 0–0.02 mg/kg bw and an ARfD of 0.04 mg/kg bw. The 2008 JMPR established a residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities of *cypermethrin (sum of isomers)*. The residue is fat-soluble.

Cypermethrin was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received information on GAP, residue trials and processing studies on ginseng.

#### **Methods of analysis**

The analytical method used for analysis of cypermethrin residues in fresh ginseng and the processed products (dried-, red ginseng, the water extracts) involved extraction with acetone or acetonitrile, partitioning with dichloromethane, clean-up using florisil and determination by GC-ECD. Procedural recoveries ranged from 79-106% (RSDs  $\leq$  10%) and the LOQ values for cypermethrin were 0.03 mg/kg in fresh ginseng and 0.06 mg/kg in the ginseng processed products.

#### **Stability of residues in stored analytical samples**

The 2011 JMPR concluded that cypermethrin is stable for at least 18 months in frozen plant matrices of high water and high oil content. The residue sample storage intervals used in the field trials considered by the current Meeting were covered by the demonstrated stability period.

#### **Results of supervised residue trials on ginseng**

The critical GAP for cypermethrin on ginseng in the Republic of Korea is 3 foliar applications at a rate of 0.005 kg ai/hL with a 45 day PHI. Six independent trials conducted in the Republic of Korea matched the critical GAP. Cypermethrin residues in fresh ginseng were  $< 0.03$  mg/kg (n = 6).

The Meeting estimated a maximum residue level of 0.03(\*) mg/kg, a STMR of 0.03 mg/kg and a HR of 0.03 mg/kg for cypermethrin in ginseng.

#### **Fate of residues during processing**

The Meeting received information on the fate of cypermethrin residues during processing of ginseng. In these studies residues of cypermethrin in the raw agricultural commodity (fresh ginseng) were all less than LOQ. Therefore, the Meeting could not estimate processing factors for ginseng processed products.

The Meeting noted that in all the field trials matching GAP, fresh ginseng samples were washed and dried to produce dried ginseng, or steamed and dried to produce red ginseng. Residues of cypermethrin were measured in the dried and red ginseng and in their water extracts.

Cypermethrin residues in dried and red ginseng were  $< 0.06$  (9), 0.06 (2), and 0.10 mg/kg (n = 12).

Cypermethrin residues in water extracts of dried and red ginseng were  $< 0.06$  (12) mg/kg (n = 12).

The Meeting estimated a maximum residue level of 0.15 mg/kg, a STMR of 0.06 mg/kg and a HR of 0.10 mg/kg for cypermethrin in ginseng, dried including red ginseng. The Meeting estimated a

maximum residue level of 0.06(\*) mg/kg, a STMR of 0.06 mg/kg and a HR of 0.06 mg/kg for cypermethrin in ginseng, extracts.

### 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 and animal commodities:  
*cypermethrin (sums of isomers)*

Definition of the residue for dietary risk assessment for plant and animal commodities:  
*cypermethrin (sums of isomers)*

The residue is fat-soluble.

### DIETARY RISK ASSESSMENT

#### ***Long-term dietary exposure***

The ADI for cypermethrin is 0–0.02 mg/kg bw. The STMRs/STMR-Ps for food commodities estimated by the current Meeting did not affect the International Estimated Daily Intakes (IEDIs) for cypermethrin calculated by the 2011 JMPR. The Meeting concluded that long-term dietary exposure to residues of cypermethrin from uses considered by the JMPR is unlikely to present a public health concern.

#### ***Acute dietary exposure***

The ARfD for cypermethrin is 0.04 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for cypermethrin were calculated for the food commodities (raw and 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 2019 JMPR Report.

The IESTIs were 0% of the ARfD for children and the general population. The Meeting concluded that acute dietary exposure to residues of cypermethrin from the use considered by the present Meeting is unlikely to present a public health concern.

## 5.10 Dimethoate (027)/Omethoate (055)

### TOXICOLOGY

Dimethoate is the ISO-approved common name for *O,O*-dimethyl-*S*-((methylcarbamoyl)methyl)phosphorodithioate-2-dimethoxyphosphinothioylsulfanyl-*N*-methylacetamide (IUPAC), with the CAS number 60-51-5.

Dimethoate is an organophosphate insecticide, having contact and systemic action, against a broad range of insects in agriculture and also used for the control of the housefly. It acts by inhibiting acetylcholinesterase.

Dimethoxon (also known as omethoate), the oxygen analogue metabolite of dimethoate, appears to play a dominant role in its toxicity for insects and mammals.

Dimethoate was previously evaluated by JMPR in 1963, 1965, 1967, 1984, 1987 and 1996. An ADI of 0–0.002 mg/kg bw was established in 1996 on the basis of the apparent [sic] NOAEL of 1.2 mg/kg bw per day for reproductive performance in a study of reproductive toxicity in rats, and with a safety factor of 500. Although a safety factor of 100 would have normally been used in deriving an ADI from a study of this type, the Meeting was concerned about the possibility that reproductive performance might have been affected at 1.2 mg/kg bw per day in this study and therefore used a safety factor that was higher than normal. No data were available to assess whether the effects on reproductive performance were secondary to the inhibition of acetylcholinesterase activity. The 1996 JMPR concluded that it was not appropriate to base the ADI on the results of studies of volunteers, since the crucial end-point (reproductive performance) had not been assessed in humans.

The 2003 Meeting established an ARfD of 0.02 mg/kg bw on the basis of the overall NOAEL of 2 mg/kg bw for acetylcholinesterase inhibition in studies in rats, using a safety factor of 100. This ARfD was consistent with the NOAEL of about 0.2 mg/kg bw per day in studies on volunteers receiving single or repeated doses, which were evaluated by the 1996 JMPR.

Dimethoate was reviewed by the present Meeting as part of the periodic review programme of CCPR.

A number of newly submitted studies, published and unpublished, covering a range of end-points, not available to the 1996/2003 Meetings, together with previous studies, were evaluated by the present Meeting. A literature search was performed which did not provide useful information for the evaluation of the compound.

Unless otherwise specified, critical studies contained statements of compliance with GLP and were conducted in accordance with relevant national or international test guidelines.

#### **Biochemical aspects**

Oral absorption of dimethoate in rats was extensive ( $\geq 90\%$  based on urinary excretion) after dosing with 10 mg/kg bw (low) and 100 mg/kg bw (high). Excretion of the radioactivity was rapid, with 52–72% of the dose excreted in urine (predominant route of excretion) within the first six hours of treatment, and 80–90% within 24 hours. In general, concentrations in tissues were the highest at 0.5 hour after dosing, though maximum concentrations were occasionally reached at two hours in males. In all cases, concentrations in tissues declined rapidly after reaching the maximum concentration, with only low levels present 48 hours after dosing. Highest concentrations were found in kidneys and liver, with low levels in brain and fat. There was clear evidence of radioactivity in the bone marrow following oral dosing.

At least eight metabolites and unchanged dimethoate were isolated in urine after oral dosing. Dimethoate is mainly metabolized via initial cleavage of the C–N bond, yielding dimethoate carboxylic acid (29–46% of parent excreted through urine), dimethyldithiophosphate (20–30% of parent excreted through urine), thiophosphate and phosphate esters. A subordinate biotransformation pathway is

oxidation to the oxygen analogue, omethoate. There were no significant differences in the proportions of the various metabolites between the sexes.

### **Toxicological data**

The acute toxicity of dimethoate in mice and rats was studied by the oral route and the LD<sub>50</sub> in mice was at 60 mg/kg bw. In rats the LD<sub>50</sub> was 245 mg/kg bw. By the dermal route LD<sub>50</sub> in rats was > 2000 g/kg bw and by inhalation in rats LC<sub>50</sub> was 1.68 mg/L air. Dimethoate is very slightly irritating to the skin of rabbits and mildly irritating to the eyes of rabbits. Dimethoate is not a skin sensitizer in guinea pigs in the Magnusson and Kligman maximization test or in the Buehler test.

In repeated-dose toxicity studies in rats and dogs, the predominant effect was inhibition of acetylcholinesterase.

In a four-week study in rats, dimethoate was administered in the diet at a concentration of 0, 5, 25 and 75 ppm (equivalent to 0, 0.5, 2.5 and 7.5 mg/kg bw per day) The NOAEL was 5 ppm (equivalent to 0.5 mg/kg bw per day) based on the decreased acetylcholinesterase activity in erythrocytes and brain at dose levels of 25 ppm (equivalent to 2.5 mg/kg bw per day).

In a four-week dose range-finding study in rats dimethoate was administered in the diet at concentrations of 0, 13, 38 and 157 ppm (equal to 0, 0.83, 2.48 and 10.4 mg/kg bw per day) for males and 0, 11, 35 and 135 ppm (equal to 0, 0.85, 2.68 and 11 mg/kg bw per day) for females. The NOAEL was 13 ppm (equal to 0.85 mg/kg bw per day) based on a decrease in erythrocyte acetylcholinesterase activity at 35 ppm (equal to 2.68 mg/kg bw per day) in females on day 29.

The Meeting identified an overall NOAEL for rats as 0.85 mg/kg bw per day, and an overall LOAEL as 2.5 mg/kg bw per day.

In a 28-day dietary study in dogs, dimethoate was administered in the diet at dose levels of 0, 2, 10, 50, 250 and 1250 ppm (equal to 0, 0.09, 0.43, 2.20, 11.1 and 49.8 mg/kg bw per day) The NOAEL was 10 ppm (equal to 0.43 mg/kg bw per day) based on brain and erythrocyte acetylcholinesterase inhibition at a LOAEL of 50 ppm (equal to 2.20 mg/kg bw per day).

In a 98-day dog dietary study, dimethoate was administered at dose levels of 0, 4, 6 and 9 ppm (equivalent to 0, 0.1, 0.15 and 0.225 mg/kg bw per day) The NOAEL was 9 ppm (equivalent to 0.225 mg/kg bw per day), the highest dose tested.

In a one-year dietary study, dogs were given dimethoate at a concentration of 0, 5, 20 or 125 ppm (equal to 0, 0.18, 0.70, 4.81 mg/kg bw per day for males, 0, 0.19, 0.76, 4.31 mg/kg bw per day for females). The NOAEL was 5 ppm (equal to 0.18 mg/kg bw per day) based on reduction in erythrocyte acetylcholinesterase activity in males at 20 ppm (equal to 0.70 mg/kg bw per day).

The overall NOAEL for dogs was 0.43 mg/kg bw per day, based on an overall LOAEL of 0.70 mg/kg bw per day for erythrocyte acetylcholinesterase activity inhibition.

In a 78-week study of carcinogenicity in mice, dimethoate was administered at dietary concentrations of 0, 25, 100 or 200 ppm (equal to dosages of 0, 3.6, 13.7 and 31.1 mg/kg bw per day in males, 0, 5.2, 18.2 and 35.6 mg/kg bw per day in females). The LOAEL for toxicity was 25 ppm (equal to 3.6 mg/kg bw per day), the lowest dose tested, based on decreases in RBC acetylcholinesterase activity at this dose. The NOAEL for carcinogenicity in mice was 200 ppm (equal to 31.1 mg/kg bw per day), the highest dose tested.

In a two-year combined chronic toxicity feeding and carcinogenicity study in Wistar rats dimethoate was administered at concentrations of 0, 1, 5, 25 and 100 ppm (equal to 0, 0.04, 0.23, 1.2 and 4.8 mg/kg bw per day in males, 0, 0.06, 0.3, 1.5 and 6.3 mg/kg bw per day in females). The BMDL<sub>20</sub> for inhibition of brain acetylcholinesterase, calculated by the Meeting, was 0.31 mg/kg bw per day in males and 0.37 mg/kg bw per day in females. The Meeting noted that the haemangiomas/haemangiosarcomas in spleen and mesenteric lymph nodes occurred at higher incidence in treated animals without any dose-response or precursor lesion (endothelial proliferation).

Consequently, the Meeting concluded that these tumours were not related to treatment. The NOAEL for carcinogenicity was 100 ppm (equal to 4.8 mg/kg bw per day), the highest dose tested.

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

Dimethoate has been tested in a range of in vitro and in vivo genotoxicity studies. Dimethoate did not cause chromosomal aberrations in vivo, but appeared weakly positive at high concentrations in some in vitro mutagenicity tests. There were no adequate in vivo tests for mutagenicity. However, the Meeting noted that the critical (sometimes only) effects of dimethoate were related to inhibition of acetylcholinesterase. Consequently, the rate of phosphorylation of acetylcholinesterase appears to be the predominant reaction of dimethoate, whereas mutations resulting from reactions with DNA can only be detected at much higher concentrations. Therefore, the Meeting concluded that DNA alkylation is unlikely to occur at doses of dimethoate that are not strongly inhibitory to erythrocyte/brain acetylcholinesterase activity.

Based on the weight of evidence, the Meeting concluded that dimethoate is unlikely to be genotoxic at doses that do not inhibit acetylcholinesterase activity.

As dimethoate is unlikely to be genotoxic at doses that do not inhibit acetylcholinesterase and in view of the absence of carcinogenicity in mice and rats, the Meeting concluded that dimethoate is unlikely to pose a carcinogenic risk to humans.

In a non-GLP, three-generation study of reproductive toxicity in which mice were fed diets containing dimethoate at concentrations of 0, 5, 15 or 50 ppm (equal to 0, 1.3, 4.1 and 13.6 mg/kg bw per day for males, 0, 1.5, 4.6 and 15.3 mg/kg bw for females, respectively) the NOAEL for reproductive and offspring toxicity was 50 ppm (equal to 13.6 mg/kg bw per day), the highest dose tested. The NOAEL for parental toxicity was 15 ppm (equal to 4.1 mg/kg bw per day) based on tremors in dams at 50 ppm (equal to 13.6 mg/kg bw per day). Acetylcholinesterase activity was not measured in this study.

In a two-generation reproductive study in rats, when dimethoate was administered through diet during premating at levels of 0, 1, 15 or 65 ppm (equal to 0, 0.08, 1.2 and 5.46 mg/kg bw per day for males and 0, 0.09, 1.3, 6.04 mg/kg bw per day for females). The NOAEL for parental toxicity was 1 ppm (equal to 0.08 mg/kg bw per day) on the basis of inhibition of erythrocyte and brain acetylcholinesterase activity and a slightly reduced body weight gain in parental females at 15 ppm (equal to 1.3 mg/kg bw per day). The NOAEL for reproductive toxicity was 15 ppm (equal to 1.2 mg/kg bw per day). It was based on decreased fertility in the F<sub>1b</sub>, F<sub>2a</sub> and F<sub>2b</sub> matings; decreased body weight during lactation in both sexes and generations; and decreased litter size at birth among F<sub>1a</sub> and F<sub>2b</sub> litters at 65 ppm (equal to 5.46 mg/kg bw per day). These effects on reproduction at the high dose level (65 ppm), decreased fertility in the F<sub>1b</sub>, F<sub>2a</sub> and F<sub>2b</sub> matings; decreased body weight during lactation in both sexes and generations; and decreased litter size at birth among F<sub>1a</sub> and F<sub>2b</sub> litters, are possibly a result of marked inhibition of acetylcholinesterase. The NOAEL for offspring toxicity was 1 ppm (equal to 0.08 mg/kg bw per day) based on reduced brain and erythrocyte acetylcholinesterase activity in the F<sub>1a</sub> generation at a LOAEL of 15 ppm (equal to 1.2 mg/kg bw per day).

In subsequent two-generation reproductive toxicity study in rats, dimethoate was administered in diets adjusted to provide dose levels of 0, 0.2, 1.0 and 6.5 mg/kg bw per day. The NOAEL for parental toxicity and offspring toxicity was 1.0 mg/kg bw per day based on statistically significant reduction in body weight gain shown by the F<sub>2B</sub> pups of high-dose F<sub>1</sub> females, histopathological findings in prostate and epididymides of high dose F<sub>0</sub> and F<sub>1</sub> males, as well as statistically significant and toxicologically relevant reductions of erythrocyte and brain acetylcholinesterase activities in high-dose F<sub>0</sub> and F<sub>1</sub> parental generations of both sexes, effects that were apparent at 6.5 mg/kg bw per day. The NOAEL for reproductive toxicity was 6.5 mg/kg bw per day, the highest dose tested.

The Meeting concluded that the more recent study has a higher number of animals and a more comprehensive evaluation of parameters, hence it was considered more reliable for identifying relevant toxicological effects.

In a developmental toxicity study in rats with gavage dosing at 0, 3, 6 and 18 mg/kg bw per day on days 6–15 of gestation, a NOAEL for maternal toxicity was 6 mg/kg bw per day based on body tremor, hypersensitivity, abnormal gait, reduced body weight gain and food consumption, at 18 mg/kg bw per day. The embryo/fetal NOAEL was 18 mg/kg bw per day, the highest dose tested. Acetylcholinesterase activity was not measured in this study.

In a developmental toxicity study in rabbits using gavage dosing at 0, 10, 20 or 40 mg/kg bw per day on days 7–19 of gestation, the NOAEL for maternal toxicity was 10 mg/kg bw per day, based upon effects on weight gain at higher dose levels in dams and an NOAEL for embryo and fetal toxicity which was 40 mg/kg bw per day, the highest dose tested. Acetylcholinesterase activity was not measured in this study.

The Meeting concluded that dimethoate is not teratogenic.

An acute neurotoxicity gavage study in rats provided a single dimethoate dose of 0, 2, 20, or 200 mg/kg bw. The NOAEL for acute neurotoxicity in rats was 2 mg/kg bw on the basis of cholinergic signs at 20 mg/kg bw. Acetylcholinesterase activity was not measured in this study.

In a study for acute neurotoxicity, dimethoate was given to rats at dietary concentrations adjusted to provide doses of 0, 1, 2, 3 or 15 mg/kg bw. The NOAEL was 2 mg/kg bw on the basis of inhibition of acetylcholinesterase activity in erythrocytes in males at 3 mg/kg bw.

A 13-week dietary study for neurotoxicity fed rats a dose of 0, 1, 50 or 125 ppm (equal to intakes of 0, 0.06, 3.22 and 8.13 mg/kg bw per day for males, 0, 0.08, 3.78 and 9.88 mg/kg bw per day for females). This continued for 91, 92, 93 or 94 days. The NOAEL for systemic toxicity and neurotoxicity was 1 ppm (equal to 0.06 mg/kg bw per day) on the basis of inhibition of erythrocyte acetylcholinesterase activity at 50 ppm (equal to 3.22 mg/kg bw per day).

In a dose range-finding gavage study for developmental neurotoxicity in rats, dose levels of 0, 0.2, 3 and 6.0 mg/kg bw per day were given in water to dams between GD days six and 20 or during GD 6 and PND 10, and to offspring during PND 11–21. The NOAEL was 0.2 mg/kg bw per day for dams and their offspring based on statistically significantly reduced maternal body weight gain from GD 6 until GD 20, and inhibition of erythrocyte and brain acetylcholinesterase in the dams and offspring at 3 mg/kg bw per day.

In the main developmental neurotoxicity oral gavage study, rats were given a dose in water of 0, 0.1, 0.5 or 3 mg/kg bw per day during GD 10–PND10 (dams), and during PND 11–21 (offspring). The NOAEL in the offspring was 0.5 mg/kg bw per day based on poor general condition, developmental delay in some functional parameters and increased pup mortality at a dose of 3 mg/kg bw per day. A dose of up to 3 mg/kg bw per day, the highest dose tested, was not associated with any selective developmental neurotoxicity. Acetylcholinesterase activity was not measured in this study.

A study supplemental to a developmental neurotoxicity study was conducted to assess the influence on offspring survival of maternal exposure to dimethoate during gestation and the postnatal period. Groups of mated female rats were allocated one of three treatments: a control group, a 3 mg/kg bw per day group, or a 6 mg/kg bw per day group; offspring were then cross-fostered. Excess mortality, behavioural and clinical effects were observed in pups reared by treated dams, irrespective of pups' in utero exposure.

In a special study designed to assess effects on acetylcholinesterase activity, pregnant rats, preweaning rats and young adult rats received dimethoate by gavage at 0, 0.1, 0.5 or 3 mg/kg bw per day either once or for 11 days (preweaning and young adult), or from GD6 to GD20 (dams), or from GD6 to PND10 (dams) followed by pups treatment until PND 21. The NOAEL for dimethoate given as a single dose was 0.5 mg/kg bw per day on the basis of inhibition of erythrocyte acetylcholinesterase activity in preweaning females (26%) and in young adult females (27%) at 3 mg/kg bw per day. The NOAEL for dimethoate given as repeated doses was 0.1 mg/kg bw per day on the basis of inhibition (23%) of erythrocyte acetylcholinesterase activity in female pups on PND 21 at 0.5 mg/kg bw per day.

The Meeting identified an overall NOAEL of 2 mg/kg bw for acute treatment based on inhibition of erythrocyte acetylcholinesterase activity in an acute neurotoxicity study, and a special

study in preweaning females and in young adult females with an overall LOAEL of 3 mg/kg bw per day.

In a GLP-compliant study it was concluded that administration of dimethoate, either orally or subcutaneously, at a dose level of 55 mg/kg bw (the oral LD<sub>50</sub> value) did not produce any clinical signs of delayed neurotoxicity in domestic hens.

Dimethoate is neurotoxic via inhibition of acetylcholinesterase but is not neuropathic.

No evidence of dimethoate-mediated oestrogenic, androgenic or steroidogenic activity was observed in a battery of in vivo and in vitro tests.

No immunotoxicity studies were available, but there was no indication of immunotoxic effects in the short- or long-term toxicity studies.

### **Data on metabolites**

#### **Omethoate**

The Meeting noted the conclusion of the 1996 JMPR: "*Omethoate has been extensively investigated for mutagenicity in vitro and in vivo. The Meeting concluded that it has clear mutagenic potential but that the weight of the evidence observed in vivo was negative; however, the positive result obtained in the mouse spot test could not be completely disregarded.*"

At that Meeting the ADI for omethoate was withdrawn. Although a number of new studies focused on the antiacetylcholinesterase activity of omethoate, no new genotoxicity studies were provided to the present Meeting. Consequently, the Meeting was unable to complete the assessment of omethoate with respect to its mutagenic potential.

Apart from omethoate, a number of plant metabolites have been identified, including dimethoate carboxylic acid, *O*-desmethyl dimethoate carboxylic acid, *O*-desmethyl dimethoate, *N*-desmethyl dimethoate, *O*-desmethyl omethoate, *O*-Desmethyl-*N*-desmethyl omethoate, *O*-desmethyl omethoate carboxylic acid, hydroxy-omethoate, isodimethoate, *O*-desmethyl isodimethoate and hydroxydimethoate (and its glucose conjugate). These plant metabolites occur at different levels. Dimethoate carboxylic acid is a major rat metabolite, therefore, the Meeting concluded that the toxicity of this metabolite would be covered by that of dimethoate. As for the remaining metabolites, although the desmethylated metabolites are less potent inhibitors of acetylcholinesterase, the Meeting noted that they are also likely to retain the moiety for genotoxic activity. Therefore, in the absence of genotoxicity studies, no conclusion can be drawn as to the genotoxic potential of these metabolites.

#### **Human data**

The medical surveillance data of manufacturing personnel did not reveal any indications of negative health effects caused by the exposure to dimethoate during its manufacturing or formulation.

The Meeting also considered a number of studies in human volunteers, which indicated that single or repeated oral doses of dimethoate of up to 0.2 mg/kg bw did not induce clinical effects or inhibit acetylcholinesterase activity in the blood. Since these studies were not conducted according to current standards (no details on study design were given, for example age and sex of individual volunteers, nor were raw data provided) they could not form the basis for the ADI and ARfD.

A number of reported cases, both accidental and voluntary, of acute poisoning by dimethoate or omethoate are available in the literature. The effects observed appeared to be the cholinergic syndrome and no long-term consequences, including delayed polyneuropathy, have been described.

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

### Toxicological evaluation

The Meeting withdrew the previous ADI and established an ADI for dimethoate of 0–0.001 mg/kg bw on the basis of the NOAEL of 0.1 mg/kg bw per day for inhibition of erythrocyte acetylcholinesterase activity in female pups on PND 21 at 0.5 mg/kg bw in the developmental special study designed to assess effects of dimethoate on acetylcholinesterase activity in pregnant rats, pre-weaning rats and young adult rats. A safety factor of 100 was applied.

The Meeting reaffirmed the ARfD for dimethoate of 0.02 mg/kg bw on the basis of an overall NOAEL of 2 mg/kg bw per day based on inhibition of erythrocyte acetylcholinesterase activity in an acute neurotoxicity study and a special study in preweaning females and in young adult females with an overall LOAEL of 3 mg/kg bw per day. A safety factor of 100 was applied.

The Meeting noted that the data from the human volunteer studies are consistent with the proposed ADI and ARfD where there was apparent a NOAEL of about 0.2 mg/kg bw per day in studies in volunteers receiving single or repeated doses.

#### Levels relevant to risk assessment of dimethoate

Species	Study	Effect	NOAEL	LOAEL
Mouse	78-week study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	-	25 ppm equal to 3.6 mg/kg bw per day <sup>c</sup>
		Carcinogenicity	200 ppm equal to 31.1 mg/kg bw per day <sup>c</sup>	-
	Three-generation reproductive toxicity <sup>a,f</sup>	Reproductive toxicity	50 ppm equal to 13.6 mg/kg bw per day <sup>c</sup>	-
		Parental toxicity	15 ppm equal to 4.1 mg/kg bw per day	50 ppm equal to 13.6 mg/kg bw per day
		Offspring toxicity	50 ppm equal to 14.4 mg/kg bw per day <sup>c</sup>	-
	Rat	Four-week study on toxicity <sup>a, b</sup>	Toxicity	0.83 mg/kg bw per day
Two-year study on toxicity and carcinogenicity <sup>a</sup>		Toxicity	BMDL <sub>20</sub> : 0.31 mg/kg bw per day <sup>g</sup>	-
		Carcinogenicity	100 ppm equal to 4.8 mg/kg bw per day <sup>c</sup>	-
Two-generation study of reproductive toxicity <sup>a, b</sup>		Reproductive toxicity	6.5 mg/kg bw per day <sup>c</sup>	-
		Parental toxicity	1.0 mg/kg bw per day	6.5 mg/kg bw per day
		Offspring toxicity	1.0 mg/kg bw per day	6.5 mg/kg bw per day
Developmental Toxicity study <sup>d, b</sup>		Maternal toxicity	6 mg/kg bw per day	18 mg/kg bw per day
		Embryo and fetal toxicity	18 mg/kg bw per day <sup>c</sup>	-



Species	Study	Effect	NOAEL	LOAEL
	Acute neurotoxicity study <sup>b, d</sup>	Neurotoxicity	2 mg/kg bw per day	3 mg/kg bw per day
	91–94 day neurotoxicity study <sup>a, f</sup>	Neurotoxicity	0.06 mg/kg bw per day	3.22 mg/kg bw per day
	Study of acetylcholinesterase activity after single and repeated doses of dimethoate	ChE activity after single dose in preweaning rats and young adults	0.5 mg/kg bw	3 mg/kg bw
		ChE activity after repeat dose in female pups on PND 21	0.1 mg/kg bw per day	0.5 mg/kg bw per day
	Developmental neurotoxicity <sup>d</sup>	Functional development of nervous systemic toxicity in offspring	0.5 mg/kg bw per day	3 mg/kg bw per day
		Developmental neurotoxicity	3 mg/kg bw per day <sup>c</sup>	-
Rabbit	Developmental toxicity study <sup>d</sup>	Maternal toxicity	10 mg/kg bw per day	20 mg/kg bw per day
		Embryo and fetal toxicity	40 mg/kg bw per day <sup>c</sup>	-
Dog	28-day, 98-day and one-year studies of toxicity <sup>a, b</sup>	Toxicity	10 ppm equal to 0.43 mg/kg bw per day	20 ppm equal to 0.70 mg/kg bw per day

<sup>a</sup> Dietary administration

<sup>b</sup> Two or more studies combined

<sup>c</sup> Highest dose tested

<sup>d</sup> Gavage administration

<sup>e</sup> Lowest dose tested

<sup>f</sup> Cholinesterase activity not measured

<sup>g</sup> BMDL<sub>20</sub> calculated with BMDS

*Acceptable daily intake (ADI) for dimethoate*

0–0.001 mg/kg bw

*Acute reference dose (ARfD) for dimethoate*

0.02 mg/kg bw

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

Results from further epidemiological, occupational health and other such observational studies of human exposure; clarification on the genotoxic potential of omethoate and related metabolites.

**Critical end-points for setting guidance values for exposure to dimethoate**

<b>Absorption, distribution, excretion and metabolism in mammals</b>	
Rate and extent of oral absorption	Rapidly and extensively absorbed ( $\geq 90\%$ )
Dermal absorption	Approximately 40%
Distribution	Widely distributed, highest concentration found in kidney and liver
Potential for accumulation	None
Rate and extent of excretion	Excretion is rapid: 52–72% of the dose excreted in urine within the first six hours, and 80–90 % by 24 hours
Metabolism in animals	Extensive
Toxicologically significant compounds in animals and plants	Dimethoate, omethoate, dimethoate carboxylic acid, <i>O</i> -desmethyl dimethoate carboxylic acid, <i>O</i> -desmethyl dimethoate, <i>N</i> -desmethyl dimethoate, <i>O</i> -desmethyl omethoate, <i>O</i> -Desmethyl- <i>N</i> -desmethyl omethoate, <i>O</i> -desmethyl omethoate carboxylic acid, Hydroxy-omethoate, isodimethoate, <i>O</i> -desmethyl isodimethoate and hydroxydimethoate (and its glucose conjugate)
<b>Acute toxicity</b>	
Rat, LD <sub>50</sub> , oral	245–414 mg/kg bw
Rat, LD <sub>50</sub> , dermal	> 2000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	1.68 mg/L
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Mildly irritating
Guinea pig, dermal sensitization	Not sensitizing (Buehler and maximization)
<b>Short-term studies of toxicity</b>	
Target/critical effect	Inhibition of acetylcholinesterase
Lowest relevant oral NOAEL	0.43 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	10 mg/kg bw per day (rat)
Lowest relevant inhalation NOAEC	No data
<b>Long-term studies of toxicity and carcinogenicity</b>	
Target/critical effect	Inhibition of erythrocyte and brain acetylcholinesterase (rat, mouse)
Lowest relevant NOAEL	0.31 mg/kg bw per day (rat) (BMDL <sub>20</sub> )
Carcinogenicity	Not carcinogenic in mice and rats <sup>a</sup>
<b>Genotoxicity</b>	Unlikely to be genotoxic in vivo <sup>a</sup>
<b>Reproductive toxicity</b>	
Target/critical effect	No reproductive effects
Lowest relevant parental NOAEL	1 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	1 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	1.2 mg/kg bw per day, highest dose tested (rat)
<b>Developmental toxicity</b>	
Target/critical effect	No developmental effect (rat, rabbit)
Lowest relevant maternal NOAEL	6 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	18 mg/kg bw per day, highest dose tested (rat )
<b>Neurotoxicity</b>	
Acute neurotoxicity NOAEL	2 mg/kg bw (rat)

Subchronic neurotoxicity NOAEL	0.06 mg/kg bw per day, (rat)
Lowest acetylcholinesterase activity NOAEL	0.04 mg/kg bw per day
Developmental neurotoxicity NOAEL	0.5 mg/kg bw (rat)
<b>Immunotoxicity</b>	No specific studies available, but no indication of immunotoxic effects in the short- and long-term toxicity studies.
<b>Human data</b>	Studies on volunteers not adequate for risk assessment Poisoning case reports showing cholinergic toxicity

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet

### Summary

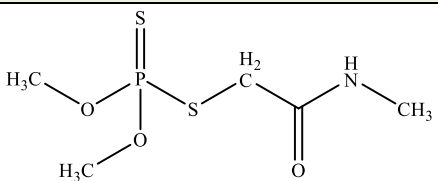
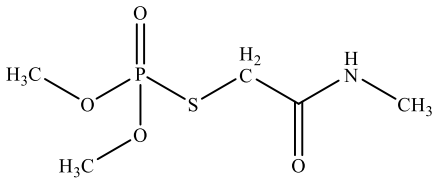
	Value	Study	Safety factor
ADI	0–0.001 mg/kg bw	Special study in pups and young adults on acetylcholinesterase activity after repeated doses.	100
ARfD	0.02 mg/kg bw	Overall NOAEL of acute neurotoxicity study in rats and special study in pups and young adults, supported by studies in volunteers receiving single or repeated doses.	100

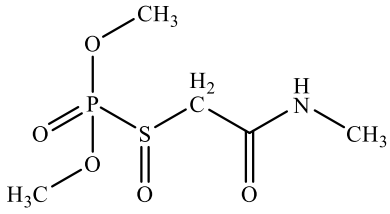
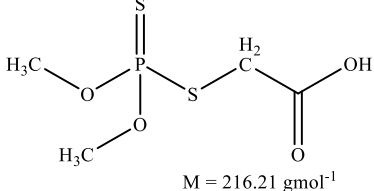
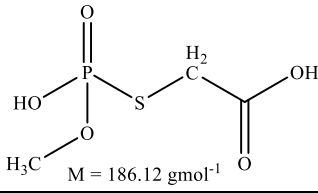
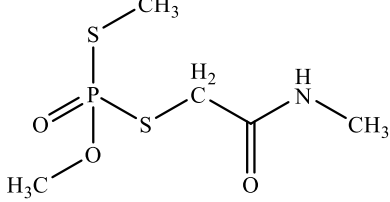
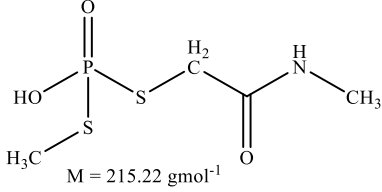
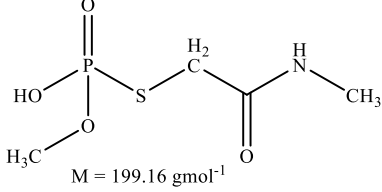
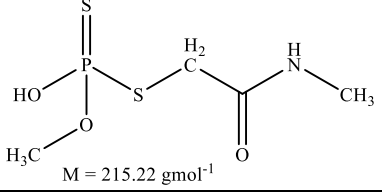
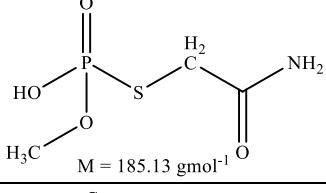
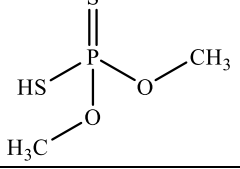
### RESIDUE AND ANALYTICAL ASPECTS

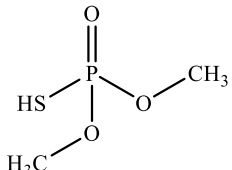
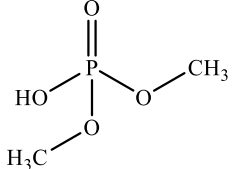
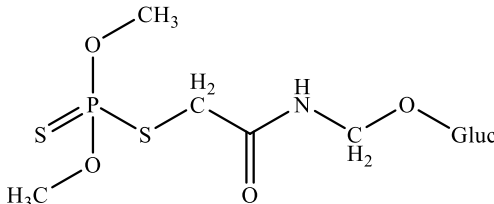
Dimethoate is an organophosphate insecticide which acts through acetylcholinesterase inhibition. It was scheduled by the Fiftieth Session of the CCPR (2018) for periodic review evaluation by the 2019 JMPR. Dimethoate has been evaluated on numerous occasions by the JMPR commencing in 1963. The most recent periodic review was in 1996 (toxicology) and 1998 (residues), with a subsequent evaluation for toxicology and residues in 2003 to establish an acute reference dose and consider additional plant metabolism studies. Residue data for additional uses was evaluated in 2006 and 2008.

The Meeting considered information supplied by the sponsor on identity, physicochemical properties, metabolism and environmental fate, methods of residue analysis, freezer storage stability, registered use patterns, supervised residue trials, fate of residues in processing, and animal feeding studies. Additional supervised residue trial data was supplied by Australia for mandarin, oranges, avocados, mangoes, capsicum and pulses, and by Thailand for yard-long bean.

Table 1 Metabolites of dimethoate

Component name	Structure	Origin
Dimethoate		Parent compound
Omethoate		Potato, olives, wheat, rat, goat, hen

Component name	Structure	Origin
Omethoate sulfoxide		Goat (intermediate), hen (intermediate)
Dimethoate carboxylic acid	 <p>M = 216.21 gmol<sup>-1</sup></p>	Potato, olives, wheat, rat, goat, hen
O-desmethyl omethoate carboxylic acid	 <p>M = 186.12 gmol<sup>-1</sup></p>	Potato, wheat
Isodimethoate		Olives (intermediate), wheat (probable intermediate)
O-desmethyl isodimethoate	 <p>M = 215.22 gmol<sup>-1</sup></p>	Potato, olives, wheat
O-desmethyl omethoate	 <p>M = 199.16 gmol<sup>-1</sup></p>	Potato, olives, wheat
Desmethyl dimethoate	 <p>M = 215.22 gmol<sup>-1</sup></p>	Potato, hydrolysis, soil (minor component)
O-desmethyl N-desmethyl omethoate	 <p>M = 185.13 gmol<sup>-1</sup></p>	Potato, olives, wheat
Dimethyl dithiophosphate and conjugates		Potato, wheat, rat, goat, hen

Component name	Structure	Origin
Dimethyl thiophosphate		Hydrolysis
Dimethyl phosphate		Rat
Hydroxy dimethoate glucose conjugate		Potato, wheat

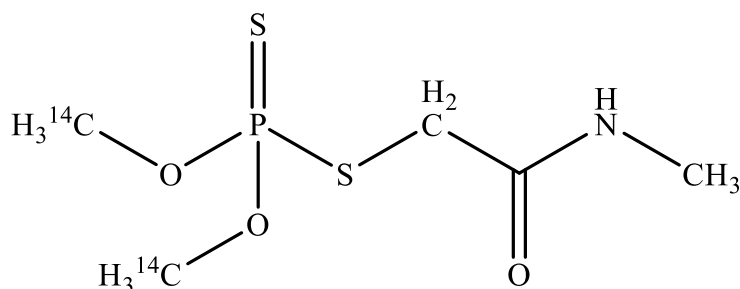
### Physicochemical properties

Dimethoate is moderately water soluble (28.2 g/L in purified water at 20 °C), and very soluble in polar organic solvents such as dichloromethane, acetonitrile, and methanol. With an octanol/water partition coefficient ( $\log_{10}P_{OW}$ ) of 0.75, dimethoate is not expected to partition into fat. Hydrolysis is slow at acidic pH ( $t_{1/2} = 156$  days at pH 5), becoming more rapid as the pH is increased ( $t_{1/2} = 4.4$  days at pH 9).

Omethoate is highly soluble in water (> 500 g/L) and has a very low octanol/water partition coefficient at -0.74, indicating that it is not expected to partition into fat.

### Plant Metabolism

Metabolism studies were conducted using dimethoate labelled with carbon-14 at both methoxy groups.



The Meeting received plant metabolism studies conducted on olives, potatoes, and wheat.

An olive tree was treated with  $4 \times 0.72$  kg ai/ha foliar applications at retreatment intervals of 57, 30, and 44 days. The first application was made at BBCH 51–69 (inflorescence emergence to end of flowering) with the final application at BBCH 75–89 (fruit at 50% final size and above), 28 days before harvest maturity. Fruit was sampled just before and just after the third application, at two intervals between the third and fourth applications, and at 0-, 0+ (green and black olives), 14, 21 and 28 days (green and black olives) after the final application. Leaves were sampled after the first application, 43 days after the third application and 14, 21 and 28 days after the fourth application.

In leaves collected on the day of the first application, residues were easily removed by washing or simple solvent extraction, with 70% TRR (30 mg eq/kg) removed by the surface washes, and 30% TRR (13 mg eq/kg) extracted with acetonitrile and acetonitrile water, leaving only 0.2% TRR

(0.08 mg eq/kg) unextracted. Most of the residue was present as unchanged parent compound (96% TRR).

Olives were surface washed with acetonitrile then separated into flesh and stone fractions. For olive flesh collected between 30 days after application 2 and 28 days after the final application, small fractions of radioactivity were removed in surface washes (1.5–17% TRR or 0.05–1.0 mg eq/kg), with the majority being extracted with hexane, acetonitrile, and acetonitrile/water (73–88% TRR or 2.5–4.3 mg eq/kg). Harsher extractions removed further proportions of the radioactive residues, with base extractions (1 M NaOH followed by 6 M NaOH) being the most successful, removing up to 10% TRR, reflecting the incorporation of some radioactivity into fatty acids. Much lower proportions of the residue were readily extractable from olive stone samples, with acetonitrile, acetonitrile/water and water extractions removing only 29–44% TRR (0.58–1.2 mg eq/kg), with unextracted residues correspondingly comprising 56–71% TRR (1.3–1.9 mg eq/kg).

Parent dimethoate was a major residue component in olive flesh shortly after an application, at 31% TRR (1.5 mg eq/kg) on the day of the third application, and 33% TRR (1.9 mg eq/kg) on the day of the fourth application. At other intervals, the largest component of the residue was O-desmethyl-N-desmethyl omethoate, at 36–60% TRR (1.5–2.9 mg eq/kg). The next largest component was OL-L4, which comprised mainly radioactivity incorporated into triglycerides and sterols, at 3.5–9.7% TRR (0.16–0.42 mg eq/kg). Other components identified in olive flesh were O-desmethyl isodimethoate, at 1.5–6.9% TRR (0.07–0.27 mg eq/kg), omethoate, at 0.4–3.2% TRR (0.02–0.16 mg eq/kg), dimethoate carboxylic acid, at < 0.1–2.7% TRR (< 0.01–0.10 mg eq/kg), O-desmethyl omethoate, at < 0.1–1.7% TRR (< 0.01–0.09 mg eq/kg), and isodimethoate, at < 0.1–2.5% TRR (< 0.01–0.08 mg eq/kg).

Potatoes were treated with  $2 \times 0.34$  kg ai/ha foliar applications of  $^{14}\text{C}$ -methoxy dimethoate at 14-day intervals at BBCH 45–47. Foliage and tuber samples were collected at intervals from 0 to 28 days after the second application. Foliage was surface washed with acetonitrile, then homogenised and extracted with acetonitrile, acetonitrile/water and water. Tubers were homogenised and extracted with acetonitrile and acetonitrile/water. Unextractable residues were further investigated by treating subsamples in parallel with acid (0.1 M HCl for 20 hours at 37 °C), base (0.1 M NaOH for 20 hours at 37 °C), or enzyme (bacterial protease type VIII digestion in phosphate buffer at 37 °C for 20 hours).

Total radioactive residues in foliage were 12.30 mg eq/kg at day 0 (after the second application), declining to 1.3 mg eq/kg by day 14, with a subsequent increase to 3.5 mg eq/kg day 28 due to drying of the foliage. Tuber residues were lower at 0.30 mg eq/kg at day 0, declining only slightly to 0.19 mg eq/kg at day 14 and 0.24 mg eq/kg at day 28. Solvent extractability was 85% in foliage at day 0, decreasing to 56% at day 14 and 46% at day 28, and 90% in tubers at day 0, remaining high at 85% and 83% at days 14 and 28 respectively.

In foliage, dimethoate and omethoate accounted for 68% and 6% of the TRR respectively (8.4 and 0.73 mg eq/kg) on day 0. By day 14, dimethoate and omethoate accounted for 15% and 9% of the TRR in foliage respectively (0.2 and 0.12 mg eq/kg). Other residue components in foliage were O-desmethyl N-desmethyl omethoate (1.8% TRR, 0.22 mg eq/kg at day 0 and 8.7% TRR, 0.11 mg eq/kg at day 14), followed by O,O-dimethyl dithiophosphoric acid (0.3% TRR, 0.04 mg eq/kg at day 0 and 4.5% TRR, 0.06 mg eq/kg at day 14), O-desmethyl omethoate (3.2% TRR, 0.39 mg eq/kg at day 0 and 3.2% TRR, 0.04 mg eq/kg at day 14), co-eluting O-desmethyl isodimethoate and dimethoate carboxylic acid (0.8% TRR, 0.10 mg eq/kg at day 0 and 3.1% TRR, 0.04 mg eq/kg at day 14), hydroxy dimethoate glucose conjugate (2.3% TRR, 0.28 mg eq/kg at day 0 and 4.8% TRR, 0.06 mg eq/kg at day 14), desmethyl dimethoate (1.2% TRR, 0.02 mg eq/kg at day 14), and O-desmethyl omethoate carboxylic acid (1.5% TRR, 0.02 mg eq/kg at day 14).

No dimethoate or omethoate was detected in the tubers. The components identified in potato tubers were O-desmethyl N-desmethyl omethoate (0.23 mg eq/kg, 76% TRR at day 0, 0.09 mg eq/kg, 46% TRR at day 14, and 0.10 mg eq/kg, 44% TRR at day 28), O-desmethyl omethoate, (< 0.01 mg eq/kg at day 0, 0.02 mg eq/kg, 12% TRR at day 14 and 0.04 mg eq/kg, 15% TRR at day 28), and O-desmethyl omethoate carboxylic acid (0.02 mg eq/kg, 6.1% TRR at day 0, 0.03 mg eq/kg, 18% TRR at day 14), and 0.03 mg eq/kg, 12% TRR at day 28). Neither dimethoate nor omethoate are translocated from the foliage to the tubers and metabolism occurs mainly in the foliage.

**Wheat** (grown outdoors) was treated with two foliar applications, at BBCH 24 and 69. A 1× trial was carried out with application rates of 0.68 and 0.40 kg ai/ha for the first and second applications, and a 5× trial at rates of 3.4 and 2.0 kg ai/ha respectively. Samples were collected after the first application (day 0) and after 14, 26 and 39 days. Samples were also taken after the second application (day 41), and after 62 (early harvest) and 73 days (normal harvest). For the exaggerated rate trial, only grain, hull and straw were collected at 73 days. Depending on the growth stage of the plant, samples consisted of whole plant, ear, remaining plant, grain, hull or straw. Samples were extracted with acetonitrile and acetonitrile/water. Where significant radioactivity remained in the post-extraction solids (PES), further harsher extraction techniques were employed - dilute acid (0.1 M HCl), dilute base (0.1 M or 1 M NaOH), strong base (6 M NaOH) or enzymes (protease, cellulose/hemicellulose, and amylase).

Residues were highest in plant material immediately after application, with TRRs of 30 mg eq/kg in whole plant at day 0 after one application at 0.68 kg ai/ha, declining to 0.90 mg eq/kg in remaining plant at day 39 (before the second application). At harvest maturity, TRRs were 2.3 mg eq/kg at day 62 (21 days after application 2) and 4.3 mg eq/kg at day 73 (32 DAA2) in grain, 23 and 34 mg eq/kg at 21 and 32 DAA2 in hulls, and 6.4 and 7.8 mg eq/kg at 21 and 32 DAA2 in straw. Solvent extractability was generally high in plant material, at 99.8% of TRR at day 0 after the first (0.68 kg ai/ha application, declining to 91% of TRR in ears and 78% of the TRR in remaining plant at 39 days after the first application. At harvest, extractability was 81% and 66% of TRR from grain at 21 and 32 days after 0.68 + 0.40 kg ai/ha applications, 92% and 84% from hulls respectively and 79% and 72% from straw respectively. Only grain at 32 days after the second application was analysed from the exaggerated rate trial, with a TRR of 20 mg eq/kg. 63% of TRR was extractable with acetonitrile/water.

In whole wheat plants immediately after the first application at 0.68 kg ai/ha, the residues was mainly unmetabolized dimethoate at 98% TRR (29 mg eq/kg), with small amounts of omethoate (0.7% TRR, 0.21 mg eq/kg), and O-desmethyl N-desmethyl omethoate (0.4% TRR, 0.12 mg eq/kg). Dimethoate was rapidly metabolized in wheat. At 14 days after the first application, the residue components were dimethoate (4.1% TRR, 0.07 mg eq/kg), omethoate (7.8% TRR, 0.13 mg eq/kg), O-desmethyl isodimethoate (30% TRR, 0.49 mg eq/kg), O-desmethyl N-desmethyl omethoate (26% TRR, 0.44 mg eq/kg), O,O-dimethyl dithiophosphate (4.5% TRR, 0.08 mg eq/kg), and O-desmethyl omethoate carboxylic acid (1.1% TRR, 0.02 mg eq/kg). At 39 days, residue components in plant material after removal of ears were O-desmethyl N-desmethyl omethoate (42% TRR, 0.37 mg eq/kg), O-desmethyl isodimethoate (22% TRR, 0.20 mg eq/kg), O-desmethyl omethoate carboxylic acid (5.7% TRR, 0.05 mg eq/kg), and O,O-dimethyl dithiophosphate (2.6% TRR, 0.02 mg eq/kg).

At harvest, no residues of dimethoate or omethoate were found in grain. The residue components in grain sampled at 21 days after the second application (0.68 + 0.40 kg ai/ha) were O-desmethyl N-desmethyl omethoate (54% TRR, 1.2 mg eq/kg), O-desmethyl isodimethoate (11% TRR, 0.26 mg eq/kg), and O-desmethyl omethoate carboxylic acid (3.8% TRR, 0.09 mg eq/kg). In straw at 21 days, residue components were dimethoate (6.2% TRR, 0.40 mg eq/kg), omethoate (3.4% TRR, 0.22 mg eq/kg), O-desmethyl N-desmethyl omethoate (36% TRR, 2.3 mg eq/kg), O-desmethyl isodimethoate (20% TRR, 1.3 mg eq/kg), O-desmethyl omethoate carboxylic acid (4.6% TRR, 0.30 mg eq/kg), and O,O-dimethyl dithiophosphoric acid (2.8% TRR, 0.18 mg eq/kg). At 32 days, the composition of the residue in grain and straw were similar.

In the exaggerated rate grain samples, residue components were O-desmethyl N-desmethyl omethoate (39% TRR, 8.0 mg eq/kg), O-desmethyl isodimethoate (16% TRR, 3.1 mg eq/kg), O-desmethyl omethoate carboxylic acid (6.4% TRR, 1.3 mg eq/kg), dimethoate (0.5% TRR, 0.10 mg eq/kg), and omethoate (0.3% TRR, 0.06 mg eq/kg).

The metabolism of [<sup>32</sup>P]dimethoate in lemons, sugar beet, maize, cotton, peas, potatoes and beans was reported. The reports were summaries which did not provide the level of detail given in a contemporary metabolism study. Generally, the main components of the radiolabelled residue were dimethoate, omethoate, dimethoate carboxylic acid, dimethyl hydrogen phosphate and O,O-dimethyl hydrogen phosphorodithioate, indicating oxidation to omethoate, omethoate carboxylic acid and

dimethoate carboxylic acid, and cleavage of the P-S linkage either before or after oxidation. The metabolic pathways in these studies were similar to the olive, potato and wheat study.

In the bean study, after foliar treatment with [<sup>14</sup>C-methoxy]-dimethoate, parent compound comprised 40% of the foliage TRR, omethoate 1.6% TRR, while N-desmethyl dimethoate, dimethoate carboxylic acid, and O-desmethyl dimethoate carboxylic acid all comprised less than 1% of TRR.

In a study of the metabolism of [<sup>32</sup>P]-dimethoate in excised cotton leaves with the cut petioles immersed in an aqueous solution of the radiolabel, dimethoate comprised 70% of the TRR on day 1, declining to 1.9% on day 14. The components identified were dimethoate carboxylic acid (15–50%), O,O-dimethyl dithiophosphoric acid (4–11%), omethoate (approximately 6%), dimethyl phosphate (2.5–11%), O,O-dimethyl thiophosphoric acid (1.6–12%), O-desmethyl dimethoate carboxylic acid (no fraction given), and phosphoric acid (no fraction given).

After foliar application of [<sup>32</sup>P]-dimethoate to lemons, residue components identified were dimethoate, omethoate, dimethyl phosphoric acid, phosphoric acid, O,O-dimethyl thiophosphoric acid, and desmethyl dimethoate.

### *Summary of plant metabolism*

The major metabolic pathways observed in plants treated by foliar application were:

- Oxidation to omethoate.
- O-Demethylation of omethoate to give O-desmethyl omethoate, and either subsequent N-demethylation to yield O-desmethyl N-desmethyl omethoate or amide hydrolysis to give O-desmethyl omethoate carboxylic acid.
- O-Demethylation and rearrangement to yield des-O-methyl isodimethoate.
- Hydroxylation of the N-methyl group in potatoes, with subsequent glucose conjugation.
- Hydrolysis of the amide bond and subsequent degradation to give dimethoate carboxylic acid, followed by dimethyl dithiophosphate.
- Incorporation into fatty acids was observed in olives.

### *Environmental Fate*

The Meeting received studies of aerobic soil metabolism, soil surface photolysis, hydrolysis, aqueous photolysis, and laboratory and field soil dissipation of dimethoate, as well as field soil dissipation of omethoate.

#### *Hydrolysis*

Hydrolysis of <sup>14</sup>C-methoxydimethoate at 25 ± 1 °C was rapid at pH 9, with a half-life of 4.4 days, and significantly slower under neutral and acid conditions, with half-lives of 68 and 156 days at pH 7 and 5, respectively. The main hydrolysis products were O-desmethyldimethoate and O,O-dimethylphosphorothioic acid, which comprised 62.1% and 36.0% of the applied radioactivity at day 30 in the pH 9 study, while parent comprised only 1.1% of AR. Hydrolysis is not a significant degradation pathway under environmental conditions.

#### *Aqueous photolysis*

Photolysis is not a significant environmental degradation pathway for dimethoate, as shown by an aqueous photolysis study which determined a half-life of > 175 days (pH 5, 25 ± 1 °C, irradiation equivalent to at least 30 days of natural equatorial sunlight).

#### *Soil surface photolysis*

Photolysis at the soil surface did not occur, with essentially there being no difference in the degradation



rate in the irradiated and dark control samples (half-lives of 10.5 and 7.9 days respectively (SFO model)).

#### *Aerobic soil degradation*

In aerobic soil incubated at  $20 \pm 2$  °C in the dark, degradation of radiolabelled dimethoate was rapid, with parent being less than 1% of AR at day 21. The DT50 and DT90 were calculated at 2.6 and 8.6 days respectively by the SFO model. Mineralisation was the major degradation pathway, with  $^{14}\text{CO}_2$  at 53% of AR at day 21, with significant fractions of the applied radioactivity being found as fluvic acids, humins, and humic acids (25%, 13%, and 4.5%, respectively). Levels of other degradation products were low, with desmethyl-dimethoate being found at < 5%, and omethoate not being detected.

In a laboratory study conducted at  $20 \pm 3$  °C with three different UK soils with unlabeled compound, dimethoate was rapidly degraded, with DT50 values of 2.0–4.1 days, and D90 values of 6.8–13.5 days.

#### *Field soil dissipation - dimethoate*

In field studies conducted in Europe (one site each in Germany, Italy, the Netherlands and Spain) and the USA (one site in each of California, New York and Texas), degradation of dimethoate was rapid, with half-lives ranging from 2.2 to 9.8 days.

#### *Field soil dissipation - omethoate*

Field soil dissipation studies were conducted at four sites in Europe where omethoate was applied directly to soil. Degradation was very rapid, with half-lives ranging from 1.3–2.9 days, and DT<sub>90</sub> values from 4.4–9.8 days. Similar results were obtained from some of the US dimethoate dissipation studies, where an omethoate half-life was calculated after measurement of both components, with half-lives for omethoate being < 1 day.

Neither dimethoate nor omethoate are persistent in soil.

#### *Confined Rotational Crops*

A confined rotational cropping study on wheat, lettuce and turnips was conducted using [ $^{14}\text{C}$ -methoxy]dimethoate. Planting boxes containing a sandy loam soil (pH 6.4, organic matter 1.6%) were treated with the test substance at 0.56 kg ai/ha. The test crops were planted in the  $^{14}\text{C}$ -dimethoate treated soil at 30 and 120 days after treatment.

Wheat forage was harvested 62 and 168 days after application for the first and second rotation respectively. Lettuce was harvested 78 and 174 days after application, turnip (root and foliage) at 100 and 208 days after application, wheat hay at 97 and 216 days after application, while wheat grain and straw was harvested 141 and 272 days after application for each rotation.

TRRs were low, ranging from 0.008 mg eq/kg in turnip root to 0.045 mg eq/kg in wheat straw at the 30-day PBI and 0.001 mg eq/kg in turnip root to 0.020 mg eq/kg in wheat straw at the 120-day PBI. Extractability with acetonitrile and acetonitrile/HCl was variable, ranging from 3.1% in 120-day PBI grain, to 74% in 30-day PBI lettuce. Neither dimethoate nor omethoate could be identified. The extractable residue was characterized as consisting of multiple highly polar components.

Residues of dimethoate in rotational crops are not expected to be significant.

#### *Animal Metabolism*

The Meeting received animal metabolism studies for dimethoate in rats, hens and goats.

##### *Rats*

Evaluation of the metabolism studies in rats was carried out by the WHO Core Assessment Group.

Residue components observed in rat metabolism were dimethoate, omethoate, dimethoate carboxylic acid, dimethyl dithiophosphate, dimethyl thiophosphate, and dimethyl phosphate.

### Goats

Lactating goats were treated with [<sup>14</sup>C-methoxy]dimethoate by capsule once daily for 3 consecutive days at a dose equivalent to 30 ppm in the diet (1.6 mg/kg bw per day). Milk was collected twice daily. The animals were sacrificed 23 hours after the final dose for tissue collection.

Recovery of the administered dose was good, at 92–96% in excreta, milk and tissues. Total residues in milk ranged from 0.035–0.23 mg eq/kg, and were higher in samples collected within 8 hours post treatment, compared to samples collected 8 to 24 hours post treatment each day, suggesting rapid elimination of dimethoate from milk.

Total residues in tissues were 1.2 mg eq/kg in liver, 0.15 mg eq/kg in kidney, 0.070 mg eq/kg in muscle, and 0.045 mg eq/kg in fat.

Solvent extractability (acetonitrile, acetonitrile/water, acetone, and methanol/1 M NH<sub>4</sub>OH) was variable, ranging from 28% in fat, to 90% in milk. The liver PES was subjected to harsher extraction techniques, with protease removing a further 22% of TRR, 6 M HCl at 90 °C removing 14% of TRR, and 3 M NaOH removing 1.8% of TRR.

Dimethoate was rapidly metabolized. In tissues and milk, the bulk of the residue comprised radioactivity incorporated into natural products (released by the solvent extraction, protease and acid extraction). Phosphorylated natural products comprised 62% TRR/0.76 mg eq/kg in liver, 87% TRR/0.13 mg eq/kg in kidney, 70% TRR/0.049 mg eq/kg in muscle, and 65% TRR/0.15 mg eq/kg in milk. Residues in fat were not further analysed due to the low levels. Anionic species (mainly dimethyl phosphate, dimethyl thiophosphate and dimethyl dithiophosphate) comprised 6.2% TRR/0.076 mg eq/kg in liver, 13% TRR/0.02 mg eq/kg in kidney, 2.9% TRR/0.002 mg eq/kg in muscle, and 2.2% TRR/0.005 mg eq/kg in milk. No parent compound was identified. Omethoate was found at 9.8% TRR/0.12 mg eq/kg in liver, while dimethoate carboxylic acid was found at 2.5% TRR/0.031 mg eq/kg in liver, and 8.3% TRR/0.019 mg eq/kg in milk. Both dimethoate carboxylic acid and omethoate were released from liver by protease digestion.

### Hens

Three groups of laying White Leghorn hens were administered [<sup>14</sup>C-methoxy]dimethoate by capsule once daily for 7 consecutive days at a dose rate equivalent to 10 ppm in the diet (approximately 0.9 mg/kg bw per day). Eggs were collected daily and separated into yolks and white for analysis. The birds were sacrificed approximately 23 hours after the final dose for tissue collection.

Mean cumulative radioactivity recovered in excreta (including cage wash) was 75%, in GI tract < 1% and in bile < 1%. Mean cumulative radioactivity recovered in eggs accounted for < 1% of the administered dose. Mean daily total residues in yolks ranged from 0.018 to 0.34 mg eq/kg, and in whites ranged from 0.090 to 0.180 mg eq/kg. A plateau in egg residues was not reached during dosing. Total residues in tissues were 0.62–0.69 mg eq/kg in liver, 0.079–0.10 mg eq/kg in muscle, 0.024–0.061 mg eq/kg in fat, and 0.042–0.066 mg eq/kg in skin.

Extractability of radioactivity from tissues and eggs with acetonitrile and water ranged from 8.9% in liver to 50% in egg white. Significant proportions were released by harsher treatments, with 10–44% of TRR released by protease digestion, 1–14% by weak base extraction, 2.4–18% by strong base reflux, and 1.2–27% by strong acid reflux.

Dimethoate was not detected in any of the tissues, egg, excreta or blood extracts, indicating rapid metabolism. Omethoate (3.1% TRR/0.004 mg eq/kg in egg white and 9.9% TRR/0.081 mg eq/kg in liver) and dimethoate carboxylic acid (3.9% TRR/0.005 mg eq/kg in egg white and 16% TRR/0.13 mg eq/kg in liver) were identified by HPLC. The largest fractions of these metabolites were released from liver and egg white by protease treatment.

The bulk of the residue in all matrices was characterized as phosphorylated natural products, at essentially 100% TRR/0.10 mg eq/kg in breast muscle, 92% TRR/0.072 mg eq/kg in thigh muscle, 70% TRR/0.027 mg eq/kg in skin, 62% TRR/0.51 mg eq/kg in liver, 94% TRR/0.18 mg eq/kg in egg yolk, 81% TRR/0.10 mg eq/kg in egg white, and 58% TRR/0.016 mg eq/kg in fat.

### ***Summary of animal metabolism***

The metabolic pathways in animal are qualitatively similar in rats, goats and hens.

The major metabolic reactions in animals are oxidation to give omethoate, and hydrolysis of the amide functional group giving dimethoate carboxylic acid, followed by further hydrolysis to anionic (thio)phosphate species, such as O,O-dimethyldithiophosphate, which can then be further oxidised to O,O-dimethylthiophosphate and O,O-dimethylphosphate. Formation of adducts of these anions with natural components, such as lipids and proteins was observed in goats and hens.

### ***Methods of analysis***

#### ***Plant matrices***

The Meeting received a number of validated methods for determination of dimethoate, omethoate, and other plant metabolites in plant matrices.

A method for determination of dimethoate and omethoate involved extraction with dichloromethane followed by cleanup by liquid-liquid partition and dSPE and column chromatography, with analysis by GC-FPD or LC-MS. The method was successfully validated for both dimethoate and omethoate with an LOQ of 0.01 mg/kg in orange (GC-FPD) and a range of plant matrices (LC-MS).

A second GC-FPD method involved extraction with acetonitrile (olive oil) or ethyl acetate (other matrices). Samples were cleaned up by gel permeation chromatography. The method was validated with an LOQ of 0.01 mg/kg for both dimethoate and omethoate in olives, olive oil, orange, lettuce and wheat grain.

QuEChERS-based methods involve extraction with acetonitrile or acetonitrile/water, with cleanup by liquid/liquid partition and dSPE, followed by LC-MS/MS analysis. QuEChERS methods were validated in an extensive range of plant matrices for analysis of dimethoate and omethoate with an LOQ of 0.001 mg/kg and an LOQ of 0.01 mg/kg for dimethoate carboxylic acid in olives, wheat green plants, grain and straw, and sugar beet roots and tops.

An LC-MS/MS method was developed and validated for determination of O-desmethyl omethoate carboxylic acid, O-desmethyl isodimethoate, desmethyl dimethoate, O-desmethyl omethoate, and O-desmethyl N-desmethyl omethoate in olives, wheat green plants, grain and straw, and sugar beet roots and tops. Samples were extracted with methanol/water and cleanup by column SPE before LC-MS/MS analysis. Good recoveries were achieved at 0.01 and 0.10 mg/kg for all analytes.

#### ***Animal matrices***

A QuEChERS-based method was reported for determination of dimethoate and omethoate in animal matrices. Samples were extracted with acetonitrile (with the addition of water for fat samples), cleaned up by liquid/liquid partition and dSPE, and analysed by LC-MS/MS. Good recoveries were achieved at the LOQ (0.001 mg/kg), 0.005 and 0.5 mg/kg for both dimethoate and omethoate in milk, eggs, and tissues.

### ***Stability of pesticide residues in stored analytical samples***

#### ***Plant matrices***

Residues of dimethoate and omethoate were shown to be stable for 27 months frozen storage in a range of plant matrices, including high starch (sorghum grain and potato), high oil (cottonseed), and high acid (orange) commodities.

The stability of additional metabolites was studied in wheat, olive and sugar beet matrices.

Dimethoate carboxylic acid was stable for at least 12 months in olives, wheat grain, straw and forage, and sugar beet roots and tops.

O-Desmethyl omethoate carboxylic acid was stable for up to 12 months in wheat straw, 3 months in olives, and wheat forage and grain, 1 month in sugar beet roots, and < 1 month in sugar beet tops.

O-Desmethyl isodimethoate was stable for up to 12 months in olives, and wheat grain and straw, 3 months in wheat forage, 4 months in sugar beet roots and 2 months in sugar beet tops.

O-Desmethyl omethoate was stable for up to 14 months in wheat grain, 3 months in olives, 2 weeks in wheat straw, 1 month in sugar beet roots, and < 1 month in sugar beet tops.

Desmethyl dimethoate was stable for up to 14 months in wheat grain, at least 6 months in wheat straw, 3 months in olives, 12 months in sugar beet roots, and 2 months in sugar beet tops.

O-Desmethyl N-desmethyl omethoate was stable for up to 8 weeks in olives, 6 weeks in wheat straw, 2 weeks in wheat forage, 1 month in wheat grain, and < 1 month in sugar beet roots or tops.

### *Animal matrices*

A stability study in tissues, milk and eggs showed that dimethoate was stable on frozen storage for up to 12 months in muscle, fat, milk, and egg, and 6 months in liver and kidney. Omethoate was stable for up to 12 months in milk and fat, 9 months in muscle, 2 months in eggs, and only 2 weeks in liver and 1 week in kidney. Samples in the feeding studies were analysed within the verified period of stability.

### *Residue Definition*

#### *Plant commodities*

Metabolism studies in olives, potatoes and wheat were submitted to the Meeting, along with a number of older studies with limited supporting information (mainly published papers) previously submitted to JMPR which included summarized metabolism data on lemons, sugar beet, maize, cotton, peas, potatoes and beans.

In the olive, wheat and potato studies, the major components of the residue in matrices treated directly with dimethoate at shorter sampling intervals (0–14 days) were: dimethoate (15–68% TRR, 0.20–8.4 mg/kg in potato foliage; 4.1–98% TRR, 0.07–29 mg/kg in wheat whole plants; 31–33% TRR, 1.9 mg/kg in olive flesh), omethoate (5.9–16% TRR, 0.12–0.73 mg eq/kg in potato foliage; 0.7–7.8% TRR, 0.13–0.42 mg eq/kg in wheat whole plants; 1.8–3.2% TRR, 0.11–0.16 mg eq/kg in olive flesh), O-desmethyl N-desmethyl omethoate (1.8–8.7% TRR, 0.11–0.24 mg eq/kg in potato foliage; 0.4–26% TRR, 0.12–0.71 mg eq/kg in wheat whole plants; 35–36% TRR, 0.18–2.1 mg eq/kg in olive flesh), and O-desmethyl isodimethoate (< 0.2–3.7% TRR, < 0.01–0.17 mg eq/kg in potato foliage; < 0.1–30% TRR, < 0.03–0.60 mg eq/kg in wheat whole plants; 1.5–3.2% TRR, 0.07–0.19 mg eq/kg in olive flesh).

In matrices to which residues are translocated, and at longer intervals after application, the metabolite pattern is different and dimethoate and omethoate are no longer present, or are only present at low levels. Total residues in these matrices are generally lower than in the foliage and fruit matrices closer to application. In olive flesh 28–43 days after 3 or 4 applications, the major residues were O-desmethyl N-desmethyl omethoate (53–60% TRR, 2.2–2.9 mg eq/kg) and O-desmethyl isodimethoate (4.0–6.9% TRR, 0.21–0.27 mg eq/kg). In wheat grain at 21–32 days after the second application, the major residues were O-desmethyl N-desmethyl omethoate (46–54% TRR, 1.2–2.0 mg eq/kg), O-desmethyl isodimethoate (6.8–11% TRR, 0.26–0.29 mg eq/kg), and O-desmethyl omethoate carboxylic acid (3.6–3.8% TRR, 0.09–0.15 mg eq/kg). In potato tubers at 0–28 days after the second application the major residues were O-desmethyl N-desmethyl omethoate (40–76% TRR, 0.09–0.23 mg eq/kg), O-desmethyl omethoate (< 0.1–28% TRR, < 0.01–0.07 mg eq/kg), and O-desmethyl omethoate carboxylic acid (6.1–18% TRR, 0.02–0.03 mg eq/kg).

Dimethoate was a significant residue component in bean forage, and omethoate was a significant component in lemons. In excised cotton leaves, dimethoate carboxylic acid was a major component.

In a number of residue trials in wheat, olives and sugar beet, dimethoate, omethoate, dimethoate carboxylic acid, O-desmethyl omethoate, O-desmethyl N-desmethyl omethoate, O-desmethyl omethoate carboxylic acid, O-desmethyl isodimethoate, and desmethyl dimethoate were analysed.

Table 2 Summary of residue components in field trials for olives, sugar beet and wheat

Component	Maximum residues (mg/kg)					
	Olives	Sugar beet roots	Sugar beet tops	Wheat grain	Wheat forage/hay	Wheat straw
Dimethoate	6.3	< 0.01	3.6	< 0.01	8.3	0.76
Omethoate	1.1	< 0.01	0.33	< 0.01	0.32	0.07
Dimethoate carboxylic acid	0.02	< 0.01	0.01	< 0.01	0.08	0.12
O-desmethyl isodimethoate	0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01
O-desmethyl omethoate carboxylic acid	0.35	< 0.01	< 0.01	< 0.01	< 0.01	0.05
Desmethyl dimethoate	0.33	0.03	0.60	< 0.01	0.22	0.21
O-desmethyl omethoate	0.13	< 0.01	0.18	< 0.01	0.02	0.08
O-desmethyl N-desmethyl omethoate	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01

No residues of any of the components were found above the LOQ in wheat grain, apart from a single detection of dimethoate at the LOQ in one of the 16 samples. In sugar beet roots, all components other than desmethyl dimethoate were below the LOQ, while low levels of desmethyl dimethoate (maximum 0.03 mg/kg) were found in 8 out of 48 samples. In olives, dimethoate and omethoate were the most significant residue components, with dimethoate reaching a maximum of 6.3 mg/kg and omethoate a maximum of 1.1 mg/kg, with O-desmethyl omethoate carboxylic acid, desmethyl dimethoate, and O-desmethyl omethoate reaching maximum levels of 0.35, 0.33 and 0.13 mg/kg.

Based on the metabolism studies and field trials, dimethoate and omethoate are good marker compounds particularly for shorter pre-harvest intervals, and in directly treated commodities such as leafy vegetables and fruits. In the olive residue studies, dimethoate and omethoate were by far the most significant residue components in olive fruit. For commodities to which dimethoate residues are translocated, such as grain, bulbs or tubers, total residues are generally low. Levels of dimethoate, omethoate, and six other metabolites were mostly undetectable in sugar beet roots and wheat grain in the field residue studies discussed above.

Residues of dimethoate or its metabolites are unlikely to occur in rotational crops based on the confined rotational crop metabolism study.

Therefore, in practice, the most suitable marker residues in plant commodities are considered to be dimethoate and omethoate. The Meeting noted that suitable validated methods were available for dimethoate and omethoate in an extensive range of plant commodities.

The Meeting further noted that in residue trials for some commodities, for example cherries and olives, omethoate was often present at higher levels than dimethoate, particularly around harvest. Therefore, inclusion of both dimethoate and omethoate in the definition for compliance with MRLs is warranted. The Meeting noted that omethoate is itself a pesticide and should therefore be measured separately from dimethoate.

The Meeting considered that a suitable residue definition for compliance with MRLs in plant commodities is *dimethoate and omethoate, measured and reported separately*.

The Meeting considered that dimethoate and omethoate were expected to have similar bioavailability to livestock, and determined that the *sum of dimethoate and omethoate* would be used to estimate median and highest residues in feed commodities for estimation of livestock dietary burden.

As a result of concerns relating to the genotoxicity of omethoate and other related metabolites, a conclusion was unable to be reached on a residue definition for dietary risk assessment.

### ***Animal commodities***

In goats, dimethoate carboxylic acid was identified at 0.019 mg eq/kg in milk and 0.031 mg eq/kg in liver, while omethoate was identified in liver at 0.12 mg eq/kg. The bulk of the radioactivity in goat milk and tissues was comprised of phosphorylated natural products. A similar pattern was observed in hens, with only dimethoate carboxylic acid (0.13 mg eq/kg in liver and 0.005 mg eq/kg in egg white) and omethoate (0.004 mg eq/kg in egg white and 0.081 mg eq/kg in liver) identified, and the major component of the residue incorporated into natural products.

In the lactating cattle feeding study, no residues of dimethoate were found above the LOQ in milk, muscle, liver, or kidney, while low levels of omethoate were detected in milk, kidney, and muscle for the highest dose group, in liver for the highest and second highest dose groups, while low levels of dimethoate were detected in fat at all doses, without any clear correlation between dose and residue level. Omethoate was detected in fat at higher dose levels.

In the laying hen feeding study, no residues of dimethoate or omethoate were detected in tissues or eggs at any dose level.

Dimethoate and omethoate, are considered to be the most suitable marker residues for enforcement in animal commodities. The Meeting noted that suitable validated methods were available for dimethoate and omethoate in milk, eggs and tissues.

The Meeting considered that a suitable residue definition for compliance with MRLs in animal commodities is *dimethoate and omethoate, measured and reported separately*.

The octanol-water partition coefficients of dimethoate and omethoate ( $\log_{10}K_{OW}$  values) are 0.75 and -0.74 respectively, indicating that neither compound is lipophilic. The Meeting further noted that residues of dimethoate and omethoate did not preferentially partition into cream rather than skim milk in the cattle feeding study. Residues of dimethoate and omethoate are not fat-soluble.

As for plant commodities, the Meeting was unable to reach a conclusion on a residue definition for dietary risk assessment in animal commodities.

### ***Results of supervised residue trials on crops***

The residue trial tables include values for the sum of dimethoate and omethoate for used livestock dietary burden calculation where applicable.

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):

Table 3 Convention adopted for summing of residues

Dimethoate (mg/kg)	Omethoate (mg/kg)	Sum of dimethoate and omethoate (mg/kg)
0.30	0.04	0.34
0.30	< 0.01	0.31
< 0.01	< 0.01	< 0.02

As a conclusion could not be reached on a residue definition for dietary risk assessment, the Meeting withdrew all previous recommendations for maximum residue limits for dimethoate and omethoate, including the spice MRLs.

### *Citrus fruit*

There are two GAPs for citrus fruit in Australia:

- 3 × 0.03 kg ai/100 L dilute foliar applications (14-day intervals), with a 7-day PHI OR
- A post-harvest dip or flood spraying application at a concentration of 0.04 kg ai/100 L (40 ppm), with no withholding period required. Use instructions in Australia preclude both the foliar application and the post-harvest application being made to the same fruit.

Residue trial data from Australia were conducted in accordance with the Australian post-harvest GAP.

Residues of dimethoate in mandarin (whole fruit) were (n = 4) 0.58, 0.70, 0.71, and 0.82 mg/kg.

Residues of omethoate in mandarin (whole fruit) were (n = 4) < 0.01 (4) mg/kg.

Residues of dimethoate in orange (whole fruit) were (n = 6) 0.51, 0.59, 0.60, 0.63, 0.66, and 0.67 mg/kg.

Residues of omethoate in orange (whole fruit) were (n = 6) 0.003 (3), 0.004 (2), and 0.005 mg/kg.

No residue data in accordance with the Australian foliar application GAP were available to the Meeting.

Residue trials for a foliar GAP in Brazil (dilute foliar applications at 0.04 kg ai/100 L with a 3-day PHI) are available. The Meeting noted that this GAP is in excess of the Australian foliar treatment GAP. Based on the residue levels in the Brazilian trials and in the Australian post-harvest trials, the Meeting considered that the post-harvest GAP in Australia was the critical GAP and that maximum residue levels based on the post-harvest GAP would cover residues arising from the alternative foliar Australian GAP.

The Meeting noted that the GAPs for post-harvest treatment of oranges and mandarins in Australia are the same and investigated combining the data sets for mutual support. The mandarin and orange data were likely to come from the same population (Mann-Whitney).

Combined mandarin and orange dataset for dimethoate: (n = 10) 0.51, 0.58, 0.59, 0.60, 0.63, 0.65, 0.67, 0.70, 0.71, and 0.82 mg/kg.

Combined mandarin and orange dataset for omethoate: (n = 10) 0.003 (3), 0.004 (2), 0.005, and < 0.01 (4) mg/kg.

The Meeting considered that mandarins and oranges were representative crops for the subgroups of mandarins and oranges respectively.

Based on the combined dataset, the Meeting estimated maximum residue levels of 2 mg/kg for dimethoate in the subgroup of mandarins and the subgroup of oranges.

The Meeting estimated maximum residue levels of 0.02 mg/kg for omethoate in the subgroup of mandarins and the subgroup of oranges.

### *Cherries*

The critical GAP for cherries is in the USA (a single application at 1.5 kg ai/ha with a 21-day PHI). No trials were available matching that GAP.

The GAP for cherries in the Czech Republic is a single application at 0.4 kg ai/ha with a 28-day PHI. Trials were conducted in northern Europe in accordance with this GAP.

Residues of dimethoate in cherries after treatment in accordance with the Czech GAP were (n = 4) < 0.01 (3), and 0.01 mg/kg.

Residues of omethoate in cherries were (n = 4) < 0.01, 0.04, 0.05, and 0.08 mg/kg.

The Meeting concluded that there was insufficient data matching GAP to estimate a maximum residue level for cherries.

### *Olives*

The critical GAP for olives is in Greece, with a single bait spray application applied to the trunk of 100 trees per hectare at a rate of 0.05 kg ai/ha followed after 10 days by  $2 \times 0.48$  kg ai/ha foliar applications at a 14-day retreatment interval, with a 28-day PHI.

There were no residue trials available to the Meeting involving both the bait spray and the foliar applications being made to the same trees.

Residue data were available from trials in southern France, Greece, Italy and Spain in accordance with the  $2 \times 0.48$  kg ai/ha foliar use pattern.

Residues of dimethoate in olives (whole fruit) were ( $n = 28$ )  $< 0.01$  (8), 0.02, 0.04 (2), 0.05, 0.06 (2), 0.07, 0.11 (2), 0.12, 0.22, 0.34, 0.41, 0.55, 0.63, 0.74, 0.76, 1.2, and 1.5 (2) mg/kg. .

Residues of omethoate were ( $n = 28$ )  $< 0.01$  (2), 0.03, 0.05, 0.07, 0.11, 0.15, 0.20, 0.21 (2), 0.22, 0.24, 0.26, 0.27 (2), 0.28 (2), 0.29 (2), 0.30, 0.34, 0.35 (2), 0.36, 0.50, 0.69, 0.78, and 0.88 mg/kg.

Two trials in accordance with the bait spray application use pattern were conducted in Greece. The latest sampling interval in these trials was 42 days after application. At 42 days, residues of dimethoate were  $< 0.01$  (2) mg/kg and residues of omethoate were  $< 0.01$  and 0.01 mg/kg.

Residues from the bait spray application are therefore expected to be much lower than those arising from the foliar application and therefore not expected to make a significant contribution to the residue in mature olives. The maximum residue level parameters estimated based on the foliar use pattern trials are therefore considered to accommodate residues from both the bait and foliar use patterns.

Based on the foliar application dataset, the Meeting estimated maximum residue levels of 3 mg/kg for dimethoate in table olives and olives for oil production.

The Meeting estimated maximum residue levels of 1.5 mg/kg for omethoate in table olives and olives for oil production.

### *Tropical fruit – inedible peel*

#### *Avocados*

The critical GAP for avocados in Australia is dilute foliar applications at 0.03 kg ai/100 L as required, with a 7-day PHI, followed by a post-harvest dipping application at 0.04 kg ai/100 L for 1 minute followed by packing the fruit after allowing to drain. A withholding period is not required for the post-harvest application.

Trials were conducted in avocados in Australia at GAP, with avocado orchards being treated with three dilute foliar spray applications at 0.03 kg ai/100 L at a 21- then a 7-day interval, fruit being harvested 7 days after the last application and then given a post harvest dip at 0.04 kg ai/100 L.

Residues of dimethoate in whole avocados were ( $n = 4$ ) 0.41, 0.44, 0.71, and 0.75 mg/kg.

Residues of omethoate in whole avocados were ( $n = 4$ ) 0.016, 0.025, 0.042, and 0.067 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for dimethoate in avocado.

The Meeting estimated a maximum residue level of 0.15 mg/kg for omethoate in avocado.

#### *Mangoes*

The critical GAP for mangoes in Australia is dilute foliar applications at 0.03 kg ai/100 L as required, with a 3-day PHI, followed by a post-harvest dipping application at 0.04 kg ai/100 L for 1 minute followed by packing the fruit after following draining. A withholding period is not required for the post-



harvest application.

Trials were conducted in mangoes in Australia at GAP, with mango orchards being treated with three dilute foliar spray applications at 0.03 kg ai/100 L at a 7-day interval, fruit being harvested 3 days after the last application and then given a post harvest dip at 0.04 kg ai/100 L.

Residues of dimethoate in whole mangoes were (n = 4) 0.17, 0.24, 0.34, and 0.43 mg/kg.

Residues of omethoate in whole mangoes were (n = 4) < 0.02, 0.03, 0.05, and 0.06 mg/kg.

The Meeting considered that there were insufficient data to estimate a maximum residue level for mangoes.

### *Onion, bulb*

The critical GAP for onions is in Australia, with applications at 0.3 kg ai/ha as required, with a 7-day PHI. However, no trials matching that GAP were available to the Meeting.

The GAPs for onions in the Czech Republic and Greece is a  $2 \times 0.24$  kg ai/ha applications, with a 14-day PHI.

Trials were conducted in France, Germany, Greece, Italy and the UK in accordance with the Czech and Greek GAPs.

Residues of dimethoate in onion bulbs were (n = 8) < 0.001 (7), and 0.005 mg/kg.

Residues of omethoate were (n = 8) < 0.001 (7), and 0.001 mg/kg.

The Meeting estimated maximum residue levels of 0.01 mg/kg for dimethoate and omethoate in onion (bulb).

### *Brassica vegetables*

#### *Subgroup of flowerhead brassicas*

There were no trials available to the Meeting matching the US GAPs for broccoli, or cauliflower ( $3 \times 0.56$  kg ai/ha applications, and a 7-day PHI).

The GAP in Estonia for broccoli, and cauliflower is  $2 \times 0.24$  kg ai/ha applications at a 7-day retreatment interval and with a 21-day PHI.

Trials in broccoli and cauliflower conducted in Denmark, France, Germany, and the UK in accordance with the Estonian GAP were available to the Meeting.

Residues of dimethoate in broccoli were (n = 4) < 0.01 (4) mg/kg.

Residues of omethoate in broccoli were (n = 4) < 0.01 (4) mg/kg.

Residues of dimethoate in cauliflower were (n = 9) < 0.01 (5), 0.01 (3), and 0.13 mg/kg.

Residues of omethoate in cauliflower were (n = 9) < 0.01 (9) mg/kg.

The Meeting noted that the GAPs were the same for broccoli and cauliflower and that the data were likely to come from the same population (Mann-Whitney). The Meeting agreed to combine the broccoli and cauliflower data sets for estimating a subgroup maximum residue level.

Residues of dimethoate in flowerhead brassicas: (n = 13) < 0.01 (9), 0.01 (3), and 0.13 mg/kg.

Residues of omethoate in flowerhead brassicas: (n = 13) < 0.01 (13) mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for dimethoate in the subgroup of flowerhead brassicas.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for omethoate in the subgroup of flowerhead brassicas.

*Subgroup of head brassicas*

The GAP in the Czech Republic for Brussels sprouts is  $2 \times 0.24$  kg ai/ha applications with a 21-day PHI.

Trials in Brussels sprouts conducted in Denmark, France, Germany, and the UK in accordance with the Estonian GAP were available to the Meeting.

Residue of dimethoate in Brussels sprouts were: (n = 9) < 0.01 (3), 0.01, 0.02 (3), and 0.03 (2) mg/kg.

Residues of omethoate in Brussels sprouts were: (n = 9) < 0.01 (8), and 0.01 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg for dimethoate in Brussels sprouts.

The Meeting estimated a maximum residue level of 0.015 mg/kg for omethoate in Brussels sprouts.

The GAP in Estonia for cabbage, head is  $2 \times 0.24$  kg ai/ha applications with a 10-day retreatment interval and a 14-day PHI.

Residue data from trials in northern Europe in accordance with the Estonian GAP was available to the Meeting.

Residues of dimethoate in cabbage, head (with wrapper leaves) were (n = 4) < 0.01 (4) mg/kg.

Residues of omethoate in cabbage, head (with wrapper leaves) were (n = 4) < 0.01 (4) mg/kg.

The Meeting considered that there were insufficient data to estimate a maximum residue level for cabbage, head.

*Melons*

There were no trials available to the Meeting matching the US GAP ( $2 \times 0.56$  kg ai/ha applications with a 3-day PHI), or the Australian GAP (applications at 0.3 kg ai/ha, or 0.03 kg ai/100 L with a 7-day PHI).

The GAP in Greece is 2 applications before flowering at 0.24 kg ai/ha, with a harvest PHI not required.

Residues trials conducted in Greece, Italy, and Spain were available to the Meeting, but the trials did not match GAP, as the applications were conducted too late in the season (last application between BBCH 71 and 82).

*Fruiting vegetables, other than Cucurbits**Peppers, sweet (capsicum)*

There were no trials available to the Meeting matching the US GAP ( $5 \times 0.37$  kg ai/ha applications with a 0-day PHI).

The GAP in Australia for peppers, sweet (capsicum) is dilute foliar application at 0.03 kg ai/100 L up to 0.3 kg ai/ha with a 3-day PHI.

Trials were conducted at GAP in Australia.

Residues of dimethoate were (n = 5) 0.04, 0.08, 0.14, 0.15, and 0.32 mg/kg.

Residues of omethoate were (n = 5) < 0.02, 0.02, < 0.04, 0.04, and 0.11 mg/kg.

The Meeting concluded that there was insufficient trial data to estimate a maximum residue level.

### *Tomato*

No trials were available matching the Brazilian or US GAPs.

The critical GAP for tomatoes in Australia is  $2 \times 0.3$  kg ai/ha applications at a 14-day retreatment interval and with a 21-day PHI.

Trials conducted in southern Europe involved  $2 \times 0.6$  kg ai/ha applications, with a 21-day harvest PHI and these matched the Australian GAP with the exception of the higher application rate. The Meeting considered that the proportionality principle could be applied.

Residues of dimethoate were ( $n = 8$ )  $< 0.01$  (8) mg/kg.

Residues of omethoate were ( $n = 8$ )  $< 0.01$  (6), and 0.01 (2) mg/kg.

Applying a scaling factor (0.5 $\times$ ) for the Australian GAP for tomatoes:

Residues of dimethoate:  $< 0.005$  (8) mg/kg

Residues of omethoate:  $< 0.005$  (6) and 0.005 (2) mg/kg

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for dimethoate in tomatoes.

The Meeting estimated a maximum residue level of 0.01 mg/kg for omethoate in tomatoes.

### *Eggplant*

The GAP for eggplant in Greece is  $2 \times 0.24$  kg ai/ha foliar applications with a 21-day PHI.

Two trials were conducted in Australia, however these did not match GAP as the PHI was too short. The Meeting considered there was insufficient data to estimate a maximum residue level for eggplant.

### *Leafy vegetables*

#### *Lettuce*

No trials were available matching the US GAP ( $3 \times 0.28$  kg ai/ha with a 14-day PHI).

The critical GAP for lettuce in the Czech Republic is  $2 \times 0.24$  kg ai/ha foliar applications with a 21-day PHI.

Trials were conducted in leaf lettuce varieties in Denmark, France, Poland, and the UK, in accordance with the Czech GAP.

Residues of dimethoate in lettuce, leaf were ( $n = 8$ )  $< 0.01$  (6), 0.01, and 0.09 mg/kg.

Residues of omethoate in lettuce, leaf were ( $n = 8$ )  $< 0.01$  (7), and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for dimethoate in lettuce, leaf.

The Meeting estimated a maximum residue level of 0.06 mg/kg for omethoate in lettuce, leaf.

#### Turnip greens

The GAP in the USA in turnips is  $7 \times 0.28$  kg ai/ha applications at 3-day intervals with a 14-day PHI.

Trials were conducted in turnips in the USA, however, these did not match the maximum GAP, as only three applications were made, at 7-day intervals.

### *Legume vegetables*

#### *Peas (succulent without pods)*

The GAP in the USA for peas without pods is 2 applications at  $0.20 + 0.36$  kg ai/ha (maximum individual rate of 0.36 kg ai/ha and maximum seasonal rate of 0.56 kg ai/ha), with a 0-day PHI.

A number of trials from the USA was available to the Meeting, however these did not match GAP.

#### *Peas (succulent with pods)*

The GAP for peas with pods is  $3 \times 0.18$  kg ai/ha with a 0-day PHI.

A number of trials from the USA was available to the Meeting, however these did not match GAP.

#### *Yard long bean*

The GAP in Thailand for yard long bean is  $4 \times 0.6$  kg ai/ha foliar applications with a 7-day PHI.

Trials were conducted in Thailand, with either 3 or  $4 \times 0.6$  kg ai/ha applications being made. There was no significant difference in residues at a 7-day PHI after either three or four applications at the label rate, and trials with both three and four applications are considered representative of the residues expected after treatment in accordance with the GAP.

Residues of dimethoate in yard long bean were ( $n = 6$ )  $< 0.05$  (5) and 0.05 mg/kg.

Residues of omethoate in yard long bean were ( $n = 6$ )  $< 0.05$  (6) mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg for dimethoate in yard long bean.

The Meeting estimated a maximum residue level of 0.05 mg/kg for omethoate in yard long bean.

#### *Pulses*

##### *Peas (dry)*

The US GAP for peas (dry) is 2 applications at  $0.20 + 0.36$  kg ai/ha (maximum individual rate of 0.36 kg ai/ha and maximum seasonal rate of 0.56 kg ai/ha), with a 0-day PHI.

Residue trials were conducted in the USA, however, only two independent trials were available. Further, only dimethoate residues were tested and the trials did not match GAP. The Meeting concluded that there was insufficient data to estimate a maximum residue level for peas (dry).

##### *Beans (dry)*

The critical GAP for beans (dry), including adzuki beans, cowpeas, mung beans, navy beans, Borlotti beans, and field beans in Australia is an unspecified number of applications at a rate of 0.32 kg ai/ha and 14-day intervals, with a PHI of 14 days for both grazing and harvest.

Residue data matching the Australian GAP for beans except soya beans ( $3 \times 0.32$  kg ai/ha applications at 14-day intervals) was available for mung beans and navy beans.

Residues of dimethoate in dry beans (mung and navy beans) were ( $n = 6$ )  $< 0.05$  (4), 0.066, and 0.40 mg/kg.

Residues of omethoate in dry beans (mung and navy beans) were ( $n = 6$ )  $< 0.05$  (5), and 0.064 mg/kg.

Residues for livestock dietary burden estimation (sum of dimethoate and omethoate) in dry beans were ( $n = 6$ )  $< 0.10$  (4), 0.17, and 0.46 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for dimethoate in the subgroup of dry beans.

The Meeting estimated a maximum residue level of 0.08 mg/kg for omethoate in the subgroup of dry beans.

The Meeting estimated a median residue of 0.10 mg/kg.

### *Soya bean (dry)*

The critical GAP for soya beans in Australia is an unspecified number of applications at a rate of 0.136 kg ai/ha and 14-day intervals, with a PHI of 14 days for both grazing and harvest.

Residues of dimethoate in soya bean, dry were < 0.05 (3) mg/kg.

Residues of omethoate in soya bean, dry were < 0.05 (3) mg/kg.

The Meeting considered that there were insufficient data to estimate a maximum residue level for soya bean.

### *Root and tuber vegetables*

#### *Carrot*

The critical GAP for carrots is in Estonia, with 3 × 0.24 kg ai/ha applications at a 7-day retreatment interval and with a 28-day PHI.

Two series of residue trials were conducted in Europe, one with 3 × 0.24 kg ai/ha foliar applications and the other with 4 × 0.24 kg ai/ha foliar applications. Decline data was available from a number of the trial sites, and a median half-life of 9.9 days for the sum of dimethoate and omethoate (residue definition for chronic risk assessment) was calculated from eight trials. Based on a re-treatment interval of 7 days and a PHI of 28 days, residues at harvest after four applications would be approximately 1.1× those expected after three applications. The Meeting therefore considered that the data from trials with four applications could be combined with the data from trials with three applications for the purpose of estimated a maximum residue level and dietary intake parameters for carrots.

Residues of dimethoate were (n = 16) < 0.001 (8), 0.001 (3), 0.002 (2), 0.004, 0.006, and 0.008 mg/kg.

Residues of omethoate were (n = 16) < 0.001 (4), 0.001, 0.0013 (2), 0.002, 0.003 (3), 0.004, 0.005, 0.006, 0.008, and 0.013 mg/kg.

Residues of dimethoate + omethoate for estimation of livestock dietary burden were (n = 16) < 0.002 (5), 0.002 (2), 0.003, 0.004, 0.005, 0.006 (2), 0.007, 0.012, 0.014, and 0.016 mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg for dimethoate in carrots.

The Meeting estimated a maximum residue level of 0.02 mg/kg for omethoate in carrots.

The Meeting estimated median and highest residues for livestock dietary burden calculation of 0.0035 and 0.016 mg/kg respectively.

The Meeting noted that the GAPs in Estonia for parsnip and parsley, turnip rooted were the same as those for carrot. The Meeting agreed to extrapolate the estimations for carrots to parsnips and parsley, turnip rooted.

#### *Sugar beet*

The critical GAPs for sugar beet are in the Czech Republic and Greece, 2 × 0.24 kg ai/ha applications with a 28-day PHI.

An extensive data set from northern and southern Europe, matching the Czech and Greek GAPs, was available to the Meeting.

Residues of dimethoate in sugar beet roots were (n = 17) < 0.001 (17) mg/kg.

Residues of omethoate in sugar beet roots were (n = 17) < 0.001 (17) mg/kg.

The Meeting estimated maximum residue levels of 0.001(\*) mg/kg for both dimethoate and omethoate in sugar beet.

### *Turnip*

The GAP in the USA in turnips is  $7 \times 0.28$  kg ai/ha applications at 3-day intervals with a 14-day PHI.

Trials were conducted in turnips in the USA, however, these did not match the maximum GAP, as only three applications were made, at 7-day intervals.

### *Asparagus*

Two Italian trials in asparagus were available to the Meeting, however they did not match any of the GAPs available.

### *Cereals*

#### *Barley*

The GAP for barley in Estonia is a single 0.20 kg ai/ha application up to BBCH 59 (end of heading, inflorescence fully emerged), with a PHI not required.

Trials were conducted in barley in Europe in accordance with the Estonian GAP.

Residues of dimethoate in barley were ( $n = 7$ )  $< 0.001$  (6) and 0.016 mg/kg.

Residues of omethoate in barley were ( $n = 7$ )  $< 0.001$  (6) and 0.003 mg/kg.

Residues for livestock dietary burden estimation (sum of dimethoate and omethoate) were ( $n = 7$ )  $< 0.002$  (6), and 0.019 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg for dimethoate in barley.

The Meeting estimated a maximum residue level of 0.01 mg/kg for omethoate in barley.

The Meeting estimated a median residue of 0.002 mg/kg.

The Meeting noted that the same GAP was authorized for oats in Estonia and considered that the residue potential was similar for barley and oats. The Meeting agreed that the estimations for barley could be extrapolated to oats, and estimated maximum residue levels of 0.03 and 0.01 mg/kg for dimethoate and omethoate respectively, together with a median residue of 0.002 mg/kg.

#### *Wheat*

The GAP for wheat in the Czech Republic and Estonia is a single 0.20 kg ai/ha application up to BBCH 69 (end of flowering), with a PHI not required.

Residue trials were conducted in wheat in Europe in accordance with the Czech and Estonian GAPs.

Residues of dimethoate in wheat were ( $n = 32$ )  $< 0.001$  (13), 0.002 (2), 0.005,  $< 0.01$  (15), and 0.01 mg/kg.

Residues of omethoate in wheat were ( $n = 32$ )  $< 0.001$  (15), 0.001, and  $< 0.01$  (16) mg/kg.

Residues for livestock dietary burden estimation (sum of dimethoate and omethoate) were ( $n = 32$ )  $< 0.002$  (12), 0.002, 0.003 (2), 0.006, 0.02 (15), and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.03 mg/kg for dimethoate in wheat.

The Meeting estimated a maximum residue level of 0.03 mg/kg for omethoate in wheat.

The Meeting estimated a median residue of 0.013 mg/kg.

The Meeting noted that the same GAP was authorized for rye and triticale in the Czech Republic and Estonia, considered that the residue potential was similar for wheat, rye and triticale and agreed that the estimations for wheat could be extrapolated to rye and triticale.

The Meeting estimated maximum residue levels of 0.03 mg/kg for dimethoate and omethoate in rye and triticale, together with median residues of 0.013 mg/kg.

### *Rape seed (canola)*

The Australian GAP for rape (canola) is a single application at 0.14 kg ai/ha with a PHI of 7 days for both harvest and grazing.

Trials were conducted in canola in Australia according to GAP.

Residues of dimethoate in rape seed were (n = 8) < 0.02, 0.02, 0.026, 0.027, 0.028, 0.051, 0.066, and 0.084 mg/kg.

Residues of omethoate in rape seed were (n = 8) < 0.02 (7) and 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.15 mg/kg for dimethoate in rape seed.

The Meeting estimated a maximum residue level of 0.03 mg/kg for omethoate in rape seed.

### *Animal feeds*

#### *Sugar beet tops*

Data for sugar beet tops from trials in accordance with the Czech and Greek GAPs was available to the Meeting.

Residues for estimation of livestock dietary burden in sugar beet tops were: (n = 17) < 0.02 (12), 0.03, 0.04 (2), and 0.06 (2) mg/kg (as received basis) or < 0.13 (12), 0.20, 0.27 (2), and 0.40 (2) mg/kg (dry weight basis, converted using the default dry matter content of 15% from the OECD livestock feed tables).

The Meeting estimated a median and a highest residue of 0.13 and 0.40 mg/kg respectively (dry weight basis).

#### *Barley straw and fodder*

Residue data for barley hay and straw was available from the European trials.

Residues of dimethoate in barley hay were (n = 4) < 0.012, < 0.014 (2), and 0.14 mg/kg (dry weight basis).

Residues of omethoate in barley hay were (n = 4) < 0.012, < 0.014 (2), and 0.05 mg/kg (dry weight basis).

Residues in accordance with GAP for livestock dietary burden calculation were (n = 4) < 0.024, < 0.028 (2), and 0.19 mg/kg (dry weight basis).

Residues of dimethoate in barley straw were (n = 7) < 0.01 (6), and 0.05 mg/kg (as received basis).

Residues of omethoate in barley straw were (n = 7) < 0.01 (7) mg/kg.

Residues in accordance with GAP for livestock dietary burden calculation were (n = 7) < 0.02 (6), and 0.06 mg/kg (as received basis) or < 0.022 (6) and 0.067 mg/kg (adjusted for dry weight using the default dry matter content of 89% from the OECD livestock feed tables).

Based on the hay data, the Meeting estimated a maximum residue level of 0.3 mg/kg (dw) for dimethoate in barley straw and fodder, dry.

The Meeting estimated at maximum residue level of 0.1 mg/kg (dw) for omethoate in barley straw and fodder, dry (based on the hay data).

The Meeting estimated a median and a highest residue of 0.028 and 0.19 mg/kg respectively for dietary burden calculations (dry weight basis) for barley hay.

The Meeting estimated a median and a highest residue of 0.022 and 0.067 mg/kg respectively for dietary burden calculations (dry weight basis) for barley straw.

The Meeting noted that the same GAP was authorized for oats in Estonia and considered that the residue potential was similar for barley and oats. The Meeting agreed that the estimations for barley straw and fodder could be extrapolated to oats, and estimated the following values:

- Maximum residue level for dimethoate in oat straw and fodder, dry: 0.3 mg/kg;
- Maximum residue level for omethoate in oat straw and fodder, dry: 0.1 mg/kg;
- Median and highest residue of 0.028 and 0.19 mg/kg respectively for oat hay;
- Median and highest residue of 0.022 and 0.067 mg/kg respectively for oat straw.

#### *Wheat straw and fodder*

Residue data for wheat hay and straw was available from the European trials.

Residues of dimethoate in wheat hay were (n = 8) < 0.012 (2), < 0.013, 0.023, 0.033, 0.21, 0.37, and 1.4 mg/kg (dry weight basis).

Residues of omethoate in wheat hay were (n = 8) < 0.011, < 0.012 (3), < 0.013, 0.022, 0.033, and 0.077 mg/kg (dry weight basis).

Residues for livestock dietary burden calculation were (n = 8) < 0.024 (2), < 0.026, 0.034, 0.055, 0.22, 0.40, and 1.5 mg/kg (dry weight basis)

Residues of dimethoate in wheat straw were (n = 32) < 0.01 (17), 0.01 (3), 0.02 (3), 0.04, 0.05 (3), 0.08, 0.19, 0.65, 0.68, and 0.83 mg/kg (as received basis).

Residues of omethoate in wheat straw were (n = 32) < 0.01 (27), 0.01, 0.02, 0.05, 0.06, and 0.074 mg/kg (as received basis).

Residues for livestock dietary burden calculation were (n = 32) < 0.02 (17), 0.02 (3), 0.03 (3), 0.05, 0.06 (3), 0.09, 0.24, 0.70, 0.71, and 0.90 mg/kg (as received basis) or < 0.023 (17), 0.023 (3), 0.034 (3), 0.057, 0.068 (3), 0.10, 0.27, 0.80, 0.81, and 1.0 mg/kg (adjusted for dry weight using the default dry matter content of 88% from the OECD livestock feed tables).

Based on the hay data, the Meeting estimated maximum residue levels of 3 and 0.15 mg/kg for dimethoate and omethoate respectively in wheat straw and fodder, dry.

The Meeting estimated a median and a highest residue of 0.0455 and 1.5 mg/kg (dry weight basis) for wheat hay.

The Meeting estimated a median and a highest residue of 0.023 and 1.0 mg/kg for wheat straw (dry weight basis).

The Meeting noted that the same GAP was authorized for rye and triticale in the Czech Republic and Estonia, considered that the residue potential was similar for wheat, rye and triticale, and agreed that the estimations for wheat straw and fodder could be extrapolated to rye and triticale.

The Meeting estimated maximum residue levels of 3 mg/kg for dimethoate in rye straw and fodder, dry and triticale straw and fodder, dry.

The Meeting estimated maximum residue levels of 0.15 mg/kg for omethoate in rye straw and fodder, dry and triticale straw and fodder, dry.



The Meeting estimated a median and a highest residue of 0.0455 and 1.5 mg/kg (dry weight basis) for triticale hay.

The Meeting estimated a median and a highest residue of 0.023 and 1.0 mg/kg for rye straw and triticale straw.

### *Bean forage*

Residue data in soya bean, mung bean, and navy bean forage was available from the Australian trials.

The GAP for beans except soya beans is an unspecified number of applications at a rate of 0.32 kg ai/ha and 14-day intervals, with a grazing interval of 14 days.

The GAP for soya beans is an unspecified number of applications at a rate of 0.136 kg ai/ha and 14-day intervals, with a PHI of 14 days for both grazing and harvest.

The data for forage did not match GAP, as samples were only collected at intervals of 0 and 7 days after application.

The Meeting therefore did not estimate median or highest residues for bean forage.

### ***Fate of residues during processing***

#### *High temperature hydrolysis*

Under conditions simulating pasteurization (90 °C/pH 4/20 minutes), no significant hydrolysis of dimethoate or omethoate occurred (> 90% of AR remained as parent). Under conditions simulating baking/boiling/brewing (100 °C/pH 5/60 minutes) and sterilization (120 °C/pH 6/20 minutes), significant hydrolysis, mainly of the O-methyl groups took place, with 28%/36% of AR as the O-desmethyl metabolite for dimethoate/omethoate after baking/boiling/brewing, and 60%/63% after sterilization). No conversion from dimethoate to omethoate was observed under any of the conditions.

Processing data for oranges, olives, cabbage and wheat were available to the Meeting. Estimated processing factors are summarized in the tables below.

The Meeting noted that separate residue definitions have been established for enforcement for dimethoate and omethoate, and therefore, determination of the levels of these components in processed commodities is required in order to estimate maximum residue levels for processed commodities. The Meeting noted that that no conversion of dimethoate to omethoate was observed during the high temperature hydrolysis study. The Meeting further noted that, in the processing studies available to the Meeting, both dimethoate and omethoate were present in the raw agricultural commodities and omethoate generally transferred into processed commodities to a lesser extent than dimethoate, further indicating that conversion of dimethoate to omethoate during processing is not significant in the processed commodities considered by the present Meeting. Therefore, separate processing factors for dimethoate and omethoate have been calculated for each processed commodity, with the levels of dimethoate and omethoate (and the summed levels for dietary risk assessment) then being calculated for the processed commodities individually from each supervised residue trial. This in turn allows the estimation of processed commodity maximum residue levels for dimethoate and omethoate where required, and STMR and HR values.

### *Oranges*

Table 4 Processing factors for oranges

Processed commodity	Dimethoate	Omethoate
Juice	0.14	0.20
Dry pulp	2.1	1.6
Molasses	5.8	5.9
Orange oil	0.20	< 0.07

Table 5 Calculation of residues of dimethoate and omethoate in orange juice

Raw orange dimethoate residue (mg/kg)	PF	Orange juice dimethoate residue (mg/kg)	Raw orange omethoate residue (mg/kg)	PF	Orange juice omethoate residue (mg/kg)
0.66	0.14	0.092	0.004	0.20	0.0008
0.59		0.083	0.003		0.0006
0.67		0.094	0.005		0.001
0.60		0.084	0.004		0.0008
0.51		0.071	0.003		0.0006
0.63		0.088	0.003		0.0006

Table 6 Calculation of residues of dimethoate and omethoate in orange dried pulp

Raw orange dimethoate residue (mg/kg)	PF	Orange dried pulp dimethoate residue (mg/kg)	Raw orange omethoate residue (mg/kg)	PF	Orange dried pulp omethoate residue (mg/kg)	DM + OM (mg/kg)
0.66	2.1	1.39	0.004	1.6	0.0064	1.39
0.59		1.24	0.003		0.0048	1.24
0.67		1.41	0.005		0.008	1.42
0.60		1.26	0.004		0.0064	1.27
0.51		1.07	0.003		0.0048	1.08
0.63		1.32	0.003		0.0048	1.33
					Median:	1.30

The Meeting estimated a maximum residue level of 4 mg/kg for dimethoate in citrus pulp, dry.

The Meeting estimated a maximum residue level of 0.02 mg/kg for omethoate in citrus pulp, dry.

The Meeting estimated a median residue of 1.3 mg/kg for citrus pulp, dry for livestock dietary burden calculation.

Table 7 Calculation of residues of dimethoate and omethoate in orange oil

Raw orange dimethoate residue (mg/kg)	PF	Orange oil dimethoate residue (mg/kg)	Raw orange omethoate residue (mg/kg)	PF	Orange oil omethoate residue (mg/kg)
0.66	0.20	0.13	0.004	0.07	0.00028
0.59		0.12	0.003		0.00021
0.67		0.13	0.005		0.00035
0.60		0.12	0.004		0.00028
0.51		0.10	0.003		0.00021
0.63		0.13	0.003		0.00021

## Olives

Table 8 Processing factors for olives

Processed commodity	Dimethoate		Omethoate	
	Processing factors	Best estimate PF	Processing factors	Best estimate PF
Crude (hot pressed) oil	0.25, 0.25, 0.32, 0.33, 0.42, 0.44, 1.5	0.33	0, 0, 0, 0, < 0.01, < 0.02, < 0.04, < 0.05	0.005
Virgin (cold pressed) oil	0.5, 1.5	1.0	< 0.02, < 0.02	0.02
Refined oil	0.007, < 0.03, < 0.05, 0.12, 0.25, 0.26, 0.29, < 0.50	0.185	0, 0, 0, 0, < 0.01, 0.02, < 0.02, < 0.04, < 0.05	0.01
Canned olives in brine (sterilized)	0.03, 0.05, 0.065, 0.07, 0.08, 0.08, 0.11, 0.12, 0.31	0.08	0, 0, 0.007, 0.02, 0.02, 0.02, 0.03, < 0.04, 0.04, 0.19	0.02
Canned olives in brine (not sterilized)	0.12, 0.24, 0.28, 0.28, 0.31, 0.37, 0.74, 0.92, 1.0, 1.1, 1.3	0.37	< 0.02, 0.02, < 0.05, 0.05, 0.07, 0.08, 0.14, 0.15, 0.73, 0.84, 0.89, 1.1	0.11

Table 9 Calculation of residues of dimethoate and omethoate in canned (table) olives

Raw olive dimethoate residue (mg/kg) <sup>a</sup>	PF	Canned (table) olives dimethoate residue (mg/kg)	Raw olive omethoate residue (mg/kg) <sup>a</sup>	PF	Canned (table) olives omethoate residue (mg/kg)
1.2	0.37	0.44	0.35	0.11	0.039
0.41		0.15	0.35		0.039
0.01		0.0037	0.01		0.0011
0.63		0.23	0.2		0.022
0.55		0.20	0.24		0.026
0.11		0.041	0.29		0.032
0.11		0.041	0.3		0.033
0.06		0.022	0.69		0.076
0.07		0.026	0.28		0.031
0.02		0.0074	0.15		0.017
0.01		0.0037	0.29		0.032
0.01		0.0037	0.21		0.023
0.06		0.022	0.22		0.024
0.12		0.044	0.07		0.0077
0.22		0.081	0.28		0.031
0.74		0.27	0.78		0.086
0.34		0.13	0.5		0.055
0.76		0.28	0.26		0.029
1.5		0.56	0.36		0.040
1.5		0.56	0.88		0.097
0.01		0.0037	0.11		0.012
0.01		0.0037	0.01		0.0011
0.04		0.015	0.27		0.030
0.01		0.0037	0.05		0.0055
0.05		0.019	0.34		0.037
0.01		0.0037	0.03		0.0033
0.01		0.0037	0.21		0.023
0.04		0.015	0.27		0.030

<sup>a</sup> Residues below the LOQ in the RAC are shown at the LOQ for calculation purposes.

Table 10 Calculation of residues of dimethoate and omethoate in olive oil, virgin

Raw olive dimethoate residue (mg/kg) <sup>a</sup>	PF	Olive oil dimethoate residue (mg/kg)	Raw olive omethoate residue (mg/kg) <sup>a</sup>	PF	Olive oil omethoate residue (mg/kg)
1.2	1.0	1.2	0.35	0.02	0.00077
0.41		0.41	0.35		0.00077
0.01		0.01	0.01		0.00022
0.63		0.63	0.2		0.00044
0.55		0.55	0.24		0.00053
0.11		0.11	0.29		0.00064
0.11		0.11	0.3		0.00066
0.06		0.06	0.69		0.0015
0.07		0.07	0.28		0.00062
0.02		0.02	0.15		0.00033
< 0.01		< 0.01	0.29		0.00064
0.01		0.01	0.21		0.00046
0.06		0.06	0.22		0.00048
0.12		0.12	0.07		0.00015
0.22		0.22	0.28		0.00062
0.74		0.74	0.78		0.0017
0.34		0.34	0.5		0.0011
0.76		0.76	0.26		0.00057
1.5		1.5	0.36		0.00079
1.5		1.5	0.88		0.0019
0.01		0.01	0.11		0.00024
0.01		0.01	0.01		0.00022

Raw olive dimethoate residue (mg/kg) <sup>a</sup>	PF	Olive oil dimethoate residue (mg/kg)	Raw olive omethoate residue (mg/kg) <sup>a</sup>	PF	Olive oil omethoate residue (mg/kg)
0.04		0.04	0.27		0.00059
0.01		0.01	0.05		0.00011
0.05		0.05	0.34		0.00075
0.01		0.01	0.03		0.000066
0.01		0.01	0.21		0.00046
0.04		0.04	0.27		0.00059

<sup>a</sup> Residues below the LOQ in the RAC are shown at the LOQ for calculation purposes.

he Meeting estimated a maximum residue level of 3 mg/kg for dimethoate in olive oil, virgin.

The Meeting estimated a maximum residue level of 0.01(\*) mg/kg for omethoate in olive oil, virgin.

Table 11 Calculation of residues of dimethoate and omethoate in olive oil, refined

Raw olive dimethoate residue (mg/kg) <sup>a</sup>	PF	Olive oil dimethoate residue (mg/kg)	Raw olive omethoate residue (mg/kg) <sup>a</sup>	PF	Olive oil omethoate residue (mg/kg)
1.2	0.185	0.22	0.35	0.01	0.0035
0.41		0.076	0.35		0.0035
0.01		0.002	0.01		0.0001
0.63		0.12	0.2		0.002
0.55		0.10	0.24		0.0024
0.11		0.020	0.29		0.0029
0.11		0.020	0.3		0.003
0.06		0.011	0.69		0.0069
0.07		0.013	0.28		0.0028
0.02		0.004	0.15		0.0015
< 0.01		0.002	0.29		0.0029
0.01		0.002	0.21		0.0021
0.06		0.011	0.22		0.0022
0.12		0.022	0.07		0.0007
0.22		0.041	0.28		0.0028
0.74		0.14	0.78		0.0078
0.34		0.063	0.5		0.005
0.76		0.14	0.26		0.0026
1.5		0.28	0.36		0.0036
1.5		0.28	0.88		0.0088
0.01		0.002	0.11		0.0011
0.01		0.002	0.01		0.0001
0.04		0.007	0.27		0.0027
0.01		0.002	0.05		0.0005
0.05		0.009	0.34		0.0034
0.01		0.002	0.03		0.0003
0.01		0.002	0.21		0.0021
0.04		0.007	0.27		0.0027

<sup>a</sup> Residues below the LOQ in the RAC are shown at the LOQ for calculation purposes.

## Wheat

Table 12 Processing factors for wheat

Processed commodity	Dimethoate		Omethoate	
	Processing factors	Best estimate PF	Processing factors	Best estimate PF
Wholemeal flour	0.22, 0.62, 0.70, 3.2	0.66	< 0.3, < 0.5, 1.0	0.5
White flour	0.06, 0.10, 0.31, 0.80	0.21	< 0.3, < 0.5, < 0.5	0.5
Bran	1.4, 4.0, 4.8, 15	4.4	1.3, 3.5, 5.0	3.5
Wheat germ	0.83, 2.8, 3.0, 9.6	2.9	0.67, 2.0, 4.0	2.0
Wholemeal bread	0.72, 1.8, 1.9, 5.4	1.85	0.33, 1.5, 2.5	1.5

Table 13 Calculation of residues of dimethoate and omethoate in wheat bran

Raw wheat dimethoate residue (mg/kg)^	PF	Wheat bran dimethoate residue (mg/kg)	Raw wheat omethoate residue (mg/kg)^	PF	Wheat bran omethoate residue (mg/kg)	DM + OM (mg/kg)
< 0.001	4.4	< 0.0044	< 0.001	3.5	< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
0.002		0.0088	< 0.001		< 0.0035	0.0123
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
0.002		0.0088	< 0.001		< 0.0035	0.0123
< 0.001		< 0.0044	< 0.001		< 0.0035	< 0.0079
0.005		0.022	< 0.001		< 0.0035	0.0255
< 0.001		< 0.0044	0.001		0.0035	0.0079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
< 0.01		< 0.044	< 0.01		< 0.035	< 0.079
0.01		0.044	< 0.01		< 0.035	< 0.079
					Median	0.05225

Table 14 Calculation of residues of dimethoate and omethoate in wheat germ

Raw wheat dimethoate residue (mg/kg)^	PF	Wheat germ dimethoate residue (mg/kg)	Raw wheat omethoate residue (mg/kg)^	PF	Wheat germ omethoate residue (mg/kg)
< 0.001	2.9	< 0.0029	< 0.001	2.0	< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
0.002		0.0058	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
0.002		0.0058	< 0.001		< 0.002
< 0.001		< 0.0029	< 0.001		< 0.002
0.005		0.0145	< 0.001		< 0.002
< 0.001		< 0.0029	0.001		0.002
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02

Raw wheat dimethoate residue (mg/kg)^	PF	Wheat germ dimethoate residue (mg/kg)	Raw wheat omethoate residue (mg/kg)^	PF	Wheat germ omethoate residue (mg/kg)
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
< 0.01		< 0.029	< 0.01		< 0.02
0.01		0.029	< 0.01		< 0.02

Table 15 Calculation of residues of dimethoate and omethoate in wheat wholemeal bread

Raw wheat dimethoate residue (mg/kg)^	PF	Wholemeal bread dimethoate residue (mg/kg)	Raw wheat omethoate residue (mg/kg)^	PF	Wholemeal bread omethoate residue (mg/kg)
< 0.001	1.85	< 0.00185	< 0.001	1.5	< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
0.002		0.0037	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
0.002		0.0037	< 0.001		< 0.0015
< 0.001		< 0.00185	< 0.001		< 0.0015
0.005		0.00925	< 0.001		< 0.0015
< 0.001		< 0.00185	0.001		0.0015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
< 0.01		< 0.0185	< 0.01		< 0.015
0.01		0.0185	< 0.01		< 0.015

Table 16 Calculation of residues of dimethoate and omethoate in wholemeal flour

Raw wheat dimethoate residue (mg/kg)^	PF	Wholemeal flour dimethoate residue (mg/kg)	Raw wheat omethoate residue (mg/kg)^	PF	Wholemeal flour omethoate residue (mg/kg)
< 0.001	0.66	< 0.00066	< 0.001	0.5	< 0.0005
< 0.001		< 0.00066	< 0.001		< 0.0005
< 0.001		< 0.00066	< 0.001		< 0.0005
< 0.001		< 0.00066	< 0.001		< 0.0005



Raw wheat dimethoate residue (mg/kg)^	PF	White flour dimethoate residue (mg/kg)	Raw wheat omethoate residue (mg/kg)^	PF	White flour omethoate residue (mg/kg)
< 0.01		< 0.0021	< 0.01		< 0.005
< 0.01		< 0.0021	< 0.01		< 0.005
< 0.01		< 0.0021	< 0.01		< 0.005
< 0.01		< 0.0021	< 0.01		< 0.005
< 0.01		< 0.0021	< 0.01		< 0.005
0.01		0.0021	< 0.01		< 0.005

The Meeting estimated a maximum residue level of 0.1 mg/kg for dimethoate in wheat bran.

The Meeting estimated a maximum residue level of 0.09 mg/kg for omethoate in wheat bran.

The Meeting estimated a median residue of 0.05225 mg/kg for wheat bran for livestock dietary burden calculations.

The Meeting estimated a maximum residue level of 0.07 mg/kg for dimethoate in wheat germ.

The Meeting estimated a maximum residue level of 0.05 mg/kg for omethoate in wheat germ.

The Meeting estimated a maximum residue level of 0.05 mg/kg for dimethoate in bread and other cooked cereal products.

The Meeting estimated a maximum residue level of 0.04 mg/kg for omethoate in bread and other cooked cereal products.

### ***Farm animal dietary burden***

Farm animal feeding studies in lactating cattle and laying hens were provided to the Meeting.

#### ***Lactating cattle***

Lactating Holstein dairy cattle were dosed daily with dimethoate for 28 days at 1, 3.4, 10.1 or 33.2 ppm. Composite morning and afternoon milk samples were collected daily, along with skim milk and cream on days 13 and 28. The animals not required for the depuration phase were slaughtered on day 28 (7.5–12 hours after the final dose) and samples of round, flank and loin muscle, liver, kidney, and omental, subcutaneous and perirenal fat were collected. Three highest dose group animals were retained for the depuration phase, with one sacrificed on each of days 31, 35, and 42 (3, 7 and 14 days depuration respectively).

No residues of dimethoate were found in milk (either control or any of the treated samples) at levels above the LOQ. Low levels of omethoate (maximum 0.019 mg/kg) were found, only for some milk samples from the highest dose group. Omethoate residues in skim milk and cream were very similar, indicating no significant preferential partitioning. In muscle, again, no residues of dimethoate were found above the LOQ, while some low level residues of omethoate (up to 0.0051 mg/kg) were found only for the highest dose group. In liver, no residues were found above the LOQ for dimethoate, with low level detections of omethoate in the 10.1 and 33.2 ppm groups. For kidney, there was a single low level detection of omethoate for the highest dose group, and no detections of dimethoate. For fat, there were some low level residues of both dimethoate and omethoate, without a clear relationship between dose and residue level. The depuration data showed that clearance was rapid, with no detections above the LOQ.

#### ***Laying hens***

Laying white Leghorn hens were dosed daily with dimethoate for 28 days at 0.15, 0.40, 1.2 or 4.0 ppm. Composite morning and afternoon egg samples were collected daily. The birds not required for the depuration phase were slaughtered on day 28 (approximately 24 hours after the final dose) and samples of thigh and breast muscle, liver, and subcutaneous and abdominal fat were collected. Ten of the highest dose group birds were retained for the depuration phase, with three or four birds sacrificed on each of



days 31, 35 and 42 (3, 7 and 14 days depuration respectively).

No residues of dimethoate or omethoate were found above the LOQ in any of the egg or tissue samples.

### *Livestock dietary burden*

Dietary burden calculations for cattle and poultry are provided below. The dietary burdens were estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual<sup>10</sup>.

Table 18 Summary of livestock dietary burden (ppm dimethoate)

	USA-Canada		EU		Australia		Japan	
	Max	Mean	Max	Mean	Max	Mean	Max	Mean
Beef cattle	0.39	0.18	0.51	0.15	1.5 <sup>a</sup>	0.50 <sup>b</sup>	0.038	0.038
Dairy cattle	0.50	0.18	0.74	0.36	1.5 <sup>c</sup>	0.48 <sup>d</sup>	0.03	0.030
Broiler hens	0.037	0.037	0.055	0.045	0.093	0.093	0.003	0.003
Laying hens	0.037	0.037	0.22 <sup>e</sup>	0.054	0.093	0.093 <sup>f</sup>	0.018	0.018

<sup>a</sup> Highest maximum dietary burden for beef cattle suitable for estimation of MRLs for mammalian meat and offal.

<sup>b</sup> Highest mean dietary burden for beef cattle suitable for estimation of STMRs for mammalian meat and offal.

<sup>c</sup> Highest maximum dietary burden for dairy cattle suitable for estimation of MRLs for milk.

<sup>d</sup> Highest mean dietary burden for dairy cattle suitable for estimation of STMRs for milk.

<sup>e</sup> Highest maximum dietary burden for broiler and layer poultry suitable for estimation of MRLs for poultry meat, offal and eggs.

<sup>f</sup> Highest mean dietary burden for broiler and layer poultry suitable for estimation of STMRs for poultry meat, offal and eggs.

### *Animal commodity maximum residue levels*

#### *Mammals*

The maximum dietary burden for dairy cattle was 1.5 ppm, while the highest mean burden was 0.48 ppm.

In a lactating cow feeding study, when cattle were dosed with dimethoate daily for 28 days at levels up to 33 ppm, no residues of dimethoate were found above the LOQ (0.001 mg/kg) in milk. Low levels of omethoate residue were found above the LOQ (at 0.019 mg/kg maximum) only in animals from the 33 ppm feeding group.

The Meeting therefore estimated maximum residue levels of 0.001(\*) mg/kg for both dimethoate and omethoate in milk.

The maximum dietary burden for beef cattle was 1.5 ppm, while the highest mean burden was 0.50 ppm.

In liver and kidney, residues were below the LOQ (0.001 mg/kg) in all samples from feeding levels bracketing the maximum dietary burden (1 and 3.4 ppm). Some low level residues of omethoate were found at the 10 and 33 ppm feeding levels in liver and kidney.

The Meeting therefore estimated maximum residue levels of 0.001(\*) mg/kg for both dimethoate and omethoate in mammalian edible offal.

In muscle, residues were below the LOQ (0.001 mg/kg) in all samples from the 3.4 ppm feeding level, with low level detections of omethoate in the 33 ppm feeding level samples.

The Meeting therefore estimated maximum residue levels of 0.001(\*) mg/kg for both dimethoate and omethoate in mammalian meat.

<sup>10</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

In fat, no residues of omethoate were found above the LOQ (0.001 mg/kg) in feeding levels bracketing the maximum dietary burden (1 and 3.4 ppm dose groups), with some detections for highest dose groups. Residues of dimethoate were observed in subcutaneous, perirenal and omental fat, with levels highest in perirenal fat. In the 1 ppm feeding group, the highest residue was 0.0268 mg/kg, with the mean at 0.011 mg/kg. For the 3.4 ppm feeding group, the highest residue was 0.0014 mg/kg, while the mean was < 0.001 mg/kg.

As a conservative estimate, the residue levels from the 1 ppm dose group were used to estimate maximum residue levels for fat.

Scaling for the maximum dietary burden of 1.5 ppm, the estimated maximum dimethoate residue in fat is  $1.5 \times 0.0247 \text{ mg/kg} = 0.037 \text{ mg/kg}$ . The Meeting estimated a maximum residue level of 0.04 mg/kg for dimethoate in mammalian fats.

As the residues of omethoate in all fat samples were below the LOQ (0.001 mg/kg) for the 1 and 3.4 ppm feeding levels, the Meeting estimated a maximum residue level of 0.001(\*) mg/kg for omethoate in mammalian fats.

### **Poultry**

The maximum dietary burden for poultry for both meat and egg production was 0.22 ppm, while the highest mean dietary burden was 0.093 ppm.

In a poultry feeding study, when hens were fed dimethoate daily for 28 days at up to 4.0 ppm, no residues of dimethoate or omethoate were found above the LOQ (0.001 mg/kg) in any of the egg or tissue samples.

The Meeting therefore estimated maximum residue levels of 0.001(\*) mg/kg for both dimethoate and omethoate in poultry meat, poultry fats, poultry, edible offal of, and eggs

## **RECOMMENDATIONS**

The residue definition for compliance with the MRL in plant and animal commodities is: *dimethoate and omethoate (measured and reported separately)*.

The Meeting was unable to recommend a residue definition for dietary risk assessment.

The residue is not fat-soluble.

## **DIETARY RISK ASSESSMENT**

The WHO panel recommended an ADI of 0–0.001 mg/kg bw/day and an ARfD of 0.02 mg/kg bw for dimethoate.

The WHO panel was unable to recommend an ADI or an ARfD for omethoate, due to concerns regarding its genotoxicity.

As a result of concerns relating to the genotoxicity of omethoate and other related metabolites, a conclusion was unable to be reached on a residue definition for dietary risk assessment. Long-term and acute dietary risk assessments could not be conducted.

## 5.11 Fluazifop-P-butyl (283)

### RESIDUE AND ANALYTICAL ASPECTS

Fluazifop-P-butyl is a herbicide used for the post-emergence control of grasses in a wide range of broad-leaved crops. Fluazifop-P-butyl was first evaluated for toxicology and residues by the 2016 JMPR. An ADI of 0–0.004 mg/kg bw and an ARfD of 0.4 mg/kg bw were established. The residue definitions were established as follows:

Residue definition for compliance with the MRL in plant commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.

Residue definition for dietary risk assessment in plant commodities: the sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL), 5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid.

Residue definition for compliance with the MRL and for dietary risk assessment in animal commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid. The residue is fat-soluble.

Fluazifop-P-butyl was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 JMPR. The current Meeting received new information on the validation of analytical methods and storage stability for green onion, a label and supervised residue trials on strawberry. Since new GAP information had become available for cane berries, blueberries, strawberries and green onion, the Meeting evaluated previously submitted supervised residue trial data on these commodities against the new GAP.

#### **Analytical methods**

Method GRM044.01A (modification B) for the determination of total fluazifop (fluazifop-butyl, fluazifop acid (II) and its conjugates) in plant commodities as fluazifop acid was reviewed by the 2016 JMPR. Based on the validation data of method GRM044.01A for cane berries, blueberries and strawberries, and radiovalidation data, the 2019 JMPR considered that method GRM044.01A was suitable for determination of fluazifop-P-butyl residues in the supervised field trials on cane berries, blueberries and strawberries. The LOQs are 0.02 mg/kg for blueberries and cane berries, and 0.01 mg/kg for strawberries.

The current Meeting received validation data for green onion (GRM044.01A modification B). The Meeting considered that method GRM044.01A (modification B) was suitable for determination of fluazifop-P-butyl residues in the supervised field trials on green onion as fluazifop acid with an LOQ of 0.01 mg/kg.

#### **Storage stability of residues**

The storage stability of fluazifop acid was evaluated by the 2016 Meeting in cane berries, blueberries and strawberries. The 2016 Meeting concluded that fluazifop acid is stable when stored frozen for at least 27 months at -1 °C, 8 months at -15 °C and for 31 months at -20 °C in raspberries, blueberries and strawberries.

The current Meeting received new data on storage stability of fluazifop in green onion (spiked with fluazifop and determined by GRM044.01A modification B) at -18 °C, and concluded that fluazifop was stable for at least 20 months.

#### **Results of supervised residue trials on crops**

The Meeting received supervised residue trial data for directed ground spray applications of fluazifop-P-butyl on cane berries and blue berries, and foliar applications on strawberries and green onion.

### *Cane berries*

The current Meeting evaluated the USA trials provided to the 2016 Meeting against the GAP from the USA. Critical GAP for cane berries in the USA allows two ground banded spray applications at a rate of 0.42 kg ai/ha with an interval of 14 days and a PHI of 1 day.

Five independent supervised field trials were conducted on cane berries in the USA approximating the critical GAP.

The total fluazifop residues in blackberry were (n = 3): < 0.020 (3) mg/kg. The total fluazifop residues in raspberry were (n = 2): < 0.020, 0.05 mg/kg.

The combined total fluazifop residues in cane berries were (n = 5): < 0.020 (4), 0.05 mg/kg.

The Meeting noted that the GAP of the USA is for the cane berries subgroup, and that blackberry and raspberry are representative commodities for the subgroup of cane berries. The Meeting decided to estimate a maximum residue level of 0.08 mg/kg for the subgroup of cane berries to replace the previous recommendation. The Meeting estimated a median of 0.02 mg/kg and highest residue of 0.07 mg/kg (highest individual).

Using the multiplication factor of 1.05 to the median and highest residues, the Meeting estimated an STMR of 0.021 mg/kg and an HR of 0.074 mg/kg (highest individual  $0.07 \times 1.05$ ).

### *Bush berry*

#### *Blueberry*

The current Meeting evaluated the data from the USA provided to the 2016 Meeting against the new GAP from the USA. Critical GAP in the USA for bush berries (high bush) allows two ground banded spray applications at a rate of 0.42 kg ai/ha with an interval of 14 days and a PHI of 1 day.

Seven independent trials on blueberries were conducted in the USA approximating the cGAP. The total fluazifop residues in blueberries were (n = 7): < 0.020 (5), 0.05, 0.19 mg/kg.

The Meeting noted that the USA GAP is for the bush berries subgroup, and that blueberry is the representative commodity for the subgroup. The Meeting decided to estimate a maximum residue level of 0.3 mg/kg for the subgroup of bush berries. The Meeting estimated a median of 0.02 mg/kg and highest residue of 0.25 mg/kg (highest individual).

Using the multiplication factor of 1.05 to the median and highest residues, the Meeting estimated an STMR of 0.021 mg/kg and an HR of 0.26 mg/kg (highest individual  $0.25 \times 1.05$ ).

The Meeting noted that the USA GAP for bush berries (high bush) also covers high bush cranberries and elderberry, listed in the Codex Classification as Guelder rose (*Viburnum opulus* L) and elderberries (*Sambucus spp.*) in the subgroup of large shrub/tree berries, and agreed to extrapolate the maximum residue level of 0.3 mg/kg, STMR of 0.021 mg/kg and HR of 0.26 mg/kg for fluazifop to Guelder rose and elderberries.

The Meeting decided to withdraw the previous recommendations of 0.01(\*) mg/kg for currants, black, red, white, and for gooseberries.

#### *Strawberry*

The critical GAP in the USA for strawberry allows one foliar spray application at a rate of 0.28 kg ai/ha with a PHI of 14 days.

The Meeting received six supervised field trials conducted on strawberry in the USA approximating the critical GAP.

The total fluazifop residues in strawberry were (n = 6): 0.27, 0.37, 0.60, 0.70, 1.1 and 1.4 mg/kg.

The Meeting estimated a maximum residue level of 3 mg/kg for strawberry to replace the previous recommendation. The Meeting estimated a median of 0.65 mg/kg and highest residue of 1.43 mg/kg (highest individual).

Using the multiplication factor of 1.05 to the median and highest residues, the Meeting estimated an STMR of 0.685 mg/kg and an HR of 1.5 mg/kg (highest individual 1.43 x1.05) for strawberry.

### *Green onion*

The critical GAP in the USA for green onion allows two foliar applications of 0.42 kg ai/ha with an interval of 14 days and a PHI of 14 days.

Four independent trials were conducted in the USA on green onion approximating the US GAP, total fluazifop residues were (n = 4): 0.13, 0.36, 0.48 and 0.59 mg/kg.

The Meeting concluded that the data were insufficient for estimating a maximum residue level for green onion.

### **Residues in animal commodities**

None of the commodities for which supervised trial data were submitted to the current Meeting or their by-products are fed to animals. The Meeting confirmed its previous recommendations for animal commodities.

## **RECOMMENDATIONS**

On the basis of the data 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.

Definition of the residue for compliance with the MRL in plant commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.

Definition of the residue for dietary risk assessment in plant commodities: the sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL), 5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid.

Definition of the residue for compliance with the MRL and for dietary risk assessment in animal commodities: total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.

The residue is fat-soluble.

## **DIETARY RISK ASSESSMENT**

### **Long-term dietary exposure**

The ADI for fluazifop-P-butyl is 0–0.004 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fluazifop-P-butyl 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 2019 JMPR Report. The IEDIs ranged from 30–160% of the maximum ADI of 0.004 mg/kg bw. An exceedance was found for GEMS/Food cluster diet G16 (160%).

Based on the decision of CCPR 2017 (REP17/PR) to withdraw the draft MRLs for sweet potato and yam the IEDIs ranged from 20–90% of the maximum ADI of 0.004 mg/kg bw. On this basis, the Meeting concluded that the long-term dietary exposure to residues of fluazifop-P-butyl from uses considered by the JMPR (excluding sweet potato and yam) is unlikely to present a public health concern.

***Acute dietary exposure***

The ARfD for fluazifop-P-butyl is 0.4 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for fluazifop-P-butyl were calculated for food commodities and their processed commodities for which HRs/HR-Ps or STMRs/STMP-Ps were estimated by the current Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs varied from 0–6% of the ARfD for children and 0–3% for the general population. The Meeting concluded that acute dietary exposure to residues of fluazifop-P-butyl from uses considered by the current Meeting is unlikely to present a public health concern.

## 5.12 Fluensulfone (265)

### RESIDUE AND ANALYTICAL ASPECTS

Fluensulfone is a heterocyclic fluoroalkenyl sulfone nematicide. The mode of action is through feeding inhibition and paralysis of adults and juveniles. The IUPAC name for fluensulfone is 5-chloro-1,3-thiazol-2-yl 3,4,4-trifluorobut-3-en-1-yl sulfone.

Fluensulfone was evaluated for toxicology by JMPR in 2013 and 2014.

An ADI of 0–0.01 mg/kg bw and an ARfD of 0.3 mg/kg bw were established by the 2014 JMPR. Residues were evaluated by the JMPR in 2014 and 2016. The 2016 JMPR established the following residue definitions:

For compliance with MRLs for plant commodities: Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents.

- For estimation of dietary exposure for plant commodities: Fluensulfone.
- For compliance with MRLs and for estimation of dietary exposure for animal commodities: Fluensulfone.

The residue is fat-soluble.

The 2014 JMPR agreed that the exposure risks from the metabolite MeS should be assessed using the Threshold of Toxicological Concern (TTC) approach and the 2016 JMPR confirmed that the TTC approach for this metabolite remained appropriate.

Fluensulfone was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received new supporting data and/or GAP information for citrus, pome fruit, stone fruit, grapes, guava, tree nuts, coffee, sugar cane and black pepper, additional rotational crop studies, frozen storage stability studies, processing studies and a livestock feeding study for the BSA/TSA metabolites.

#### **Methods of analysis**

The Meeting received additional validation information on the analytical methods (based on Method MTH-083) evaluated by the 2014 JMPR and used for measuring fluensulfone and metabolite BSA residues in the commodities considered by the current Meeting.

The Meeting concluded that for the commodities considered by the Meeting, the methods used in the new residue trials were sufficiently validated and are suitable to measure fluensulfone and metabolite BSA in plant commodities.

#### **Stability of pesticide residues in stored analytical samples**

The Meeting received additional information on storage stability of fluensulfone and metabolite BSA in orange, tomato, soya bean, dry beans, cereal grains and sugar cane (raw and processed).

Storage stability studies evaluated by the current and previous Meetings showed that in analytical samples stored at or below -18 °C, fluensulfone and metabolite BSA residues were stable for at least the following intervals:

High water matrices - Fruiting vegetables for 15–16 months, sugar cane for 6 months;

High acid matrices - orange for 18 months

High starch matrices - cereal grains for 10 months; Potato for 23 months; carrot for 17.5 months

High protein matrices - dry beans for 10 months

High oil matrices - peanut for 13 months

Low moisture matrices - cereal straws for 10 months

The Meeting agreed that the demonstrated storage stability in these representative plant commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

### ***Residues in rotational crops***

#### ***Field rotational crop studies***

The 2014 JMPR evaluated confined rotational crop studies (radish, lettuce and wheat as follow crops) and concluded that overall, fluensulfone can be expected to dissipate rather rapidly in the environment, with a concomitant increase in residues of BSA, TSA, and to a much lesser extent, MeS. BSA residues should then decline but TSA appears to be stable for an extended period; may accumulate in soils following repeated uses of fluensulfone.

The 2016 JMPR evaluated a field rotational cropping study involving a single bare soil application of fluensulfone (4.0 kg ai/ha) and to accommodate residues arising in rotational crops, recommended maximum residue levels for root and tuber vegetables, leafy vegetables and legume vegetables not elsewhere specified.

The current Meeting received a new field crop rotation study involving 56 field trials where rotational cereal crops were planted after a bare soil application of fluensulfone at rates of 3.6–4.2 kg ai/ha (approximating the GAP seasonal rate). The plant-back intervals were 3 months (winter wheat) and 10 months (maize, rice, sorghum and spring wheat).

Samples of forage, grain, hay and straw were stored frozen (<-10 °C) for up to 19 months before LC-MS/MS analysis (Method MTH-083) for fluensulfone and metabolite BSA. Mean procedural recoveries ranged from 72–111% and the LOQs for both analytes were 0.01 mg/kg.

Fluensulfone residues were only detected in the 3-month PBI winter wheat hay (0.02 mg/kg), but BSA residues were present up to 0.07 mg/kg in grain, 2.4 mg/kg in forage, 4.0 mg/kg in hay and up to 2.4 mg/kg in straws and stovers. Highest total residues (fluensulfone plus BSA, expressed as fluensulfone) were 0.12 mg/kg (maize grain), 3.7 mg/kg (forages) and 6.2 mg/kg (hays and straws).

The US fluensulfone label includes a requirement to observe a plant-back interval of 90 days for wheat, barley, buckwheat and oats, and 10 month plant-back interval for all other cereal grain crops.

#### ***Cereal forages***

In 11 trials where wheat was grown as a rotational crop and in 20 trials where maize was grown as a rotational crop, residues of fluensulfone in forage were all < 0.01 mg/kg (n = 35).

For the purposes of estimating the livestock dietary burden, the Meeting agreed to extrapolate these data to cereal forages in general and established a median and highest residue of 0.01 mg/kg for fluensulfone in cereals forages (as received).

#### ***Cereal grains***

In 15 trials where wheat was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 15) and total residues were < 0.025 (10), 0.03 (2), 0.04 (2) and 0.07 mg/kg.

Extrapolating these data to the wheat subgroup, the Meeting estimated a maximum residue level of 0.08 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of wheat, similar grains, and pseudocereals without husks.

Noting that the US plant-back interval for barley and oats was the same as for wheat, the Meeting also agreed to extrapolate the wheat data to the barley sub-group and estimated a maximum residue level of 0.08 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of barley, similar grains, and pseudocereals with husks.

In 18 trials where maize was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 18) and total residues were < 0.025 (17) and 0.12 mg/kg.



Extrapolating these data to the maize and sweetcorn subgroups, the Meeting estimated a maximum residue level of 0.15 mg/kg for fluensulfone (total residues), a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroups of maize cereals and sweetcorns and a HR of 0.01 mg/kg for sweet corn (corn-on-the-cob) and baby corn.

In 11 trials where rice was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 11) and total residues were < 0.025 (10) and 0.03 mg/kg.

Extrapolating these data to the rice subgroup, the Meeting estimated a maximum residue level of 0.04 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of rice cereals.

In nine trials where sorghum grain was grown as a rotational crop, residues of fluensulfone in grain were all < 0.01 mg/kg (n = 9) and total residues were < 0.025 (8) and 0.03 mg/kg.

Extrapolating these data to the sorghum grain subgroup, the Meeting estimated a maximum residue level of 0.04 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg for fluensulfone (parent only) in the subgroup of sorghum grain and millet.

### ***Cereal fodders***

In 15 trials where wheat was grown as a rotational crop, residues of fluensulfone in hay were < 0.01 (14) and 0.02 mg/kg (n = 15) and total residues were < 0.025, 0.04, 0.07, 0.09, 0.19, 0.25, 0.30, 0.39, 0.41, 0.65, 3.1, 3.3, 4.0, 5.5 and 6.2 mg/kg (n = 15).

Noting that the US plant-back interval for barley and oats was the same as for wheat, the Meeting agreed to use the wheat data, after correction for an average 88% dry matter content, to estimate a maximum residue level of 15 mg/kg (dw) for fluensulfone (total residues), a median residue of 0.01 mg/kg (as received) and a highest residue of 0.02 mg/kg for fluensulfone (parent only) in hay or fodder (dry) of grasses except maize fodder and rice straw and fodder, dry.

In 15 trials where wheat was grown as a rotational crop, residues of fluensulfone in straw were < 0.01 (15) mg/kg (n = 15) and total residues were 0.03, 0.04 (3), 0.09 (2), 0.16 (2), 0.18, 0.42, 0.64, 1.4, 2.1, 2.3 and 3.7 mg/kg (n = 15).

Noting that the US plant-back interval for barley and oats was the same as for wheat, the Meeting agreed to use the wheat data, after correction for an average 88% dry matter content, to estimate a maximum residue level of 6 mg/kg (dw) for fluensulfone (total residues), a median residue of 0.01 mg/kg (as received) and a highest residue of 0.01 mg/kg for fluensulfone (parent only) in straw or fodder (dry) of cereal grains except maize fodder and rice straw and fodder, dry.

In 20 trials where maize was grown as a rotational crop, residues of fluensulfone in stover were < 0.01 (20) mg/kg (n = 20) and total residues were < 0.025 (11), 0.03, 0.04 (4), 0.09, 0.12, 0.36 and 0.39 mg/kg (n = 20).

After correction for an average 83% dry matter content, the Meeting estimated a maximum residue level of 0.6 mg/kg for fluensulfone (total residues) and a median residue of 0.01 mg/kg (as received) and a highest residue of 0.01 mg/kg (as received) for fluensulfone (parent only) in maize fodder.

In 11 trials where rice was grown as a rotational crop, residues of fluensulfone in straw were < 0.01 (11) mg/kg (n = 11) and total residues were < 0.025 (9), 0.04 and 0.04 mg/kg (n = 11).

After correction for an average 90% dry matter content, the Meeting estimated a maximum residue level of 0.06 mg/kg (dw) for fluensulfone (total residues) and a median residue of 0.01 mg/kg (as received) and a highest residue of 0.01 mg/kg (as received) for fluensulfone (parent only) in rice straw and fodder, dry.

### ***Results of supervised residue trials on crops***

Supervised trials were available for the use of fluensulfone on citrus fruit, pome fruit, stone fruit, grapes,

guava, sugar cane, tree nuts, coffee and black pepper.

Product labels were available from Australia, Brazil and the USA.

When calculating total fluensulfone residues (defined as the sum of fluensulfone and the BSA metabolite, expressed as fluensulfone), the concentration of BSA in each sample was multiplied by 1.53 (the ratio of the molecular weights of fluensulfone and BSA) and the resulting product added to the concentration of fluensulfone. Residues reported as <LOQ were assumed to bear residues at the LOQ.

### *Citrus fruit*

The critical GAP for fluensulfone on citrus in the USA is for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation) with a PHI of 60 days.

In independent trials on citrus, conducted in the USA and matching this GAP:-

Fluensulfone residues in oranges (eight trials) were: < 0.01 (7) and 0.014 mg/kg  
Total residues were: < 0.025 (2), 0.027 (2), 0.030, 0.040, 0.042 and 0.046 mg/kg (n = 8).

Fluensulfone residues in mandarins (three trials) were: < 0.01 (3) mg/kg  
Total residues were: 0.032, 0.058 and 0.072 mg/kg (n = 3).

Fluensulfone residues in lemons (five trials) were: < 0.01 (4) and 0.049 mg/kg  
Total residues were: < 0.025 (3), 0.087 and 0.13 mg/kg (n = 5).

Fluensulfone residues in grapefruit (six trials) were: < 0.01 (5) and 0.014 mg/kg  
Total residues were: < 0.025 (4), 0.026 and 0.077 mg/kg (n = 6).

Noting that the residues arising from an early season soil application to oranges, lemons, mandarins and grapefruit trees were not statistically different (Kruskall-Wallis), the Meeting agreed to estimate a group maximum residue level based on a combined total residue data set of < 0.025 (9), 0.026, 0.027 (2), 0.03, 0.032, 0.04, 0.042, 0.046, 0.058, 0.072, 0.077, 0.087 and 0.13 mg/kg (n = 22).

For dietary intake estimation, the combined fluensulfone data set for whole fruit is: < 0.01 (19), 0.014 (2) and 0.049 mg/kg and the highest individual residue was 0.063 mg/kg (in lemons).

The Meeting estimated a maximum residue level of 0.2 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg and a HR of 0.063 mg/kg for fluensulfone in citrus fruit.

### *Pome fruit*

The critical GAP for fluensulfone on pome fruit (except persimmons) is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

In independent trials on pome fruit, conducted in Canada and the USA and matching this GAP, fluensulfone residues in apples (16 trials) and pears (eight trials) were all < 0.01 mg/kg. Fluensulfone residues were also < 0.01 mg/kg in two exaggerated-rate (5×) trials on apples.

In these trials, total residues were:

Apples: < 0.025 (10), 0.028 (3), 0.031, 0.037 and 0.16 mg/kg (n = 16);

Pears: < 0.025 (5), 0.026, 0.11 and 0.17 mg/kg (n = 8).

Noting that the residues arising from an early season soil application to apple and pear trees were not statistically different (Kruskall-Wallis), the Meeting agreed to estimate a group maximum residue level based on a combined total residue data set of < 0.025 (15), 0.026, 0.028 (3), 0.031, 0.037, 0.11, 0.16 and 0.17 mg/kg (n = 24).

The Meeting estimated a maximum residue level of 0.2 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg and a HR of 0 mg/kg for fluensulfone in pome fruit (except persimmon, Japanese).

### *Stone fruit*

The critical GAP for fluensulfone on stone fruit is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

In independent trials on stone fruit, conducted in the USA and matching this GAP, fluensulfone residues in the flesh of cherries (five trials) and peaches (nine trials), plums (five trials) were all < 0.01 mg/kg (n = 19). Fluensulfone residues were also < 0.01 mg/kg in two exaggerated-rate (5×) trials on plums.

While residues were not measured in whole fruit, the 2017 Meeting concluded that in general, the contribution of the pit to the weight of the whole fruit is approximately 10% and that the flesh residues could be used to estimate maximum residue levels for stone fruit.

In these trials, total residues in flesh were:

Cherries: < 0.025 (2), 0.028, 0.031 and 0.050 mg/kg (n = 5);

Peaches: < 0.025 (6), 0.035, 0.046 and 0.075 mg/kg (n = 9);

Plums: < 0.025 (3), 0.026 and 0.028 mg/kg (n = 5).

Noting that the residues arising from an early season soil application to cherry, peach and plum trees were not statistically different (Kruskall-Wallis), the Meeting agreed to estimate a group maximum residue level based on a combined total residue data set of < 0.025 (11), 0.026, 0.028, 0.028, 0.031, 0.035, 0.046, 0.050 and 0.075 mg/kg (n = 19).

The Meeting estimated a maximum residue level of 0.09 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg and a HR of 0 mg/kg for fluensulfone (parent only) in stone fruit.

### *Small fruit vine climbing*

#### *Grapes*

The critical GAP for fluensulfone on small fruit vine climbing crops is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

In independent trials on grapes, conducted in the USA and matching this GAP, fluensulfone residues in berries were all < 0.01 mg/kg (n = 9). Fluensulfone residues were also < 0.01 mg/kg in two exaggerated-rate (5×) trials on grapes.

In these trials, total residues were: < 0.025 (6), 0.027, 0.050 and 0.48 mg/kg (n = 9).

Noting that grapes is a representative commodity for the small fruit vine climbing sub-group, and that the US GAP includes all commodities in this sub-group, the Meeting estimated a maximum residue level of 0.7 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg and a HR of 0 mg/kg for fluensulfone (parent only) in the small fruit vine climbing sub-group.

#### *Guava*

The critical GAP for fluensulfone on guava is in Brazil, for a banded within-row soil treatment of 0.96 kg ai/ha, at the beginning of the rainy season, when trees are growing new roots. No PHI is specified.

In four Brazilian trials where single banded soil applications of 0.96 kg ai/ha were applied during mid-late March (about the end of flowering), fluensulfone residues in fruit sampled at intervals from 60–90 DAT were all < 0.08 mg/kg and total residues were all < 0.2 mg/kg (n = 4).

The Meeting concluded that since the validated LOQ of 0.08 mg/kg was higher than the level that can be achieved using current analytical techniques (0.01 mg/kg), maximum residue levels for guava could not be recommended.

### *Sugar cane*

The critical GAP for fluensulfone on sugar cane is in the USA, for a soil broadcast or band application of 3.92 kg ai/treated ha at planting.

In independent trials on sugar cane, conducted in Australia (four trials) and the USA (seven trials) and matching this GAP, fluensulfone residues in the canes/billets were all < 0.01 mg/kg.

In these trials, total residues were: < 0.025 (9), 0.027 and 0.045 mg/kg (n = 11).

The Meeting estimated a maximum residue level of 0.06 mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg and a HR of 0.01 mg/kg for fluensulfone (parent only) in sugar cane.

### *Tree nuts*

The critical GAP for fluensulfone on tree nuts is in the USA, for a pre-flowering soil application of 3.92 kg ai/treated ha (broadcast, banded or by chemigation).

#### *Almonds*

In five independent trials on almonds conducted in Canada and the USA and matching this GAP, fluensulfone residues in nutmeat were all < 0.01 mg/kg (n = 5).

In these trials, total residues in nutmeat were: < 0.025 (5) mg/kg (n = 5).

#### *Pecans*

In five independent trials on pecans conducted in Canada and the USA and matching this GAP, fluensulfone residues in nutmeat were all < 0.01 mg/kg (n = 5).

In these trials, total residues in nutmeat were all < 0.025 mg/kg (n = 5).

Noting that the residues arising from an early season soil application to almond and pecan trees were relatively consistent the Meeting agreed to estimate a group maximum residue level.

The Meeting estimated a maximum residue level of 0.025 (\*) mg/kg for fluensulfone (total residues) and a STMR of 0.01 mg/kg and a HR of 0.01 mg/kg for fluensulfone (parent only) in tree nuts.

### *Coffee beans*

The critical GAP for fluensulfone on coffee is in Brazil, for a banded within-row soil treatment of 0.96 kg ai/ha, at the beginning of the rainy season, when bushes are growing new roots. No PHI is specified.

In eight Brazilian trials where single banded soil applications of 0.96 kg ai/ha were applied mid-late February (over flowering and up to early fruit formation), fluensulfone residues in fruit sampled at intervals from 150–210 DAT were all < 0.08 mg/kg and total residues were all < 0.2 mg/kg (n = 8).

In a further set of Brazilian trials conducted in 2017, where single banded soil applications of 0.96 kg ai/ha (eight trials) were applied early-mid February (early fruit formation), fluensulfone residues in fruit sampled at intervals from 150–210 DAT were: < 0.01 (7) and 0.01 mg/kg. Fluensulfone residues were also < 0.01 mg/kg in three exaggerated-rate (5×) trials on coffee. Total residues in the eight (1× rate) trials were: < 0.025 (5), 0.025 (2) and 0.041 mg/kg (n = 8).

Based on the results of the 2017 trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for fluensulfone (total residues) and a STMR of 0 mg/kg for fluensulfone (parent only) in coffee bean.

### *Pepper, black*

The critical GAP for fluensulfone on black pepper is in Brazil, with a banded within-row soil treatment

of 0.96 kg ai/ha, at the beginning of the rainy season, when vines are growing new roots. No PHI is specified.

In four Brazilian trials where single banded soil applications of 0.96 kg ai/ha were applied during early fruit formation (mid-July), fluensulfone residues in fruit sampled at intervals from 55–70 DAT were all < 0.08 mg/kg and total residues were all < 0.2 mg/kg (n = 4).

The Meeting agreed that the number of trials was not sufficient to recommend a maximum residue level for fluensulfone in pepper, black, white, pink, green.

### **Residues in animal feeds**

#### **Almond hulls**

In five independent trials on almonds conducted in Canada and the USA and matching the US GAP, fluensulfone residues in almond hulls were all < 0.01 mg/kg (n = 5) and total residues were: 0.78, 1.8, 2.3, 2.4 and 3.0 mg/kg.

The Meeting estimated a maximum residue level of 7 mg/kg (dw) for fluensulfone (total residues) and a median residue of 0.01 mg/kg (as received) for fluensulfone (parent only) in almond hulls.

### **Fate of residues during processing**

The Meeting received new information on the fate of fluensulfone residues during processing in apples, plums and grapes. Processing studies on citrus and sugar cane were evaluated by the 2017 JMPR.

For dietary risk assessment, in the citrus processing studies, fluensulfone residues were present in orange oil, but not detected in whole fruit. Processing factors could therefore not be calculated. However, since residues concentrated in oil, the Meeting agreed to use proportionality to estimate dietary exposure to fluensulfone in citrus oils.

In the processing studies involving an application rate of 8.1 kg ai/ha, the highest fluensulfone residue in orange oil was 0.7 mg/kg. When scaled to the GAP application rate (3.92 kg ai/ha), the Meeting estimated a STMR-P of 0.34 mg/kg for fluensulfone in citrus oil.

For estimating maximum residue levels, processing factors for total residues (sum of fluensulfone + BSA, expressed as fluensulfone) in the commodities considered at this Meeting are summarized below.

Table 1 Fluensulfone (total residue) processing factors for maximum residue level estimation

Raw commodity [MRL]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	RAC MRL × PF (mg/kg)	MRL (mg/kg)
Orange fruit [0.2 mg/kg]	Pulp (dry)	5.1, 6.3	5.7	1.1	1.5
	Oil	12, 0.72	6.3	1.3	1.5
Apple [0.2 mg/kg]	Juice (raw)	1.4, 2.1	1.7	0.35	0.4
	Sauce	1.0, 1.0	1.0	0.2	Not required
	Dried	3.7, 5.9	4.8	1	1
Plum [0.09 mg/kg]	Dried (prunes)	2.6, 3.1	2.9	0.26	0.3
	Juice	1.1, 1.3	1.2	0.11	Not required
Grape [0.7 mg/kg]	Dried (raisins)	2.4	2.4	1.7	2
Sugar cane [0.06 mg/kg]	Molasses	7.4	7.4	0.5	0.5

Using the estimated maximum residue levels for the raw commodities and applying the calculated mean processing factors, the Meeting estimated maximum residue levels of 1.5 mg/kg for citrus oil (extrapolated from orange oil) and citrus pulp, dry; 0.4 mg/kg for apple juice; 1.0 mg/kg for apples, dried; 0.3 mg/kg for prunes, 2 mg/kg for dried grapes and 0.5 mg/kg for sugar cane molasses.

For livestock dietary burden calculation, no processing factor could be calculated for citrus pulp, dry, since there were no measurable residues of fluensulfone in the whole fruit in the processing studies. However, by scaling the fluensulfone residues (0.02 mg/kg) in citrus pulp, dry from fruit treated with 8.1 kg ai/ha to the GAP application rate of 3.92 kg ai/ha, the Meeting estimated a median residue of 0.01 mg/kg for citrus pulp, dry.

### ***Farm animal dietary burden***

The highest maximum dietary burdens in beef cattle and dairy cattle calculated by the 2016 JMPR, based on the commodities considered by that Meeting, were 2.1 and 1.0 ppm respectively (about 5× less than the 10 ppm dose used in the goat metabolism study).

The Meeting estimated that the additional feed commodities considered by the current Meeting (cereal grains and forages, citrus dried pulp, almond hulls and hays of cereals except maize and rice) would not contribute more than 0.04 ppm to these maximum and mean dietary burdens, and agreed there was no need to revise the previous maximum residue level recommendations for mammalian commodities.

For poultry, the highest maximum dietary burden for broiler and layer poultry estimated by the 2016 JMPR was 0.51 ppm. The additional dietary burden from fluensulfone residues in the new feed commodities (cereal grains and forages) is not more than 0.015 ppm. The Meeting agreed that a revision of the previously estimated maximum residue level recommendations for poultry commodities was unnecessary.

## **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 (plant commodities): the sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents.

Definition of the residue for compliance with the MRL (animal commodities): *fluensulfone*

Definition of the residue for dietary risk assessment (plant and animal commodities): *fluensulfone*

The residue is fat-soluble.

## **DIETARY RISK ASSESSMENT**

### ***Long-term dietary exposure***

The ADI for Fluensulfone is 0–0.01 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for fluensulfone 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 2019 JMPR Report.

The IEDIs ranged from 1–3% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of fluensulfone from uses considered by the JMPR is unlikely to present a public health concern.

**Acute dietary exposure**

The ARfD for fluensulfone is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for fluensulfone 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 2019 JMPR Report.

The IESTIs varied from 0–1% of the ARfD for children and 0–1% of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of fluensulfone from uses considered by the present Meeting is unlikely to present a public health concern.

**Threshold of toxicological concern (TTC) consideration for metabolites****MeS (2-Methylsulfonylthiazole)**

The 2016 JMPR applied the TTC approach to assess the metabolite MeS. Based on the uses considered by the 2014 and 2016 Meetings, the estimated dietary exposure of 0.07 µg/kg bw per day was below the TTC for Cramer Class III compounds of 1.5 µg/kg bw per day. The 2016 Meeting concluded that dietary exposure to MeS was unlikely to present a public health concern for the crops considered by that Meeting.

For the food commodities considered at the current Meeting (citrus fruit, pome fruit, small fruit vine climbing, sugar cane, tree nuts, coffee and cereal grains), residues of MeS were not measured in the field trials. However, MeS is predominantly a minor soil degradate (with a half-life of about 30 days) and was not found in the plant metabolism studies (tomato, lettuce, potato), nor in the rotational crop metabolism studies. In field trials where MeS residues were measured, residues above the LOQ were only found in peppers, cucumber and summer squash. For permanent crops, the Meeting considered that any uptake of MeS from soil would be insignificant. Based on the rotational crop metabolism studies (including wheat as a rotational crop), where MeS was not found, significant residues of MeS are not expected in sugar cane and cereal grains.

The Meeting recalculated its estimation of dietary exposure to residues of MeS resulting in a revised exposure estimate of 0.077 µg/kg bw per day, below the TTC for Cramer Class III compounds of 1.5 µg/kg bw per day. The Meeting concluded that dietary exposure to MeS in the commodities considered by the JMPR is unlikely to present a public health concern. Should further uses be considered in the future, these conclusions may need to be re-evaluated.





## 5.13 Kresoxim-methyl (199)

### RESIDUE AND ANALYTICAL ASPECTS

Kresoxim-methyl is a strobilurin fungicide, acting by inhibiting mitochondrial respiration.

Kresoxim-methyl was first evaluated for toxicology and residues by JMPR in 1998 and a periodic evaluation was conducted by the 2018 JMPR. An ADI of 0-0.3 mg/kg bw was established and an ARfD was not considered necessary.

For plant commodities, the definition of the residue for compliance with the MRL is: *kresoxim-methyl* and for dietary risk assessment is: *Sum of kresoxim-methyl and metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) including their conjugates, expressed as kresoxim-methyl*

For animal commodities, the definition of the residue for compliance with the MRL and for dietary risk assessment is: *Sum of metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9), expressed as kresoxim-methyl*

The residue is not fat-soluble.

The 2018 JMPR also noted that if future uses of kresoxim-methyl result in an increase of the dietary exposure to metabolite 490M2, to more than the threshold of toxicological concern (TTC) for a Cramer Class III compound, a reconsideration of the residue definition for dietary exposure may be necessary.

Kresoxim-methyl was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received new GAP information and new supporting residue information for pome fruit.

#### **Results of supervised residue trials on crops**

New supervised trials from Canada and the USA were available for the use of kresoxim-methyl on pome fruit. The analytical methods used in these trials were reviewed by the 2018 JMPR and the demonstrated stability of residues in frozen samples (12 months) covered the storage intervals in the trials considered by the Meeting.

Product labels were available from Australia, Belgium, Canada, France, the Netherlands, Spain, the UK and the USA.

For dietary risk assessment, 'total residues' refers to the sum of kresoxim-methyl and metabolites 490M1 and 490M9, expressed as kresoxim-methyl. The parent-equivalent conversion factors were 1.047 (490M1) and 0.994 (490M9).

#### **Pome fruit**

The critical GAP for kresoxim-methyl on pome fruit is in the USA, with a maximum of 4 foliar applications of 0.22 kg ai/ha, a minimum retreatment interval of 7 days and a pre-harvest interval of 30 days.

In trials from Canada and the USA on apples and pears, matching the GAP in the USA, residues of kresoxim-methyl in apples were: < 0.05 (8), 0.05 (2), 0.06 (3), 0.07 and 0.08 (3) mg/kg (n = 17) and in pears were: < 0.05 (6), 0.06 and 0.09 mg/kg (n = 8).

For maximum residue level estimation, the combined kresoxim-methyl data set for apples and pears, matching the critical GAP for pome fruit in the USA is: < 0.05 (14), 0.05 (2), 0.06 (4), 0.07, 0.08 (3) and 0.09 mg/kg (n = 25).

For dietary risk assessment, total residues (parent, 490M1 and 490M9, expressed as kresoxim-methyl) in apples from trials matching the GAP in the USA were: < 0.1 (7), 0.1 (2), 0.11 (2), 0.12 (2), and 0.13 (4) mg/kg and in pears were: < 0.1 (2), 0.11 (2), 0.13, 0.14, 0.19 and 0.2 mg/kg.

The combined data set for total residues in apples and pears, matching the GAP in the USA is: < 0.1 (9), 0.1 (2), 0.11 (4), 0.12 (2), 0.13 (5), 0.14, 0.19 and 0.2 mg/kg (n = 25).

The Meeting estimated a maximum residue level of 0.15 mg/kg for kresoxim-methyl and an STMR of 0.11 mg/kg for total residues in pome fruit except persimmon, Japanese to replace the previous recommendation for pome fruit.

### ***Fate of residues during processing***

The 2018 JMPR reviewed information on the fate of kresoxim-methyl and metabolites 490M1 and 490M9 residues during processing of apples.

Table 1 Processing factors for total residues in apple commodities estimated by the 2018 JMPR for dietary exposure estimation

Raw commodity [STMR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)	Median residue = STMR <sub>RAC</sub> × PF (mg/kg)
Apple [0.11 mg/kg]	Apple sauce	0.23, 0.26, 0.27, 0.29, 0.31, 0.50, 0.63	0.29	0.032	
	Wet pomace	0.31, 0.47, 1.4, 2.1, 2.2, 2.6, 2.7, 4.0	2.2		0.24
	Apple juice	0.10, 0.10, 0.12, 0.13, 0.26, 0.30, 0.31, 0.63	0.2	0.022	
	Dried apples	0.23, 0.30, 0.42, 0.61	0.39	0.043	
	Dried pomace	4.5, 8.7, 9.1, 16	8.9		0.98

### ***Residues in animal commodities***

#### ***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 in 2018 and by the current Meeting.

The additional residue burdens arising from the consumption of wet apple pomace do not change the conclusions of the 2018 JMPR. For beef and dairy cattle, the maximum and mean dietary burdens remain at 3.2 ppm and 1.5 ppm, respectively.

Wet apple pomace is not a component of the poultry diets, and maximum and mean dietary burdens for poultry estimated by the 2018 JMPR remain unchanged.

#### ***Animal commodity maximum residue levels***

The Meeting agreed that since the kresoxim-methyl maximum and mean livestock dietary burdens have not changed, the 2018 JMPR recommendations for animal commodities need not be revised.

## **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 assessments.

Definition of the residue for compliance with the MRL for plant commodities: *Kresoxim-methyl*

Definition of the residue for dietary risk assessment for plant commodities: *Sum of kresoxim-methyl and metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) including their conjugates, expressed as kresoxim-methyl*

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: *Sum of metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9), expressed as kresoxim-methyl*

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

### **Long-term dietary exposure**

The ADI for kresoxim-methyl (and applying to metabolites 490M1 and 490M9) is 0–0.3 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for kresoxim-methyl 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 2019 JMPR Report.

The IEDIs ranged from 0–0.4% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of kresoxim-methyl from uses considered by the JMPR is unlikely to present a public health concern.

### **Acute dietary exposure**

The 2018 JMPR decided that an ARfD for kresoxim-methyl is unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of kresoxim-methyl from the uses considered is unlikely to present a public health concern.

### **Threshold of toxicological concern (TTC) consideration for metabolites**

#### **Metabolite 490M2**

The 2018 JMPR applied the TTC approach to assess the metabolite 490M2 and concluded that the maximum long-term dietary exposure (0.30 µg/kg bw per day) was below the 1.5 µg/kg bw per day threshold for a Cramer Class III compound.

The current Meeting noted that with the additional residue contribution from the pome fruit commodities considered by the Meeting, the maximum long-term dietary exposure for metabolite 490M2 increased to 0.34 µg/kg bw per day. The Meeting concluded that dietary exposure to residues of 490M2 in food commodities considered by the current and previous Meetings is unlikely to present a public health concern.



## 5.14 Lambda-cyhalothrin (146)

### RESIDUE AND ANALYTICAL ASPECTS

Lambda-cyhalothrin consists of two of the four isomers of cyhalothrin. It was first evaluated by the JMPR in 1984 (T, R) and has undergone numerous subsequent evaluations. It was evaluated under the periodic review programme in 2007 (T) and 2008 (R). A group ADI for cyhalothrin and lambda-cyhalothrin was established at 0–0.02 mg/kg bw and a group ARfD of 0.02 mg/kg bw was established by the 2007 JMPR. In 2008 the Meeting agreed that the residue definition for compliance with the MRL and for dietary risk assessment for both plant and animal commodities should be cyhalothrin, sum of all isomers. The residue is fat-soluble.

At the Fiftieth Session of the CCPR (2018) lambda-cyhalothrin was scheduled for the evaluation of an additional use on pineapple by the 2019 JMPR. The current Meeting received residues data for pineapple, methods of analysis and freezer storage stability data.

#### ***Methods of analysis***

The Meeting received additional information on analytical methods for the determination of lambda-cyhalothrin in pineapple.

Method GRM043.01A involved the extraction with acetone: hexane (1:1, v/v) with final determination by LC-MS/MS. The LOQ of the method is 0.01 mg/kg.

The Meeting concluded that the method was sufficiently validated for the determination of lambda-cyhalothrin in pineapple.

#### ***Stability of residues in stored analytical samples***

The Meeting received new storage stability data for lemons (high acid commodity) and lentils (high protein commodity). The Meeting concluded that the data support the stability of lambda-cyhalothrin in lemon (high acid) and in lentils (high protein commodities) for at least 24 months of frozen storage at  $\leq -18$  °C.

The samples from the residue trials were stored for up to 5 months of storage and the Meeting agreed the available storage data support this length of storage.

Samples of processed fractions (juice and wet pulp/waste) were stored for up to 7 months prior to analysis. Data evaluated by the 2008 JMPR supports the storage stability in high water commodities for 26 months. The Meeting concluded that the data for high water and high acid commodities were sufficient to cover the 7 months of storage at  $\leq -18$  °C for the processed fractions.

#### ***Results of supervised residue trials on pineapple***

Two GAPs are authorised on pineapple in Guatemala; 3 applications of 37.5 g ai/ha with a PHI of 15 days and 3 applications of 106 g ai/ha with a PHI of 29 days. Residue trials reflecting the individual use patterns were not provided and the Meeting could therefore not identify the critical GAP. In addition, all trials involved 6 applications per season and contained insufficient information to determine the contribution of the first applications to the final residue.

The Meeting agreed that a maximum residue level could not be estimated for pineapple in the absence of trials conducted in accordance with the critical GAP.

#### ***Fate of residues during processing***

The 2008 JMPR concluded that lambda-cyhalothrin was stable to high temperature hydrolysis.

The current Meeting received information on the fate of lambda-cyhalothrin during the processing of pineapples to juice and wet pulp/waste. Based on one trial, processing factors of 0.06 and 3.6 were estimated for juice and wet pulp/waste respectively.

Pineapple process waste may be fed to livestock. As trials conducted in accordance with the critical GAP were not provided the Meeting could not estimate a median residue.

## 5.15 Mandestrobin (307)

## RESIDUE AND ANALYTICAL ASPECTS

At the Forty-ninth Session of the CCPR (2017), mandestrobin was scheduled for toxicology and residue evaluation as a new compound by the 2018 JMPR. During the 2018 JMPR it appeared that soil degradation studies, field dissipation studies and additional supervised field trials were available that could aid in the definition of the residue. The residue evaluation was therefore postponed to the 2019 JMPR.

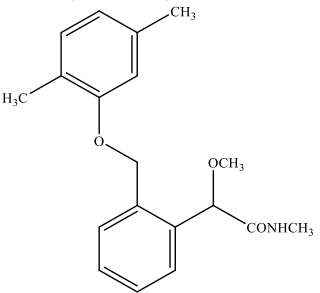
The 2018 JMPR established an ADI of 0–0.2 mg/kg bw and an ARfD of 3.0 mg/kg bw for women of childbearing age. The 2018 Meeting concluded that it was not necessary to establish an ARfD for mandestrobin for the remainder of the population.

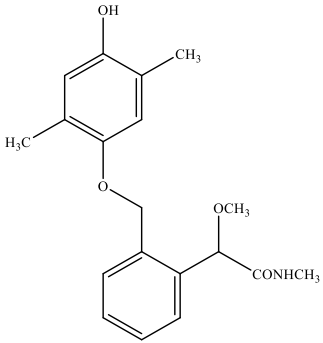
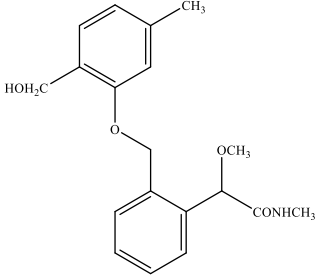
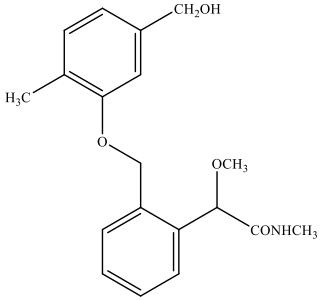
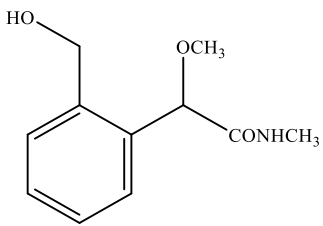
Mandestrobin is a systemic strobilurin fungicide. It acts on various fungi and also on the control of bacterial nuclear disease. Mandestrobin acts by inhibiting mitochondrial respiration. It binds at the Qo-centre on cytochrome b and blocks electron transfer between cytochrome b and cytochrome c1, disrupting the energy cycle within the fungus by halting the production of ATP.

The Meeting received information from the manufacturer on identity, physical and chemical properties, metabolism in plant and livestock, confined and field rotational crop studies, soil degradation studies, field dissipation studies, residue analysis, storage stability, use patterns, supervised residue trials, fate of residues during processing and livestock feeding studies.

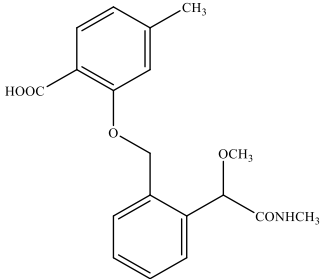
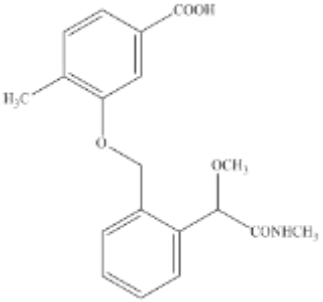
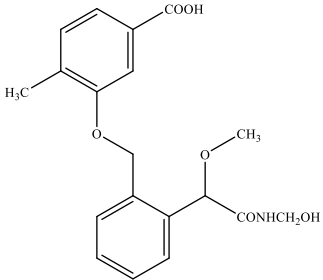
The IUPAC name of mandestrobin is (RS)-2-methoxy-N-methyl-2-[ $\alpha$ -(2,5-xylyloxy)-o-tolyl]acetamide. The CAS name is 2-[(2,5-dimethylphenoxy)methyl]phenyl]- $\alpha$ -methoxy-N-methylbenzeneacetamide. Mandestrobin (S-2200) is a racemic mixture of S-2167 (R-isomer) and S-2354 (S-isomer). All compounds referred to in the appraisal are listed in the table below.

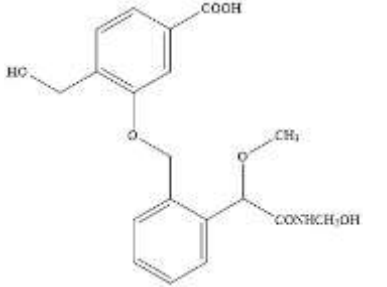
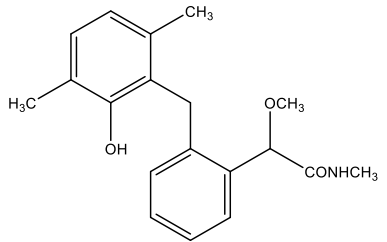
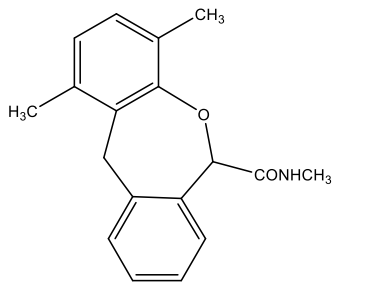
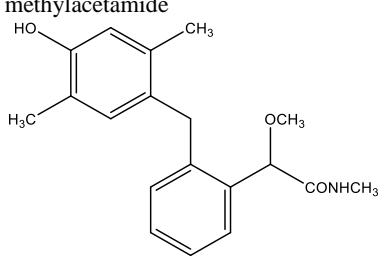
Table 1 Abbreviations for the relevant compounds referred to in the appraisal

Abbreviation	Trivial and systematic chemical names Other abbreviations used in study reports Structural formula	Found as or in
Mandestrobin	IUPAC: (2RS)-2-((2,5-dimethylphenoxy)methyl)phenyl)-2-methoxy-N-methylacetamide  MW = 313.39	Hydrolysis in water Photolysis in water Soil surface photodegradation Laboratory aerobic soil degradation Field dissipation Tomato fruits; Tomato leaves Immature lettuce; Mature lettuce Wheat forage; Wheat hay; Wheat straw Green rape seed fodder (BBCH > 60); Rape seed [application at bloom] Rotated wheat grain; Rotated wheat straw Rotated wheat forage; Rotated wheat hay Rotated immature lettuce; Rotated mature lettuce Rotated carrot root; Rotated carrot leaves Egg Poultry liver Poultry muscle Poultry skin; Poultry fat Milk fat; Skimmed milk Ruminant liver; Ruminant kidney Ruminant muscle; Ruminant fat
4-OH- mandestrobin	IUPAC: (2RS)-2-[2-(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide	Immature lettuce; Mature lettuce Wheat forage; Wheat hay; Wheat straw Green rape seed fodder (BBCH > 60) Rape seed [application before or at bloom] Rotated wheat forage; Rotated wheat hay Rotated wheat grain; Rotated wheat straw Rotated immature lettuce; Rotated mature lettuce

Abbreviation	Trivial and systematic chemical names Other abbreviations used in study reports Structural formula	Found as or in
	 <p>MW = 329.39</p>	Rotated carrot leaves Egg Poultry liver Poultry muscle Poultry skin; Poultry fat Milk fat; Skimmed milk Ruminant liver; Ruminant kidney
2-CH <sub>2</sub> OH-mandestrobin	IUPAC: (2 <i>RS</i> )-2-[2-(2-hydroxymethyl-5-methylphenoxy)methyl]phenyl]-2-methoxy- <i>N</i> -methylacetamide  <p>MW = 329.39</p>	Immature lettuce; Mature lettuce Wheat forage; Wheat hay; Wheat straw Wheat grain Green rape seed fodder (BBCH > 60) Rape seed [application before or at bloom] Rotated wheat forage; Rotated wheat hay Rotated wheat straw Rotated immature lettuce; Rotated mature lettuce Rotated carrot root; Rotated carrot leaves Poultry liver Poultry muscle Poultry skin Milk fat; Skimmed milk Ruminant liver; Ruminant kidney Ruminant muscle; Ruminant fat
5-CH <sub>2</sub> OH-mandestrobin	IUPAC: (2 <i>RS</i> )-2-[2-(5-hydroxymethyl-2-methylphenoxy)methyl]phenyl]-2-methoxy- <i>N</i> -methylacetamide  <p>MW = 329.39</p>	Immature lettuce; Mature lettuce Wheat forage; Wheat hay; Wheat straw Green rape seed fodder (BBCH > 60) Rape seed [application at bloom] Rotated wheat forage; Rotated wheat hay Rotated wheat straw Rotated immature lettuce; Rotated mature lettuce Rotated carrot leaves Milk fat Ruminant liver; Ruminant kidney
De-Xy- mandestrobin	IUPAC: (2 <i>RS</i> )-2-(2-hydroxymethylphenyl)-2-methoxy- <i>N</i> -methylacetamide  <p>MW = 210.253</p>	Photolysis in water Soil surface photodegradation Laboratory aerobic soil degradation Field dissipation Immature lettuce; Mature lettuce Wheat forage; Wheat hay; Wheat straw Wheat grain Egg Poultry liver Poultry skin; Poultry fat Milk fat; Skimmed milk Ruminant liver; Ruminant kidney Ruminant muscle; Ruminant fat



Abbreviation	Trivial and systematic chemical names Other abbreviations used in study reports Structural formula	Found as or in
2-COOH-mandestrobin	IUPAC: 2-({2-[(1 <i>RS</i> )-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid  MW = 343.38	Photolysis in water (tentative; not confirmed) Soil surface photodegradation Laboratory aerobic soil degradation Field dissipation Egg Poultry liver Poultry skin Ruminant liver; Ruminant kidney Ruminant muscle; Ruminant fat
5-COOH-mandestrobin	IUPAC: 3-({2-[(1 <i>RS</i> )-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid  MW = 343.38	Photolysis in water (tentative; not confirmed) Soil surface photodegradation Laboratory aerobic soil degradation Field dissipation Wheat straw Rape seed [before and at bloom] Rotated wheat forage; Rotated wheat hay Rotated wheat straw Rotated immature lettuce; Rotated mature lettuce Rotated carrot root; Rotated carrot leaves Poultry skin Ruminant liver; Ruminant kidney Ruminant fat
5-CA-mandestrobin-NHM	3-((2-(2-((hydroxymethyl)amino)-1-methoxy-2-oxoethyl)benzyl)oxy)-4-methylbenzoic acid  MW = 359.38	Egg Poultry skin; Poultry fat Skimmed milk Ruminant liver
5-CA-2-HM-mandestrobin-NHM	4-(hydroxymethyl)-3-((2-(2-((hydroxymethyl)amino)-1-methoxy-2-oxoethyl)benzyl)oxy)benzoic acid	Poultry skin Ruminant liver; Ruminant kidney

Abbreviation	Trivial and systematic chemical names Other abbreviations used in study reports Structural formula	Found as or in
	 <p>MW = 375.38</p>	
Mandestrobin-OR	<p>(<i>RS</i>)-2-(2-(2-hydroxy-3,6-dimethylbenzyl)phenyl)-2-methoxy-N-methylacetamide</p> 	<p>Photolysis in water Soil surface photodegradation</p> <p>The benzyl radical recombined at the o- position of the phenoxy radical.</p>
Mandestrobin-ORC	<p>(<i>RS</i>)-N,1,4-trimethyl-6,11-dihydrodibenzo[b,e]oxepine-6-carboxamide</p> 	<p>Photolysis in water Analysed in soil surface photodegradation but not detected</p> <p>Formed from mandestrobin-OR by cyclisation.</p>
Mandestrobin-PR	<p>(<i>RS</i>)-2-(2-(4-hydroxy-2,5-dimethylbenzyl)phenyl)-2-methoxy-N-methylacetamide</p> 	<p>Photolysis in water Analysed in soil surface photodegradation but not detected</p> <p>The benzyl radical recombined at the p- position of the phenoxy radical.</p>

### Physical and chemical properties

Mandestrobin is not volatile ( $3.4 \times 10^{-5}$  mPa at 20 °C). Solubility in water is low (15.8 mg/L) and higher in various organic solvents (up to 522 g/L in acetone). Hydrolysis is unlikely to be a significant route of degradation in the environment, but photodegradation in water to 3% TRR was shown within 30

days.

### ***Plant metabolism***

The Meeting received plant metabolism studies for mandestrobin under greenhouse conditions (topical and soil applications on tomato plants and foliar spray applications on lettuce and wheat), under outdoor conditions (foliar application on oilseed rape), and on seed treatments of maize grains and soya bean seeds.

In all plant metabolism studies the R/S ratio of mandestrobin remained approximately 1:1.

Where two values are separated by “/”, they account for the phenoxy [Ph-<sup>14</sup>C]- and benzyl [Bz-<sup>14</sup>C] labelled mandestrobin, respectively.

### ***Plant metabolism after greenhouse applications***

The metabolic fate of [Ph-<sup>14</sup>C]-mandestrobin or [Bz-<sup>14</sup>C]-mandestrobin was also studied in greenhouse grown tomato plants following 3 topical applications, using syringes, to fruits or leaves at a rate approximating 0.3 kg ai/ha each, with a 10-day interval. Plants were harvested 3 days after the last treatment. Total radioactive residues in fruit and leaves were 7.4–14 mg eq/kg and 87–199 mg eq/kg, respectively. Fruit and leaves were surface rinsed with acetonitrile and extracted with acetone/water. No residues were detected in the untreated leaves and fruits indicating no translocation from the treated fruits or leaves to the other parts of the plants. The majority of the radioactivity (95–99%) of the total radioactive residue (TRR) remained on the fruit or leaf surface, suggesting mandestrobin is not systemic. The major compound was identified as parent: 99–100% TRR in fruits and 98–99% TRR in leaves.

The metabolic fate of [Ph-<sup>14</sup>C]-mandestrobin or [Bz-<sup>14</sup>C]-mandestrobin was studied in greenhouse grown tomato plants following a single soil application at a rate of 0.9 kg ai/ha at fruit developing stage. Plants and soil were collected at 24 days after treatment. Insignificant translocation from soil to plant was observed: 0.06–0.08% of the total applied radioactivity (TAR) was found in leaves and none in fruits.

The metabolism of [Ph-<sup>14</sup>C]-mandestrobin or [Bz-<sup>14</sup>C]-mandestrobin was studied in greenhouse grown lettuce following two foliar applications each at 0.82 kg ai/ha with a 10-day interval. Lettuce was treated at BBCH 43 and BBCH 48. Samples of immature and mature lettuce were taken 5 days after each treatment, respectively. Total radioactive residues in immature and mature lettuce were 35 and 43 mg eq/kg for the phenoxy label and 28 and 42 mg eq/kg for the benzyl label, respectively. A high proportion of the residue was removed by acetonitrile surface wash (78–88% TRR) and the total amount extracted with acetone/water, including the acetonitrile surface wash, was > 98% TRR. The principal component of the residue in the immature and mature lettuce plant was the parent compound (89–94% TRR).

The metabolism of [Ph-<sup>14</sup>C]-mandestrobin or [Bz-<sup>14</sup>C]-mandestrobin was studied in greenhouse grown wheat following a single foliar spray application at 0.31 or 0.30 kg ai/ha, respectively. Wheat was treated at BBCH 32. Samples of wheat forage and wheat hay (each BBCH 37) were taken 7 and 14 days after treatment, respectively. Grain and straw samples were collected at maturity at 104 days after treatment. Total radioactive residues in wheat forage, hay, straw and grain were 11/10 mg eq/kg, 6.2/9.0 mg eq/kg, 1.9/2.5 mg eq/kg and 0.012/0.089 mg eq/kg, respectively.

Acetonitrile surface wash removed a total of 41/34% TRR in wheat forage, 23/19% TRR in wheat hay, and 3.7/2.8% TRR in wheat straw samples, harvested at 7, 14 and 104 days after treatment, respectively. A total of 91/92, 84/90, 45/49 and 54/53% TRR could be extracted from wheat forage, hay, straw and grain with acetone/water (including the surface wash), respectively. The remaining residues from hay and straw could be released with enzymes, acid and base until less than 2% TRR remained as solids.

In wheat grains a total of 64% TRR was identified for the benzyl label only. Parent mandestrobin was not detected and De-Xy-mandestrobin was the major component with 61% TRR

(0.054 mg eq/kg). None of the  $^{14}\text{C}$ -phenoxy labelled material could be identified, noting the low total residues.

A total of 71/81% TRR was identified in wheat forage, 59/51% TRR in wheat hay, and 18/30% TRR in wheat straw. Parent was the major component in wheat forage (51/60% TRR or 5.7–6.2 mg eq/kg) and hay (26/23% TRR or 1.6/2.1 mg eq/kg). In wheat straw, parent mandestrobin accounted only for 1.4/2.0% TRR (0.026/0.050 mg eq/kg). The residue in wheat straw consisted of several low level components with De-Xy-mandestrobin (up to 12% TRR) being the major component. De-Xy-mandestrobin accounted for 3.2% TRR in wheat forage and 1.5% TRR in wheat hay. Free and malonylglucoside conjugated 4-OH-mandestrobin was detected in wheat straw, forage and hay with levels ranging from 1.2/1.5% TRR in straw to 13/5.5% TRR in hay. Free and malonylglucoside conjugated 2- $\text{CH}_2\text{OH}$ -mandestrobin accounted for 11/5.5% TRR in wheat forage, 11/13% TRR in hay and 9.5/6.4% TRR in straw. Other identified and unidentified metabolites accounted for less than 10% TRR (< 0.83 mg eq/kg).

#### *Plant metabolism after outdoor applications*

The metabolism of [ $\text{Ph-}^{14}\text{C}$ ]-mandestrobin or [ $\text{Bz-}^{14}\text{C}$ ]-mandestrobin was studied in field grown oilseed rape following either one application at 0.39 kg ai/ha at BBCH 55–61 or following two foliar spray applications of 0.39–0.38 kg ai/ha each, applied at BBCH 55–61 (pre-bloom) and BBCH 66–67 (full bloom), with an interval of 14 days. Rape seed samples were harvested at maturity (BBCH 89) at 54 days after the single treatment or at 40 days after the double treatment. Green rape fodder samples (BBCH > 60) were collected 14 days after the double treatment only. Total radioactive residues were 3.4–4.0 mg eq/kg in green rape fodder, 0.47–0.64 mg eq/kg in rape seed at DAT 40 (double treatment) and 0.050–0.11 mg eq/kg in rape seed at DAT 54 (single treatment).

In rape seeds (DAT 40) after two applications, hexane combined with acetone/water extracted 78/92% TRR, while 58/46% TRR was identified. Parent was the major compound with 31/25% TRR (0.14/0.16 mg eq/kg). The major metabolite was malonylglucoside conjugated 4-OH-mandestrobin, which was found at 14/11% TRR (0.068–0.071 mg eq/kg). Other identified and unidentified metabolites were below 10% TRR.

In rape seed (DAT 54) after one application, hexane combined with acetone/water extracted 72/79% TRR, while only 20/0% TRR was identified. None of the components were found at levels above 10% TRR. Parent was not detected. Malonylglucoside conjugated 4-OH-mandestrobin (8.0% TRR), malonylglucoside conjugated 2- $\text{CH}_2\text{OH}$ -mandestrobin (3.6% TRR) and free 5-COOH-mandestrobin (8.7% TRR) were the major components identified in the phenoxy label only. None of the residues in the  $^{14}\text{C}$ -benzyl label experiment were identified.

In green rape fodder (DAT 14) after two applications, acetone/water extracted 87/89% TRR (including 34–37% TRR that was removed with an acetonitrile surface wash). A total of 73/65% TRR was identified. The principal component of the residue was the malonylglucoside conjugated form of 4-OH-mandestrobin (36/27% TRR), followed by parent (20/22% TRR) and the free and malonylglucoside conjugated form of 2- $\text{CH}_2\text{OH}$ -mandestrobin (12/13% TRR). Other identified and unidentified metabolites were below 10% TRR.

The Meeting noted that the two studies on rape seeds had different metabolic profiles. The single application and the first of the two applications were conducted before flowering, i.e. prior to seed formation. Since the GAP indicates that application should be conducted at flowering (BBCH 62–65), the study where the second application was conducted at BBCH 66–67 is considered more relevant for the definition of the residue.

#### *Metabolism after seed treatment*

The metabolic fate of [ $\text{Ph-}^{14}\text{C}$ ]-mandestrobin or [ $\text{Bz-}^{14}\text{C}$ ]-mandestrobin was studied in maize grains and soya bean seeds following seed treatment at 9.3–12 g ai/100 kg of seeds. Seeds were planted 6 days after treatment. Harvest occurred at appropriate growth stages. The soya bean food RACs and the maize food and feed RACs did not take up mandestrobin related residues to any significant extent

(< 0.005 mg eq/kg). Significant residues were found only in maize fodder (< 0.005–0.008 mg eq/kg; benzyl label only), soya bean forage (0.038–0.061 mg eq/kg) and soya bean hay (0.030–0.050 mg eq/kg).

Extraction with acetonitrile and acetonitrile/water released a total of 71% TRR from maize fodder (benzyl label only), 87/89% TRR from soya bean forage and 48/53% TRR from soya bean hay, while only 8.2, 29/7.6, 3.7/3.4% TRR was identified, respectively. The major compound identified in soya bean forage was De-Xy-mandestrobin at 5.3–12% TRR (0.005 mg eq/kg). Identified components in maize fodder and soya bean hay were all below 10% TRR. Mandestrobin was found at 1.2–1.9% TRR (soya bean hay), 2.3–7.9% TRR (soya bean forage) and 2.8% TRR (maize fodder), but never exceeded 0.003 mg eq/kg. HPLC profiles showed two major unidentified fractions which accounted for 14–29% TRR (0.001–0.022 mg eq/kg) and 9.6–22% TRR (0.002–0.016 mg eq/kg).

### *Metabolism in confined rotational crops*

In a confined rotational crop study, [Ph-<sup>14</sup>C]-mandestrobin or [Bz-<sup>14</sup>C]-mandestrobin was applied to bare soil at a single rate of 1.6 kg ai/ha. Rotational crops (lettuce, carrots and wheat) were planted at intervals (PBI) of 30, 120 and 365 days after application. Wheat forage, hay, straw and grain, lettuce, carrot roots and leaves were harvested at appropriate growth stages. Significant residues (0.019–4.5 mg eq/kg) were found in all crop commodities at all plant back intervals, except in wheat grains and carrot roots at PBI 365 where total radioactivity did not exceed 0.01 mg eq/kg. Total radioactivity of residues in rotational crops generally declined from PBI 30 to PBI 120 and PBI 365.

Acetone/water extracted 77–87% TRR from carrot roots, 59–92% TRR from lettuce, carrot leaves and wheat forage, 45–62% TRR from wheat hay, and 34–64% TRR from wheat straw. Residues from wheat grain could not be extracted to a significant extent, with only 5.2–5.8% TRR for the phenoxy label and 31–37% TRR for the benzyl label. Only 47–65% TRR (carrot roots, benzyl label, but was higher for the phenyl-label), 6.9–53% TRR (wheat forage), 16–71% TRR (lettuce), 5.4–26% TRR (carrot leaves), 9.3–45% TRR (wheat hay), and 14–33% TRR (wheat straw) was identified.

Parent was present at low concentrations in all crop commodities, with a maximum of 78% TRR (0.040 mg eq/kg) in carrot roots at PBI 30 days or 1.8% TRR (0.045 mg eq/kg) in wheat forage at PBI 30 days. Major metabolites found in free and malonylglucoside or glucoside conjugated form were 4-OH-mandestrobin (at 2.7–34% TRR in all samples, except carrot roots), 5-CH<sub>2</sub>OH-mandestrobin (1.7–32% TRR in all samples, except wheat grain) and to a minor extent 2-CH<sub>2</sub>OH-mandestrobin (0–16% TRR in all samples, except wheat grain). Metabolite De-Xy-mandestrobin was not observed in the confined rotational crop study. Other identified and unidentified metabolites were below 10% TRR.

### *Summary and conclusion of metabolism in primary and rotational crops*

Mandestrobin remains at the treated surface of the plant with very little translocation, absorption and degradation during the first 5 days after treatment under greenhouse conditions as was shown for tomato and lettuce (> 80% TRR in surface wash). With increasing time, parent compound is absorbed and metabolized as was shown by the decreasing amounts of residues found in the surface washes of field grown green rape fodder (34–37% TRR at DALT 14) and greenhouse grown wheat forage (34–41% TRR at DAT 14) and wheat straw (2.8–3.7% TRR at DAT 104).

In lettuce and tomato the TRR consisted nearly completely of unchanged parent (98–100% TRR). Parent (23–60% TRR) was also the major compound in wheat forage, wheat hay, and green rape fodder after foliar treatment, but not in wheat straw and wheat grain (DAT 104). In rotational root crop commodities (carrot roots) at PBI 30 and 120 days, parent accounted for 53–78% TRR, albeit at low absolute levels (0.015–0.040 mg eq/kg). For applications with increasing PHI and/or where uptake via the soil is possible, a larger variety of metabolites occur. De-Xy-mandestrobin was the major and only identified compound in wheat grain (61% TRR) and it was also the major compound in primary wheat straw (12% TRR). Both parent and De-Xy-mandestrobin were found at low levels (< 0.005 mg eq/kg) in seed treated feed commodities (soya bean forage, maize fodder). Compounds at levels above 10% TRR were free and (malonyl)glucoside conjugated 4-OH-mandestrobin (3.4–36% TRR), 2-CH<sub>2</sub>OH-mandestrobin (3.6–14% TRR), and 5-CH<sub>2</sub>OH-mandestrobin (4.3–6.8% TRR). Major compounds in the

confined rotational crops were free and (malonyl)glucoside conjugated 4-OH-mandestrobin (1.7–24% TRR), 5-CH<sub>2</sub>OH-mandestrobin (2.9–27% TRR) and 2-CH<sub>2</sub>OH-mandestrobin (0.69–16% TRR). The identity of the residues in the wheat grain from field grown rotational crops remains unknown, with parent compound and 4-OH-mandestrobin detected at trace levels (< 0.001–0.008 mg eq/kg).

The metabolism of mandestrobin in primary and rotational crops is essentially the same, although quantitative levels of parent and metabolites differ.

The metabolic pathway of mandestrobin included monohydroxylation of the dimethylphenoxy ring to form 4-OH-mandestrobin followed by formation of the glucoside and (malonyl)glucoside conjugates. Oxidation of the methyl groups attached to the 2- and 5-positions on the dimethylphenoxy ring to form 2-CH<sub>2</sub>OH-mandestrobin, 5-CH<sub>2</sub>OH-mandestrobin and 5-COOH-mandestrobin was followed by formation of the corresponding (malonyl)glucoside conjugates. Minor metabolic pathways included the O-demethylation of the methoxy-group of the side chain. Another metabolic pathway includes cleavage of the ether linkage to form De-Xy-mandestrobin, which can only be detected with the benzyl label.

Since a photolysis study in water indicates that significant photo-degradation may occur, the Meeting discussed whether the metabolism studies using foliar treatments conducted in a greenhouse (lettuce, wheat) were representative for uses in the field. Comparison of the nature and magnitude of residues found in green rape fodder (outdoor, DALT 14 days) and in wheat hay (greenhouse, DALT, 14 days) shows no accelerated degradation by photolysis, since parent compound accounted for 20/22% TRR and 26/22% TRR, respectively for green rape fodder and wheat hay. Although no photolytic degradation products were used as reference compounds in any of the metabolism studies, all unknowns in the metabolism studies were below 10% TRR or < 0.01 mg eq/kg, indicating that photolytic degradation products may be present at trace levels only. From this, the Meeting concluded that photolysis is not a significant form of degradation. Therefore, the metabolism studies in the greenhouse can be used in support of outdoor uses.

All plant metabolites identified in the primary and rotational crop studies were found in the rat metabolism study.

### ***Animal metabolism***

The Meeting received information on the fate of orally-dosed mandestrobin in rat, lactating goats and laying hens. Where two values are given divided by “/”, they account for the [Ph-<sup>14</sup>C]- and [Bz-<sup>14</sup>C]-mandestrobin labels, respectively.

Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2018.

Lactating goats were orally dosed with [Phenoxy-<sup>14</sup>C]-mandestrobin or [Benzyl-<sup>14</sup>C]-mandestrobin, equivalent to 13–14 ppm in the feed for 7 consecutive days. Goats were sacrificed 6 hrs after the last dose. The majority of the cumulative administered dose was recovered in urine and faeces at 35–40 and 38–42% TAR, respectively. Radioactivity recovered in tissues (liver, kidney, muscle and fat) accounted for a total of 0.27–0.33% TAR. Radioactivity accounted for 0.002–0.005% TAR in milk fat and 0.024–0.073% TAR in skimmed milk. The highest recovery found in edible tissues was in liver (0.22–0.29% TAR).

Steady state conditions in milk were achieved within 1 day of the first dose administration, indicating that mandestrobin is rapidly eliminated. TRR levels in milk were 0.006 and 0.035 mg eq/kg in the aqueous and fat fraction of milk, respectively. Highest TRR levels were found in liver (0.32/0.61 mg eq/kg), followed by kidney (0.17/0.41 mg eq/kg), fats (0.012–0.031 mg eq/kg) and loin and flank muscle (0.010–0.015 mg eq/kg).

Extractability of radioactivity from milk, kidney, muscle and fat with solvents (hexane, acetonitrile and ethyl acetate) ranged from 72–100% TRR, except liver (60–70% TRR). Only liver post-extracted solids were treated with enzymes, acid and base until less than 6% TRR remained as solids.

Only 53/47 (milk fat), -/32 (skimmed milk); 31/36 (muscle), 65/37 (fat), 48/41 (liver) and 59/53 (kidney) as % TRR was identified.

Parent was the major compound identified in milk fat (33/32% TRR), goat muscle (23/18% TRR) and fat (50/23% TRR). In liver, kidney and skimmed milk lower levels of parent were found (1.6 to 7.7% TRR). A major metabolite identified in goat liver (20/11% TRR) and kidney (25/20% TRR) was free 5-COOH-mandestrobins. A second major metabolite identified in kidney was free and glucuronide conjugated 4-OH-mandestrobins (17/13% TRR). Free 2-CH<sub>2</sub>OH-mandestrobins was found in muscle up to 10% TRR (0.0015 mg eq/kg). The major compound identified in skimmed milk was 5-CA-mandestrobins-NHM at 15% TRR (0.003 mg eq/kg). Several other metabolites were identified in various goat matrices but only at levels < 10% TRR and below 0.01 mg eq/kg, apart from 2-CH<sub>2</sub>OH-mandestrobins (up to 0.038 mg eq/kg in liver) and 2-COOH-mandestrobins (up to 0.014 mg eq/kg in liver). The fat extract from the benzyl label contained one region of 38% TRR (0.011 mg eq/kg) that could not be identified, despite exhaustive efforts.

Two groups of laying hens were orally dosed once daily for 14 consecutive days via capsules equivalent to 13 ppm in the feed. Hens were sacrificed 6–7 hours after dosing. The majority of the administered dose was recovered in excreta (83/98% TAR). A minor part of the total radioactivity was recovered in eggs (0.21/0.18% TAR) and tissues (0.070/0.090% TAR). The highest residue concentration in tissues was found in the liver (0.29/0.30 mg eq/kg) followed by skin (0.048/0.054 mg eq/kg), fat (0.032/0.032 mg eq/kg) and muscle (0.014/0.024 mg eq/kg). Total radioactive residues in whole eggs achieved a plateau concentration of 0.11 mg eq/kg [Ph-<sup>14</sup>C]-label after 11 days of dosing. Total radioactive residues in egg whites and egg yolk were not determined separately.

The residue after solvent extraction (hexane, ethyl acetate and acetonitrile) accounted for 86–96% TRR in fat, eggs and skin. In liver and muscle the extracted residue accounted for 63–66% TRR and 52–59% TRR, respectively. An additional 28–32% TRR was released from liver by sequential extraction with water, 1 M HCl, 1 M NH<sub>3</sub> and protease digestion. Only 19–23% (liver), 5.0–5.9% TRR (muscle), 42–59% TRR (eggs, fat) and 10–33% TRR (skin) was identified.

In eggs and hen fat, the main component of the radioactive residue was free parent, accounting for 51/33% TRR (0.058/0.025 mg eq/kg) and 50/34% TRR (0.016/0.011 mg eq/kg), respectively. All metabolites identified in egg and fat were present at levels < 0.01 mg eq/kg. In muscle and skin, parent mandestrobins and identified metabolites were found at trace levels (< 0.001 mg eq/kg).

In hen liver, parent mandestrobins accounted for 3.0/2.1% TRR (equivalent to 0.009/0.006 mg eq/kg). The main components in liver were free (8.6% TRR) and conjugated (3.6% TRR) De-Xy-mandestrobins (total of 12% TRR, equivalent to 0.036 mg eq/kg) with the [<sup>14</sup>C-Bz]-label only and free (13% TRR/-) and conjugated (2.0/2.7% TRR) 4-OH-mandestrobins (total 15/2.7% TRR, equivalent to 0.045/< 0.001 mg eq/kg). Other metabolites were present at trace levels (< 0.01 mg eq/kg).

### *Summary and conclusion of metabolism in livestock*

Parent was the major compound identified in milk fat, goat muscle and goat and poultry fat and eggs (18–51% TRR). In poultry muscle and skin, goat and poultry liver, goat kidney and skimmed milk lower levels of parent were found (1.3–7.7% TRR). Free 5-COOH-mandestrobins was identified as major metabolite in goat liver and kidney (11–25% TRR). A second major metabolite identified in kidney was free and glucuronide conjugated 4-OH-mandestrobins (13–17% TRR). Free 2-CH<sub>2</sub>OH-mandestrobins was found in muscle up to 10% TRR. The major compound identified in skimmed milk was 5-CA-mandestrobins-NHM (15% TRR). Several other metabolites were identified in various goat matrices at levels < 10% TRR and mostly below 0.01 mg eq/kg, apart from 2-CH<sub>2</sub>OH-mandestrobins (up to 0.038 mg eq/kg in liver) and 2-COOH-mandestrobins (up to 0.014 mg eq/kg in liver).

In summary, the primary metabolic process observed in lactating goats and laying hens included a series of hydroxylations and oxidations, N-demethylation, O-demethylation, ether hydrolysis and (glucuronide) conjugation. Hydroxylation of the phenoxy ring gives 4-OH-mandestrobins, and

hydroxylation of the methyl groups on the phenoxy ring gives 2-CH<sub>2</sub>OH-mandestrobin and 5-CH<sub>2</sub>OH-mandestrobin. Further oxidation of the hydroxymethyl groups to the carboxylic acid gives 2-COOH-mandestrobin, 5-COOH-mandestrobin and 5-CA-2-HM-mandestrobin. Hydroxylation also occurs on the N-methyl group, to give 5-CA-mandestrobin-NHM and 5-CA-2-HM-mandestrobin-NHM. Mandestrobin is also subject to hydrolysis of the phenoxy ether link, yielding De-Xy-mandestrobin, N-demethylation of 5-COOH-mandestrobin, and O-demethylation. The primary metabolites are further metabolized by conjugation.

The metabolic profile of mandestrobin in ruminants and poultry is very similar to that of rats.

### **Environmental fate**

The Meeting received information on hydrolysis and aqueous photolysis, aerobic degradation in soil under laboratory conditions, soil field dissipation and on field rotational crops.

Mandestrobin was shown to be stable to hydrolysis at pH 4–9. No change in ratio between the R- and S-isomers was observed. Hydrolysis is not a significant route of degradation.

Mandestrobin was extensively degraded under simulated sunlight in pH 7 water. The DT<sub>50</sub> values ranged from 3 to 5 days. Major degradation products identified were mandestrobin-OR at 22–24% TAR, mandestrobin-ORC at 16–18% TAR and mandestrobin-PR at 9.3–9.6% TAR. Mandestrobin-OR and mandestrobin-PR degrade quickly with DT<sub>50</sub> values of 5.1 and 2.5 days, respectively. Photolysis forms a significant route of degradation in water.

With DT<sub>50</sub> values ranging from 49–64 days photolysis is not considered to be a significant route of degradation on the soil surface.

DT<sub>50</sub> values for mandestrobin in aerobic soil (n = 10) under laboratory conditions ranged from 49–378 days, with a geometric mean DT<sub>50</sub> of 151 days, indicating possible accumulation in soil. No isomerisation between the R- and S-isomer of mandestrobin under aerobic soil conditions was observed. Major degradation products identified were 5-COOH mandestrobin at 3.5–20% TAR, 2-COOH-mandestrobin at 1.6–8.6% TAR, 5-CONH<sub>2</sub>-mandestrobin at 1.0–14% TAR and 2-CONH<sub>2</sub>-mandestrobin at 0.4–14% TAR. Degradation products 5-COOH-mandestrobin and 2-COOH-mandestrobin degraded rapidly with DT<sub>50</sub> values of 22–41 days and 18–26 days.

DT<sub>50</sub> values for mandestrobin in soil (n = 9) from field dissipation studies ranged from 2.3–165 days, with the high value indicating possible accumulation of mandestrobin in soil and the need to consider a plateau value for evaluating residues in rotational crops.

The maximum seasonal rate of 0.42 kg ai/ha is based on a cGAP for rape seed for application at flowering (BBCH 62–65). Although the crop may intercept the full application at this stage, rape fodder is not fed to livestock at BBCH > 60 and will be ploughed into the soil after harvest of the seeds. Therefore the full application may end up in the soil and the crop interception factor is 1.

Based on the highest DT<sub>50</sub> of 165 days in the field dissipation studies and using the formulas presented in OECD guidance (2018)<sup>11</sup>, the soil accumulation factor is 0.275, leading to a plateau value of 0.12 kg ai/ha (0.275 x 0.42 kg ai/ha). The subsequent corrected maximum seasonal rate of 0.54 kg ai/ha (0.42 kg ai/ha + 0.12 kg ai/ha) can be used for assessing potential residues in rotational crops.

### **Field rotational crop studies**

The Meeting received two field rotational crop studies. One study was conducted in France and Spain where mandestrobin was applied at a single rate of 0.21 kg ai/ha to the preceding crop oilseed rape at BBCH 65 (full bloom). Oilseed rape was crushed and incorporated into the soil 14 days after application. Follow-up crops lettuce, carrot, broccoli, and barley were planted at PBIs of 14, 120 and 365 days.

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<sup>11</sup> GUIDANCE DOCUMENT ON RESIDUES IN ROTATIONAL CROPS, OECD Environment, Health and Safety Publications, Series on Pesticides No. 97, Series on Testing & Assessment No. 279, ENV/JM/MONO(2018)9



The second study was conducted in 2011–2012 in Fresno, CA, USA. Plots with primary crop leaf lettuce were treated with four foliar applications at BBCH 15, 17, 19 (i.e. 5, 7, 9 or more true leaves unfolded) and 49 (typical size, form and firmness) of mandestrobin at a rate of 0.42 kg ai/ha (each, with an interval of 7 days) and a total seasonal rate of 1.7 kg ai/ha. The leaf lettuce was removed one day after the last application. Follow-up crops spinach, red beets, wheat or sorghum were planted at PBIs of 101, 253 and 356 days.

Succeeding crops were harvested at their appropriate growth stages. No residues (< 0.01 mg/kg in EU trials; < 0.02 mg/kg in USA trials) of parent or metabolites De-Xy-mandestrobin and free and (malonyl)glucoside conjugated 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin, and 5-CH<sub>2</sub>OH-mandestrobin were found in any succeeding crop samples at any plant back interval.

The Meeting noted that in the first field rotational crop study the application rate (0.21 kg ai/ha) was below the corrected maximum seasonal rate of 0.54 kg ai/ha and that application was on primary crop instead of bare soil. In the second field rotational crop study the application rate (4 × 0.42 kg ai/ha = 1.7 kg ai/ha) is higher than the corrected maximum seasonal rate of 0.54 kg ai/ha. However, the product was not applied to bare soil and the treated lettuce was removed from the plot 1 day after the last application. Though mandestrobin was not applied to bare soil, the Meeting concluded that the crop coverage at the first three applications would together have allowed for a total dose rate approximating 0.54 kg ai/ha of reaching the bare soil and concluded that residues in rotational crops are unlikely.

### **Methods of Analysis**

The Meeting received description and validation data for analytical methods of plant and animal commodities for the determination of mandestrobin, De-Xy-mandestrobin and free and (malonyl)glucoside conjugated 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin and 5-CH<sub>2</sub>OH-mandestrobin metabolites.

Multi-residue enforcement methods were available for plant commodities. Multi-residue method QuEChERS with HPLC-MS/MS detection was valid for the determination of mandestrobin in crops with high acid content (oranges, grapes), high water content (peaches), high oil content (soya bean seeds) and high starch content (wheat grains). Multi-residue method DFG-S19 with GC-MS detection was valid for the determination of mandestrobin in crops with high oil content (rape seeds). The limit of quantification (LOQ) was 0.01 mg/kg for each method. When the DFG-S19 method was combined with chiral HPLC-MS/MS detection, the R- and S-isomers of mandestrobin could be determined individually with an LOQ of 0.005 mg/kg for each isomer (lettuce, carrot roots and leaves, broccoli, green rape seed fodder, rape seed, barley grain and straw).

The analytical method for enforcement of animal commodities used acetone/water (7:3, v/v) for extraction. After clean-up, mandestrobin and De-Xy-mandestrobin were determined by HPLC-MS/MS with an LOQ of 0.01 mg/kg for each analyte. The method was successfully validated for free forms of mandestrobin and De-Xy-mandestrobin in liver, eggs and cream. Validation for muscle, fat and whole milk is desirable. The Meeting noted that for quantitative extraction of the residues from liver samples further treatment with 1 M HCl and protease is needed to liberate parent and De-Xy-mandestrobin.

Analytical methods used in the study reports used acetone/water (4:1, or 7:3, v/v) for extraction of residues from various plant commodities. The extracts were treated sequentially with 0.06–0.1 M NaOH (1–2 hours at room temperature) and beta-glucosidase (3 hours at 37 °C) to release the aglycons of (malonyl)glucoside conjugated 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin and 5-CH<sub>2</sub>OH-mandestrobin metabolites. After clean-up residues were determined by HPLC-MS/MS. For all methods, final quantification is achieved using HPLC-MS/MS, with an LOQ of 0.01–0.02 mg/kg for each analyte.

Radiovalidation with <sup>14</sup>C labelled green rape seed fodder and rape seed from a metabolism study indicated that the extraction efficiency for acetone/water 4:1 and 7:3 is sufficient. Efficient hydrolysis of the (malonyl)glucoside conjugated hydroxylated mandestrobin metabolites could be demonstrated in green rape seed fodder but not in rape seed.

All methods for plant commodities were successfully validated for mandestrobin, De-Xy-mandestrobin and free 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin and 5-CH<sub>2</sub>OH-mandestrobin metabolites, demonstrating good reproducibility in the concentration range up to 0.2 mg/kg per analyte. Considering the single validation results in the different high acid matrices as a whole (n > 5), would lead to acceptable validation of the levels expected in the residue trials (up to 3.6 mg/kg in grapes).

Analytical methods used in the study reports on animal commodities used acetonitrile and hexane for extraction of mandestrobin. After clean-up, mandestrobin was determined by HPLC-MS/MS with an LOQ of 0.02 mg/kg. The method was successfully validated for the free forms of mandestrobin in liver, kidney, muscle, fat and milk. The Meeting noted that for quantitative extraction of residues from liver samples further treatment with 1 M HCl and protease is needed to liberate parent.

### ***Stability of pesticide residues in stored analytical samples***

The Meeting received storage stability studies in plant and animal commodities. No change in the ratio between R- and S-isomers was detected during storage.

The R- and S-isomers of mandestrobin and metabolite De-Xy-mandestrobin are stable for at least 12 months in crop commodities representative of high water (lettuce), high acid (orange, strawberry, grape, grape juice), high starch (barley grain), high protein (dry bean seed) commodity groups as well as in barley straw and at least 39 months in commodities with high oil content (rape seed) when stored at or below -18 °C. Storage stability studies with incurred residues suggest that storage stability for mandestrobin and De-Xy-mandestrobin can be extended to 538 days for grapes and grape juice, 385 days for grape raisins and 571 days for strawberries.

Metabolites 4-OH-mandestrobin and 2-CH<sub>2</sub>OH-mandestrobin are stable for at least 26 months in crop commodities representative of high acid content (orange) and at least 12 months in crop commodities representative of high water (lettuce), high starch (barley grain), high protein (dry bean seed), high oil (rape seed) commodity groups as well as in barley straw when stored frozen at or below -18 °C.

Metabolite 5-CH<sub>2</sub>OH-mandestrobin is stable for at least 12 months in crop commodities representative of the high water (lettuce) and high protein (dry bean seed) commodity groups as well as in barley straw when stored at or below -18 °C.

Mandestrobin (racemic mixture) is stable for at least 62 days in milk, 78 days in fat and 93 days in liver, kidney and muscle.

### ***Definition of the residue***

#### ***Residue definitions for plant commodities***

Parent was the major compound (20–100% TRR) in the majority of crop commodities (tomatoes, lettuce, rape seed, green rape seed fodder, wheat forage, wheat hay). Parent was not detected or only at very low concentrations in wheat grain and wheat straw (DAT 104). De-Xy-mandestrobin was the major compound (12–61% TRR) in wheat grain and wheat straw. Both parent and De-Xy-mandestrobin were found at low levels in feed commodities grown from treated seed (soya bean forage, maize fodder).

No residues are expected in rotational crops and mandestrobin is stable under the processing conditions representing pasteurisation, cooking and sterilisation.

Supervised field trials on fruits (grapes, strawberries), oilseeds (rape seeds) and feed (green rape seed fodder, soya bean forage and fodder) show that parent compound is the major compound found. Residues at or below the LOQ were found in pulses (dry soya bean seeds). GAPs and trials on cereals were not submitted.

Suitable analytical methods for enforcement are available for mandestrobin.

The Meeting concluded that mandestrobin can be considered a suitable marker compound for enforcement purposes and decided to define the residue for enforcement/monitoring as mandestrobin.

If uses are extended to include uses on cereals the residue definition for plant commodities may need to be revisited.

Besides parent, several compounds observed in the metabolism studies were considered for dietary risk assessment. These compounds include De-Xy-mandestrobin and free and malonylglucoside conjugated 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin and 5-CH<sub>2</sub>OH-mandestrobin. These metabolites were not observed in supervised field trials on dry soya bean seeds and rape seeds and they were incidentally found at low levels up to 0.02–0.05 mg/kg in supervised field trials on grapes and strawberries at cGAP rates, but below 4% of parent. In the metabolism study on lettuce these metabolites were found at absolute levels between 0.10–1.2 mg eq/kg, but the sum of metabolites was below 6.3% of parent. The metabolites were only found at significant levels (> 10% parent) in metabolism studies and supervised trials on feed items (such as forage/fodder crops of pulses, oilseeds and cereals).

Both the free and conjugated forms of metabolite 4-OH-mandestrobin are found in rat (free form < 1% of the applied dose; conjugated form > 30% of the applied dose in bile). Limited toxicity studies were available. Based on these studies and the high levels in bile, the (acute and long term) toxicity of the free and conjugated 4-OH-mandestrobin metabolite is considered to be covered by the parent compound. Furthermore, field residue trial data show that exposure from plant commodities is very low relative to parent compound, either <LOQ or approximating 1% of parent mandestrobin, with the exception of 1 trial.

Metabolite De-Xy-mandestrobin and the free form of metabolites 2-CH<sub>2</sub>OH-mandestrobin and 5-CH<sub>2</sub>OH-mandestrobin were found in rat (< 1% of the applied dose). Limited toxicity studies were available leading to the conclusion that the acute toxicity of De-Xy-mandestrobin, free and conjugated 2-CH<sub>2</sub>OH-mandestrobin is considered to be similar to that of the parent compound. No experimental data were available for 5-CH<sub>2</sub>OH-mandestrobin. Quantitative structure-activity relationship (QSAR) analysis indicates that the metabolite is of similar toxicity to parent. Furthermore, the similarity with the chemical structure of 2-CH<sub>2</sub>OH-mandestrobin allows for a read-across approach, also concluding its similarity with parent mandestrobin. Residue trial data show that exposure to these metabolites through the current uses is low relative to parent compound (< 5%).

For long-term toxicity, the TTC approach could be applied for those three metabolites using Cramer Class III.

The estimated long-term exposure based on uses on fruits, fruiting vegetables, pulses and oilseeds and using maximum values found in the supervised residue trials resulted in the following maximum long-term dietary exposures:

De-Xy-mandestrobin	0.58 µg/kg bw per day;
2-CH <sub>2</sub> OH-mandestrobin (including conjugates)	0.29 µg/kg bw per day;
5-CH <sub>2</sub> OH-mandestrobin (including conjugates)	0.43 µg/kg bw per day.

The Meeting noted that all estimated exposures are below the threshold of toxicological concern for Cramer Class III compounds (1.5 µg/kg bw per day for long-term risk assessment).

The Meeting concluded that De-Xy-mandestrobin and the hydroxy-mandestrobin compounds and their conjugates would not contribute significantly to the dietary exposure of mandestrobin and decided to define the residue for dietary risk assessment for plant commodities as mandestrobin.

The Meeting noted that the current uses do not lead to livestock exposure. For future uses, De-Xy-mandestrobin, 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin (including conjugates) and 5-CH<sub>2</sub>OH-mandestrobin (including conjugates) should be reconsidered, as these compounds may contribute significantly to the dietary burden and may contribute to residues of concern in animal commodities.

#### *Residue definitions for commodities of animal origin*

In animal metabolism studies parent was identified in all animal commodities, albeit at low levels in goat liver, kidney of goat and hen, hen muscle and skin (1.3–7.7% TRR). The Meeting concluded that

mandestrobin parent (free) is therefore a suitable marker compound for enforcement. A suitable analytical method for determining free forms of mandestrobin is available.

The Meeting decided to define the residue for enforcement/monitoring in animal commodities as mandestrobin.

The log  $K_{ow}$  for mandestrobin is 3.4–3.5. The goat and hen metabolism studies showed a clear tendency of the parent compound to partition into the fat tissues, with a ratio of approximately 40:1 observed in hen fat and muscle and a ratio between fat and aqueous fraction in milk of 15:1. The effect was less pronounced in goat fat and muscle, but also showed a tendency to concentrate in the fat fraction. The Meeting concluded that the residue is fat-soluble.

Besides parent, several compounds observed in the metabolism studies were considered for dietary risk assessment. These compounds include De-Xy-mandestrobin, 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin, 2-COOH-mandestrobin, 5-COOH-mandestrobin, 5-CA-2-HM-mandestrobin-NHM and 5-CA-mandestrobin-NHM.

Metabolite 5-CA-mandestrobin-NHM was found to be a major metabolite (15% TRR) in skimmed milk only, but found in absolute levels below 0.01 mg eq/kg. Metabolite 5-CA-2-HM-mandestrobin-NHM was found at low levels in liver and kidney (0.88–5.2% TRR), generally < 0.01 mg eq/kg, but up to 0.021 mg eq/kg in one kidney sample (one label). The mean contribution of this compound to the toxicologically significant residue is less than 10%. Both metabolites were therefore excluded from the residue definition for dietary risk assessment.

Other metabolites, De-Xy-mandestrobin, 4-OH-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin, 2-COOH-mandestrobin, 5-COOH-mandestrobin, and their conjugates, were found at levels above 0.01 mg eq/kg in liver and/or kidney and they were found at levels that were higher than the parent compound. Their contribution relative to parent compound amounted to 105–571% for De-Xy-mandestrobin, 11–812% for 4-OH-mandestrobin, 32–252% for 2-CH<sub>2</sub>OH-mandestrobin, 80–221% for 2-COOH-mandestrobin and 143–1250% for 5-COOH-mandestrobin.

The acute and long-term toxicity of 4-OH-mandestrobin and its conjugates is covered by the parent. The metabolite should be included in the definition for dietary risk assessment.

Metabolites De-Xy-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin, 2-COOH-mandestrobin, and 5-COOH-mandestrobin are found in rat ( $\leq$  1.3% of the applied dose). Limited toxicity studies were available leading to the conclusion that the acute toxicity of metabolites De-Xy-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin, 2-COOH-mandestrobin and 5-COOH-mandestrobin is considered to be similar to that of the parent compound and should be included in the residue definition for acute dietary risk assessment.

The Meeting decided to define the residue for **acute** dietary risk assessment in animal commodities as: the sum of parent and 4-OH-mandestrobin, De-Xy-mandestrobin, 2-CH<sub>2</sub>OH-mandestrobin, 2-COOH-mandestrobin, and 5-COOH-mandestrobin and their conjugates, expressed as parent compound.

The toxicological data were insufficient to conclude on the long-term toxicity for these compounds. For long-term dietary risk assessment, the TTC approach could be applied using Cramer Class III. Since there is no exposure to livestock based on the current uses, long-term exposure is 0  $\mu$ g/kg bw per day, and thus below the threshold of toxicological concern for Cramer Class III compounds (1.5  $\mu$ g/kg bw per day for long-term risk assessment).

The Meeting decided to define the residue for **long-term** dietary risk assessment in animal commodities as: the sum of parent and 4-OH-mandestrobin and its conjugates, expressed as parent compound.

The Meeting calculated conversion factors based on the results of the animal metabolism studies to be used to convert parent to the residue definitions for dietary risk assessment.

Table 2 Conversion factors for dietary risk assessment for animal commodities

	Acute dietary risk assessment	Long term dietary risk assessment
Milk fat	1.3	1.1
Skimmed milk	2.8	1.5
Mammalian muscle	1.7	-
Mammalian fat	1.3	-
Mammalian liver	8.1	1.2
Mammalian kidney	26	9.1
Poultry liver	7.5	4.1
Poultry muscle	3.3	2.9
Poultry fat	1.3	1.1
Poultry skin	6.5	3.6
Eggs	1.1	1.1

### *In summary*

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

The Meeting may revisit the residue definition with uses on cereals.

Definition of the residue for acute dietary risk assessment in animal commodities: *sum of parent, De-XY-mandestrobin, 4-OH-mandestrobin, 2-CH<sub>2</sub>-OH-mandestrobin, 2-COOH-mandestrobin, and 5-COOH-mandestrobin and their conjugates, expressed as parent compound.*

Definition of the residue for long-term dietary risk assessment in animal commodities: *sum of parent and 4-OH-mandestrobin and its conjugates, expressed as parent compound.*

The Meeting considers the residue *fat-soluble*.

### **Results of supervised residue trials on crops**

The Meeting received supervised trials data for the foliar application of mandestrobin on grapes, strawberry and rape seed. Residue trial data were made available from Canada, Europe and the USA. Labels were available from Canada and the USA describing the registered uses of mandestrobin.

#### **Grapes**

The critical GAP for mandestrobin on grapes in Canada and the USA is a foliar application at a rate of  $3 \times 0.42$  kg ai/ha with an interval of 10 days and a PHI of 10 days.

In the trials on grapes in Canada and the USA matching the US GAP an adjuvant was used. Residue levels in grapes (parent) in ranked order were (n = 11): 0.74, 0.79, 1.0, 1.0, 1.3, 1.4, 1.4, 1.9, 2.0, 2.4 and 3.5 mg/kg (highest individual value: 3.7 mg/kg).

The Meeting estimated a maximum residue level 5 mg/kg, an STMR of 1.4 mg/kg and an HR of 3.7 mg/kg for mandestrobin on grapes.

#### **Strawberry**

The critical GAP for mandestrobin on strawberries in Canada and the USA is a foliar application at a rate of  $4 \times 0.42$  kg ai/ha with an interval of 7 days and a PHI of 0 days.

In the trials from Canada and the USA matching the US GAP, an adjuvant was used. Residue levels in strawberries (parent) in ranked order were (n = 8): 0.45, 0.48, 0.70, 0.82, 0.92, 1.2, 1.2 and 2.0 mg/kg (highest individual value: 2.2 mg/kg).

Based on the Canadian and US trials for strawberries, the Meeting estimated a maximum residue level of 3 mg/kg, an STMR of 0.87 mg/kg and an HR of 2.2 mg/kg for mandestrobin on strawberries.

**Rape seed**

The critical GAP for mandestrobin on rape seed in Canada and the USA is a single foliar application at a rate of 0.42 kg ai/ha with an instruction for growth stage (20–50% bloom, BBCH 62–65) and PHI (35 days). The Meeting decided that trial data reflecting application at growth stage up to BBCH 69 with a PHI of 35 days are suitable for maximum residue level and STMR estimation.

Trials performed on rape seed from Canada and the USA matching the US GAP were selected based on BBCH 61–69 and a PHI of 35 days (-25%). Residue levels in rape seed (parent) in ranked order were (n = 9): < 0.01, < 0.02 (5), 0.046, 0.11, and 0.13 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR of 0.02 mg/kg.

**Soya bean (dry)**

Supervised trials on dry soya bean were submitted, but no GAP was provided or intended.

**Soya bean forage and fodder**

Supervised trials on soya bean forage and fodder were submitted, but no GAP was provided or intended.

**Rape seed fodder**

Supervised trials on rape seed fodder were submitted. As the GAP requires application beyond BBCH 60 and rape seed fodder beyond BBCH 60 is not suitable as livestock feed, the trials were not used to derive median or highest residues.

**Fate of residues during processing****High temperature hydrolysis**

The degradation of (Ph-<sup>14</sup>C)-mandestrobin was studied under hydrolytic conditions at high temperatures (90–120 °C) in sterile aqueous buffers at pH 4, 5 and 6 to simulate common processing practice (pasteurisation, baking/brewing/boiling and sterilisation). No degradation was observed at any of the investigated pH and temperature ranges.

The Meeting concluded that mandestrobin is stable under hydrolytic conditions typically occurring during processing.

**Residues in processed commodities**

The Meeting received information on the fate of mandestrobin during processing in grapes (juice and raisins) and rape seed (refined oil and extracted meal). Considering the LogK<sub>ow</sub> of 3.4–3.5 a processing factor of 1.4 was not considered representative for juice. Noting that only one trial was available, and the Meeting decided not to calculate an STMR-P for grape juice.

Table 3. Estimated processing factors for the commodities considered at this Meeting

Raw commodity [STMR/HR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)	HR-P = HR <sub>RAC</sub> × PF (mg/kg)
STMR grapes (parent): 1.4 mg/kg, HR: 3.7 mg/kg					
Grapes	Raisins	2.0	2.0	2.8	7.4
STMR rape seed (parent): 0.02 mg/kg					
Rape seed	Refined oil <sup>a</sup>	0.06	0.06	0.0012	-
	Extracted meal	0.20 <sup>b</sup>	0.20 <sup>b</sup>	0.004 <sup>b</sup>	-

<sup>a</sup> Refined, bleached, deodorized

<sup>b</sup> Based on parent. Though, according to metabolism studies metabolites could be expected in rape, no metabolites were

observed in the field residue trials even when high levels of parent were found.

The Meeting estimated a maximum residue level of 10 mg/kg (MRL<sub>grapes</sub> of 5 mg/kg × 2.0) for Grapes, dried.

### **Residues in animal commodities**

#### **Farm animal dietary burden**

Grape pomace and rape seed meal are the only feed items relevant to the uses considered by the current Meeting. Based on the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual<sup>12</sup>, grape pomace (dry) is only a significant feed item in Australia. As there is no registration for use of mandestrobin on grapes in Australia, and import of grape pomace would not occur, the Meeting did not include grape pomace in the dietary burden for mandestrobin. Using the median value of 0.004 mg/kg for rape seed meal in the dietary burden calculator, results in very low dietary burdens for livestock.

Table 4 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: mandestrobin, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
<b>Beef cattle</b>	0.0002	0.0002	-	-	0.0009	0.0009	-	-
<b>Dairy cattle</b>	0.0005	0.0005	0.0005	0.0005	0.0007	0.0007	-	-
<b>Poultry – broiler</b>	0.0007	0.0007	0.0008	0.0008	0.0002	0.0002	-	-
<b>Poultry – layer</b>	0.0007	0.0007	0.0005	0.0005	0.0002	0.0002	-	-

#### **Farm animal feeding studies**

The Meeting received a bovine feeding study (beef and dairy cattle), which provided information on likely residues resulting in animal tissues and milk from mandestrobin residues in animal diets.

Mandestrobin was fed via the diet to three to six dairy or beef cattle animals per dose group for 27 consecutive days. Animals were administered mandestrobin via bail feed (dairy cattle) or oral drench (beef cattle). The animals received 0 (1 animal), 25, 75, or 150 ppm in dry feed, corresponding to a calculated mean dose of 0, 0.97, 2.9 and 5.8 mg/kg bw per day in both dairy cattle (milk) and beef cattle (tissues). Animals were sacrificed 24 hours after the last dose, and tissues were analysed for residues of mandestrobin; metabolite residues were not analysed.

Mandestrobin residues were <LOQ (0.02 mg/kg) in whole milk, muscle or kidney at all dose levels, <LOQ in cream at the 25 and 75 ppm dose levels, and <LOQ in fat or liver at the 25 ppm dose level. At the 75 ppm dose level, mean and highest residues of 0.048 and 0.057 mg/kg were observed in liver and < 0.02 and 0.023 mg/kg in fat. At the 150 ppm dose level, mean and highest residues of 0.16 and 0.28 mg/kg were observed in liver, 0.033 and 0.040 mg/kg in fat and 0.021 and 0.034 mg/kg in milk cream.

The Meeting did not receive residue data from poultry feeding studies.

#### **Animal commodity maximum residue levels**

Since livestock is not significantly exposed ( $< 1.0 \times 10^{-3}$  ppm, based on rape seed meal) and mandestrobin was not observed in the dietary feeding study in lactating cows dosed at 25 ppm feed, residues of mandestrobin, including all toxicologically relevant metabolites, are not expected in milk,

<sup>12</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

eggs, and livestock tissues. As a valid analytical method for determination of parent compound in animal commodities is available, the Meeting decided to estimate maximum residue levels for animal commodities.

The Meeting recommended a maximum residue level of 0.01(\*) mg/kg and an STMR and HR of 0 mg/kg in mammalian meat (muscle, fat), mammalian fat, mammalian edible offal, poultry meat (muscle, fat), poultry fat, poultry edible offal, and eggs and a maximum residue level of 0.01(\*) mg/kg and an STMR of 0 mg/kg in milk.

### FURTHER WORK OR INFORMATION

Desirable:

- Validated analytical methods for all relevant metabolites and their conjugates in animal commodities.
- Feeding study, where all relevant metabolites are analysed if livestock dietary burdens become significant.

### 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.

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

The Meeting may revisit the residue definition with uses on cereals.

Definition of the residue for acute dietary risk assessment in animal commodities: the sum of parent, (2RS)-2-[2-(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide (4-OH-mandestrobin) + (2RS)-2-(2-hydroxymethylphenyl)-2-methoxy-N-methylacetamide (De-XY-mandestrobin) + 2RS)-2-[2-(2-hydroxymethyl-5-methylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide (2-CH<sub>2</sub>-OH-mandestrobin) + 2-({2-[(1RS)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (2-COOH-mandestrobin), + 3-({2-[(1RS)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (5-COOH-mandestrobin) and their conjugates, expressed as parent compound.

Definition of the residue for long-term dietary risk assessment in animal commodities: the sum of parent, (2RS)-2-[2-(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide (4-OH-mandestrobin), and its conjugates, expressed as parent compound.

The residue is fat-soluble.

### DIETARY RISK ASSESSMENT

#### **Long-term dietary exposure**

The ADI for mandestrobin is 0–0.2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for mandestrobin 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 2019 JMPR Report.

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

#### **Acute dietary exposure**

The 2018 JMPR established an ARfD for mandestrobin of 3.0 mg/kg bw for women of childbearing age. The 2018 Meeting concluded that it was not necessary to establish an ARfD for mandestrobin for



the remainder of the population. The International Estimate of Short Term Intakes (IESTIs) for mandestrobin 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 2019 JMPR Report.

The IESTIs varied from 0–4% of the ARfD for women of childbearing age. The Meeting concluded that acute dietary exposure to residues of mandestrobin from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.16 Metconazole (313)

### TOXICOLOGY

Metconazole is the ISO-approved common name for (1*RS*,5*RS*;1*RS*,5*SR*)-(chlorophenyl)methyl-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl) cyclopentanol, with the CAS number 125116-23-6 (unstated stereochemistry).

Metconazole is a fungicide and belongs to the chemical class of triazoles. As manufactured it consists of two diastereomers (*cis* 85% and *trans* 15%). Metconazole acts by inhibition of P450 sterol 14 $\alpha$ -demethylase (CYP51).

Metconazole has not previously been evaluated by JMPR and was reviewed by the present Meeting at the request of CCPR. All studies were conducted in compliance with GLP and other internationally recognized guidelines, unless otherwise specified. A literature search did not identify any toxicological information additional to that submitted for the current assessment.

#### **Biochemical aspects**

The fate of both *cis/trans*-metconazole (*cis:trans*, 85:15) and *cis*-metconazole was investigated in rats.

In bile cannulated-rats administered 2 mg/kg bw of *cis*-metconazole, bile was the major route of excretion, as up to 83% of radioactivity was eliminated via bile. Smaller amounts were excreted via urine (up to 12%) and only 0.2–0.3% in faeces. When total recovery of radioactivity was calculated based on radioactive levels in bile, urine, carcass, and cage washes, it appeared that 87–96% was absorbed during the first 48 hours. Metconazole is rapidly absorbed, as 50–69% of the dose was eliminated in bile six hours after dosing.

When rats without bile cannulation were treated with 2 mg/kg bw of *cis/trans*-<sup>14</sup>C-metconazole, 59–72% was voided via the faeces, and 14–24% eliminated renally after 48 h. By 72 h, 93–96% of the dose had been excreted. Based upon the plasmakinetic study in rats dosed at 2 mg/kg bw and 200 mg/kg bw of *cis/trans*-metconazole, and since the AUC<sub>0- $\infty$</sub>  values were nearly proportional to dose levels, it was estimated that the absorption rate of the test substance was dose-independent. However, the time to reach C<sub>max</sub> was dose-dependent: C<sub>max</sub> was reached more slowly at the single high-dose level (four hours after dosing) than at the single low-dose level (within 0.25 h).

In rats administered *cis/trans*-metconazole at 2 mg/kg bw as a single dose and as repeated doses (14 consecutive daily low doses, 2 mg/kg bw) radioactivity was widely distributed into various organs and tissues, with the highest levels of residual radioactivity found in the liver, GI tract and adrenals, showing similar amounts after 72 h or 96 h. When a single high dose of 164 mg/kg bw *cis/trans*-metconazole was administered to rats, the distribution pattern was qualitatively similar. The parent compound was detected in small amounts;  $\leq$  2% of the dose was recovered in the faeces. Based on the identified metabolites in metabolism studies, the metabolism of metconazole appears to be initiated by monohydroxylation at the benzylic methylene, methylene, methyl groups and phenyl rings (14% in urine, 21% faeces), M21 (6% in faeces), M15 (14% in urine as conjugate and 3% in faeces) and M19 (14% in urine as conjugate and 9% in faeces). Monohydroxylation at the methylene linkage resulted in the release of triazole. The other monohydroxylated metabolites were either conjugated or further oxidized to yield carboxylated metabolites such as M12 (8% in urine, 14% faeces) and M13 (1% in urine and  $<$  5% in faeces), dihydroxy, polyhydroxy, or hydroxylcarboxy metabolites.

The test substance isomer ratio, or dosing vehicle did not affect ADME of metconazole.

In a comparative in vitro metabolism study using *cis/trans*-<sup>14</sup>C-metconazole no human-specific metabolites were found, and the metabolic degradation in the tested species (human, rat and rabbit) was similar.

#### **Toxicological data**

The acute oral LD<sub>50</sub> of *cis/trans*-metconazole in rats was between 500 and 2000 mg/kg bw. The oral

LD<sub>50</sub> for *cis*-metconazole in rats was 1312 mg/kg bw. In mice, the LD<sub>50</sub> for *cis/trans*-metconazole was 410 mg/kg bw. The acute dermal LD<sub>50</sub> of *cis/trans*-metconazole was > 2000 mg/kg bw in rats and rabbits and the acute inhalation LC<sub>50</sub> was > 5.2 mg/L in rats. Metconazole is neither a skin nor eye irritant in rabbits nor a skin sensitizer in guinea pigs when examined by the maximization and Buehler tests.

Short-term toxicity of metconazole was evaluated for both the isomer mix (the particular isomer ratios ranged from *cis:trans* 77:18, to *cis:trans*, 84:17; nominally 80:15) and the *cis* isomer in subacute studies (rat, dog) and subchronic studies (rat, mouse, dog). Similar effects were observed in rat, mouse and dog. These consisted of a decrease in food consumption and body weight, clinical chemistry changes indicating a hepatotoxic effect associated with increase in liver weight and liver histopathological findings.

In a 90-day study, mice were treated with metconazole (*cis:trans*, 84:16) at 0, 30, 300, and 3000→2000 ppm (3000 on days 1–7 reduced to 2000 on days 7–90). This was equal to 0, 4.6, 50.5, and 341 mg/kg bw per day for males, 0, 6.4, 60.7, and 438 mg/kg bw per day for females. The NOAEL was 30 ppm (equal to 4.6 mg/kg bw per day) based on increased liver and spleen weights with corresponding macroscopic and microscopic changes corroborated by clinical chemistry findings observed at 300 ppm (equal to 50.5 mg/kg bw per day).

In a 28-day study on metconazole (*cis:trans*, 83:17) rats were fed with diets containing 0, 30, 100, 1000, and 3000 ppm metconazole (equal to 0, 2.7, 9.1, 90.5, 261 mg/kg bw per day for males, 0, 3.1, 10.1, 97.0, 287 mg/kg bw per day for females), the NOAEL was 100 ppm (equal to 9.1 mg/kg bw per day) based on reduced body weight and food consumption as well as liver weight increase with corresponding macroscopic and microscopic changes (liver pallor/enlargement and hepatocellular vacuolation/hypertrophy) corroborated by clinical chemistry findings (enhanced aspartate aminotransferase, alanine aminotransferase reduced cholesterol and triglycerides) observed at 1000 ppm (equal to 90.5 mg/kg bw per day).

In a 28-day study on *cis*-metconazole, rats were fed with diets containing 0, 30, 100, 300, 1000, and 10 000 ppm metconazole (equal to 0, 2.7, 9.2, 27.3, 89.3, 721 mg/kg bw per day for males, 0, 3.0, 9.5, 29.8, 101, 784 mg/kg bw per day for females), the NOAEL was 300 ppm (equal to 27.3 mg/kg bw per day) based on reduced body weight and food consumption as well as increased liver weight with corresponding macroscopic (pallor of the liver) and microscopic (hepatocellular vacuolation) changes observed at 1000 ppm (equal to 89.3 mg/kg bw per day).

In a 90-day study rats were fed with diets containing metconazole (*cis:trans*, 76.5:18) at 0, 30, 100, 300, 1000, and 3000 ppm (equal to 0, 1.9, 6.4, 19.2, 64.3, 193 mg/kg bw per day for males, 0, 2.1, 7.2, 22.1, 71.4 and 208 mg/kg bw per day for females). The NOAEL was 100 ppm (equal to 6.4 mg/kg bw per day) based on hepatocellular fatty vacuolation observed at 300 ppm (equal to 19.2 mg/kg bw per day).

In a 90-day study with *cis*-metconazole, rats were fed with diets containing 0, 50, 150, 450, 1350, and 4050 ppm (equal to 0, 3.2, 9.7, 28.8, 88.6, 265 mg/kg bw per day for males, 0, 3.7, 11.0, 33.0, 96.8, and 267 mg/kg bw per day for females). The NOAEL was 450 ppm (equal to 28.8 mg/kg bw per day) based on reduced body weight and food consumption as well as increased liver and spleen weights with correlating hepatic macroscopic and microscopic changes This was corroborated by clinical chemistry findings observed at 1350 ppm (equal to 88.6 mg/kg bw per day).

In a 90-day study, dogs were fed with diets containing 0, 60, 600, and 6000 ppm metconazole (*cis:trans*, 79.8:15.5; equal to 0, 2.5, 24.4, and 225 mg/kg bw per day for males, 0, 2.6, 24.3, 207 mg/kg bw per day for females). The NOAEL was 60 ppm (equal to 2.6 mg/kg bw per day) based on decreased food consumption and body weight gain observed in females at 600 ppm (equal to 24.3 mg/kg bw per day).

In a one-year study dogs were fed with diets containing 0, 30, 300, 1000, and 3000 ppm metconazole (*cis:trans*, 79.8:15.5; equal to 0, 1.1, 12.0, 38.5, and 110 mg/kg bw per day for males, 0, 1.1, 10, 36.5, and 114 mg/kg bw per day for females), the NOAEL was 300 ppm (equal to 10 mg/kg bw

per day) based on significantly increased alkaline phosphatase activity in both sexes and decreased body weight gain in males observed at 1000 ppm (equivalent to 36.5 mg/kg bw per day).

The overall dog NOAEL for metconazole (*cis:trans*, 79.8:15.5) was 300 ppm (equal to 10 mg/kg bw per day) based on decreased food consumption and body weight gain at 600 ppm (equal to 24.3 mg/kg bw per day).

In a 22-month carcinogenicity study in mice, metconazole (*cis:trans*, 79.8:15.5) was administered at dietary concentrations of 0, 30, 300, and 1000 ppm (equal to 0, 4.4, 43.6, and 145 mg/kg bw per day in males, 0, 5.2, 53.0, and 179 mg/kg bw per day in females), the NOAEL was 30 ppm (equal to 4.4 mg/kg bw per day) based on liver (hypertrophic and hyperplastic events) and spleen (atrophy) at 300 ppm (equal to 43.6 mg/kg bw per day). The presence of liver adenoma at medium and high doses and of liver carcinoma at the high dose in female mice was considered to be treatment-related and led to the NOAEL for carcinogenicity of 30 ppm (4.4 mg/kg bw per day).

In a two-year chronic toxicity study in the rat, metconazole (*cis:trans*, 79.8:15.5) was administered at dietary concentrations of 0, 10, 100, 300, and 1000 ppm (equal to 0, 0.4, 4.3, 13.1, 43.9 mg/kg bw per day in males, 0, 0.5, 5.3, 16.0, and 53.8 mg/kg bw per day in females). The NOAEL was 100 ppm (equal to 4.3 mg/kg bw per day) based on increased liver and spleen weight, as well as hepatocellular hypertrophy and adrenal cortical vacuolation at 300 ppm (equal to 13.1 mg/kg bw per day).

In a carcinogenicity study in the same rat strain with metconazole (*cis:trans*, 79.8:15.5) at similar concentrations of 0, 100, 300, and 1000 ppm (equal to 0, 4.6, 13.8, 46.5 mg/kg bw per day in males, 0, 5.5, 16.6, 56.2 mg/kg bw per day in females), the NOAEL for chronic toxicity was 100 ppm (equal to 4.6 mg/kg bw per day) based on effects in the liver (pigment deposit and centrilobular hypertrophy) and the adrenals (cortical vacuolation) at 300 ppm (equal to 13.8 mg/kg bw per day). No treatment-related effects on the types or incidences of neoplasia were observed at any concentration; the NOAEL for carcinogenicity was 1000 ppm (equal to 46.5 mg/kg bw per day), the highest dose tested.

In a mechanistic study (28-day, rats and mice) conducted to investigate the MOA for mouse liver tumour, a number of biochemical parameters were assessed after exposure to 300 ppm of *cis*-metconazole or 0.05% phenobarbital.

It was demonstrated that both metconazole and phenobarbital significantly induced CYP3A, CYP2B and CYP4A.

In a mechanistic study, mice were administered metconazole (*cis:trans*: 83:16) via the diet for 14 days. Hepatic cytochrome P450 (CYP), enzyme induction, production of reactive oxygen species (ROS), and transient cell proliferation were observed at 1000 ppm in a similar way to phenobarbital, a known hepatocarcinogen which is mitogenic, but not genotoxic. The NOAEL for the effects was 30 ppm.

No *in vitro* investigation is available on expression of Cyp2b transcription levels in mouse and human hepatocytes, but in a preliminary report on a murine constitutive androstane receptor (mCAR) nuclear translocation assay in cultured primary mouse hepatocytes, metconazole seemed to stimulate mCAR translocation in primary mouse hepatocyte cultures with translocation dynamics similar to those obtained with phenobarbital, which is the prototypical CAR activator.

These data, although not exhaustive, are consistent with a CAR-mediated MOA, an MOA that is not relevant to humans.

The Meeting concluded that metconazole is carcinogenic in female mice, but not in rats or male mice.

Metconazole has been tested for genotoxicity in a battery of studies *in vitro* and *in vivo*. Some limitations were noted regarding these *in vitro* and *in vivo* assays, nevertheless the meeting concluded that metconazole is unlikely to be genotoxic.

As metconazole is unlikely to be genotoxic and the liver tumours in female mice occur with an MOA not relevant to the human, the Meeting concluded that metconazole is unlikely to pose a carcinogenic risk to humans from the diet.

In a two-generation study, rats were administered *cis*-metconazole in the diet at levels that were adjusted at intervals to maintain calculated chemical intakes of 0, 2, 8, 32 or 48 mg/kg bw per day throughout two generations. The NOAEL for parental toxicity was 8 mg/kg bw per day based on decreased body weights and ovarian weight changes at 32 mg/kg bw per day in the F<sub>1</sub> generation. The NOAEL for reproductive toxicity was 8 mg/kg bw per day based on increased gestation length and decreased post-implantation survival in the F<sub>2</sub> generation at 32 mg/kg bw per day. The offspring NOAEL was 8 mg/kg bw per day, based on decreased body weight gain of F<sub>1</sub> pups until weaning at 32 mg/kg bw per day.

In another two-generation study, rats were fed dietary concentrations of 0, 30, 150 or 750 ppm of metconazole (*cis:trans*, 83:16; equal to 0, 1.3, 6.3, 32.9 mg/kg bw per day for males, 0, 1.3, 6.4, 33.5 mg/kg bw per day for females). The parental NOAEL was 150 ppm (equal to 6.3 mg/kg bw per day), based on increased mortality, decreased body weight gain and increased liver weights associated with hepatocyte fatty changes at 750 ppm (equal to 32.9 mg/kg bw per day). The NOAEL for reproduction was 150 ppm (equal to 6.4 mg/kg bw per day) based on increased gestation length and decreased gestation index in F<sub>1</sub> at 750 ppm (equal to 33.5 mg/kg bw per day). The NOAEL for offspring was 150 ppm (equal to 6.3 mg/kg bw per day) based on decreased live litters born (F<sub>1</sub>, F<sub>2</sub>), decreased viability index (F<sub>2</sub>) and decreased body weight of F<sub>2</sub> generation at 750 ppm (equal to 32.9 mg/kg bw per day).

A mechanistic one-generation study in rats investigated the mechanism by which slightly prolonged duration of gestation and dystocia had occurred when metconazole was administered in generational studies. Metconazole (*cis:trans*, 83:16) was administered at concentrations of 0, 30, 150, or 750 ppm (equal to 0, 1.82, 8.89, and 43.0 mg/kg bw per day). In this supplementary study a significant lack of increase in the 17 $\beta$ -estradiol:progesterone (E/P) ratio was observed on GDs 19 and 21 at the high dose of 750 ppm. Decreases in the E/P ratio at the top dose were mainly attributed to decreased serum 17 $\beta$ -estradiol concentrations on GDs 19 and 21. The delayed onset of parturition and difficult delivery might be associated with the decrease in the E/P ratio on GDs 19 and 21 observed in this study. Based on these results, the dose level of 150 ppm was considered to be the NOAEL for female rats which demonstrated no adverse effects to increases in the E/P ratio.

Developmental toxicity studies have been conducted in rats and rabbits with both *cis/trans* mixture and the *cis* isomer of metconazole (treatment during GD 6–15). The toxicity of both compounds towards dams and fetuses was similar.

Metconazole (*cis:trans*, 84:16), was administered to rats by gavage on GD 6–15 at dose levels of 0, 12, 30 or 75 mg/kg bw per day. The NOAEL for maternal toxicity was 12 mg/kg bw per day, based on reductions in body weight gain at 30 mg/kg bw per day. The NOAEL for developmental toxicity was 12 mg/kg bw per day based on increases in skeletal ossification variations at 30 mg/kg bw per day; two cases of hydrocephaly were observed at the top dose of 75 mg/kg bw per day.

In a second rat developmental study, metconazole (*cis:trans*, 84:16) was given at doses of 0, 1, 4, 16 and 64 mg/kg bw per day. The maternal NOAEL was 16 mg/kg bw per day, based on bodyweight loss and lower food intake at 64 mg/kg bw per day. The embryo/fetal NOAEL was 16 mg/kg bw per day, based on postimplantation loss, reduced live litter size, increased placental weight, reduction in mean fetal weight and increased incidence of minor fetal variations at 64 mg/kg bw per day.

In a rat developmental study with *cis*-metconazole the compound was administered by gavage at dose levels of 0, 6, 24 and 60 mg/kg bw per day from GD 6 to GD 15. The NOAEL for maternal toxicity was 24 mg/kg bw per day based on increased water consumption, decreased food consumption, and decreased bodyweight gain at 60 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 24 mg/kg bw per day based on increased placental weight, decreased fetal weight and decreased litter size/viability, and increased postimplantation loss (early and late resorptions) at 60 mg/kg bw per day.

In a developmental toxicity study, rabbits received metconazole (*cis:trans*, 80:15) by gavage at dose levels of 0, 5, 10, 20 and 40 mg/kg bw per day from GD 6 to GD 28. The maternal NOAEL was 20 mg/kg bw per day based on small increases in postimplantation loss (early and late), at 40 mg/kg bw per day. The embryo/fetal NOAEL was 20 mg/kg bw per day based on slightly decreased fetal weights and litter size at 40 mg/kg bw per day. No malformations or variations in the fetuses were attributable to treatment with the test substance.

A total of four additional main rabbit developmental toxicity studies with treatment during GD 7–19 were conducted with *cis*-metconazole and/or *cis/trans*-metconazole at doses up to 62.5 mg/kg bw per day. In these studies, clear fetotoxic and developmental effects were only observed at maternally toxic dose levels. The critical finding in the rabbit was the increased occurrence of hydrocephaly. Hydrocephaly was seen in all of these four rabbit studies (including the dose range-finding studies), and although the incidence was very low or not clearly dose-related, it was seen consistently in all four studies. In one of these additional main rabbit studies, metconazole (*cis:trans*, 84:13) dosed at 0, 2, 4 and 10 mg/kg bw per day from GD 7 to GD 19, an increased incidence of hydrocephaly was observed, above the historical control range, at 10 mg/kg bw per day in the absence of maternal toxicity.

The overall NOAEL for embryo/fetal toxicity in rabbits was 4 mg/kg bw per day based on an increased incidence of hydrocephaly above the historical control range at 10 mg/kg bw per day in one rabbit study.

The Meeting concluded that metconazole is teratogenic producing hydrocephaly in rats and rabbits.

Metconazole did not cause neurotoxic effects in a two-week oral neurotoxicity (range finding) study in rats at concentrations of 0, 100, 540 or 3000 ppm (equal to 0, 11.0, 59.6 and 217 mg/kg bw per day for males, 0, 10.6, 52.8 and 206 mg/kg bw per day for females) and in a four-week oral main neurotoxicity study in rats at dietary concentrations of 0, 50, 170 and 500 ppm (equal to 0, 4.84, 15.7 and 47.1 mg/kg bw per day for males, 0, 5.1, 17.6, and 49.8 mg/kg bw per day for females).

The Meeting concluded that metconazole is not neurotoxic.

No immunotoxic potential was observed in a 28-day immunotoxicity study in rats using dietary dose levels of 0, 70, 210 and 630 ppm (equal to 0, 5.4, 17 and 52 mg/kg bw per day).

The Meeting concluded that metconazole is not immunotoxic.

In a recombinant aromatase assay, *cis/trans*-metconazole, *cis*-metconazole and *trans*-metconazole inhibited rat and human aromatase activity. The resulting human aromatase IC<sub>50</sub> values were 0.721 μM, 0.569 μM and 2.47 μM for *cis/trans*-metconazole, *cis*-metconazole and *trans*-metconazole, respectively. The resulting rat aromatase IC<sub>50</sub> values were 0.157 μM, 0.223 μM and 0.579 μM for *cis/trans*-metconazole, *cis*-metconazole and *trans*-metconazole, respectively.

### **Toxicological data on metabolites and/or degradates**

Metabolites *cis*-M555F001 and *cis*-M555F012 were found in rat urine at about 10% of the dose, and their toxicity is considered to be covered by the parent compound.

Metabolite *cis*-M555F011 had an acute oral LD<sub>50</sub> in rats of greater than 5000 mg/kg bw, and was not mutagenic in an Ames test. Metabolites *cis*-M555F021, *cis*-M555F030 and *cis*-M555F031 were investigated in *in vitro* genotoxicity studies (Ames) and all the tests were negative. For metabolites *cis*-M555F011, *cis*-M555F021, *cis*-M555F030 and *cis*-M555F031, the TTC approach can be applied (Cramer class III) for chronic toxicity.

For metconazole and its plant metabolites, the presence for potential structural alerts was evaluated with different QSAR models. Models used were the OASIS TIMES and VEGA (CAESAR, ISS and SarPy). Results showed that the assessment was in domain negative for Ames and *in vivo* micronucleus test, indicating no genotoxic potential.

Several unidentified hydroxylated metabolites were found in residue studies and were of potential relevance for the residue definition for risk assessment. The Meeting concluded that, as the addition of a hydroxylated group is unlikely to add any alerts for genotoxicity, the TTC approach can be applied (Cramer class III) for chronic toxicity.

Triazole derivative metabolites were detected in animal matrix (1,2,4-triazole) and plant matrix (triazolyl alanine and triazolyl acetic acid). A relevant complete evaluation has been conducted by JMPR in 2008, leading to specific reference values.

### Human data

No specific data have been provided

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

### Toxicological evaluation

The Meeting established an ADI of 0–0.04 mg/kg bw on the basis of the embryo/fetal NOAEL of 4 mg/kg bw per day from the developmental toxicity study in the rabbit based on increased incidence of hydrocephaly at 10 mg/kg bw per day. A safety factor of 100 was applied. A margin of 250 for the upper bound of the ADI to the LOAEL for the increased incidence of hydrocephaly was observed. This ADI is supported by the NOAELs in several other studies (90-day mouse, 18-month mouse, two-year rat).

The Meeting established an ARfD for women of child-bearing age of 0.04 mg/kg bw, on the same basis as the ADI.

An ARfD is required for the general population based on the LD<sub>50</sub> studies. In the absence of appropriate data, the Meeting cannot establish a population-specific ARfD. Therefore the ARfD for women of child-bearing age (0.04 mg/kg bw) is used as a conservative value.

A toxicological monograph was prepared.

### Levels relevant to risk assessment of metconazole

Species	Study	Effect	NOAEL	LOAEL
Mixed cis/trans isomers				
Mouse	90-day <sup>a</sup>	Toxicity	30 ppm, equal to 4.6 mg/kg bw per day	300 ppm, equal to 50.5 mg/kg bw per day
	22-month study on toxicity and carcinogenicity <sup>a</sup>	Toxicity	30 ppm, equal to 4.4 mg/kg bw per day	300 ppm, equal to 43.6 mg/kg bw per day
		Carcinogenicity	30 ppm, equal to 4.4 mg/kg bw per day	300 ppm, equal to 43.6 mg/kg bw per day
Rat	90-day toxicity study <sup>a</sup>	Toxicity	100 ppm, equal to 6.4 mg/kg bw per day	300 ppm, equal to 19.2 mg/kg bw per day
	Two-year chronic toxicity and carcinogenicity <sup>a</sup>	Toxicity	100 ppm, equal to 4.6 mg/kg bw per day	300 ppm, equal to 13.8 mg/kg bw per day
		Carcinogenicity	1000 ppm, equal to 46.5 mg/kg bw per day <sup>c</sup>	-



Species	Study	Effect	NOAEL	LOAEL
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	150 ppm, equal to 6.3 mg/kg bw per day	750 ppm, equal to 32.9 mg/kg bw per day
		Parental toxicity	150 ppm, equal to 6.3 mg/kg bw per day	750 ppm, equal to 32.9 mg/kg bw per day
		Offspring toxicity	150 ppm, equal to 6.4 mg/kg bw per day	750 ppm, equal to 33.5 mg/kg bw per day
	Developmental toxicity <sup>b</sup>	Maternal toxicity	12 mg/kg bw per day	30 mg/kg bw per day
		Embryo and fetal toxicity	12 mg/kg bw per day	30 mg/kg bw per day
Rabbit	Developmental toxicity <sup>b</sup>	Maternal toxicity	10 mg/kg bw per day <sup>c</sup>	-
		Embryo and fetal toxicity	4 mg/kg bw per day	10 mg/kg bw per day
Dog	90 day and 1 year <sup>a, d</sup>	Toxicity	10 mg/kg bw per day	24.3 mg/kg bw per day
Cis isomer alone				
Rat	Two-generation study of reproductive toxicity <sup>a, d</sup>	Reproductive toxicity	8 mg/kg bw per day	32 mg/kg bw per day
		Parental toxicity	8 mg/kg bw per day	32 mg/kg bw per day
		Offspring toxicity	8 mg/kg bw per day	32 mg/kg bw per day
Rabbit	Developmental toxicity <sup>b</sup>	Maternal toxicity	4 mg/kg bw per day	10 mg/kg bw per day
		Embryo and fetal toxicity	4 mg/kg bw per day	10 mg/kg bw per day

<sup>a</sup> Dietary administration

<sup>b</sup> Gavage administration

<sup>c</sup> Highest dose tested

<sup>d</sup> Two or more studies combined

*Acceptable daily intake (ADI) applies to metconazole, M1 and M12, expressed as metconazole*

0–0.04 mg/kg bw

*Acute reference dose (ARfD) applies to metconazole, M1 and M12, expressed as metconazole*

0.04 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 metconazole**

<b>Absorption, distribution, excretion and metabolism in mammals</b>	
Rate and extent of oral absorption	Rapid and efficient (95–97%)
Dermal absorption	Not evaluated
Distribution	Widely distributed up to 72 hours, residue radioactivity: highest tissue levels found in GI tract, liver and adrenals
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid excretion mainly in the faeces, following biliary excretion (79–83% within 48 h) for the low dose; elimination was delayed by approximately 48 h for the repeated dosing and for the high dose
Metabolism in animals	Extensively metabolized, mainly by hydroxylation of cyclopentane or benzyl rings
Toxicologically significant compounds in animals and plants	Metconazole, (sum of <i>cis</i> and <i>trans</i> isomers), M1, M12, M11, M21, M30, M31 and hydroxylated metabolites
<b>Acute toxicity</b>	
Mouse LD <sub>50</sub> oral	410 mg/kg bw
Rat LD <sub>50</sub> oral	> 500 and < 2000 mg/kg bw
Rat, rabbit LD <sub>50</sub> dermal	> 2000 mg/kg bw
Rat LC <sub>50</sub> inhalation	> 5.2 mg/L
Rabbit, dermal irritation	Non-irritant
Rabbit, ocular irritation	Non-irritant
Guinea pig, dermal sensitization	Not sensitizing (maximization, Buehler)
<b>Short-term studies of toxicity</b>	
Target/critical effect	Liver, mild hypochromic microcytic anaemia, adrenal (rat) Liver, slight microcytic anaemia at highest dose (mouse) Reduction in body weight gain, increased AP; lens degeneration at higher dose levels (dog)
Lowest relevant oral NOAEL	4.6 mg/kg bw per day (mouse) 19.2 mg/kg bw per day (rat) 10 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rabbit)
Lowest relevant inhalation NOAEL	No data
<b>Long-term studies of toxicity and carcinogenicity</b>	
Target/critical effect	Liver toxicity; corticomedullary adrenal pigmentation, spleen atrophy, reduced cholesterol/triglyceride level
Lowest relevant oral NOAEL	4.3 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in female mice but not in rats or male mice; mode of action not relevant for humans <sup>a</sup>
<b>Genotoxicity</b>	Unlikely to be genotoxic <sup>a</sup>

**Reproductive toxicity**

Target/critical effect	Parental toxicity: reduced body weight and body weight gain, increased liver weights, hepatocyte fatty change Reproductive toxicity: prolonged gestation length, dystocia and associated maternal deaths, decreased gestation index, reduced post-implantation survival Offspring toxicity: decreased number of live fetuses, reduced bw gain
Lowest relevant parental NOAEL	6.3 mg/kg bw per day (with <i>cis/trans</i> -metconazole)
Lowest relevant offspring NOAEL	6.4 mg/kg bw per day (with <i>cis/trans</i> -metconazole)
Lowest relevant reproductive NOAEL	6.3 mg/kg bw per day (with <i>cis/trans</i> -metconazole)

**Developmental toxicity**

Target/critical effect	Maternal toxicity: reduced bw gain and food consumption (rat, rabbit) Embryo/fetal toxicity: increased skeletal ossification variations, increased placental weight (rat), increased post implantation loss, decreased live litter size, reduced fetal weight, and hydrocephaly (rat, rabbit)
Lowest relevant maternal NOAEL	10 mg/kg bw/d (rabbit)
Lowest relevant embryo/fetal NOAEL	4 mg/kg bw/d (rabbit, with <i>cis/trans</i> -metconazole)

**Neurotoxicity**

Acute neurotoxicity NOAEL	No findings indicative of neurotoxic potential reported
Sub-chronic neurotoxicity NOAEL	47.1 mg/kg bw (highest dose tested) (rat, in 2-week and 4-week neurotoxicity studies)
Developmental neurotoxicity	No data

## Other toxicological data

## Mechanism studies

***cis*-metconazole**

28-day mechanistic study (male rats and mice): hepatic CYP induction (rat, mouse): pattern similar, but not identical to phenobarbital

**Metconazole, (*cis/trans* mix)**

14-day mechanistic study in female mice: CYP2B induction (protein and enzyme activity) and transient hepatocellular proliferation after 3 and 7 days at 300 and 1000 ppm.

28-day immunotoxicity study in rats: no immunotoxin potential

Mechanistic 1-generation study: extended gestation length and dystocia may be associated with decrease of E/P (estradiol/progesterone) ratio during late gestation, mainly due to decreases in serum estradiol.

**Metconazole: *cis/trans*, *cis*, and *trans***

Recombinant aromatase assay on rat and human enzymes: inhibition of aromatase activity (rat greater than human; *cis/trans* and *cis* similar, and greater than *trans* alone.)

**Metabolite data**

Oral LD <sub>50</sub>	<i>cis</i> -M555F011: > 5000 mg/kg bw (rat)
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Genotoxicity	<i>cis</i> -M555F011, <i>cis</i> -M555F021, <i>cis</i> -M555F030, <i>cis</i> -M555F031: No genotoxic concern (Ames test and QSAR)
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<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet

**Summary***Metconazole*

	Value	Study	Safety factor
ADI	0–0.04 mg/kg bw <sup>a</sup>	Rabbit developmental	100
ARfD	0.04 mg/kg bw <sup>a</sup>	Rabbit developmental	100

*1,2,4-Triazole<sup>b</sup>*

ADI	0–0.2 mg/kg bw	Two-generation	100
ARfD	0.3 mg/kg bw	Rabbit developmental	100

*Triazole alanine and triazole acetic<sup>b</sup>*

ADI	0–1 mg/kg bw	Rat developmental	100
ARfD	Unnecessary		

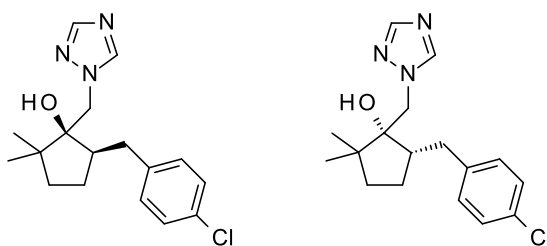
<sup>a</sup> Applies to metconazole, M1 and M12, expressed as metconazole

<sup>b</sup> Triazole fungicide metabolites from JMPR 2008, pp 437–490

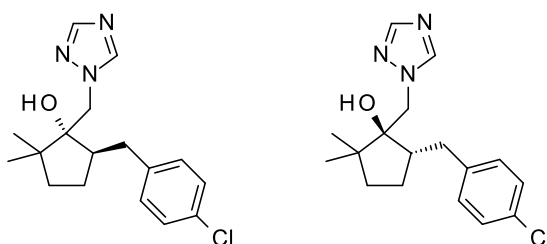
**RESIDUE AND ANALYTICAL ASPECTS**

Metconazole is a systemic triazole fungicide and plant growth regulator. It acts by inhibiting ergosterol biosynthesis. Metconazole was scheduled by the Fiftieth Session of the CCPR for first evaluation by the 2019 JMPR for toxicology and residues.

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



cis-isomers  
Reg.no. 4079468

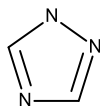
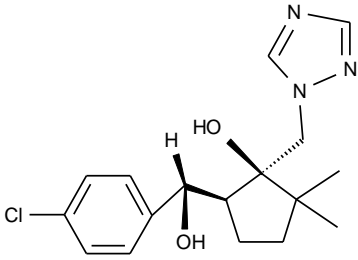
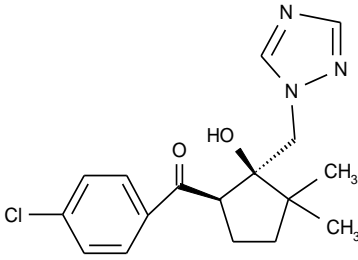
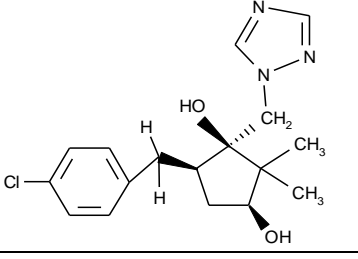
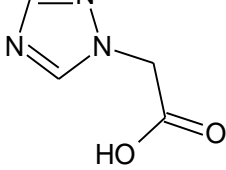
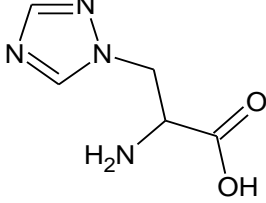
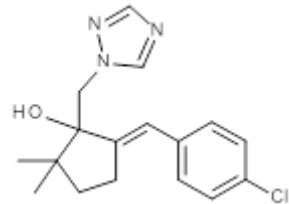


trans-isomers  
Reg.no. 4079654

The IUPAC name of metconazole is (1*RS*,5*RS*;1*RS*,5*SR*)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol. The isomeric ratio of cis- and trans-metconazole is at about 80–85:15–20 (molecular weight of metconazole is 319.8).

Table 1 Overview of metabolites referred to in the appraisal

Code Names	Chemical Names (IUPAC)	Structure
M1 CL 359451	(1 <i>RS</i> ,2 <i>SR</i> ,5 <i>RS</i> )-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol (Molecular weight of M1 is 335.8)	
M11 CL 382390	(1 <i>RS</i> ,5 <i>SR</i> )-5-[( <i>SR</i> )-(4-chlorophenyl)(hydroxy)methyl]-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol	
M12 (4543815) CL 359138	(1 <i>RS</i> ,2 <i>SR</i> ,3 <i>RS</i> )-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid (Molecular weight of M12 is 349.8)	

Code Names	Chemical Names (IUPAC)	Structure
M20 87084 M555F020	1,2,4-(1H)-triazole	
M21 CL 197130	(1RS,5SR)-5-[(RS)-(4-chlorophenyl)(hydroxy)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	
M30 4110625 CL 382389 M555F030cis	(1RS,5SR)-5-(4-chlorobenzoyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	
M31 5968488	(1RS,3SR,5RS)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentane-1,3-diol	
M34 Triazolyl acetic acid WL 161417	2-(1,2,4-triazol-1-yl)acetic acid	
M35 Triazolyl alanine WL161416 CL 147267	2-amino-3-(1H-1,2,4-triazol-5-yl)propanoic acid	
M40 M555F040	(5Z)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	

### Physical and chemical properties

Metconazole is not volatile. It generally has a higher solubility in organic solvents in comparison to

water. The n-octanol water partition coefficient  $\log P_{ow}$  is 3.8 at 20 °C, suggesting that the parent has the potential to partition into fat. Metconazole was shown to be hydrolytically stable at pH 4, 7 and 9.

### **Plant metabolism**

The Meeting received plant metabolism studies in wheat, canola, banana, mandarins and peas following application of either [triazole-<sup>14</sup>C]-, [cyclopentyl-<sup>14</sup>C]- or [p-chlorophenyl-<sup>14</sup>C]-metconazole.

#### **Mandarin**

To mandarins, [cyclopentyl-<sup>14</sup>C]- and [triazole-<sup>14</sup>C]-radiolabelled metconazole were applied in a single foliar application at a rate equivalent to 0.2 kg ai/ha at the fruit stage (about 2 months before maturity). Fruit and leaf samples were taken at 0 (immediately after the treatment), 28 and 56 days after treatment (DAT). A subset of fruit was also separated into peel and pulp.

TRRs were highest in leaves ranging between 3.1–4.8 mg eq/kg, while levels in fruits were significantly lower ranging between 0.072–0.13 mg eq/kg.

Mandarin leaves and fruits were surface rinsed with methanol, followed by extraction with methanol/water (1:1, v/v) for the leaves and methanol/water (7:3, v/v) for peel and pulp. Conjugates in extracts were hydrolyzed by treatment with either 0.1 M HCl (100 °C, 1 d) or cellulase. Radioactivity in the surface rinse from fruits dropped from > 80% TRR at 0 DAT to 12–15% TRR at 56 DAT. Total extracted radioactivity (rinse + extract) in the leaves and whole fruits ranged between 90–99% TRR and 93–100% TRR, respectively.

Parent metconazole was the predominant residue in mandarin fruits accounting for 47–94% TRR (0.034–0.12 mg eq/kg) and in leaves accounting for 45–95% (1.5–4.6 mg eq/kg). No major metabolites were identified. The sum of other metabolites, including isomers of hydroxylated metconazole as well as conjugates, accounted for 32–36% TRR (0.024–0.039 mg eq/kg) in 28 and 56 DAT fruits and 33–37% TRR (1.1–1.2 mg eq/kg) in leaves.

#### **Banana**

To banana, [triazole-<sup>14</sup>C]- and [p-chlorophenyl-<sup>14</sup>C]-radiolabelled metconazole were applied in five foliar applications at 14-day intervals from flowering, at a rate equivalent to 0.14 kg ai/ha per application. Banana fruits were sampled at 0 DALA (56 DAT1) and a subsample separated into peel and pulp.

TRRs were highest in banana peel ranging between 1.6–2.5 mg eq/kg, while levels in banana pulp were significantly lower ranging between 0.61–0.78 mg eq/kg.

Banana samples were extracted with methanol, followed by 2% HCl in methanol. Extracted radioactivity in the whole fruit, as well as in peel and pulp ranged between 96–98% TRR.

Parent metconazole was the predominant residue in all matrices accounting for 86–89% TRR (0.52–2.2 mg eq/kg). No major metabolites were identified.

#### **Peas**

To peas, [triazole-<sup>14</sup>C]- and [p-chlorophenyl-<sup>14</sup>C]-radiolabelled metconazole were applied in two (green pea scenario) or three (dry pea scenario) foliar applications at a rate equivalent to 0.22 kg ai/ha per application and a retreatment interval of 13–14 days. Foliage samples were taken after each treatment at 0, 13, 27 DAT1. For the green pea scenario (peas and foliage) samples were harvested at 26 DAT1 (13 DAT2) (BBCH 79) and for the dry pea scenario (peas and straw) at 42 DAT1 (15 DALA) (BBCH 89).

TRRs were highest in pea straw (dry pea scenario) ranging between 49–168 mg eq/kg, followed by foliage (green pea scenario) at up to 21 mg eq/kg. In pea seed, the TRR was higher in the dry pea scenario with 0.2–3.9 mg eq/kg compared to the green pea scenario with 0.038–1.6 mg eq/kg.

All samples except pea seeds were surface extracted by submersion in acetone/water (7:3), followed by extraction with acetone and acetone/methanol/water (1:1:1) for forage 0 and 13 DAT1 and with methanol/water (4:1) and water for forage 27 DAT1, straw and seeds. To liberate conjugates, aliquots of the straw extracts (15 DALA) were subjected to acidic hydrolysis (1 M HCl, refluxed for 5 h) and additionally incubated with  $\beta$ -glucosidase. Extracted radioactivity ranged between 97–100% TRR in foliage, 91–94% in straw (both scenarios) and 85–100% TRR in seeds (both scenarios).

In both scenarios, parent metconazole was a major residue in foliage, straw and seeds (*p*-chlorophenyl-label only) accounting for 67–96% TRR (4.8–10 mg eq/kg), 54–68% TRR (4.6–33 mg eq/kg) and 21–36% TRR (0.016–0.043 mg eq/kg), respectively. The only major identified metabolite was triazolyl alanine in pea seeds at 75–85% TRR (1.2–3.2 mg eq/kg). Additionally, a mixture of isomers of hydroxylated metconazole as well as conjugates were identified at up to 38% TRR (23 mg eq/kg) in pea straw.

### *Wheat*

To wheat, [triazole-<sup>14</sup>C]- or [cyclopentyl-<sup>14</sup>C]-metconazole were applied in one foliar application at BBCH 57–60 using a rate equivalent to 0.36–0.37 kg ai/ha. Samples of straw and grain were taken at 61 or 74 DAT.

Maximum TRR levels for both labels ranged between 5.9–6.3 mg eq/kg in straw, and in grain were 0.074 mg eq/kg (cyclopentyl-label) and 0.66 mg eq/kg (triazole-label).

Samples were sequentially extracted with acetone and acetonitrile (triazole-label only), as well as with acetonitrile/water (at various ratios) and water. Extracted radioactivity was equal to 82–92% TRR in grain and 74–81% TRR in straw.

While parent metconazole was not detected in wheat grain, it accounted for 19–32% TRR (1.2–1.9 mg eq/kg) in wheat straw. In wheat grain, major identified metabolites were triazolyl alanine at 69% TRR (0.46 mg eq/kg) and triazolyl acetic acid at 23% TRR (0.16 mg eq/kg). In wheat straw, major identified metabolites were M11 at 9.8% TRR (0.58 mg eq/kg) and M21 at 9.7% TRR (0.57 mg eq/kg).

### *Rape seed*

To rape seed, [triazole-<sup>14</sup>C]- or [*p*-chlorophenyl-<sup>14</sup>C]-metconazole were applied in two foliar applications at a rate equivalent to 0.26–0.27 kg ai/ha per application. The first treatment occurred at BBCH 65 (full flowering); while the second treatment occurred 14 days later at BBCH 67 (flowering declining). Oilseed rape foliage was sampled at 0 DAT1, 0 DALA (14 DAT1), 14 DALA (28 DAT1) and 28 DALA (42 DAT1), while the pods and seeds were harvested at 44–50 DALA.

TRRs were highest in foliage (28 DALA) at up to 20 mg eq/kg and in pods at up to 21 mg eq/kg, while levels in seeds were significantly lower ranging between 1.9–2.4 mg eq/kg.

Foliage and pods were extracted with methanol (pods were soaked in water overnight prior to extraction), while seeds were extracted with hexane, followed by methanol and water. Extracted radioactivity ranged between 61–98% TRR in foliage, 65–74% in pods and 72–80% TRR in seeds.

Parent metconazole was the predominant residue in foliage, pods (*p*-chlorophenyl-label only) and seeds accounting for 40–96% TRR (2.6–13 mg eq/kg), 21% TRR (4.4 mg eq/kg) and 20–29% TRR (0.47–0.53 mg eq/kg), respectively. The only major identified metabolite was triazolyl alanine in oilseed rape seeds at 39% TRR (0.92 mg eq/kg). Additionally, a mixture of glucose conjugates of metconazole and monohydroxylated metconazole metabolites were identified at up to 63% TRR (12 mg eq/kg) in pods.

In summary, metconazole was only moderately metabolized in studies performed with wheat, oilseed rape, banana, mandarin and pea. Parent metconazole was a major residue (19–96% TRR) in all crops, except wheat grain where it was not detected. Major identified metabolites were triazolyl alanine accounting for 39–69% TRR in wheat grain, oilseed rape seed and pea seed, as well as triazolyl acetic acid accounting for 23% TRR in wheat grain. In wheat straw, metabolites M11 accounted for 9.8% TRR and M21 for 9.7% TRR. Additionally, significant residues of hydroxylated metconazole



metabolites and/or their conjugates were detected in mandarin fruit, pea seed and oilseed rape seed, ranging between 19–67% TRR.

### **Animal metabolism**

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

#### **Goats**

In lactating goats, the metabolic fate of metconazole was investigated using [cyclopentyl-<sup>14</sup>C]-or [triazole-<sup>14</sup>C]-metconazole. In two studies [cyclopentyl-<sup>14</sup>C]-metconazole was administered orally at different isomeric ratios: a) a *cis:trans* ratio of 85:15 was administered to two lactating goats at 14 ppm (0.47 mg/kg bw per day) and 24 ppm (0.48 mg/kg bw per day) for 3–4 consecutive days; b) the *cis*-isomer only was administered to one goat at 11 ppm (0.64 mg/kg bw per day) for 4 consecutive days. Moreover, in a third study, [triazole-<sup>14</sup>C]-radiolabelled metconazole containing a *cis:trans* ratio of 85:15 was administered to one goat at 10 ppm (0.46 mg/kg bw per day) for 4 consecutive days.

For both labels most of the administered radioactivity was recovered from urine (28–43% AR) and faeces (25–50% AR). In edible tissues residues were low in all studies. The highest TRRs were found in liver ranging from 0.22 mg eq/kg (10 ppm dose rate) to 0.56 mg eq/kg (24 ppm dose rate) and in kidney ranging from 0.11 mg eq/kg (10 ppm dose rate) to 0.28 mg eq/kg (24 ppm dose rate); while in other edible tissues residue levels were significantly lower (0.001–0.015 mg eq/kg).

In milk, the radioactive residues ranged between 0.011–0.017 mg eq/kg for both labels. A plateau was reached after approximately 3 days in the studies dosed at 10–14 ppm. However, for the study using [cyclopentyl-<sup>14</sup>C]-metconazole dosed at 24 ppm, no plateau was reached after 4 days.

Tissue samples of the [cyclopentyl-<sup>14</sup>C]-metconazole dosed goats were extracted with acetonitrile, followed by acetonitrile/water 1:1, v/v) or acetonitrile/ water (9:1, v/v), followed by methanol, while tissues of the [triazole-<sup>14</sup>C]-metconazole dosed goat were extracted with acetonitrile, followed by a single extraction with water and ethanol. Resulting extraction rates were 94–96% TRR in liver and 96–98% TRR in kidney. To liberate conjugates, extracts of the [cyclopentyl-<sup>14</sup>C]- and [triazole-<sup>14</sup>C]-metconazole dosed goats were hydrolysed with 2 M HCl or 6 M HCl, respectively.. It was also recognized that a shift of the *cis:trans* ratio of metconazole indicated a faster metabolism of the *cis* isomer.

Identification and characterization of the radioactivity in liver and kidney was done in all studies and in one study additionally in muscle and fat. Metconazole (sum of free and conjugated) was the major identified residue in liver, accounting for 33–42% TRR (0.09–0.24 mg eq/kg), with the contribution of conjugated metconazole being about 6–10%. Additionally, several metabolites were detected for both labels at significant levels: M1 (conjugated) in kidney ranging between 12–14% TRR (0.014–0.038 mg eq/kg); M12 (free) in kidney ranging between 13–21% TRR (0.020–0.055 mg eq/kg) and M31 (free and conjugated) in liver and kidney ranging between 15–24% TRR (0.022–0.063 mg eq/kg). Levels of M1 and M12 in kidney were 4–12 times higher compared to parent, while levels of M31 were similar, or below parent. 1,2,4-triazole was not detected in any of the samples from the [triazole-<sup>14</sup>C]-metconazole dosed goat.

#### **Laying hens**

In laying hens, the metabolic fate of metconazole was investigated using [cyclopentyl-<sup>14</sup>C]-or [triazole-<sup>14</sup>C]-metconazole. In three separate studies, [cyclopentyl-<sup>14</sup>C]-metconazole was administered orally to laying hens at 7 ppm (0.6 mg/kg bw per day) for 28 consecutive days, at 8 ppm (0.64 mg/kg bw per day) for 14 consecutive days or at 14 ppm (0.73 mg/kg bw per day) for 4.5 consecutive days. In the third study, [triazole-<sup>14</sup>C]-radiolabelled metconazole was also administered to laying hens at 13 ppm (0.75 mg/kg bw per day) for 4.5 consecutive days.

Most of the administered radioactivity was recovered from excreta (91–97% AR). In egg whites the radioactive residues ranged between < 0.001–0.09 mg eq/kg (cyclopentyl-label) and < 0.001–0.17 mg eq/kg (triazole-label) and in egg yolk between < 0.001–0.18 mg eq/kg (cyclopentyl-label) and < 0.001–0.16 mg eq/kg (triazole-label). TRR levels in eggs did reach a plateau after 8 days. In edible tissues the highest TRRs were found in liver at 0.60–0.79 mg eq/kg (cyclopentyl-label) and 0.97 mg eq/kg (triazole-label) and in kidney at 0.33–0.36 mg eq/kg (cyclopentyl-label); while in other edible tissues residue levels were significantly lower at 0.024–0.13 mg eq/kg (cyclopentyl-label) and 0.14–0.19 mg eq/kg (triazole-label).

In the third study, following dosing [cyclopentyl-<sup>14</sup>C]-metconazole at 14 ppm and [triazole-<sup>14</sup>C]-metconazole at 13 ppm for 4.5 days, samples were collected for the purpose of characterization of the radioactive residue. Samples of liver, breast muscle, thigh muscle, abdominal fat, skin with fat, egg white and egg yolk, were extracted three times with acetonitrile, followed by two times with water. Insoluble oily droplets were dissolved with hexane. The extract (cyclopentyl label only) and PES from liver samples of both labels was hydrolysed with 6 M and 2 M HCl, respectively. Extractability ranged for all matrices between 86–99% TRR.

Parent metconazole was identified as a major residue for both labels in abdominal fat at 35–37% TRR (0.033–0.050 mg eq/kg) and skin with fat at 20–28% TRR (0.021–0.027 mg eq/kg), as well as for [cyclopentyl-<sup>14</sup>C]-metconazole in egg yolk at 11% TRR (0.010 mg eq/kg). In tissues of hens treated with the [triazole-<sup>14</sup>C]-metconazole, metabolite 1,2,4-triazole was also quantified in all tissues at levels ranging between 27–77% TRR (0.019–0.27 mg eq/kg). Several additional metabolites were detected for both labels at significant levels: M1 (free and conjugated) in liver at 16% TRR (0.13 mg eq/kg) and M12 (free and conjugated) in liver at 12% TRR (0.091 mg eq/kg). The sum of the co-eluting metabolites M1 and M31 in abdominal fat, skin with fat and egg yolk, as well as whole egg accounted for 11–28% TRR (0.010–0.025 mg eq/kg).

In summary, extensive metabolic degradation of metconazole was observed with similar pathways in lactating goats and laying hens. Parent metconazole (mostly unconjugated) was quantified at major amounts in goats (liver) and hens (fat, skin and egg yolk), accounting for 11–42% TRR. Major metabolites were M1 at 12–16% TRR and M12 at 12–21% TRR in goats (kidney) and hens (liver), as well as M31 at 15–24% TRR in goats (liver & kidney). The sum of metabolites M1 and M31 accounted for 11–28% TRR in hens (fat, skin and egg yolk). Metabolite 1,2,4-triazole was quantified in all tissues of laying hens at 27–77% TRR.

### ***Environmental fate in soil***

The Meeting received studies on aerobic soil degradation, soil photolysis, confined rotational crop metabolism and field rotational crops.

#### ***Aerobic soil degradation***

In aerobic soil degradation studies, moderate degradation of <sup>14</sup>C-metconazole was observed with estimated half-lives in various soils ranging from 84–128 days. The only identified metabolites were M30 at up to 4.9% AR, M40 (and/or unknown) at up to 1.8% AR and 1,2,4-triazole at up to 1.2% AR.

Half-lives of <sup>14</sup>C-metconazole for soil photolysis under the assumption of an average daylight period of 12 hours were estimated at 63–136 days (1<sup>st</sup> order kinetics) and 73 days (square root 2<sup>nd</sup> order kinetics). The only identified metabolite was M30 at up to 3.7% AR. The Meeting concluded that photolysis does not represent a significant degradation pathway for metconazole.

#### ***Confined rotational crops***

A confined rotational crop metabolism study was conducted with [cyclopentyl-<sup>14</sup>C]- and [triazole-<sup>14</sup>C]-radiolabelled metconazole applied at a rate equivalent to 0.4 kg ai/ha to a sandy loam soil. After plant-back intervals (PBIs) of 30 and 120 days the nature and level of radioactive residues were investigated in lettuce, radish and wheat.

At 120-days PBI, the measured TRR was often at similar or higher levels compared to the 30-day PBI. At harvest, the highest total radioactive residues were found in wheat straw (0.61–0.73 mg eq/kg). In edible commodities radioactive residues were highest in radish root, up to 0.71 mg eq/kg (triazole-label, 120 DAT) and 0.37 mg eq/kg (cyclopentyl-label, 120 DAT), followed by wheat grain, up to 0.49 mg eq/kg (triazole-label, 120 DAT), and lettuce leaf up to 0.2 mg eq/kg (triazole-label, 120 DAT) and 0.10 mg eq/kg (cyclopentyl-label, 120 DAT).

All samples were extracted with acetonitrile/water at various ratios and water. Subsequently the extracts were partitioned with ethyl acetate, dichloromethane or hexane. Conjugates present in the extracts were hydrolyzed by either acid (2 M HCl) or base hydrolysis (0.1 M NaOH). For both labels and PBIs, the extracted radioactivity in radish (root and tops), lettuce, wheat straw and wheat grain ranged between 84–97% TRR.

Parent metconazole was identified as the major component in radish roots and tops at the 30-day PBI at 15–41% TRR (0.07–0.13 mg eq/kg) and in lettuce at the 120-day PBI at 20% TRR (0.02 mg eq/kg). Metconazole was also a major residue in radish from the 120-day PBI and lettuce and wheat straw from the 30-day PBI, but could not be unequivocally identified due to interference.

Metabolite M35 (triazolyl alanine) was a major residue in the 30-day PBI radish roots and tops, as well as in the 120-day wheat grain making up 18–59% TRR (0.07–0.29 mg eq/kg), while M34 (triazolyl acetic acid) was found at up to 20% TRR (0.10 mg eq/kg) in the 120-day PBI wheat grain. Metabolite M12 was a significant residue in the 30-day PBI radish tops at up to 14% TRR (0.09 mg eq/kg), but was not found in the 120-day PBI samples. Additionally, glycoside conjugates were detected at up to 18% TRR (0.13 mg eq/kg) in wheat straw at the 120-day PBI.

In two field rotational crop trials, conducted in Germany, metconazole was applied twice to bare soil a rate of 0.09 kg ai/ha with an interval of 21 days. Carrots and lamb's lettuce were planted 30–31 DALA while winter wheat was planted 98–99 DALA. Carrots and lamb's lettuce were sampled at the earliest time the crop could be commercially used and at maturity. Winter wheat was sampled immature (whole plant, ears and rest of plant) and at maturity (grain and straw).

Residues of metconazole in crops planted at 30/31 days (carrot and lamb's lettuce) and 99 days (winter wheat) after treatment of the soil were not quantifiable (LOQ: 0.01 mg/kg; straw: 0.03 mg/kg).

The Meeting noted that residues of metconazole are moderately persistent in soil (DT<sub>50</sub> up to 128 days). In the confined rotational crop metabolism study performed at 0.4 kg ai/ha, metconazole was the predominant residue in all plant commodities, except wheat grain. Also, the concentrations in the 30 and 120-day PBI samples were in the same range or increased with time, reaching up to 0.13 mg eq/kg in edible parts.

The two field rotational crop studies performed at 2 × 0.09 kg ai/ha did not result in any detectable residues of metconazole in succeeding crops. Data from field trials on potato treated at a rate of 4 × 0.14 kg ai/ha (approx. three times higher compared to the available field rotational crop data) resulted in no residues >LOQ. The Meeting concluded that there is no concern for carry over of metconazole residues in rotational crops.

In addition to parent metconazole, the metabolites triazolyl alanine and triazolyl acetic acid, common to the whole group of triazole fungicides, were found.

### **Methods of residue analysis**

The Meeting received analytical methods for the determination of metconazole and metabolites M11, M21 and M30 in plant matrices, as well as for the triazole metabolites 1,2,4-triazole, triazolyl alanine, triazolyl acetic acid and triazolyl lactic acid.

For matrices of plant origin, most methods employed extraction with acetone/hexane, acetone/water, acetonitrile, acetonitrile/water, methanol or methanol/water. Clean-up was done by either liquid-liquid partitioning alone or in combination with GPC or SPE. Parent metconazole was determined by LC-MS/MS, GC-NPD or GC-MS, while all metabolites were determined by LC-MS/MS only. Among all available methods, the validated LOQ for parent metconazole ranged between 0.005–

0.05 mg/kg. For the metabolites M11, M21 and M30, the LOQ was at 0.01 mg/kg or 0.02 mg/kg, and for the triazole metabolites at 0.01 mg/kg, except for one method for triazolyl acetic acid where the LOQ was also at 0.05 mg/kg. Mean recoveries were, with few exceptions, within the acceptable range of 70–120% with a RSD of < 20%.

For animal matrices, methods were provided for parent metconazole and metabolites M1, M12 and 1,2,4-triazole.

In animal matrices, most methods employed extraction with acetone/water, ethyl acetate/methanol, acetonitrile, methanol or methanol/water. Clean-up was done by either liquid-liquid partitioning alone or in combination with SPE. Conjugates of M1 were additionally cleaved by acidic hydrolysis using 3 M HCl. Parent metconazole was determined by LC-MS/MS or GC-NPD, while all metabolites were determined by LC-MS/MS only. The method for 1,2,4-triazole also involved a derivatization step with dansyl chloride. Among the available methods, the validated LOQ for parent metconazole ranged between 0.005–0.02 mg/kg. For metabolites M1 and M12 the validated LOQ was equal to 0.02 mg/kg and for 1,2,4-triazole equal to 0.01 mg/kg. Mean recoveries were within the acceptable range of 70–120% with a RSD of < 20%.

The Meeting concluded that suitable data generation and monitoring methods are available to measure residues of metconazole and metabolites M11, M21 and M30, 1,2,4-triazole, triazolyl alanine, triazolyl acetic acid and triazolyl lactic acid in plants, as well as parent metconazole and metabolites M1, M12 and 1,2,4-triazole in animal commodities.

The Meeting also noted that with the DFG S19 method, a suitable multi-residue method for the monitoring of metconazole residues in plant and animal matrices is available.

#### ***Stability of residues in stored analytical samples***

The Meeting received information on the storage stability of *cis*- and *trans*-metconazole and metabolites M21, M11, M30, 1,2,4-triazole, triazolyl alanine and triazolyl acetic acid in a variety of plant matrices stored under frozen conditions.

Residues of *cis*- and *trans*-metconazole were stable in high starch matrices for at least 12 months (wheat grain and carrot), for at least 31 months (potato) and at least 26 months (radish root); in high protein matrices for at least 14 months (pea seed); in high water matrices for at least 12 months (lettuce); in high oil matrices for at least 12 months (rape seed and oil) and for at least 26 months (soya bean seed); and in blueberries for at least 9 months. Additionally, storage stability in wheat hay was demonstrated for at least 26 months.

Metabolites M11 and M21 were stable in high starch matrices (wheat grain, sugar beet root), high water content matrices (radish tops) and high oil matrices (soya bean seed) for at least 26 months. Additionally, storage stability in wheat straw and hay was demonstrated for at least 26 months.

Metabolite M30 was stable in high starch matrices for at least 26 months (wheat grain) and up to 12 months (sugar beet root). In high water content matrices (radish tops) and high oil matrices (soya bean seed), as well as in wheat straw and hay M30 was stable for up to 12 months.

Metabolite 1,2,4-triazole was stable in high water content matrices (radish tops) for at least 26 months, and in high starch matrices (radish root) as well as in high oil content matrices (soya bean seed) for up to 12 months.

Metabolites triazolyl alanine and triazolyl acetic acid were stable in high starch matrices (wheat grain, radish roots), high water content matrices (radish tops) and high oil matrices (soya bean seed) for at least 26 months.

For animal matrices, the Meeting received information on the storage stability of *cis*- and *trans*-metconazole and metabolites M1 and M12 in animal matrices stored at -20 °C.

Residues of *cis*- and *trans*-metconazole were not stable in muscle and liver, but stable in fat for up to 3 months. Metabolite M1 was stable in liver for at least 9 months and in kidney, muscle, and fat

for at least 8 months. Metabolite M12 was stable in liver and kidney for at least 8 and 9 months, respectively.

### **Definition of the residue**

In the plant metabolism studies conducted on wheat, canola, banana, mandarins and peas, the predominant residue was parent metconazole at 20–29% TRR in rape seeds, 86–89% TRR in banana, 47–94% TRR in mandarins and 21–36% TRR in pea. Only in wheat grain were no parent metconazole or metconazole specific metabolites detected (parent metconazole was detected frequently in cereal grain from field trials). In feed matrices, residues of metconazole ranged from 19–32% TRR in wheat straw, 40–96% TRR in rape forage, 67–96% TRR in pea foliage (vines) and 54–68% TRR in pea straw (hay/fodder).

Analytical methods are capable of monitoring metconazole in all plant matrices.

The Meeting concluded that parent metconazole (sum of *cis* and *trans* isomer) is a major residue in plants and is 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 candidates M11, M21 and M30. All three metabolites were analysed in various food and feed commodities from supervised field trials, but residues were only found in cereal commodities. These metabolites were also identified in plant metabolism studies, but always as minor components of the residue (up to 30% of parent).

Metabolites M11, M21 and M30 were either not detected in the rat or only at small amounts (M21 at < 1–6% AD), and no indications of genotoxicity were identified. Therefore, the TTC approach for a Cramer Class III compound was applied.

Estimated long-term exposures were based on uses in plant and animal commodities and using maximum values found in supervised field trials. Actual measured concentrations from field trials were used where metabolites M11, M21, and M30 were analysed in the field trials. In trials where only metconazole was measured, a maximum value was estimated assuming 30% contribution of each metabolite relative to parent. The estimated long-term maximum dietary exposures for metabolites M11, M21 and M30 were 0.81 µg/kg bw per day –for each metabolite.

The Meeting noted that the estimated exposures for metabolites M11, M21 and M30 are each below the threshold of toxicological concern for Cramer Class III compounds (1.5 µg/kg bw per day), and concluded that dietary exposure to these metabolites is unlikely to present a public health concern.

Triazole derived metabolites were found in significant amounts in wheat grain, oilseed rape seed and pea seed (triazolyl alanine), as well as in wheat grain (triazolyl acetic acid) from primary plant metabolism studies. Moreover, these two metabolites were also frequently detected in crops from supervised field trials (e.g. cereal grains). The Meeting concluded that these metabolites can arise from other sources and have toxicities known to be different from metconazole. These metabolites should be assessed separately, considering their source and respective toxicities, and were not further considered in the current evaluation.

In primary metabolism studies, significant residues of unidentified hydroxylated metconazole metabolites and/or their conjugates were detected in mandarin fruit, pea seed and oilseed rape seed, ranging between 19–67% TRR. These metabolites occurred at lower or similar levels relative to parent metconazole, except for pea seed. Since no genotoxicity was indicated for hydroxylated metconazole metabolites, the TTC approach for Cramer Class III compounds was applied. Estimated long-term exposure was based on consumption of plant and animal commodities and using maximum values of parent metconazole found in supervised field trials corrected for the estimated fraction of the hydroxylated metconazole metabolites.

The following factors were derived from results in metabolism studies (mandarin, pea, oilseed rape) comparing parent and total hydroxylated metconazole metabolites (free and conjugated) and assigning them to associated crops to reflect their nature, where possible. If a crop could not be assigned

to a matching matrix from the metabolism studies, the most conservative factor of 3.6 was applied (e.g. bulb and root vegetables).

Stone fruit, blueberries:	0.6 (mandarin fruit, 28 DAT);
Banana:	0.06 (mandarin fruit, 0 DAT);
Green beans, sweet corn:	3.6 (green pea);
Dried peas, soya beans, cereal grain, maize:	3.0 (dry pea);
Sugar cane, soya bean forage, sugar beet tops, maize forage, rape forage:	0.8 (mandarin leaf);
Oilseeds (oilseed rape, sunflower, cotton seed), peanuts, tree nuts:	2.1 (rape seed);
Straw, hay, stover, almond hulls, cotton gin by-product:	0.5 (pea straw);
Bulb onion, garlic, potato, sugar beet:	3.6 (unassigned).

The estimated long-term maximum dietary exposure, calculated for the total of hydroxylated metconazole metabolites, was 0.75 µg/kg bw per day.

The Meeting noted that the estimated exposure is below the threshold of toxicological concern for Cramer Class III compounds (1.5 µg/kg bw per day) and concluded that dietary exposure to these metabolites is unlikely to present a public health concern.

The Meeting agreed the definition of the residue for dietary risk assessment for plant commodities should be: metconazole (sum of cis and trans isomer)

In animal metabolism studies performed with lactating goats and laying hens, parent metconazole (mostly unconjugated) was quantified at major amounts in goats (liver) and hens (fat, skin and egg yolk), accounting for 11–42% TRR. Major metabolites were M1 (free and conjugated) at 12–16% TRR and M12 (free and conjugated) at 12–21% TRR in goats (kidney) and hens (liver), as well as M31 (free and conjugated) at 15–24% TRR in goats (liver & kidney). The sum of metabolites M1 and M31 accounted for 11–28% TRR in hens (fat, skin and egg yolk). Additionally, metabolite 1,2,4-triazole was quantified in all tissues of laying hens at 27–77% TRR.

A cow feeding study was conducted at treatment rates of 5, 15 and 50 ppm in the diet. In milk no residues >LOQ (0.02 mg/kg) were detected in all dose groups. Residues of parent metconazole were <LOQ (0.04 mg/kg) in muscle, fat, liver and kidney in the highest dose group. Metabolite M1 (free and conjugated) was quantified in the highest dose group in kidney and liver at up to 0.02 mg/kg and 0.03 mg/kg, respectively. Additionally, metabolite M12 (free) was quantified only in kidney from the 15 ppm dose group at 0.02 mg/kg and from the 50 ppm dose group at 0.04 mg/kg.

A poultry feeding study was conducted at treatment rates of 2, 6 and 20 ppm. While residues of parent metconazole in eggs were <LOQ in the lower dose groups, residues ranged between 0.043–0.062 mg/kg at the highest dose group. In tissues, no residues of parent metconazole were detected >LOQ in any dose group. Metabolite M1 was quantified in liver only at the 6 ppm level at 0.02 mg/kg and at the 20 ppm level at 0.04 mg/kg. Additionally, metabolite 1,2,4-triazole was quantified in eggs in the 20 ppm dose group ranging between 0.010–0.024 mg/kg as well as in muscle and liver at 0.028 mg/kg and at 0.029 mg/kg, respectively.

Parent metconazole was identified as a major residue in liver, fat skin and egg yolk during animal metabolism studies. Additionally, it was the only identified compound in eggs during a poultry feeding study. While no suitable marker compound could be identified for all matrices, parent was generally present. Hence, the Meeting decided to include only metconazole (sum of cis and trans isomers) into the residue definition for compliance with MRLs. Analytical methods are capable of measuring metconazole in animal matrices.

In muscle and fat tissues of all animals investigated, residue concentrations were of similar proportions. The log  $P_{ow}$  of metconazole is 3.8. The Meeting concluded that residues are not fat-soluble.

On 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 candidates M1, M12 and M31. The three metabolites were detected in animal metabolism studies in their free and conjugated (conjugated fraction: M1: 83–100%; M12: 0% (ruminant); 64% (poultry); M31: 72–100%) forms in liver and kidney. However, levels of M1 (free and conjugated) and M12 (free) in their free form found in liver and kidney during ruminant and poultry feeding studies were low. Since the method used in the feeding studies did not include a hydrolysis step, residue levels could be underestimated for total free and conjugated M12 in poultry. M1 and M12 were observed in the rat and are of no greater toxicity than parent metconazole and are covered by its toxicological reference values. Therefore, the Meeting decided to include the metabolites into the residue definition for dietary exposure purposes. Metabolite M31 was not detected in the rat and no indications on genotoxicity were identified. Therefore, the TTC approach for a Cramer Class III compound was applied. Potential long-term exposure to M31 was estimated using the maximum values found in liver and kidney in the metabolism studies.

The estimated long-term maximum dietary exposure, calculated for metabolite M31 was 0.01 µg/kg bw per day.

The Meeting noted that the estimated dietary exposure to M31 is below the threshold of toxicological concern for Cramer Class III compounds (1.5 µg/kg bw per day) and concluded that dietary exposure to this metabolite is unlikely to be of public health concern.

Triazole metabolite 1,2,4-triazole was found in significant amounts in a poultry metabolism study and feeding study. The Meeting concluded that triazole metabolites, such as 1,2,4-triazole, can arise from other sources and have toxicities known to be different from metconazole. These metabolites should be assessed separately, considering their source and respective toxicities and were not further considered in the current evaluation.

For dietary exposure purposes for animal commodities, based on the results of the animal metabolism studies, the Meeting decided to include metabolites M1 and M12 (free and conjugated) in the residue definition, together with parent metconazole (sum of *cis* and *trans* isomer).

Definition of the residue for compliance with the MRL for plant and animal commodities: *Metconazole (sum of cis and trans isomer)*

Definition of the residue for dietary risk assessment for plant commodities: *Metconazole (sum of cis and trans isomer)*

Definition of the residue for dietary risk assessment for animal commodities: *Sum of metconazole (cis and trans-isomer) and metabolites (1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol (M1; free and conjugated) and (1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid (M12; free and conjugated), expressed as metconazole*

*The residue is not fat-soluble.*

### **Results of supervised residue trials on crops**

#### **Stone fruit (peach, plum, cherry)**

The critical GAP for stone fruit in the USA allows three foliar applications of metconazole at 140 g ai/ha, at full bloom, petal fall and pre-harvest and a PHI of 14 days.

The ranked order of residues in peach approximating GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 8): 0.040(2), 0.045(3), 0.050, 0.060, 0.085 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg, a STMR of 0.045 mg/kg and a HR of 0.09 mg/kg (highest individual value) for metconazole in the subgroup of peaches.

The ranked order of residues in plum approximating GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 5): < 0.04(2), 0.040(2), 0.045 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, a STMR of 0.040 mg/kg and a HR of 0.05 mg/kg (highest individual value) for metconazole in the subgroup of plums.

The ranked order of residues in cherry approximating GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 7): < 0.04, 0.040, 0.060, 0.070, 0.080, 0.090 and 0.14 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, a STMR of 0.07 mg/kg and a HR of 0.16 mg/kg (highest individual value) for metconazole in the subgroup of cherries.

### ***Blueberries***

The critical GAP for blueberries in Canada allows three foliar applications of metconazole at 90 g ai/ha applied at flowering and pre-harvest with no more than two sequential applications and a PHI of 7 days.

Field trials conducted with blueberries in Canada and the USA were performed with three foliar applications of metconazole at rates of 90–100 g ai/ha with a RTI of 27–63 days between the first and second treatment and 6–14 days between the second and third treatment.

The ranked order of residues approximating GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 11): < 0.10(2), 0.12, 0.13, 0.14(2), 0.16, 0.18, 0.19, 0.20, 0.31 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg, a STMR of 0.14 mg/kg and HR of 0.33 mg/kg (highest individual value) for metconazole in blueberries.

### ***Banana***

The critical GAP for banana in Mexico allows three foliar applications of metconazole at 90 g ai/ha with a RTI of 14 days and a PHI of 0 days.

Field trials conducted with banana in the Costa Rica (3), Ecuador (3), Honduras (3), and Mexico (3) were performed with seven foliar applications of metconazole at rates of 150 g ai/ha with an RTI of 11–15 days. Bananas were harvested at 0 DALA.

The ranked order of residues in these trials for estimating maximum residue levels and dietary risk assessment was (n = 12): < 0.10(12) mg/kg.

Although the number of applications in field trials was 7 instead of 3, the Meeting concluded that recommendations could be given since all residues even at the higher number of applications were <LOQ and estimated a maximum residue level of 0.1(\*) mg/kg and a STMR and HR of 0.1 mg/kg in banana.

### ***Bulb onions, Subgroup of***

The critical GAP for bulb onion and garlic in Brazil allows three foliar applications of metconazole at 90 g ai/ha with a RTI of 7 days and a PHI of 14 days.

#### ***Bulb onion***

Field trials conducted with bulb onion in Brazil were performed approximating the GAP.

The ranked order of residues in bulb onions following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 3): < 0.02, < 0.05(2) mg/kg.

#### ***Garlic***

Field trials conducted with garlic in Brazil were performed approximating the GAP.



The ranked order of residues in garlic following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 3): < 0.02, < 0.05(2) mg/kg.

The Meeting decided to combine the data sets from bulb onions and garlic to mutually support maximum residue levels for bulb onion and garlic. The ranked order of residues following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 6): < 0.02(2), < 0.05(4) mg/kg.

The Meeting estimated a maximum residue level of 0.05(\*) mg/kg, a STMR and HR of 0.05 mg/kg for metconazole in bulb onion and garlic.

#### ***Beans with pods (Phaseolus spp.) (immature pods and succulent seeds)***

The critical GAP for green beans in Brazil allows three foliar applications of metconazole at 14 g ai/ha with a RTI of 7 days and a PHI of 15 days.

Field trials conducted with green beans in Brazil were performed with three foliar applications of metconazole at considerably higher rates of 45–180 g ai/ha with a RTI of 7 days and PHI of 14–15 days.

The ranked order of residues for estimating maximum residue levels and dietary risk assessment was (n = 4): < 0.02, < 0.05(3) mg/kg.

The Meeting noted that green beans fall under category 3 of the minor crop classification, requiring a minimum of five supervised field trials to estimate maximum residue levels. Although the number of trials was only 4, the Meeting estimated a maximum residue level of 0.05(\*) mg/kg and a STMR and HR of 0 mg/kg, since no residues >LOQ were detected at a considerably higher treatment rates.

#### ***Dry beans (except soya beans), Subgroup of***

The critical GAP for dry beans except soya beans in Canada and the USA allows two foliar applications of metconazole at 140 g ai/ha with a RTI of 7 days and a PHI of 21 days.

In field trials conducted with dry beans in Canada and the USA, the ranked order of residues following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 18): < 0.04(18) mg/kg.

The Meeting noted that the GAP covers the subgroup of dry beans except soya beans and estimated a maximum residue level of 0.04(\*) mg/kg, and a STMR of 0.04 mg/kg for metconazole in the subgroup of dry beans (except soya bean).

#### ***Soya beans***

The critical GAP for soya beans in the USA allows two foliar applications of metconazole at 63 g ai/ha with a RTI of 10 days and a PHI of 30 days.

In field trials conducted with soya beans in the USA, the ranked order of residues for estimating maximum residue levels and dietary risk assessment was (n = 21): < 0.01(17), 0.011, 0.012, 0.030, 0.046 mg/kg. Using scaling a factor of 0.8, scaled residues in ranked order were (n = 21): < 0.01(17), 0.01(2), 0.024, 0.037

The Meeting estimated a maximum residue level of 0.04 mg/kg, and a STMR of 0.01 mg/kg for metconazole in soya beans.

#### ***Dry peas, Subgroup of***

The critical GAP for dry peas in Canada and the USA allows two foliar applications of metconazole at 140 g ai/ha with a RTI of 7 days and a PHI of 21 days.

In field trials conducted with dry peas in Canada and the USA, the ranked order of residues following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 14): < 0.04(5), 0.041, 0.042, 0.043, 0.048, 0.051, 0.056, 0.061, 0.073, 0.084 mg/kg.

The Meeting noted that the GAP covers the subgroup of dry peas and estimated a maximum residue level of 0.15 mg/kg, and a STMR of 0.0425 mg/kg for metconazole in the subgroup of dry peas.

#### *Tuberous and corm vegetables, Subgroup of*

The critical GAP for the subgroup of tuberous and corm vegetables in the USA allows four foliar applications of metconazole at 140 g ai/ha with a RTI of 7 days and a PHI of 1 day.

In field trials conducted with potato in the USA, the ranked order of residues following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 14): < 0.04(14) mg/kg.

The Meeting noted that the GAP covers the subgroup of tuberous and corm vegetables and estimated a maximum residue level of 0.04(\*) mg/kg, and a STMR and HR of 0 mg/kg for metconazole in the subgroup of tuberous and corm vegetables, including potato.

#### *Sugar beet*

The critical GAP for sugar beet in Canada allows two outdoor foliar applications of metconazole at 113 g ai/ha with a RTI of 14 days and a PHI of 14 days.

In field trials conducted with sugar beet in the USA, the ranked order of residues following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 11): < 0.01, 0.010(3) 0.020(3), 0.022, 0.030(2), 0.044 mg/kg.

The Meeting estimated a maximum residue level of 0.07 mg/kg and a STMR of 0.02 mg/kg for metconazole in sugar beet.

#### *Barley, oats, rye, wheat*

The critical GAP for barley, oat, rye, triticale and wheat in the USA allows two outdoor foliar applications of metconazole at 112 g ai/ha with a RTI of 6 days and a PHI of 30 days.

The ranked order of residues in barley following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 1): 0.83 mg/kg.

The Meeting concluded that no maximum residue level could be estimated for metconazole in barley.

The ranked order of residues in oats following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 2): 0.21, 0.31 mg/kg.

The Meeting concluded that no maximum residue level could be estimated for metconazole in oat.

The ranked order of residues in rye following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 3): 0.068, 0.074, 0.15 mg/kg.

The Meeting concluded that no maximum residue level could be estimated for metconazole in rye.

The ranked order of residues in wheat following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 4): 0.011, 0.013, 0.015, 0.051 mg/kg.

The Meeting concluded that no maximum residue level could be estimated for metconazole in wheat.

Since the residue populations were significantly different according to the Kruskal-Wallis H-test between cereals, the Meeting decided that it was not possible to combine the data for mutual support.

### *Maize*

The critical GAP for maize in the USA allows four foliar applications of metconazole at 92 g ai/ha with a RTI of 7 days and a PHI of 20 days.

In field trials conducted with maize in the USA, the ranked order of residues following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 20): < 0.01(18), 0.010, 0.015 (highest individual value: 0.018) mg/kg.

The Meeting estimated a maximum residue level of 0.015 mg/kg, and a STMR of 0.01 mg/kg for metconazole in maize.

### *Sweet corn (Corn-on-the-cob)*

The critical GAP for sweet corn in the USA allows four foliar applications of metconazole at 92 g ai/ha with a RTI of 7 days and a PHI of 7 days.

In field trials conducted with sweet corn in the USA the ranked order of residues following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 12): < 0.01(11), 0.01 mg/kg.

The Meeting estimated a maximum residue level of (\*)0.015 mg/kg, and a STMR and HR of 0.01 mg/kg for metconazole in sweet corn (Corn-on-the-cob).

### *Sugar cane*

The critical GAP for sugar cane in the USA allows four foliar applications of metconazole at 91 g ai/ha with a RTI of 14 days and a PHI of 14 days.

In field trials conducted with sugar cane in the USA, the ranked order of residues following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 8): < 0.01(2), 0.019, 0.020, 0.021, 0.023, 0.030, 0.036 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg, a STMR of 0.0205 mg/kg and HR of 0.036 mg/kg for metconazole in sugar cane.

### *Tree nuts*

The critical GAP for tree nuts in the USA allows four foliar applications of metconazole at 123 g ai/ha (pistachios: 140 g ai/ha) with a RTI of 7 days (14 days filberts and pistachios) and a PHI of 25 days.

#### *Pecan nuts*

Field trials with pecan nuts conducted in the USA were performed with 2 foliar applications of metconazole at rates of 268–306 g ai/ha with a 145–178 day interval between applications and harvested at 25 DALA.

The ranked order of residues in these trials for estimating maximum residue levels and dietary risk assessment was (n = 3): < 0.04(3) mg/kg.

#### *Almonds*

Field trials with almonds conducted in the USA were performed with 2 foliar applications of metconazole at rates of 153–307 g ai/ha and one trial at an exaggerated rate of 607–608 g ai/ha with a 133–155 day interval between applications and harvested at 25 DALA.

The ranked order of residues in these trials for estimating maximum residue levels and dietary risk assessment was (n = 7): < 0.04(7) mg/kg.

The Meeting noted that all trials for pecan and almonds were overdosed with the last application according to the PHI of the critical GAP and all residues were <LOQ, and decided to estimate a maximum residue level of 0.04(\*) mg/kg and a STMR and HR of 0 mg/kg for the group of tree nuts.

### *Rape seed*

The Meeting noted a GAP from the USA involving one single application of metconazole at 140 g ai/ha with a 35 day PHI. However, residue levels observed in oilseed rape from corresponding field trials in the USA indicated that this was not the most critical GAP available. Therefore, the Meeting based its recommendations on a more critical GAP as reflected in the European field trials.

The critical GAP for oilseed rape in Chile allows two foliar applications of metconazole at 90 g ai/ha with a PHI of 42 days.

Field trials conducted with oilseed rape in France were performed with two foliar applications of metconazole at rates of 90 g ai/ha (RTI not stated) and harvest at 39–70 DALA.

The ranked order of residues in rape seed following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 2): 0.050, 0.090 mg/kg.

The critical GAP for oilseed rape in the United Kingdom allows a maximum of two foliar applications of metconazole at 72 g ai/ha at up to BBCH 71 (10% of pods at final size) with a RTI of 14 days.

In field trials conducted with oilseed rape in France, the ranked order of residues in rape seed following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 11): < 0.02(5), 0.02(2), 0.04, 0.05, 0.07, 0.09 mg/kg.

Based on the UK GAP, which was supported with a sufficient number of supervised field trials, the Meeting estimated a maximum residue level of 0.15 mg/kg and a STMR of 0.02 mg/kg for metconazole in rape seed.

### *Sunflower seeds, Subgroup of*

The critical GAP for sunflower in Canada and the USA allows two foliar applications of metconazole at 140 g ai/ha with a RTI of 7 days and a PHI of 21 days.

In field trials conducted with sunflower in Canada and the USA, the ranked order of residues in sunflower seeds following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 7): < 0.04, 0.040, 0.043, 0.089, 0.096, 0.24, 0.68 mg/kg.

The Meeting estimated a maximum residue level of 1.5 mg/kg, and a STMR of 0.089 mg/kg for metconazole in the subgroup of sunflower seeds.

### *Cotton seed*

The critical GAP for cotton seed in the USA allows three foliar applications of metconazole at 92 g ai/ha with a RTI of 7 days and a PHI of 30 days.

In field trials conducted with cotton in the USA, the ranked order of residues in cotton seed following GAP treatment ( $\pm 25\%$ ) for estimating maximum residue levels and dietary risk assessment was (n = 12): 0.020, 0.021, 0.022, 0.024(2), 0.027, 0.042, 0.051, 0.068, 0.071, 0.075, 0.23 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg, and a STMR of 0.0345 mg/kg for metconazole in cotton seed.

### *Peanuts*

The critical GAP for peanuts in the USA allows four foliar applications of metconazole at 140 g ai/ha

with a RTI of 14 days and a PHI of 14 days.

Field trials conducted with peanuts in the USA were performed with two foliar applications of metconazole at rates of 270–290 g ai/ha and harvest at 13–15 DALA. Since no residues occurred at a 2X application rate, the Meeting assumed that four application at 1X, would also not result in residues >LOQ. Residue levels from additional trials performed at a 4X or 10X application rate were also <LOQ or only slightly above.

The ranked order of residues in peanut for estimating maximum residue levels and dietary risk assessment was (n = 14): < 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.04(\*) mg/kg, and a STMR of 0.04 mg/kg for metconazole in peanuts.

### ***Animal feeds***

#### ***Soya bean forage***

The critical GAP for soya bean forage in the USA allows two outdoor foliar applications of metconazole at 63 g ai/ha with no livestock feeding restrictions.

Field trials conducted with soya bean forage in the USA, were performed with two foliar applications of metconazole at rates of 80 g ai/ha with a PHI of 7–8 days. The Meeting noted that since there were no livestock feeding restrictions a 7 day pre-grazing or feeding interval would be practical.

The ranked order of residues was (n = 21): 0.56, 0.71, 0.73, 0.96, 1.0(2), 1.1, 1.2(3), 1.3, 1.4, 1.6, 1.7, 1.8, 1.9(4), 2.2(2) mg/kg (2.4 mg/kg highest individual). Using scaling a factor of 0.8, scaled residues in ranked order were (n = 21): 0.45, 0.57, 0.58, 0.77, 0.8(2), 0.88, 0.96(3), 1.0, 1.1, 1.3, 1.4(2), 1.5(4), 1.8(2) mg/kg (1.92 mg/kg highest individual scaled).

The Meeting estimated a highest residue of 1.92 mg/kg (as received) for metconazole in soya bean forages and a median residue of 1.0 mg/kg (as received).

#### ***Soya bean hay***

The critical GAP for soya bean hay in the USA allows two outdoor foliar applications of metconazole at 63 g ai/ha with no livestock feeding restrictions.

Field trials conducted with soya bean hay in the USA were performed with two foliar applications of metconazole at rates of 80 g ai/ha and harvest 7–8 or 20 DALA. The Meeting noted that since there were no livestock feeding restrictions a minimum 7 day pre-grazing or feeding interval would be practical.

The ranked order of residues was (n = 21): 0.6, 1.1, 1.3, 1.4(3), 1.7, 2.0(2), 2.1(2), 2.3, 2.6(3), 3.0, 3.2(2), 3.3, 3.4, 3.9 mg/kg (4.0 mg/kg highest individual). Using scaling a factor of 0.8, scaled residues in ranked order were (n = 21): 0.48, 0.88, 1.0, 1.1(3), 1.4, 1.6(2), 1.7(2), 1.8, 2.1(3), 2.4, 2.6(3), 2.7, 3.1 mg/kg (3.2 mg/kg highest individual scaled).

The Meeting estimated a highest residue of 3.2 mg/kg (as received) for metconazole in soybean hay, a median residue of 1.7 mg/kg (as received) and a maximum residue level of 8 mg/kg (DM, based on 85% DM content).

#### ***Sugar beet tops***

The critical GAP for sugar beet in Canada allows two outdoor foliar applications of metconazole at 113 g ai/ha with no livestock feeding restrictions.

Field trials conducted with sugar beet in the USA were performed with two foliar applications of metconazole at rates of 109–114 g ai/ha and harvest at 14–15 DALA. The Meeting noted that sugar beet tops are normally harvested (or grazed) at the same time as beet harvesting. Hence, the 14 day PHI for beet would also reflect grower practice for sugar beet tops.

The ranked order of residues in sugar beet tops following GAP treatment was (n = 11): 0.09, 0.11, 0.12, 0.13, 0.14, 0.15, 0.58, 0.97, 1.0(2), 1.2 mg/kg as received.

The Meeting estimated a highest residue of 1.2 mg/kg (as received) for metconazole in sugar beet tops and a median residue of 0.15 mg/kg (as received).

#### *Hay (barley, oats, rye, wheat)*

The critical GAP for hay of wheat, oat, barley, rye and triticale in the USA allows two foliar applications of metconazole at 112 g ai/ha with no livestock feeding restrictions.

The ranked order of residues in barley hay following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 11): 0.79, 0.82, 1.2, 1.5, 2.2, 3.0, 3.1, 3.2(2), 4.1, 4.4 mg/kg.

The ranked order of residues in oat hay following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 12): 2.4, 2.6, 3.7, 3.8, 4.8, 4.9, 6.0, 6.1, 6.6, 9.4(2), 11 mg/kg.

The ranked order of residues in wheat hay following GAP treatment for estimating maximum residue levels and dietary risk assessment was (n = 15): 1.4, 2.0, 3.9, 4.2, 5.2, 5.5, 5.9(2), 6.2, 6.3, 6.7, 7.3, 9.7, 11, 13 mg/kg.

The Meeting noted that median residues in barley, oats and wheat hay and straw are within a 5-fold range. However, since the residue populations were significantly different according to the Kruskal-Wallis H-test between cereals, the Meeting decided to estimate a maximum residue level and median residue value based on the highest individual dataset for wheat hay (see JMPR Report 2013, 2.9).

Based on wheat hay, the Meeting estimated a highest residue of 13 mg/kg (as received), a median residue of 5.9 mg/kg (as received) and a maximum residue level of 25 mg/kg (DM, based on 88% DM content) for hay of barley, oat, rye, wheat, extrapolated to triticale.

#### *Straw (barley, oats, rye, wheat)*

The critical GAP for straw of wheat, oat, barley, rye and triticale in the USA allows two foliar applications of metconazole at 112 g ai/ha with no livestock feeding restrictions. The Meeting noted that the GAP for barley, oat, rye, triticale and wheat grains in the USA has a PHI of 30 days.

The ranked order of residues in barley straw approximating GAP was (n = 1): 2.6 mg/kg (3.1 mg/kg highest individual).

The ranked order of residues in oat straw approximating GAP was (n = 2): 1.0, 1.8, mg/kg (2.1 mg/kg highest individual).

The ranked order of residues in rye straw approximating GAP was (n = 3): 2.3, 5.0, 8.5 mg/kg (8.8 mg/kg highest individual).

The ranked order of residues in wheat straw approximating GAP was (n = 4): 0.42, 1.2, 2.3, 4.8 mg/kg (5.1 mg/kg highest individual).

The Meeting decided to combine the data sets for straw as they were considered similar. The ranked order of residues in straw following treatment approximating GAP for estimating maximum residue levels and livestock burden was (n = 10): 0.42, 1.0, 1.2, 1.8, 2.3(2), 2.6, 4.8, 5.0, 8.5 mg/kg (8.8 mg/kg highest individual residue).

The Meeting estimated a highest residue of 8.8 mg/kg (as received), a median residue of 2.3 mg/kg (as received) and a maximum residue level of 20 mg/kg (DM, based on 88% DM content) for straw of barley, oat, rye, wheat, extrapolated to triticale.

### ***Maize forage***

The critical GAP for maize forage in the USA allows four foliar applications of metconazole at 92 g ai/ha with a PHI of 7 days.

In field trials conducted with maize in the USA, the ranked order of residues in maize forage following GAP treatment ( $\pm 25$ ) was (n = 25): 0.04, 0.09, 0.10(2), 0.11, 0.17, 0.19, 0.48, 0.52, 0.53, 0.80, 0.82, 0.91, 0.97, 1.1, 1.2(4), 1.3(2), 1.5, 1.8, 1.9, 2.7 mg/kg as received.

The Meeting estimated a highest residue of 2.7 mg/kg (as received) for metconazole in maize forage and a median residue of 0.91 mg/kg (as received).

### ***Maize fodder***

The critical GAP for maize fodder in the USA allows four foliar applications of metconazole at 92 g ai/ha with a PHI of 20 days.

In field trials conducted with maize in the USA, the ranked order of residues in maize fodder following GAP treatment ( $\pm 25$ ) was (n = 20): 0.14, 0.94, 1.2, 1.4, 1.5(2), 1.6, 1.8(3), 1.9(2), 2.0(2), 2.1, 2.3, 2.5, 2.7(2), 3.2 mg/kg as received (3.5 mg/kg highest individual value).

The Meeting estimated a highest residue of 3.5 mg/kg (as received) for metconazole in maize fodder, a median residue of 1.85 mg/kg (as received) and a maximum residue level of 7 mg/kg (DM, based on 83% DM content)

### ***Almond hulls***

The critical GAP for almonds in the USA allows four outdoor foliar applications of metconazole at 123 g ai/ha with a PHI of 25 days, with no more than 2 sequential applications after petal fall before switching to an alternative fungicide.

No trials provided matched the GAPs. Hence, the Meeting concluded that no maximum residue level could be estimated for metconazole in almond hulls.

### ***Rape seed forage***

The critical GAP for oilseed rape in Chile allows two outdoor foliar applications of metconazole at 90 g ai/ha with a PHI of 42 days.

In field trials conducted with oilseed rape in France, the ranked order of residues in rape forage following GAP treatment ( $\pm 25$ ) was (n = 7): 0.050, 0.060, 0.070, 0.090, 0.12, 0.13(2) mg/kg.

The Meeting estimated a highest residue of 0.13 mg/kg (as received) for metconazole in oilseed rape forage and a median residue of 0.09 mg/kg (as received).

### ***Cotton gin by-products***

The critical GAP for cotton seed in the USA allows three outdoor foliar applications of metconazole at 92 g ai/ha with a PHI of 30 days.

In field trials conducted with cotton in the USA, the ranked order of residues in cotton gin by-products following GAP treatment ( $\pm 25$ ) was (n = 6): 0.17, 0.18, 2.5, 2.8, 3.7, 4.1 mg/kg (4.6 mg/kg highest individual value).

The Meeting estimated a highest residue of 4.6 mg/kg (as received) for metconazole in cotton gin by-products, a median residue of 2.65 mg/kg (as received) and a maximum residue level of 10 mg/kg (DM, based on 90% DM content).

### ***Fate of residues during processing***

The Meeting received information on the hydrolysis of *cis*-enriched  $^{14}\text{C}$ -labelled-metconazole, simulating typical processing conditions (pH 4,5 and 6 with 90 °C, 100°C and 120 °C for 20, 60 and 20

minutes). No significant hydrolysis of metconazole was observed at the conditions studied.

The Meeting concluded that metconazole is stable under the conditions of pasteurisation, boiling, baking and brewing, as well as sterilisation.

The fate of metconazole residues has been examined simulating household and commercial processing of plums, soya bean, potato, sugar beet, barley, oat, maize, wheat, sugar cane, oilseed rape seed, cotton seed and peanut.

Table 2 Estimated processing factors for maximum residue and dietary exposure of processed commodities according to the residue definition *metconazole* (sum of *cis* and *trans* isomer)

Crop	Residue (mg/kg) in RAC			Processed commodity	Individual PF	Median or best estimate PF	Residue (mg/kg) in processed commodity		
	MRL	STMR	HR				MRL-P	STMR-P	HR-P
Plum	0.1	0.04	0.05	Prunes, dried	2.3	2.3	0.5	0.092	0.115
Soya bean	0.04	0.01	-	Refined oil	< 0.48, < 0.53, 0.69	0.53	-	0.005	-
Sugar beet	0.07	0.02	-	Sugar	0.5, < 0.6, 1.2	0.6	-	0.012	-
Sugar cane	0.06	0.021	0.036	Ref. sugar	< 0.10	< 0.10	-	0.002	-
				Molasses	1.3	1.3	0.08	0.027	-
Rape seed	0.15	0.02	--	Refined oil	1.5, 1.6, 1.6, 1.8	1.6	0.5	0.032	-
Cotton seed	0.3	0.035	-	Refined oil	0.12	0.12	-	0.004	-
Peanut	0.04(*)	0.04	-	Refined oil	1.4	1.4	0.06	0.056	-

### **Residues in animal commodities**

#### **Farm animal feeding studies**

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

The study with lactating cows was conducted at treatment rates of 5, 15 and 50 ppm. In milk, skim milk and cream residues of *cis*- and *trans*-metconazole were <LOQ in the 50 ppm dose group throughout the study. Residues of parent metconazole were <LOQ (< 0.04 mg/kg) in muscle, fat, liver kidney, at the highest dose group. Metabolite M1 (free and conjugated) was quantified in the highest dosing group in kidney and liver at up to 0.02 mg/kg and 0.03 mg/kg, respectively. Additionally, metabolite M12 (free) was quantified only in kidney at the 15 ppm level at 0.02 mg/kg and at the 50 ppm level at 0.04 mg/kg.

The study with laying hens was conducted at treatment rates of 2, 6 and 20 ppm. While residues of parent metconazole in eggs were <LOQ in the lower dose groups, residues ranged between 0.043–0.062 mg/kg at the highest dose group. In tissues, no residues of parent metconazole were detected >LOQ in any dose group. Metabolite M1 (free and conjugated) was quantified in liver only at the 6 ppm level at 0.02 mg/kg and at the 20 ppm level at 0.04 mg/kg. Additionally, metabolite 1,2,4-triazole was quantified in eggs at the 20 ppm dose group ranging between 0.010–0.024 mg/kg as well as in muscle and liver at 0.028 mg/kg and at 0.029 mg/kg, respectively.

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

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



Table 3 Estimated livestock dietary burden for *metconazole* (sum of *cis* and *trans* isomer)

Livestock dietary burden, ppm of dry matter diet								
	US-Canada		EU		Australia		Japan	
	max.	Mean	max.	mean	max.	Mean	max.	Mean
<b>Beef cattle</b>	2.5	1.2	8.6	3.2	15 <sup>a</sup>	6.7 <sup>b</sup>	0.010	0.010
<b>Dairy cattle</b>	6.2	2.8	7.9	2.5	15 <sup>a</sup>	6.7 <sup>b</sup>	3.8	1.4
<b>Poultry – broiler</b>	0.040	0.040	0.028	0.028	0.046	0.046	0.008	0.008
<b>Poultry – layer</b>	0.040	0.040	2.2 <sup>c</sup>	0.94 <sup>d</sup>	0.046	0.046	0.009	0.009

<sup>a</sup> Highest maximum dietary burden for beef or dairy cattle; suitable for estimating the maximum residue levels for mammalian meat and milk

<sup>b</sup> Highest mean dietary burden for beef or dairy cattle; suitable for estimating STMRs for mammalian meat and milk

<sup>c</sup> Highest maximum dietary burden for broiler chickens or laying hens suitable for estimating maximum residue levels for poultry meat, fat, offal, and eggs

<sup>d</sup> Highest mean dietary burden for laying hens; suitable for estimating the STMRs for poultry meat, fat, offal, and eggs.  
none no relevant feed items

#### *Animal commodities maximum residue levels*

For beef and dairy cattle, a maximum and mean dietary burden of 15 ppm and 6.7 ppm were estimated, respectively. The estimated dietary burdens are evaluated against a lactating cow feeding study involving administration of metconazole at 5, 15 and 50 ppm.

For maximum residue level estimation, the Meeting noted that even at the 50 ppm feeding level no residues of metconazole >LOQ were detected in milk and tissues and estimated maximum residues levels of 0.04(\*) mg/kg for mammalian meat, milks, fat and edible offal (mammalian).

For STMR and HR estimations in milk and tissues, the mean and maximum dietary burdens of 6.7 ppm and 15 ppm, respectively, were evaluated against the residues in milk and tissues of the lactating cow feeding study at the 15 ppm dosing level. Levels in milk, muscle and fat (parent only measured) and liver and kidney (parent, metabolite M1 (free and conjugated) and M12 (free) measured) were < LOQ at 15 ppm (except for M12 in kidney found at 0.02 mg/kg at 15 ppm). Levels of metabolites M1 (free and conjugated) and M12 (free) in milk, muscle and fat in a goat metabolism study dosed at 24 ppm were < 0.01 mg/kg. Conjugated M12 was not found in the goat metabolism study.

The Meeting estimated STMR and HR values of 0 mg/kg in mammalian meat, milks and fat.

As residues of parent were <LOQ, even at the 50 ppm feeding level, the Meeting decided to set the value at 0 for estimating STMR and HR values in edible offal (mammalian). The Meeting estimated a STMR and HR of 0.037 mg/kg for edible offal (mammalian) based on kidney

For poultry, a maximum and mean dietary burden of 2.2 ppm and 0.94 ppm were estimated, respectively. The estimated dietary burdens are evaluated against a poultry feeding study involving administration of metconazole at 2, 6 and 20 ppm.

For a maximum residue level, the Meeting noted that even at the 20 ppm feeding level no residues of metconazole >LOQ were detected in eggs and poultry tissues and estimated maximum residues levels of 0.04(\*) mg/kg in poultry meat, eggs, fat and edible offal.

For STMR and HR estimations in eggs and poultry tissues, the mean and maximum dietary burden of 0.94 ppm and 2.2 ppm were evaluated against the residues in eggs and tissues of the poultry feeding study at the 2 ppm and 6 ppm dosing level, respectively. Levels in eggs (parent only measured) were <LOQ at 2 and 6 ppm. Residues of metabolites M1 and M12 in eggs from a poultry metabolism study dosed at 14 ppm or 13 ppm, scaled to the mean dietary burden of 0.94 ppm were < 0.01 mg/kg. In tissues (parent, metabolite M1 (free and conjugated) and M12 (free) measured) were <LOQ at 2 and

6 ppm (except for M1 in liver found at 0.02 mg/kg at 6 ppm). . Since no conjugates of M12 were determined, residue levels could be underestimated for total free and conjugated M12 in poultry. However, considering the contribution of conjugated M12 (up to 64% of total M12) and that residues of M12 (free) were <LOQ at even 20 ppm, no residues of M12 (conjugated) >LOQ are expected at the relevant dietary burden.

The Meeting estimated STMR and HR values of 0 mg/kg for poultry eggs, meat and fat.

As residues of parent and M12 in liver were <LOQ in all dose groups, the Meeting decided to set these values at 0 for estimating STMR and HR values in poultry edible offal. The Meeting estimated a STMR of 0.019 mg/kg and a HR of 0.020 mg/kg in 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 are suitable for establishing maximum residue limits and for IEDI and IESTI assessments.

Definition of the residue for compliance with the MRL for plant and animal commodities: *Metconazole (sum of cis and trans isomer)*

Definition of the residue for dietary risk assessment for plant commodities: *Metconazole (sum of cis and trans isomer)*

Definition of the residue for dietary risk assessment for animal commodities: *Sum of metconazole (cis and trans-isomer) and metabolites (1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol (M1; free and conjugated) and (1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid (M12; free and conjugated), expressed as metconazole*

*The residue is not fat-soluble.*

## Dietary risk assessment

### Long-term dietary exposure

The ADI for metconazole is 0–0.04 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for metconazole 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 2019 JMPR Report.

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

### Acute dietary exposure

The ARfD for metconazole is 0.04 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for metconazole 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 2019 JMPR Report.

The IESTIs varied from 0–20% of the ARfD for children and 0–10% of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of metconazole from uses considered by the present Meeting is unlikely to present a public health concern.

## 5.17 Penthiopyrad (253)

### RESIDUE AND ANALYTICAL ASPECTS

Penthiopyrad is a locally systemic carboxamide fungicide used for the control of foliar and soil-borne plant diseases. Penthiopyrad was first evaluated in 2011 for toxicology, and an ADI of 0–0.1 mg/kg bw and an ARfD of 1 mg/kg bw were established. For residues, penthiopyrad was first evaluated by the 2012 JMPR. The residue definition for compliance with the MRL for plant commodities is penthiopyrad. For compliance with the MRL for animal commodities and dietary risk assessment for plant and animal commodities, the residue definition is the sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad. The residue is not fat-soluble. Additional uses were evaluated by the 2013 JMPR.

Penthiopyrad was scheduled at the Fiftieth Session of the CCPR for evaluation of additional uses by the 2019 JMPR. The Meeting received information on supervised residue trials and GAP information for caneberry and blueberry.

#### **Methods of analysis**

Residues of penthiopyrad and its metabolites (PAM and PCA, 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid) were analysed by the method evaluated by the 2012 JMPR. The current Meeting received additional method validation and concurrent recovery data on caneberry and blueberry. The method involving extraction and partitioning with organic solvent and determination by LC-MS/MS, was sufficiently validated for caneberry and blueberry. Mean recoveries ranged from 80–115% (RSDs ≤ 15%). The LOQs for the analytes were 0.01 mg/kg.

#### **Stability of residues in stored analytical samples**

The 2012 JMPR agreed that penthiopyrad, PAM and PCA are stable for at least 18 months in frozen plant matrices. The residue sample storage intervals used in the field trials considered by the current Meeting were covered by the demonstrated stability period.

#### **Results of supervised residue trials on crops**

Supervised trials were available for the use of penthiopyrad on caneberry and blueberry. Product labels were available from Canada.

For dietary risk assessment, the sum of penthiopyrad and PAM (conversion factor into penthiopyrad, 1.86) is referred to as "total". If both analytes were below LOQs (< 0.01 mg/kg), the total residues were assumed to be < 0.01 mg/kg, and for all other cases, <LOQ values were handled as their numeric value (e.g. < 0.01 mg/kg as 0.01 mg/kg).

#### **Cane berries, Subgroup of**

##### ***Blackberry and raspberry***

The critical GAP for penthiopyrad on caneberries in Canada is 3 foliar spray applications of 0.35 kg ai/ha each with a minimum retreatment interval of 7 days and a PHI of 0 days. One field trial on blackberry conducted in the USA and four independent field trials on raspberry conducted in Canada or the USA matched the critical GAP. Noting that the cGAP was for caneberries, the Meeting decided to combine the data from raspberries and blackberries to consider a group maximum residue level.

For the purposes of maximum residue level estimation penthiopyrad residues in raspberries and blackberries from trials matching the Canadian GAP were (n = 5): 2.0, 3.4, 3.7, 3.7 and 4.3 (blackberry) mg/kg.

For the dietary risk assessment purposes the total residues in caneberry were (n = 5): 2.0, 3.4, 3.7, 3.8 and 4.3 mg/kg (highest individual value was 4.8 mg/kg).

The Meeting estimated a maximum residue level of 10 mg/kg, a STMR of 3.7 mg/kg and a HR of 4.8 mg/kg for penthiopyrad in the Subgroup 004A Caneberries.

### **Blueberries**

The critical GAP for penthiopyrad on bushberries is 3 spray applications at a rate of 0.35 kg ai/ha with a minimum retreatment interval of 7 days and a PHI of 0 days. Seven independent trials on highbush blueberry conducted in Canada or the USA matched the critical GAP.

For the purposes of maximum residue level estimation penthiopyrad residues in blueberry were (n = 7): 0.57, 1.2, 1.5, 1.7, 1.7, 2.6 and 3.9 mg/kg.

For the dietary risk assessment purposes the total residues in blueberry were (n = 7): 0.59, 1.3, 1.5, 1.7, 1.7, 2.6 and 4.0 mg/kg.

Noting that blueberry is a representative crop for bushberries, the Meeting estimated a maximum residue level of 7 mg/kg, a STMR of 1.7 mg/kg and a HR of 4.0 mg/kg for penthiopyrad in the Subgroup 004B Bush berries.

The Meeting noted that the Canadian bushberries group includes highbush cranberries, listed in The Codex Classification as Guelder rose (*Viburnum opulus* L.) and Elderberries (*Sambucus* spp.) in the subgroup of large shrub/tree berries, and agreed to extrapolate the maximum residue level of 7 mg/kg, the STMR of 1.7 mg/kg and the HR of 4.0 mg/kg for penthiopyrad to Guelder rose and Elderberries.

### **Residues in animal feeds**

The additional uses submitted to the current Meeting are not relevant to animal feeds.

## **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: *penthiopyrad*

Definition of the residue for compliance with the MRL for animal commodities and for dietary risk assessment for plant and animal commodities: *sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad*

The residue is not fat-soluble.

## **DIETARY RISK ASSESSMENT**

### **Long-term dietary exposure**

The ADI for penthiopyrad is 0–0.1 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for penthiopyrad were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR values estimated by the JMPR. The results are shown in Annex 3 of the 2019 JMPR Report.

The IEDIs ranged from 1–8% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of penthiopyrad from uses considered by the JMPR is unlikely to present a public health concern.

### **Acute dietary exposure**

The ARfD for penthiopyrad is 1 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for penthiopyrad were calculated for the food commodities for which HRs were estimated by the present

Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs varied from 0–5% of the ARfD for children and general population. The Meeting concluded that acute dietary exposure to residues of penthiopyrad from uses considered by the present Meeting is unlikely to present a public health concern.



## 5.18 Picoxystrobin (258)

### RESIDUE AND ANALYTICAL ASPECTS

Picoxystrobin is a strobilurin fungicide with systemic and translaminar properties. The mode of action is by blocking cytochrome electron transfer, inhibiting mitochondrial respiration.

Picoxystrobin was first evaluated for toxicology by JMPR in 2012. An ADI of 0–0.09 mg/kg bw and an ARfD of 0.09 mg/kg bw were established. The residue definition established by the 2017 JMPR for compliance with the MRL and dietary risk assessment for plant and animal commodities is picoxystrobin. The residue is fat-soluble.

The 2017 JMPR also concluded that based on the uses considered by that Meeting, there were no dietary exposure concerns with respect to the metabolites IN-H8612, IN-QDK50 and IN-U3E08, since their chronic exposure levels were below the 1.5 µg/kg bw per day Threshold of Toxicological Concern (TTC) for a Cramer Class III compound. However it was noted that these conclusions would need to be re-evaluated if additional use patterns are presented to the JMPR in the future.

Picoxystrobin was scheduled at the Fiftieth Session of the CCPR for additional uses by the 2019 JMPR. The Meeting received additional analytical method validation data, new GAP information and new supporting residue information from the manufacturer for mango, root and tuber vegetables, bulb vegetables, leafy vegetables, brassica vegetables, celery, legume vegetables, fruiting vegetables, tree nuts, oilseeds, alfalfa grass, sorghum, rice and coffee. Additional processing studies were also provided for tomatoes, potatoes, sugar beet and rice and on the nature of residues following high temperature hydrolysis.

#### ***Methods of analysis***

The Meeting received additional validation information for the LC-MS/MS methods used in the new supervised residue trials. The validation data were for picoxystrobin and metabolites IN-QDK50, IN-QDY62 and IN-QDY63 and covered representative matrices with high oil content (almonds, cotton seed, peanuts), high water content (mangos, onions, mustard greens, cucumbers, tomatoes), high starch content (rice, radish roots), high protein content (beans) and also coffee beans, alfalfa hay, processed potato and sugar beet matrices.

The Meeting concluded that the analytical methods used in the supervised trials were sufficiently validated and are suitable to measure picoxystrobin, IN-QDK50, IN-QDY62 and IN-QDY63 in plant commodities.

#### ***Results of supervised residue trials on crops***

Supervised trials were available for the use of picoxystrobin on mango, a wide range of vegetable crops, cereals, tree nuts, oilseeds, coffee, alfalfa and tea.

Product labels were available from Brazil, Canada, China, India, Thailand, the USA and Vietnam.

The supervised trials were well documented and included procedural recoveries with spiking at residue levels similar to those occurring in samples from the supervised trials and the storage intervals of frozen samples were covered by the storage stability studies reviewed by the 2012 JMPR.

The Meeting noted that for a number of crops, the supervised residue trials were conducted using 1 foliar spray of 0.2 kg ai/ha picoxystrobin, followed by 2 sprays of 0.4 kg ai/ha, with retreatment intervals of 5–7 days and PHIs of 0–7 days. However, the associated GAPs generally involved lower application rates and different numbers of applications.

The Meeting agreed that for brassica vegetables; fruiting vegetables, cucurbits; fruiting vegetables other than cucurbits and root vegetables, where no trials matched the critical GAP, using the proportionality approach was not appropriate, since both the application rates and the number of

applications deviated from the critical GAP and the available residue decline information was not sufficient to conclude that the first application did not contribute to the final residue at harvest.

The Meeting also agreed that for bulb vegetables; brassica leafy vegetables; legume vegetables; tuberous and corm vegetables; tree nuts; peanut and sunflower seed, where no trials matched the critical GAP, using the proportionality approach was not suitable (multiple application rates in the trials) and the available residue decline information was not sufficient to consider using the ‘Anticipated Residue Comparison’ model described in the 2017 JMPR Report (General Considerations, pp 4–8) for estimating maximum residue levels.

The Meeting therefore agreed that the data were not sufficient to estimate maximum residue levels for picoxystrobin on commodities associated with the crop groups listed above.

### *Mango*

The critical GAP for picoxystrobin on mango is in Vietnam, with 2 foliar applications of 0.019 kg ai/hL, a minimum retreatment interval (RTI) of 10 days and a PHI of 7 days.

No trials matched this GAP, but in four trials conducted in Thailand and Vietnam, matching the GAP application rate but with four applications, picoxystrobin residues in whole fruit sampled 7 DALA were: 0.063, 0.11, 0.17 and 0.30 mg/kg. In these trials, picoxystrobin residues in mango flesh were < 0.01, < 0.01, < 0.01 and 0.01 mg/kg.

The Meeting agreed that the first two applications were likely to contribute significantly to the final residue (mean half-life of about 10 days) and that there were insufficient trials to estimate a maximum residue level for picoxystrobin in mango.

### *Rice*

The critical GAP for picoxystrobin on rice is in India, with foliar applications of 0.15 kg ai/ha and a PHI of 12 days.

In trials conducted in India and Thailand, matching the Indian GAP, residues of picoxystrobin were 0.14, 0.23 and 0.26 mg/kg.

The Meeting agreed the number of trials was not sufficient to estimate a maximum residue level for picoxystrobin in rice.

### *Sorghum grain*

The critical GAP for picoxystrobin on sorghum is in the USA, involving 3 foliar applications of 0.22 kg ai/ha and a minimum retreatment interval of 7 days, with the last application not to be applied after flowering.

In trials conducted in the USA approximating this GAP (up to BBCH 59-61), picoxystrobin residues in sorghum grain were: < 0.01 (10) and 0.016 mg/kg (n = 11).

The Meeting estimated a maximum residue level of 0.02 mg/kg and a STMR of 0.01 mg/kg for picoxystrobin in sorghum grain.

### *Cottonseed*

The critical GAP for picoxystrobin on cotton is in the USA, with 2 foliar applications of 0.22 kg ai/ha, a minimum retreatment interval (RTI) of 5 days and a PHI of 7 days.

No trials on cotton matched the USA GAP, but in 12 independent trials on cotton conducted in USA, involving 2 foliar application of 0.5 kg ai/ha, 4-6 days apart, picoxystrobin residues in cottonseed sampled 7 DALA were: 0.088, 0.095, 0.12, 0.37, 0.39, 0.40, 0.52, 0.81, 1.0, 1.5, 1.9 and 2.0 mg/kg.

The Meeting agreed to apply the proportionality approach (scaling factor of 0.44) to estimate a maximum residue level. Scaled residues are: 0.039, 0.042, 0.051, 0.16, 0.17, 0.18, 0.23, 0.36, 0.44, 0.66, 0.84 and 0.88 mg/kg (n = 12).



The Meeting estimated a maximum residue level of 2 mg/kg and a STMR of 0.205 mg/kg for picoxystrobin in cottonseed.

### *Coffee*

The critical GAP for picoxystrobin on coffee is in Brazil, with 3 foliar applications of 0.1 kg ai/ha and a PHI of 40 days.

In trials conducted in Brazil matching this GAP, picoxystrobin residues in green coffee beans, dried in the field, were: < 0.01 (3), 0.01 (3), 0.011, 0.014 and 0.025 mg/kg (n = 9).

The Meeting estimated a maximum residue level of 0.04 mg/kg and a STMR of 0.01 mg/kg for picoxystrobin in coffee beans.

### *Tea*

The critical GAP for picoxystrobin on tea is in China, with 2 foliar applications of 0.0225 kg ai/hL, applied at least 7 days apart, and a PHI of 10 days.

In trials conducted in China matching this GAP, picoxystrobin residues in dried leaves were: 0.083, 0.47, 1.0, 1.4, 4.3 and 6.4 mg/kg (n = 6).

The Meeting estimated a maximum residue level of 15 mg/kg and a STMR of 1.2 mg/kg for picoxystrobin in Tea, Green, Black.

## ***Residues in animal feeds***

### ***Alfalfa fodder and forage***

The critical GAP for picoxystrobin on alfalfa is in Canada, with foliar applications of 0.22 kg ai/ha once 1-3 new leaves have grown after each cutting, up to 14 days before cutting, with a maximum seasonal rate of 0.66 kg ai/ha.

In trials conducted in Canada and the USA matching this GAP, where 1, 2 or 3 applications of picoxystrobin were made after the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> cuttings respectively and alfalfa samples were taken 13-15 days after treatment (but before the next cutting), highest picoxystrobin residues in alfalfa forage (as received) from each trial were: 0.092, 0.12, 0.19, 0.21, 0.23, 0.25, 0.29 (2), 0.31, 0.49, 0.52, 0.57, 1.1, 1.3, 1.4, 1.9 and 3.1 mg/kg (n = 17).

The Meeting estimated a median residue of 0.31 mg/kg (as received) and a highest residue of 3.1 mg/kg (as received) for picoxystrobin in alfalfa forage.

Highest picoxystrobin residues in alfalfa hay (as received) from these trials (matching the Canadian GAP) were: 0.31, 0.37, 0.4, 0.49, 0.53, 0.75 (2), 0.91, 1.1, 1.2 (2), 1.3, 2.3, 2.9, 3.0, 4.0 and 4.3 mg/kg (n = 17). Calculated dry weight residues were: 0.36, 0.47, 0.62, 0.71, 0.88, 0.89, 0.95, 1.2, 1.3, 1.5, 1.7, 2.3, 2.8, 3.3, 3.7, 5.2 and 7.4 mg/kg (n = 17).

The Meeting estimated a maximum residue level of 10 mg/kg (dw), a median residue of 1.3 mg/kg (dw) and a highest residue of 7.4 mg/kg (dw) for picoxystrobin in alfalfa fodder.

### ***Sorghum forage, hay***

The critical GAP for picoxystrobin on sorghum grain is in the USA, involving 3 foliar applications of 0.22 kg ai/ha, a retreatment interval of at least 7 days and with the last application not to be applied after flowering. The PHIs are 7 days for forage grazing and 14 days for harvesting hay.

In one of the sorghum trials approximating the USA GAP, picoxystrobin residues in forage sampled 7 DALA were 0.11 mg/kg (as received).

In two of the sorghum trials approximating the USA GAP, picoxystrobin residues in forage sampled 14 DALA (the GAP PHI for sorghum hay), picoxystrobin residues were: 0.023 and 0.059 mg/kg (as received).

The Meeting agreed the number of trials was not sufficient to estimate a median residue or highest residue for picoxystrobin in sorghum forage nor to estimate a maximum residue level for picoxystrobin in sorghum hay.

#### *Sorghum, straw and fodder, dry*

In trials conducted in the USA approximating the GAP for sorghum grain, picoxystrobin residues in sorghum straw (sampled at grain harvest) were (n = 11): < 0.01 (8), 0.016, 0.017 and 0.017 mg/kg (as received). Calculated dry weight residues were: 0.024, 0.030, 0.034, 0.037, 0.038, 0.042, 0.043, 0.044, 0.045, 0.046 and 0.053 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg (dw), a median residue of 0.042 mg/kg (dw) and a highest residue of 0.053 mg/kg (dw) for picoxystrobin in sorghum straw and fodder, dry.

#### *Rice straw*

The critical GAP for picoxystrobin on rice is in India, for foliar applications of 0.15 kg ai/ha and a PHI of 12 days.

In trials conducted in India and Thailand, matching the Indian GAP, residues of picoxystrobin in rice straw were 0.21, 0.4 and 0.64 mg/kg (as received).

The Meeting agreed the number of trials was not sufficient to estimate a maximum residue level for picoxystrobin in rice straw.

#### *Grass forage*

The critical GAP for picoxystrobin on grass grown for seed is in the USA, involving 3 foliar applications of 0.22 kg ai/ha, with a minimum retreatment interval of 5 days, with one application prior to each forage grazing. The PHI is 0 days for both grass forage and hay.

In independent trials conducted in the USA matching this GAP, picoxystrobin residues in grass forage (as received), 0 days after one application of 0.2 kg ai/ha were: 6.1, 6.9, 11, 12, 13, 14, 15 and 17 mg/kg (n = 8).

The Meeting estimated a median residue of 12.5 mg/kg (as received) and a highest residue of 17 mg/kg (as received) for picoxystrobin in grass forage.

#### *Grass hay*

No trials matched the US GAP for grass grown for seed and the Meeting could not estimate a maximum residue level for picoxystrobin in grass hay.

#### *Cotton gin by-products*

In four cotton trials matching the USA GAP but with higher application rates (0.5 kg ai/ha), picoxystrobin residues in cotton gin trash sampled 6-7 DALA were: 5.1, 15, 16 and 17 mg/kg (as received).

The Meeting agreed to apply the proportionality approach (scaling factor of 0.44) and the scaled data set is: 2.2, 6.6, 7.0 and 7.5 mg/kg (as received).

The Meeting estimated a median residue of 6.8 mg/kg and a highest residue of 7.5 mg/kg for picoxystrobin on cotton gin byproducts (as received).

#### *Fate of residues during processing*

The Meeting received new information on the effect of high temperature hydrolysis on residues of picoxystrobin and new processing studies on tomatoes, potatoes, sugar beet and rice.

Picoxystrobin was hydrolytically stable under representative processing conditions: pasteurization (pH 4, 90 °C, for 20 minutes), baking, brewing or boiling (pH 5, 100 °C, for 60 minutes), and sterilization (pH 6, 120 °C, for 20 minutes).

Processing studies in tomatoes, potatoes, sugar beet and rice indicate that picoxystrobin residues do not concentrate, except in wet potato peel (1.8×), sugar beet dried pulp (1.8×) and rice hulls (3.6×). Since no maximum residue levels were recommended for tomato, potato, sugar beet or rice, the Meeting did not derive any maximum residue levels for these commodities.

### **Residues in animal commodities**

#### **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.

Table 1 Additional commodities used for estimating livestock dietary burdens (including those recommended by the 2017 JMPR)

CCN	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
AL 1021	Alfalfa forage (green)	0.31 (ar)	3.1 (ar)
	Grass forage	12.5 (ar)	17 (ar)
	Peas (dry), Beans (dry)	0.0105	
	Wheat, Rye, Triticale, Maize grain	0.01	
	Oats, Barley grain	0.017	
	Soya bean forage	1.4 (dw)	3.5 (dw)
	Pea vines (fresh)	20.5 (dw)	55 (dw)
	Maize forage	7.1 (dw)	14 (dw)
	Pea hay	12.5 (dw)	64 (dw)
	Wheat, Barley, Oats, Rye, Triticale forage	4.5 (dw)	31 (dw)
	Wheat, Barley, Oats, Rye, Triticale hay	0.88 (dw)	5.5 (dw)
	Wheat, Barley, Oats, Rye, Triticale straw	0.225 (dw)	1.7 (dw)
	Maize fodder	3.8 (dw)	8.6 (dw)
	Soya bean fodder	1.2 (dw)	2.7 (dw)
	Cotton gin by-products	6.8	7.5
	Soya bean meal	0.01	
	Soya bean asp grain fraction	2.6	
	Soya bean hulls	0.043	
	Brewers grain (spent barley)	0.011	
	Maize meal	0.01	
	Maize asp grain fraction	0.15	
	Wheat asp grain fraction	0.034	

ar – as received; dw – dry weight

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the JMPR in 2017 and by the current Meeting. The dietary burdens,

estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO manual<sup>13</sup>, are presented in Annex 6 and summarized below.

Table 2 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: picoxystrobin, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
<b>Beef cattle</b>	3.8	1.8	56	32	73 <sup>a</sup>	50	4.2	2.6
<b>Dairy cattle</b>	39	25	64	37	71 <sup>b</sup>	50 <sup>c,d</sup>	14	8.2
<b>Poultry – broiler</b>	0.017	0.017	0.019	0.019	0.013	0.013	0.012	0.012
<b>Poultry – layer</b>	0.02	0.017	10 <sup>e,g</sup>	2.5 <sup>f,h</sup>	0.013	0.013	0.01	0.01

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

<sup>c</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

<sup>d</sup> Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

<sup>e</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

<sup>f</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

<sup>g</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

<sup>h</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

### Animal commodity maximum residue levels

#### Cattle

For beef and dairy cattle, the Meeting estimated maximum dietary burdens of 73 ppm and 71 ppm respectively and estimated a mean dietary burden of 50 ppm. Estimated mean and maximum residues of picoxystrobin in milk and cattle tissues, were calculated by interpolating between the 40 and 120 ppm dosing levels in the lactating cow feeding study evaluated by the 2012 JMPR.

Table 3 Estimated mean and maximum residues of picoxystrobin in milk and cattle tissues

Picoxystrobin	Feed Level (ppm) for milk residues	Picoxystrobin residues (mg/kg) in milk	Feed Level (ppm) for tissue residues	Picoxystrobin residues (mg/kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (beef or dairy cattle)							
Feeding study	40	< 0.01	40	< 0.01	0.005	< 0.01	0.007
	120	< 0.01	120	< 0.01	0.017	< 0.01	0.026
Dietary burden and estimate of highest residue	71	< 0.01	73	< 0.01	0.01	< 0.01	0.015
STMR Determination (beef or dairy cattle)							
	40	< 0.01	40	< 0.01	0.005	< 0.01	0.006
	120	< 0.01	120	< 0.01	0.013	< 0.01	0.021
Dietary burden and estimate of median residue	50	< 0.01	50	< 0.01	0.006	< 0.01	0.008

<sup>13</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

The maximum dietary burdens for beef and dairy cattle were 73 ppm and 71 ppm, respectively, and the mean dietary burden was 50 ppm.

In tissues, calculated picoxystrobin HRs were 0.015 mg/kg for fat, 0.01 mg/kg for liver and 0 mg/kg in muscle and kidney.

Calculated STMRs were 0 mg/kg for milk, muscle and kidney, 0.006 mg/kg for liver and 0.008 mg/kg for mammalian fat.

The Meeting confirmed the maximum residue levels recommended by the 2017 JMPR for milk, meat (from mammals other than marine mammals), mammalian fats and edible offal (mammalian).

### ***Poultry***

For poultry, the Meeting estimated a maximum dietary burden of 10 ppm, slightly higher than the previous estimate of 9.5 ppm. In the poultry feeding study evaluated by the 2012 JMPR, residues of picoxystrobin were not detected in the eggs, muscle or liver of hens from the 15 ppm dose group. Residues of picoxystrobin were detectable in fat but at levels < 0.01 mg/kg.

The Meeting therefore confirmed the maximum residue levels, STMRs and HRs for poultry commodities recommended by the 2017 JMPR.

## **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 and dietary risk assessment for plant commodities: *picoxystrobin*

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

*The residue is fat-soluble.*

## **DIETARY RISK ASSESSMENT**

### ***Long-term dietary exposure***

The ADI for picoxystrobin is 0–0.09 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for picoxystrobin 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 2019 JMPR Report.

The IEDIs ranged from 0–0.2% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of picoxystrobin from uses considered by the JMPR is unlikely to present a public health concern.

### ***Acute dietary exposure***

The ARfD for picoxystrobin is 0.09 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for picoxystrobin 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 2019 JMPR Report.

The IESTIs varied from 0–2% of the ARfD for children and 0–2% of the ARfD for the general population. The Meeting concluded that acute dietary exposure to residues of picoxystrobin from uses considered by the present Meeting is unlikely to present a public health concern.

### Threshold of toxicological concern (TTC) consideration for metabolites

#### *IN-U3E08*

The 2017 JMPR agreed to apply the TTC approach to assess the metabolite IN-U3E08 and estimated a long-term dietary exposure of 0.2 µg/kg bw per day (below the 1.5 µg/kg bw per day Threshold of Toxicological Concern (TTC) for a Cramer Class III compound). The 2017 JMPR concluded that for the food commodities considered at the Meeting, dietary exposure to residues of IN-U3E08 were unlikely to present a public health concern.

For the food commodities considered at the current Meeting (sorghum grain, cottonseed, coffee and tea), residues of IN-U3E08 were not measured in the field trials. Based on the results of the metabolism studies on confined rotational crops and on potatoes (involving a pre-plant soil treatment and subsequent foliar applications), the expected dietary exposures to IN-U3E08 are likely to be from rotational crops and from root and tuber vegetables. The Meeting concluded that residues of IN-U3E08 are not to be expected in permanent crops and that long-term dietary exposure from potential residues in sorghum were already covered in the estimate for rotational residues in cereal grain crops.

The current Meeting estimated the potential dietary exposure to the metabolite IN-U3E08 at 0.2 µg/kg bw per day (below the 1.5 µg/kg bw per day TTC). The Meeting concluded that for the food commodities considered by the current and previous Meetings, long-term dietary exposure to residues of IN-U3E08 are unlikely to present a public health concern. Should further uses be considered in future, these conclusions may need to be revised.

#### *IN-QDK50*

The 2017 JMPR applied the TTC approach to assess the metabolite IN-QDK50. The potential long-term dietary exposure was estimated at 1.46 µg/kg bw per day (below the 1.5 µg/kg bw per day TTC for a Cramer Class III compound). The 2017 JMPR concluded that for the food commodities considered by the 2017 Meeting, dietary exposure to residues of IN-QDK50 were unlikely to present a public health concern.

For the food commodities considered at the current Meeting, residues of IN-QDK50 were not detectable in sorghum grain and coffee beans, ranged from < 0.01-0.071 mg/kg in cottonseed (STMR of 0.018 mg/kg), and were not measured in the field trials on tea. The Meeting noted that in the alfalfa trials residues of IN-QDK50, measured in new fresh leaves 14 days after treatment with picoxystrobin, averaged about 70% of the parent residues. The Meeting agreed to apply this factor to the picoxystrobin residues reported in fresh tea leaves to estimate potential residues of IN-QDK50 in tea.

Based on data from field trials for crops with direct uses, expected residues in rotational crops (based on the confined crop rotation study), and residues in animal commodities (based on metabolism data) and using separate refined estimates for root vegetables and tuber vegetables, the Meeting revised the potential dietary exposures for the metabolite IN-QDK50.

For food commodities considered by the current and previous Meetings, the estimated long-term dietary exposure is 0.48 µg/kg bw per day (below the 1.5 µg/kg bw per day TTC). The Meeting concluded that for the food commodities considered by the current and previous Meetings, long-term dietary exposure to residues of IN-QDK50 are unlikely to present a public health concern. Should further uses be considered in future, these conclusions may need to be revised.

#### *IN-H8612*

The 2013 JMPR applied the TTC approach to assess the metabolite IN-H8612. The potential long-term dietary exposure was 0.53 µg/kg bw per day (below the 1.5 µg/kg bw per day TTC for a Cramer Class III compound). The 2013 JMPR concluded that for the food commodities considered by that Meeting, residues of IN-H8612 were unlikely to present a public health concern.

For the food commodities considered at the current Meeting (sorghum grain, cottonseed, coffee and tea), residues of IN-H8612 were not measured in the field trials. However, for sorghum grain the

Meeting agreed to apply the 2012 conclusions for the individual cereal grains considered by that Meeting. Based on the available plant and rotational crop metabolism studies, the Meeting concluded that residues of IN-H8612 are not to be expected in cottonseed, coffee and tea.

The Meeting revised the potential dietary exposure estimate for the metabolite IN-H8612 to 0.81 µg/kg bw per day (below the 1.5 µg/kg bw per day TTC). The Meeting concluded that for the food commodities considered by the current and previous Meetings, long-term dietary exposure to residues of IN-H8612 are unlikely to present a public health concern. Should further uses be considered in future, these conclusions may need to be revised.





## 5.19 Pydiflumetofen (309)

### RESIDUE AND ANALYTICAL ASPECTS

Pydiflumetofen is a broad-spectrum fungicide belonging to the carboxamide group. It acts through inhibition of succinate dehydrogenase in complex II of fungal mitochondrial respiration. Pydiflumetofen was first evaluated for toxicology and residues by JMPR in 2018. An ADI of 0–0.1 mg/kg bw and an ARfD of 0.3 mg/kg bw were established. The residue definition for compliance with the MRL for plant and animal commodities, and dietary risk assessment for plant commodities is pydiflumetofen. The residue definition for dietary risk assessment for animal commodities other than mammalian liver and kidney is the sum of pydiflumetofen and 2,4,6-TCP and its conjugates, expressed as pydiflumetofen and for dietary risk assessment for mammalian liver and kidney is the sum of pydiflumetofen, 2,4,6-TCP and its conjugates, and SYN547897 and its conjugates, expressed as pydiflumetofen. The residue is fat-soluble.

The 2018 JMPR noted that pydiflumetofen residues may be taken up by rotational crops and considered very persistent in soil (up to 2380 days  $DT_{50}$ ), and its accumulation, following subsequent years of treatment is expected. Therefore, the 2018 JMPR concluded that the information available did not allow the estimation of pydiflumetofen residues in rotational crops, especially in view of expected plateau soil concentrations being significantly higher than the rate applied in the available field rotational crop study.

The Meeting received information on field soil degradation studies for pydiflumetofen from several regions and field rotational crop studies.

#### **Environmental fate**

The Meeting received field soil degradation studies for pydiflumetofen to estimate the expected plateau level of pydiflumetofen in soil treated with pydiflumetofen.

#### **Soil degradation (field studies)**

Pydiflumetofen soil  $DT_{50}$  values were calculated based on 22 trials conducted in Canada, China, France, Germany, Italy, Japan, Republic of Korea, Spain, the UK, and the USA.  $DT_{50}$  values for pydiflumetofen ranged from 96.3 to > 10 000 days, with a geometric mean of 603 days. Noting that the maximum value (> 10 000 days) is not an evidence-based estimate and that field dissipation studies are typically conducted for a duration of 2 years, the Meeting decided that the geometric mean of 603 days was the most suitable value for estimating the plateau level in soil.

#### **Calculation of soil plateau level**

Based on the soil  $DT_{50}$  (603 days) of pydiflumetofen, the accumulation factor ( $f_{acc}$ ) was calculated using the equation of  $f_{acc} = e^{-kt} / (1 - e^{-kt})$ , with degradation rate ( $k$ ) and an application interval ( $t$ ) of 365 days. Degradation rate ( $k$ ) is calculated as  $\ln 2 / DT_{50}$  (= 0.001149). Therefore,  $f_{acc}$  of pydiflumetofen is 1.918.

The plateau background residue level ( $A_{plateau}$ ) can be calculated as  $A_{0ofsoil}f_{acc}$ .

$A_0$  = Total seasonal application rate to target crop (g ai/ha).

$f_{soil}$  = Fraction of the seasonal application rate reaching the soil after crop interception.

Pydiflumetofen is a foliage-applied product, though application timings are variable dependent on crop and timing of disease development. As a reasonable worst case use pattern, pydiflumetofen was assumed to have been applied at the earliest foliar stage (BBCH 10–19: Leaf development stage). According to FOCUS guidance (2015)<sup>n</sup>, crop interception rate of 23% was calculated by taking the geometric mean of minimal crop cover stage (BBCH 10–19) of all crops excluding permanent crops such as citrus and olive trees. The amount reaching the soil after crop interception ( $f_{soil}$ ) was assumed

<sup>n</sup> Generic guidance for FOCUS surface water scenarios, Version: 1.4, Date: May 2015

to be 0.77 (77%). The maximum seasonal application rate for pydiflumetofen ( $A_0$ ) is 400 g ai/ha. Therefore,  $A_{\text{plateau}}$  of pydiflumetofen ( $400 \times 0.77 \times 1.918$ ) is 591 g ai/ha.

According to OECD rotational crop guidance (2018)<sup>o</sup>, application rates employed in crop rotation studies should be the sum of the maximum use rate for the compound (400 g ai/ha) and the calculated soil plateau level (591 g ai/ha), which leads to 991 g ai/ha. Moreover, for the trial design of rotational crop studies involving application to bare soil and subsequent sowing/planting, the proportionality concept is applicable.

### Rotational crop studies

The current Meeting received additional field rotational crop studies conducted in European countries.

#### Field rotational crop studies

Pydiflumetofen SC formulation was applied to bare soil at 0.60 kg ai/ha. The trials were established for each of nine representative rotated crops (kale, tomato, maize, soya bean, bean, strawberry, spinach, carrot and radish) at a number of plant back intervals (30, 120, 270, 330–365 days).

Residues of pydiflumetofen were below the LOQ (0.01 mg/kg) in kale, tomato, maize (whole cobs), bean (fresh seed, remaining plant and dry seed) and strawberry at all plant back intervals.

Residues of pydiflumetofen were found at 0.01–0.02 mg/kg in maize (remaining plant: 120 and 330 day plant back interval (PBI), soya bean (forage: 30, 120, 270 and 330 day PBI), spinach (immature: 30 and 270 day PBI, mature: 120, 270 and 330 day PBI), carrots (roots: 30, 120, 270 and 330–365 day PBI, tops: 30 and 120 day PBI), radish (roots: 120 day PBI, tops: 30 and 120 day PBI).

Residues of pydiflumetofen were found in spinach (mature) at 0.03–0.05 mg/kg (30 and 270 day PBI), carrots (roots) at 0.03 mg/kg (120 day PBI), radish (tops) at 0.03 mg/kg (30 day PBI) and radish (roots) at 0.04 mg/kg (30 day PBI).

In field rotational crop studies submitted to the 2018 JMPR, pydiflumetofen SC formulation was applied to bare ground in European countries and the USA at 0.40–0.50 kg ai/ha (Europe:  $1 \times 0.50$  kg ai/ha, USA:  $2 \times 0.20$  kg ai/ha). The trials were established for each of three representative crop types (Europe: spinach, carrot and spring barley, USA: spinach/lettuce, radish and wheat) at each plant back interval (Europe: 30, 60 and 365 days, USA: 30, 60, 90 and 150 days).

Residues of pydiflumetofen were below the LOQ (0.01 mg/kg) in spinach (mature), lettuce, radish and cereal grains (barley and wheat).

Residues of pydiflumetofen were found at 0.01–0.02 mg/kg in spinach (immature: 30 and 60 day PBI), carrot (roots: 30 and 60 day PBI, tops: 60 day PBI) and cereal whole plant (barley: 30 day PBI, wheat: 90 day PBI).

Residues of pydiflumetofen were found in spring barley straw at 0.02–0.09 mg/kg (30 and 60 day PBI), and wheat hay and wheat straw at 0.01–0.11 mg/kg (90 day PBI) with a subsequent decline to < 0.01–0.07 mg/kg (150 day PBI).

Residues in rotated crops following applications at 400–600 g ai/ha were scaled with factors of 1.7–2.5 to estimate the residues expected at the higher application rate of 991 g ai/ha.

Table 1 Scaling of the highest rotational crop residues

Crop	Application rate of rotational crop studies (g ai/ha)	Scaling factor	Highest rotational residue (mg/kg)	Residue scaled to account for 991 g ai/ha
Strawberry (fruit)	600	1.7	< 0.01	< 0.02
Tomato (fruit)	600	1.7	< 0.01	< 0.02
Kale	600	1.7	< 0.01	< 0.02

<sup>o</sup> Guidance Document on Residues in Rotational Crops: OECD Environment, Health and Safety Publications Series on Pesticides No. 97, Series on Testing and Assessment No. 279. ENV/JM/MONO(2018)9

Crop	Application rate of rotational crop studies (g ai/ha)	Scaling factor	Highest rotational residue (mg/kg)	Residue scaled to account for 991 g ai/ha
Leaf lettuce	400	2.5	< 0.01	< 0.03
Spinach (immature)	500	2.0	0.02	0.04
Spinach (mature)	600	1.7	0.05	0.09
Bean (whole plant)	600	1.7	< 0.01	< 0.02
Bean (fresh seed)	600	1.7	< 0.01	< 0.02
Bean (remaining plant)	600	1.7	< 0.01	< 0.02
Bean (dry seed)	600	1.7	< 0.01	< 0.02
Soya bean (forage)	600	1.7	0.01	0.02
Soya bean (seed)	600	1.7	< 0.01	< 0.02
Carrot (tops)	500	2.0	0.01	0.02
Carrot (roots)	600	1.7	0.03	0.05
Radish (tops)	600	1.7	0.03	0.05
Radish (roots)	600	1.7	0.04	0.07
Maize (whole cobs)	600	1.7	< 0.01	< 0.02
Maize (remaining plant)	600	1.7	0.02	0.03
Barley (whole plant)	500	2.0	0.02	0.04
Barley (grain)	500	2.0	< 0.01	< 0.02
Barley (straw)	500	2.0	0.09	0.18
Wheat (forage)	400	2.5	0.01	0.03
Wheat (hay)	400	2.5	0.05	0.13
Wheat (grain)	400	2.5	< 0.01	< 0.03
Wheat (straw)	400	2.5	0.11	0.28

Table 2 The residues scaled to plateau level of pydiflumetofen in soil

“Super” Crop Group <sup>a</sup>	Commodity	Trial No.	Residue scaled (mg/kg)		
			Mean	Median	Highest
Root and tuber vegetables	Carrot roots	8	0.03	0.02	0.05
	Radish roots	7	0.02	0.02	0.07
Cereals	Wheat grain	3	< 0.03	< 0.03	< 0.03
	Barley grain	4	< 0.02	< 0.02	< 0.02
	Maize whole cobs	2	< 0.02	< 0.02	< 0.02
Leafy vegetables and Brassicas	Spinach (mature)	7	0.03	0.02	0.09
	Spinach (immature)	10	0.02	0.02	0.04
	Leaf lettuce	1	< 0.03	< 0.03	< 0.03
	Kale	4	< 0.02	< 0.02	< 0.02
Oilseeds and pulses	Soya bean seed	2	< 0.02	< 0.02	< 0.02
	Bean dry seed	3	< 0.02	< 0.02	< 0.02
Fruits and fruiting vegetables	Tomato	4	< 0.02	< 0.02	< 0.02
	Strawberry	3	< 0.02	< 0.02	< 0.02
Root leaves and tops <sup>b</sup>	Radish tops	7	0.02	0.02	0.05
	Carrot tops	8	0.02	0.02	0.02
	Beans fresh seed	3	< 0.02	< 0.02	< 0.02

<sup>a</sup> Referred to in the OECD rotational crop guidance.

<sup>b</sup> This group is not included in OECD rotational crop guidance.

Table 3 Feed residues scaled to plateau level of pydiflumetofen in soil

Animal Feeds	Commodity	Trial No.	Residue scaled (mg/kg)		
			Mean	Median	Highest
Legume animal feeds	Soya bean forage	3	0.02	0.02	0.02
	Bean forage	4	< 0.02	< 0.02	< 0.02

Animal Feeds	Commodity	Trial No.	Residue scaled (mg/kg)		
			Mean	Median	Highest
Straw and fodder of cereal grains	Maize stover	4	0.02	0.02	0.03
	Barley straw	4	0.05	0.03	0.18
	Wheat hay	3	0.06	0.06	0.11
	Wheat straw	3	0.10	0.08	0.28
Forage of cereal grains	Barley forage	4	0.02	0.02	0.04
	Wheat forage	3	0.03	0.03	0.03

### ***Results of supervised residue trials on crops***

For maximum residue level estimation of pydiflumetofen residues in plant commodities, the addition of residues arising from direct treatment in combination with root uptake of pydiflumetofen from previous years must be taken into account. The Meeting decided to use the crop groups for plant food and feed established in the Codex Classification of Foods and Animal Feeds to give recommendations on the overall residue levels of pydiflumetofen expected in these commodities.

The corresponding residue values from supervised trials are obtained from the 2018 JMPR evaluation of pydiflumetofen.

The Meeting noted that the use of statistical methods for the estimation of maximum residue levels is not possible when considering potential carryover of residues in succeeding crops, since the basis arising from the additional root uptake cannot be adequately calculated using the OECD MRL calculator.

The Meeting recognised that the estimation of maximum residue levels for permanent crops and crops cultivated in/on culture soil/medium and water are not needed, as those crops are not expected to be subject to a potential uptake of pydiflumetofen from the soil.

### ***Grapes***

Grapes are normally cultivated as permanent crops and are not expected to be subject to a potential uptake of pydiflumetofen from the soil. The Meeting confirmed its previous recommendation for the subgroup of small fruit vine climbing of 1.5 mg/kg.

### ***Bulb vegetables***

Although pydiflumetofen is not used for treatment of bulb vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. However, no residue data on suitable succeeding crops to estimate a maximum residue level for bulb vegetables were available.

The Meeting could not estimate a maximum residue level for the group of bulb vegetables.

### ***Brassica vegetables***

Although pydiflumetofen is not registered for use on Brassica vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in leafy vegetables and Brassicas (spinach) in field studies on succeeding crops of 0.03, 0.02 and 0.09 mg/kg, respectively for the estimation of a maximum residue level, STMR value and HR value for Brassica vegetables.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.09 mg/kg for the group of Brassica vegetables.

### *Fruiting vegetables, Cucurbits*

Based on the outcome of a Kruskal-Wallis H-test, the 2018 JMPR concluded that the residue populations from trials on cucumber, summer squash and cantaloupe were not different and the data could be combined to estimate a maximum residue level for fruiting vegetables, cucurbits.

The combined pydiflumetofen residues in cucumber, summer squash and cantaloupe were in rank order (n = 21): 0.056, 0.061, 0.067, 0.078, 0.10, 0.11 (5), 0.12, 0.14, 0.15, 0.16 (3), 0.17, 0.18, 0.19, 0.23 and 0.26 mg/kg.

In field studies on succeeding crops the scaled highest residue in fruiting vegetables (tomato) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.4 mg/kg, an STMR value of 0.12 mg/kg and an HR value of 0.27 mg/kg (based on the highest residue of replicate samples) for the group of fruiting vegetables, cucurbits.

### *Fruiting vegetables, other than Cucurbits*

Based on the outcome of a Mann-Whitney U-test, the 2018 JMPR concluded that the residue populations from trials on tomatoes and peppers were not different and the data could be combined to estimate a maximum residue level for fruiting vegetables, other than cucurbits except Martynia, Okra and Roselle.

The combined pydiflumetofen residues in tomatoes and peppers were in rank order (n = 21): 0.030, 0.043, 0.062, 0.075, 0.076, 0.077, 0.081, 0.082, 0.083, 0.088, 0.11, 0.13, 0.14, 0.16, 0.17, 0.20, 0.23, 0.26 (2), 0.27 and 0.37 mg/kg.

In field studies on succeeding crops the scaled highest residue in fruiting vegetables (tomato) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.5 mg/kg, an STMR value of 0.11 mg/kg and an HR value of 0.42 mg/kg (based on the highest residue of replicate samples) for the group of fruiting vegetables, other than cucurbits (except Martynia, Okra and Roselle).

### *Martynia, Okra and Roselle*

Although pydiflumetofen is not registered for use on Martynia, Okra and Roselle, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in fruiting vegetables (tomato) in field studies on succeeding crops of < 0.02, < 0.02 and < 0.02 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in Martynia, Okra and Roselle.

The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.02 mg/kg for Martynia, Okra and Roselle.

### *Leafy vegetables*

#### *Leafy greens*

The residues on head lettuce according to the US GAP were (n = 8): 0.51, 0.78, 1.2, 2.3, 2.4, 2.6, 3.0 and 4.5 mg/kg.

The residues on leaf lettuce according to the US GAP were (n = 8): 1.7, 3.5, 4.4, 5.5, 7.7, 9.7, 11 and 12 mg/kg.

The residues on spinach according to the US GAP were (n = 8): 7.5, 9.2, 9.7, 12, 13 (2), 14 and 16 mg/kg.

Based on the outcome of a Kruskal-Wallis H-test, the 2018 JMPR concluded that the residue populations from trials on head lettuce, leaf lettuce and spinach were significantly different. However, the residues in individual crops were similar (medians were within 5×). Therefore, the 2018 JMPR decided to use the dataset from spinach leading to the highest maximum residue level for leafy greens.

In field studies on succeeding crops the scaled mean, median and highest residues in leafy vegetables and Brassicas (spinach) were 0.03, 0.02 and 0.09 mg/kg, respectively. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 40 mg/kg, an STMR value of 12.5 mg/kg and an HR value of 17 mg/kg (based on the highest residue of replicate samples) for the subgroup of leafy greens.

#### *Brassica leafy vegetables*

Although pydiflumetofen is not registered for use on Brassica leafy vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in leafy vegetables and Brassicas (spinach) in field studies on succeeding crops of 0.03, 0.02 and 0.09 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in Brassica leafy vegetables.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.09 mg/kg for the subgroup of leaves of Brassicaceae.

#### *Leaves of root vegetables*

Although pydiflumetofen is not registered for use on leaves of root vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in root leaves and tops (radish) in field studies on succeeding crops of 0.02, 0.02 and 0.05 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in leaves of root vegetables.

The Meeting estimated a maximum residue level of 0.07 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.05 mg/kg for the subgroup of leaves of root and tuber vegetables except leaves of tuber vegetables.

#### *Legume vegetables*

Although pydiflumetofen is not registered for use on legume vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in beans fresh seeds in field studies on succeeding crops of < 0.02, < 0.02 and < 0.02 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in legume vegetables.

The Meeting estimated a maximum residue level of 0.02 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.02 mg/kg for the group of legume vegetables.

#### *Pulses*

##### *Dry beans and dry peas*

Based on the outcome of a Kruskal-Wallis H-test, the 2018 JMPR concluded that the residue populations from trials on dry beans, soya beans and dry peas were not different and the data could be combined to estimate a maximum residue level for subgroup of dry beans and subgroup of dry peas.

The combined pydiflumetofen residues in dry beans, soya bean and dry peas were in rank order (n = 41): < 0.01 (9), 0.011, 0.012, 0.013, 0.014, 0.016 (2), 0.18, 0.023 (2), 0.027, 0.028 (2), 0.029, 0.031,

0.032, 0.035, 0.036, 0.039, 0.041, 0.053, 0.057, 0.059, 0.060 (2), 0.063, 0.064, 0.088, 0.096, 0.10, 0.24, 0.29 and 0.37 mg/kg.

In field studies on succeeding crops the scaled highest residue in oilseeds and pulses (dry beans and soya bean) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR value of 0.028 mg/kg for the subgroup of dry beans and the subgroup of dry peas.

### *Root and tuber vegetables*

#### *Root vegetables*

Although pydiflumetofen is not registered for use on root vegetables, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in root and tuber vegetables (radish) in field studies on succeeding crops of 0.02, 0.02 and 0.07 mg/kg, respectively for an estimation of a maximum residue level, STMR value and HR value in root vegetables.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.02 mg/kg and an HR value of 0.07 mg/kg for the subgroup of root vegetables.

#### *Tuberous and corm vegetables*

The residues on potatoes according to the US GAP were (n = 22): < 0.01 (21) and 0.014 mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in root and tuber vegetables (radish) were 0.02, 0.02 and 0.07 mg/kg, respectively. The Meeting concluded that residues in potatoes, the representative commodity for tuberous and corm vegetables, may be influenced significantly by uptake of pydiflumetofen from the soil. The Meeting decided to add the scaled mean residue found in field studies on succeeding crops of 0.02 mg/kg to the median residue obtained from supervised field trials on potato of 0.01 mg/kg for an overall STMR for potatoes of 0.03 mg/kg.

For the estimation of a maximum residue level the highest residue found in root and tuber vegetables in succeeding crop field trials was 0.07 mg/kg in radish roots. The Meeting estimated a maximum residue level for tuberous and corm vegetables of 0.1 mg/kg. Adding the highest residue of 0.014 mg/kg found in supervised field trials to the highest residue of 0.07 mg/kg for radish roots in the succeeding crops, results in an overall highest residue in tuberous and corm vegetables of 0.084 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg, an STMR value of 0.03 mg/kg and an HR value of 0.084 mg/kg for the subgroup of tuberous and corm vegetables.

### *Stalk and stem vegetables*

#### *Stalk and stem vegetables – Stems and Petioles*

The residues on celery according to the US GAP were (n = 8): 2.6, 2.7, 3.9, 4.3, 4.5, 4.8, 5.4 and 8.1 mg/kg.

For stalk and stem vegetables no data from studies on succeeding crops were available. The Meeting concluded that the scaled mean, median and highest residue values of 0.03, 0.02 and 0.09 mg/kg respectively found in leafy vegetables and Brassicas (spinach) indicate that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 15 mg/kg, an STMR value of 4.4 mg/kg and an HR value of 9.3 mg/kg (based on the highest residue of replicate samples) for the subgroup of stems and petioles.

## Cereal grains

### *Wheat, similar grains, and pseudocereals without husks*

The residues on wheat grains according to the US GAP were (n = 29): 0.015, 0.025, 0.035, 0.038, 0.040 (2), 0.048, 0.050, 0.057 (3), 0.062 (2), 0.063 (2), 0.067 (2), 0.10 (2), 0.11, 0.12 (4), 0.13, 0.17, 0.19 and 0.23 (2) mg/kg.

In field studies on succeeding crops the scaled highest residue in wheat grains was < 0.03 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.4 mg/kg and an STMR value of 0.063 mg/kg for the subgroup of wheat, similar grains, and pseudocereals without husks.

### *Barley, similar grains, and pseudocereals with husks*

The combined pydiflumetofen residues in barley grains and oats were in rank order (n = 38): 0.056, 0.068, 0.079, 0.081 (2), 0.11 (2), 0.12, 0.14, 0.15 (3), 0.19 (2), 0.20 (2), 0.21, 0.22, 0.23 (2), 0.24, 0.27, 0.31, 0.32, 0.36, 0.41, 0.44, 0.48, 0.51, 0.54, 0.55, 0.57, 0.66 (2), 0.82, 0.94, 2.1 and 3.0 mg/kg.

In field studies on succeeding crops the scaled highest residue in barley grains was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 3 mg/kg and an STMR value of 0.23 mg/kg for the subgroup of barley, similar grains, and pseudocereals with husks.

### *Maize Cereals*

The residues on field corn and popcorn according to the US GAP were (n = 22): < 0.01 (21) and 0.012 mg/kg.

In field studies on succeeding crops mean, median and highest residues in maize (whole cobs) were < 0.02, < 0.02 and < 0.02 mg/kg, respectively. The Meeting concluded that residues in maize, the representative commodity for maize cereals, may be influenced by additional uptake of pydiflumetofen from the soil. The Meeting decided to add the scaled mean residue found in field studies on succeeding crops of 0.02 mg/kg to the median residue obtained from supervised field trials on field corn and popcorn of 0.01 mg/kg for an overall STMR for maize cereals of 0.03 mg/kg.

For the estimation of a maximum residue level the scaled highest residue found in succeeding crop field trials was < 0.02 mg/kg in maize. The Meeting estimated a maximum residue level of 0.04 mg/kg and an STMR value of 0.03 mg/kg for the subgroup of maize cereals.

### *Sweet Corns*

The residues on sweet corn according to the US GAP were (n = 12): < 0.01 (12) mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in maize (whole cobs) were < 0.02, < 0.02 and < 0.02 mg/kg, respectively. The Meeting concluded that residues in sweet corn, the representative commodity for sweet corns, may be influenced by an additional uptake of pydiflumetofen from the soil. It was decided to add the mean and highest residues found in field studies on succeeding crops of 0.02 mg/kg to the median and highest residues obtained from supervised field trials on sweet corn of 0.01 mg/kg for an overall STMR and HR for pydiflumetofen in sweet corns of 0.03 mg/kg.

For the estimation of maximum residue levels the scaled highest residue found in succeeding crop field trials was < 0.02 mg/kg in maize. The Meeting estimated a maximum residue level of 0.03 mg/kg, an STMR value of 0.03 mg/kg and an HR value of 0.03 mg/kg for the subgroup of sweet corns.



### *Rice Cereals, and Sorghum Grain and Millet*

Although pydiflumetofen is not registered for use on rice cereals, sorghum grain and millet, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in cereal grains (wheat) in field studies on succeeding crops of < 0.03, < 0.03 and < 0.03 mg/kg, respectively for an estimation of maximum residue levels and STMR values in these commodities.

The Meeting estimated a maximum residue level of 0.03 mg/kg and an STMR value of 0.03 mg/kg for the subgroup of rice cereals and the subgroup of sorghum grain and millet.

### *Oilseeds and Oilfruits*

#### *Small seed oilseeds*

The residues on rape seeds according to Canadian and US GAP were (n = 18): 0.020, 0.031, 0.041, 0.046, 0.048, 0.050, 0.056, 0.070, 0.094, 0.095, 0.11, 0.14, 0.15, 0.17, 0.18, 0.35, 0.46 and 0.69 mg/kg.

In field studies on succeeding crops the scaled highest residue in oilseeds and pulses (soya beans seeds and dry beans) was < 0.02 mg/kg. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 0.9 mg/kg and an STMR value of 0.0945 mg/kg for the subgroup of small seed oilseeds.

#### *Peanut*

The residues on peanut nutmeat according to Canadian and US GAP were (n = 12): < 0.01 (9), 0.012 and 0.018 (2) mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residue in oilseeds and pulses (soya beans seeds and dry beans) were < 0.02, < 0.02 and < 0.02 mg/kg respectively. The Meeting concluded that residues in peanut nutmeat may be influenced by an additional uptake of pydiflumetofen from the soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.02 mg/kg to the median residue obtained from supervised field trials on peanut nutmeat of 0.01 mg/kg for an overall STMR for pydiflumetofen in peanut of 0.03 mg/kg.

For estimation of a maximum residue level the scaled highest residue found in succeeding crop field trials was < 0.02 mg/kg in soya bean seeds and dry beans. The Meeting estimated a maximum residue level of 0.05 mg/kg and an STMR value of 0.03 mg/kg for peanut.

#### *Sunflower seeds and Cotton seed*

Although pydiflumetofen is not registered for use on sunflower seeds and cotton seed, these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median highest residues found in wheat straw (worst case) in field studies on succeeding crops of 0.10, 0.08 and 0.28 mg/kg, respectively for an estimation of a maximum residue level and STMR value in these commodities.

The Meeting estimated a maximum residue level of 0.3 mg/kg and an STMR value of 0.08 mg/kg for the subgroup of sunflower seeds and cotton seed.

### ***Residues in animal feeds***

#### *Legume animal feeds*

The residues on pea vines (as received basis) according to Canadian GAP were (n = 5): 0.36, 0.42, 0.88, 0.90 and 2.8 mg/kg.

The residues on pea hay (dry weight basis) according to Canadian GAP were (n = 5): 1.8, 3.0, 3.4, 5.9 and 17 mg/kg.

The residues on peanut hay (dry weight basis) according to the US GAP were (n = 11): 2.0, 3.1, 4.3, 4.5, 4.7, 9.2, 12 (3), 13 and 15 mg/kg.

The Meeting concluded that the application of pydiflumetofen to pea vines and peanut hay results in the highest residues in legume animal feeds and can be used for estimation of a maximum residue level, a median value and a highest value for the whole group.

In field studies on succeeding crops the scaled mean, median and highest residues in legume animal feeds (soya bean forage) were 0.02, 0.02 and 0.02 mg/kg, respectively. The Meeting concluded that residues in pea vines and peanut hay from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

Based on the residues for pea vines, the Meeting estimated a median residue value of 0.88 mg/kg and a highest residue value of 2.8 mg/kg for forage of legume animal feeds on an “as received” basis.

Based on the residues for peanut hay, the Meeting estimated a maximum residue level of 30 mg/kg, a median residue value of 9.2 mg/kg and a highest residue value of 15 mg/kg for fodder of legume animal feeds on a dry weight basis.

#### ***Straw and fodder of barley, oats, rye, triticale and wheat***

The combined pydiflumetofen residues in straw and hay of barley, oats and wheat were in rank order (n = 81): 1.4 (2), 1.8, 1.9, 2.0, 2.2, 2.5, 3.0, 3.1, 3.6, 3.7 (2), 3.8, 3.9, 4.0 (2), 4.2, 4.5, 4.7, 5.1, 5.3, 5.5, 5.7 (3), 5.9, 6.0, 6.5 (2), 6.6, 6.8 (2), 7.2, 7.5, 7.7, 8.0 (2), 8.2, 8.3, 8.4, 9.2 (2), 9.5, 9.9, 10 (3), 11 (4), 12 (2), 13 (2), 14 (2), 15, 16, 17 (3), 18 (2), 19 (2), 20 (5), 21, 23 (2), 24, 25, 26, 29, 33, 34 and 40 mg/kg on dry weight basis.

In field studies on succeeding crops the scaled mean, median and highest residues in wheat straw (fresh) were 0.10, 0.08 and 0.28 mg/kg, respectively. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting concluded that residues on straw and fodder from barley, oats and wheat may be extrapolated to straw and fodder from rye and triticale.

The Meeting estimated a maximum residue level of 50 mg/kg, a median residue value of 9.2 mg/kg and a highest residue value of 40 mg/kg for straw and fodder of barley, oats, rye, triticale and wheat on a dry weight basis.

#### ***Maize fodder***

The residues on maize stover (as received basis) according to Canadian GAP were (n = 23): 0.82, 1.1, 1.3, 1.5, 1.6 (2), 1.9, 2.1, 2.3, 2.6, 3.0, 3.1, 3.2, 3.4, 3.5 (3), 3.7, 4.2, 4.8, 5.0 (2) and 13 mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in maize stover were 0.02, 0.02 and 0.03 mg/kg, respectively. The Meeting concluded that residues from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level of 18 mg/kg (correction for an average 83% dry matter content), a median residue value of 3.1 mg/kg (as received) and a highest residue value of 13 mg/kg (as received) for the maize fodder.

#### ***Straw and fodder of millet, rice and sorghum***

Although pydiflumetofen is not registered for use on other cereal straw and fodder plants (millet, rice and sorghum), these crops may still be subject to crop rotation and therefore contain pydiflumetofen

residues following uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in wheat straw in field studies on succeeding crops of 0.10, 0.08 and 0.28 mg/kg (fresh-weight) respectively for an estimation of maximum residue levels and STMR values in straw and fodder of millet, rice and sorghum.

The Meeting estimated a maximum residue level of 0.3 mg/kg (dry weight basis), a median residue value of 0.08 mg/kg and a highest residue value of 0.28 mg/kg (as received basis) for pydiflumetofen in straw and fodder of millet, rice and sorghum.

#### ***Forage of barley, oats, rye, triticale, wheat, maize and sweet corn***

The residues on oats forage (as received basis) according to the US GAP were (n = 28): 0.47, 0.62, 0.65, 0.73, 0.75, 1.0, 1.2, 1.3, 1.5 (2), 1.6, 1.8 (2), 1.9, 2.0, 2.3 (2), 2.7, 2.9, 3.2, 3.3, 3.6, 3.7, 4.2, 5.3, 6.5, 6.6, 7.0 mg/kg.

The residues on wheat forage (as received basis) according to the US GAP were (n = 31): 0.24, 0.52, 0.97, 0.98, 1.2, 1.4, 1.6 (2), 1.7, 1.9 (2), 2.2 (2), 2.3, 2.5, 2.7, 3.3, 3.4, 3.6, 4.0, 4.2, 4.4, 4.8, 4.9, 5.4 (2), 6.2, 6.3, 7.7 and 11 (2) mg/kg.

The residues on maize forage (as received basis) according to the US GAP were (n = 20): 0.38, 0.45, 0.64, 0.67, 0.69, 0.79, 0.91, 1.0 (3), 1.3 (2), 1.5, 1.6, 2.0, 2.1, 2.2, 2.4, 2.8 and 4.9 mg/kg.

The residues on sweet corn forage (as received basis) according to the US GAP were (n = 12): 0.44, 0.49, 0.68, 0.73 (2), 0.75, 0.80, 0.90, 1.0, 1.2 (2) and 3.9 mg/kg.

In field studies on succeeding crops the scaled mean, median and highest residues in barley forage were 0.02, 0.02 and 0.04 mg/kg respectively, and in wheat forage were 0.03, 0.03 and 0.03 mg/kg respectively. The Meeting concluded that residues in forage of oats, wheat, maize and sweet corn from uptake of pydiflumetofen via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a median residue value of 1.95 mg/kg and a highest residue value of 7.0 mg/kg for oats forage (as received basis).

The Meeting concluded that residues on forage from oats may be extrapolated to forage from barley.

The Meeting estimated a median residue value of 2.7 mg/kg and a highest residue value of 11 mg/kg for wheat forage (as received basis).

The Meeting concluded that residues on forage from wheat may be extrapolated to forage from rye and triticale.

The Meeting estimated a median residue value of 1.15 mg/kg and a highest residue value of 4.9 mg/kg for maize forage (as received basis).

The Meeting estimated a median residue value of 0.775 mg/kg and a highest residue value of 3.9 mg/kg for sweet corn forage (as received basis).

#### ***Forage of cereal grain, except barley, oats, rye, triticale, wheat, maize and sweet corn***

Although pydiflumetofen is not registered for use on other cereal forage (except barley, oats, rye, triticale, wheat and maize), these crops may still be subject to crop rotation and therefore contain pydiflumetofen residues after uptake via the roots. The Meeting decided to use the scaled mean, median and highest residues found in wheat forage in field studies on succeeding crops of 0.03, 0.03 and 0.03 mg/kg (fresh-weight) respectively for an estimation of median values and highest values in forage of cereal grain, except barley, oats, rye, triticale, wheat, maize and sweet corn.

The Meeting estimated a median residue value of 0.03 mg/kg and a highest residue value of 0.03 mg/kg for pydiflumetofen in forage of cereal grain, except barley, oats, rye, triticale, wheat, maize and sweet corn (as received basis).

**Fate of residues during processing**

Processing data on various commodities are reported in the evaluation from 2018 for pydiflumetofen. All data relevant for an estimation of maximum residue levels in processed commodities or for dietary exposure calculations are summarized in the following table.

Although the studies on sweet corn were conducted at an exaggerated application rate compared to the critical GAP, pydiflumetofen residues in the RAC were below the LOQ of 0.01 mg/kg. Processing factors for sweet corn processed commodities cannot be determined.

Table 4 Processing factors and STMR-P/HR-P

Raw commodity [STMR/HR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)	HR-P = HR <sub>RAC</sub> × PF (mg/kg)
Tomato [0.11 mg/kg/ 0.42 mg/kg]	Canned	< 0.046, < 0.077	< 0.046	< 0.005	< 0.019
	Dried	9.9, 11	10.5	1.2	4.4
	Juice (Pasteurised)	< 0.046, < 0.077	< 0.046	< 0.005	
	Paste	0.55, 0.82	0.685	0.075	
	Puree	0.26, 0.41	0.335	0.037	
	Wet pomace	3.3, 4.5	3.9	0.43	
Soya bean [0.028 mg/kg]	Refined oil	0.078, 0.29	0.184	0.005	
	Miso	0.091, 0.17	0.131	0.004	
	Milk	< 0.056, < 0.064	< 0.056	< 0.002	
	Flour	< 0.056, < 0.064	< 0.056	< 0.002	
	Soya sauce	< 0.056, < 0.064	< 0.056	< 0.002	
	Tofu	0.14, 0.15	0.145	0.004	
	AGF	121, 156	139	3.9	
	Meal	0.065, 0.090	0.078	0.002	
	Hulls	2.9, 3.7	3.3	0.092	
Pollard	0.26, 0.36	0.31	0.009		
Potato [0.03 mg/kg/ 0.084 mg/kg]	Boiled (peeled)	< 0.45	< 0.45	< 0.014	< 0.038
	Baked (unpeeled)	< 0.45	< 0.45	< 0.014	< 0.038
	Dried pulp	4.3	4.3	0.13	0.36
	Chips	< 0.45	< 0.45	< 0.014	
	Crisps	< 0.45	< 0.45	< 0.014	
	Starch	< 0.45	< 0.45	< 0.014	
	Flakes	< 0.45	< 0.45	< 0.014	
	Wet peel	2.1	2.1	0.063	0.18
Wheat [0.063 mg/kg]	Bran	1.9, 2.6	2.25	0.14	
	Wholemeal bread	0.41, 0.45	0.43	0.027	
	Germs	1.0, 1.9	1.45	0.091	
	Flour	0.30, 0.34	0.32	0.020	
	Starch	0.019, 0.050	0.035	0.002	
	Gluten	1.1, 2.3	1.7	0.11	
	AGF	127, 598	363	23	
	Gluten feed meal	1.3, 2.4	1.85	0.12	
	Milled by-product	2.5, 9.7	6.1	0.38	
Barley [0.23 mg/kg]	Bran	0.24, 0.48	0.36	0.083	
	Flour	0.23, 0.23	0.23	0.053	
	Pearled barley	0.024, 0.062	0.043	0.010	
Oats [0.23 mg/kg]	Bran	0.013, 0.017	0.015	0.003	
	Flour	0.027, 0.068	0.048	0.011	
	Rolled oats	0.012, 0.013	0.013	0.003	

Raw commodity [STMR/HR]	Processed commodity	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)	HR-P = HR <sub>RAC</sub> × PF (mg/kg)
Maize [0.03 mg/kg]	Refined oil	1.5, 2.3 (wet milled)	1.9	0.057	
		< 0.42, < 1.2 (dry milled)	< 0.42	< 0.013	
	Bran (hulls)	3.7, 5.8 (dry milled)	4.75	0.14	
	Grits	< 0.42, < 1.2 (dry milled)	< 0.42	< 0.013	
	Germs	2.0, 2.2 (wet milled)	2.1	0.063	
		0.91, < 1.2 (dry milled)	0.91	0.027	
	Flour	< 0.42, < 1.2 (wet milled)	< 0.42	< 0.013	
		< 1.2, 1.6 (dry milled)	1.6	0.048	
	Meal	0.93, < 1.2 (dry milled)	0.93	0.028	
	Starch	< 0.42, < 1.2 (wet milled)	< 0.42	< 0.013	
	AGF	69, 71	70	2.1	
	Milled by-product	1.7, 2.7	2.2	0.066	
Rape seed [0.0945 mg/kg]	Refined oil	0.70, 1.9 (wet milled)	1.3	0.039	
		3.1, 3.3 (wet milled)	3.2	0.096	
Peanut [0.03 mg/kg]	Refined oil	0.36, 0.38	0.37	0.035	
		0.087, 0.094	0.091	0.009	
Peanut [0.03 mg/kg]	Meal	2.4	2.4	0.072	
		< 0.4	< 0.4	< 0.012	

On the basis of the maximum residue level, STMR and HR for fruiting vegetables, other than cucurbits and the default dehydration factor of 10, the Meeting estimated a maximum residue level of 5 mg/kg, an STMR value of 1.1 mg/kg and an HR value of 4.2 mg/kg for chili peppers (dry).

Using the estimated maximum residue level of 0.5 mg/kg for the group of fruiting vegetables, other than cucurbits and applying the processing factor of 10.5, the Meeting estimated a maximum residue level of 7 mg/kg for pydiflumetofen in dried tomato.

Using the estimated maximum residue level of 0.1 mg/kg for the subgroup of tuberous and corm vegetables and applying the processing factor of 4.3, the Meeting estimated a maximum residue level of 0.5 mg/kg for pydiflumetofen in dried potato.

Using the estimated maximum residue level of 0.4 mg/kg for the subgroup of wheat, similar grains, and pseudocereals without husks and applying the processing factor of 2.25 for wheat bran and 1.45 for wheat germs the Meeting estimated a maximum residue level of 1 mg/kg and 0.6 mg/kg for pydiflumetofen in wheat bran and wheat germ, respectively.

Using the estimated maximum residue level of 0.04 mg/kg for the subgroup of maize cereals and applying the processing factor of 1.9 for maize refined oil and 1.6 for maize flour, the Meeting estimated maximum residue levels of 0.08 mg/kg and 0.07 mg/kg for pydiflumetofen in maize oil, edible and maize flour, respectively.

Using the estimated maximum residue level of 0.05 mg/kg for peanut and applying the processing factor of 2.4, the Meeting estimated a maximum residue level of 0.15 mg/kg for pydiflumetofen in peanut oil, edible.

**Residues in animal commodities**

**Farm animal feeding studies**

Farm animal feeding studies (lactating dairy cow and laying hen) are reported in the evaluation of the 2018 JMPR.

*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 input was based on the intake of pydiflumetofen.

Table 5 Potential feed items

Codex classification	Commodity	Median residue (-P) (mg/kg)	Highest residue (-P) (mg/kg)
Grape	Grape wet pomace	0.87	
Brassica vegetables	Head cabbage leaves	0.02	0.09
Fruiting vegetables, other than Cucurbits	Tomato wet pomace	0.43	
Brassica leafy vegetables	Kale leaves	0.02	0.09
Leaves of root and tuber vegetables	Turnip tops	0.02	0.02
	Sugar beet tops	0.02	0.02
Pulses	Beans (dry) seed, Cowpea seed, Lupin seed, Field pea (dry) seed, Soya bean (dry) seed, Vetch seed	0.028	
	Soya bean aspirated grain fractions	3.9	
	Soya bean meal	0.002	
	Soya bean hulls	0.092	
	Soya bean pollard	0.009	
Root vegetables	Carrot culls, Swede roots, Turnip roots	0.02	0.07
	Potato dried pulp	0.13	
	Potato process waste (wet peel)	0.063	
Tuberous and corn vegetables	Cassava roots, Potato culls	0.03	0.084
Wheat, similar grains, and pseudocereals without husks	Rye grain, Triticale grain, Wheat grain	0.063	
	Wheat aspirated grain fractions	23	
	Wheat gluten meal	0.12	
	Wheat milled by-product	0.38	
Barley, similar grains, and pseudocereals with husks	Barley grain, Oats grain	0.23	
	Barley bran fractions	0.083	
Maize Cereals	Maize grain, Popcorn grain,	0.03	
	Maize aspirated grain fractions	2.1	
	Maize milled by-product	0.066	
	Maize meal	0.028	
	Maize gluten	0.039	
	Maize gluten meal	0.096	
Small seed oilseeds	Rape seed meal	0.009	
Peanut	Peanut meal	< 0.012	
Legume animal feeds	Forage of legume animal feeds	0.88 (as received)	2.8 (as received)
	Fodder of legume animal feeds	9.2 (dry weight)	15 (dry weight)
Straw and fodder of cereal grains	Straw and fodder of barley, oats, rye triticale, and wheat	9.2 (dry weight)	40 (dry weight)
	Maize fodder	3.1 (as received)	13 (as received)
	Straw and fodder of cereal grains, except barley, oats, rye, triticale, wheat and maize	0.08 (as received)	0.28 (as received)
	Forage of cereal grains <sup>a</sup>	1.95	7.0
Forage of cereal grains <sup>a</sup>	Forage of rye, triticale and wheat	2.7	11
	Maize forage	1.15	4.9
	Sweet corn forage	0.775	3.9
	Forage of cereal grains, except barley, oats, rye, triticale, wheat, maize and sweet corn	0.03	0.03

<sup>a</sup> levels for cereal forage are presented on as received basis.

The dietary burdens, estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 Edition of the FAO manual<sup>p</sup>, are presented in Annex 6 and summarized below.

Table 6 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: Pydiflumetofen, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	mean	max	mean	max	mean	max	mean
Beef cattle	7.9	3.3	22	7.3	44 <sup>a</sup>	11 <sup>c</sup>	0.38	0.36
Dairy cattle	21	5.9	22	7.3	42 <sup>b</sup>	10 <sup>d</sup>	7.7	2.0
Poultry – broiler	0.35	0.35	0.34	0.29	0.17	0.17	0.077	0.077
Poultry – layer	0.35	0.35	6.2 <sup>e g</sup>	2.2 <sup>f h</sup>	0.17	0.17	0.15	0.15

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

<sup>c</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

<sup>d</sup> Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

<sup>e</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

<sup>f</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

<sup>g</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

<sup>h</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

### Animal commodity maximum residue levels

#### Cattle

Residues in tissues and milk at the expected dietary burden for dairy cattle are shown in the Table below.

Table 7 Maximum residue level, STMR and HR in mammalian animal 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
MRL Determination (beef or dairy cattle)							
Feeding Study	15	< 0.01	15	< 0.01	0.02	< 0.01	0.01
	45	< 0.01	45	< 0.01	0.05	< 0.01	0.05
Dietary burden and estimate of highest residue	42	< 0.01	44	< 0.01	0.05	< 0.01	0.05
HR Determination (beef or dairy cattle)							
Feeding Study			15	< 0.02	0.08	0.08	0.03
			45	< 0.02	0.44	0.30	0.07
Dietary burden and estimate of highest residue			44	< 0.02	0.43	0.29	0.069
STMR Determination (beef or dairy cattle)							
Feeding Study	15	< 0.02	15	< 0.02	0.06	0.07	0.02
Dietary burden and estimate of highest residue	10	< 0.02	11	< 0.02	0.044	0.051	0.015

<sup>p</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

Based on pydiflumetofen residues in milk and cattle tissues, the Meeting estimated a maximum residue level of 0.01 (\*) mg/kg in milk, 0.1 mg/kg in mammalian meat (in the fat), mammalian edible offal and mammalian fat.

Based on the highest estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in muscle and fat, the Meeting estimated HR values of 0.02 mg/kg in mammalian meat and 0.069 mg/kg in mammalian fat.

Based on the highest estimated total residues of pydiflumetofen, 2,4,6-TCP and SYN547897 expressed as pydiflumetofen in liver and kidney, the Meeting estimated an HR value of 0.43 mg/kg in mammalian edible offal.

Based on the mean estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in milk, muscle and fat, the Meeting estimated STMR values of 0.02 mg/kg in milk, 0.02 mg/kg in mammalian meat and 0.015 mg/kg in mammalian fat.

Based on the mean estimated total residues of pydiflumetofen, 2,4,6-TCP and SYN547897 expressed as pydiflumetofen in liver and kidney, the Meeting estimated an STMR value of 0.051 mg/kg in mammalian edible offal.

### Poultry

Residues in tissues and eggs at the expected dietary burden for laying hen are shown in the Table below.

Table 8 Maximum residue level, STMR and HR in poultry commodities

	Feed Level (ppm) for egg residues	Total residues (mg eq/kg) in egg	Feed Level (ppm) for tissue residues	Total residues (mg eq/kg)		
				Muscle	Liver	Fat
MRL Determination (poultry broiler or layer)						
Feeding Study	3	< 0.01	3	< 0.01	< 0.01	< 0.01
	9	0.011	9	< 0.01	< 0.01	< 0.01
Dietary burden and estimate of highest residue	6.2	0.011	6.2	< 0.01	< 0.01	< 0.01
HR Determination (poultry broiler or layer)						
Feeding Study	3	< 0.02	3	< 0.02	< 0.02	< 0.02
	9	0.023	9	< 0.02	< 0.02	< 0.02
Dietary burden and estimate of highest residue	6.2	0.022	6.2	< 0.02	< 0.02	< 0.02
STMR Determination (poultry broiler or layer)						
Feeding Study	3	< 0.02	3	< 0.02	< 0.02	< 0.02
Dietary burden and estimate of highest residue	2.2	< 0.02	2.2	< 0.02	< 0.02	< 0.02

Based on pydiflumetofen residues in eggs and poultry tissues, the Meeting estimated a maximum residue level of 0.02 mg/kg in eggs, 0.01 (\*) mg/kg in poultry meat, poultry edible offal and poultry fat.

Based on the highest estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in eggs, muscle, liver and fat, the Meeting estimated HR values of 0.03 mg/kg in eggs, 0.02 mg/kg in poultry meat, 0.02 mg/kg in poultry, edible offal of and 0.02 mg/kg in poultry fat.

Based on the mean estimated total residues of pydiflumetofen and 2,4,6-TCP expressed as pydiflumetofen in eggs, muscle, liver and fat, the Meeting estimated STMR values of 0.02 mg/kg in eggs, poultry meat, poultry, edible offal of and poultry fat.

### 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 and dietary risk assessment for plant commodities: *Pydiflumetofen*

Definition of the residue for compliance with the MRL for animal commodities: *Pydiflumetofen*

Definition of the residue for estimation of dietary exposure for animal commodities other than mammalian liver and kidney: *Sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen*

Definition of the residue for estimation of dietary exposure for mammalian liver and kidney: *Sum of pydiflumetofen, 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, and 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl)ethyl]pyrazole-4-carboxamide (SYN547897) and its conjugates, expressed as pydiflumetofen*

The residue is fat-soluble.

## DIETARY RISK ASSESSMENT

### **Long-term dietary exposure**

The ADI for pydiflumetofen is 0–0.1 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for pydiflumetofen 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 2019 JMPR Report.

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

### **Acute dietary exposure**

The ARfD for pydiflumetofen is 0.3 mg/kg bw. The International Estimate of Short Term Intakes (IESTIs) for pydiflumetofen 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 2019 JMPR Report.

The IESTIs were less than 100% of the ARfD, except for spinach (up to 140% for toddlers in the Netherlands), lettuce (up to 350% for children in China) and endive (up to 230% for children in the Netherlands). The Meeting concluded that acute dietary exposure to residues of pydiflumetofen from uses considered by the present Meeting may present a health concern for these commodities.



## 5.20 Pyflubumide (314)

### TOXICOLOGY

Pyflubumide is the ISO-approved common name for 3'-isobutyl-*N*-isobutyryl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]-1*H*-pyrazole-4-carboxanilide (IUPAC), with the CAS number 926914-55-8. It is a novel acaricide and, so far, the only one with a carboxanilide structure. Its highly specific pesticidal mode of action is by inhibition of the mitochondrial complex II following formation of the active NH<sup>-</sup> form as a metabolite in the target pest.

Pyflubumide has not been evaluated before by JMPR and was reviewed by the present Meeting at the request of CCPR. Most critical studies contained statements of compliance with GLP and were conducted in accordance with current test guidelines. A few non-GLP pharmacological and mechanistic studies were also of good quality and were reported in detail. Since pyflubumide is a new compound, published information is very scarce.

#### **Biochemical aspects**

Following oral administration to rats of <sup>14</sup>C-radiolabelled pyflubumide as a single low dose of 1 mg/kg bw, the compound was rapidly absorbed ( $T_{max}$  6 h) but only partially so. Based on urinary (< 6%) and biliary (ca 43%) excretion, cage wash, tissue and carcass residues after 72 hours, absorption accounted for ca 52% of the applied dose. Absorption of a single dose of 100 mg/kg bw is expected to be only marginally lower, however, a final conclusion cannot be drawn because this high dose was not administered to bile-cannulated rats. The absorbed portion was widely distributed throughout the body, with highest concentrations found in liver and kidneys, adrenals, bone marrow and fat. Elimination was nearly complete at the low- and high-dose levels after seven days, with faeces being the main route of elimination, accounting for 90% or more. In nursing rats, excretion of pyflubumide and of some of its metabolites via the milk was demonstrated. The milk:plasma radioactivity ratio was approximately 10:1, and the AUC was up to 7.5 times higher in milk than in plasma.

Extensive metabolism of pyflubumide was observed, at least of the systemically available portion. The main metabolic pathways comprised deacylation of the nitrogen atom, followed by hydroxylation and demethylation, whereas cleavage of the molecular backbone of pyflubumide was very limited. Eight or nine metabolites were identified in urine, faeces, plasma or milk, but each of these displayed a different mix of metabolites. In bile there were 12 metabolites. Main metabolites (exceeding 10% of administered dose in either excreta or plasma in ADME studies) were pyflubumide-NH (Metabolite B), pyflubumide-NH-1-H-RfOH (Metabolite F) and pyflubumide-NH-1-H-3'-(3-OH)-RfOH (Metabolite R). The unchanged parent compound was mainly detected in the GI tract and faeces, representing the non-absorbed part, but to a small extent also in milk.

The impact of sex, dose, or position of radiolabel on toxicokinetics or metabolism was low.

#### **Toxicological data**

In rats, the acute oral and dermal LD<sub>50</sub> was > 2000 mg/kg bw whereas the inhalation LC<sub>50</sub> was above 5.23 mg/L in a 4-h, nose-only, exposure experiment. Pyflubumide was not irritating to the skin or to the eyes of rabbits and proved negative for skin sensitization in a local lymph node assay.

Oral (feeding) short-term toxicity studies with pyflubumide were performed in mice (28-day and 90-day), rats (28-day and 90-day), and dogs (90-day and one-year). In the mouse, the main target organs of toxicity were the liver and the haematopoietic system. In the rat, the main target organs of toxicity were the liver, thyroid, haematopoietic system and heart. In the dog, the main target organs of toxicity were the heart, liver and adrenals.

In a 28-day study in mice, the dietary dose levels were 0, 20, 200 and 2000 ppm (equal to 0, 3.0, 32, and 297 mg/kg bw per day in males, 4.1, 40, and 396 mg/kg bw per day in females). A further group receiving 10 000 ppm was prematurely terminated due to excessive toxicity. The dose of 20 ppm

(equal to 3.0 mg/kg bw per day) was the NOAEL, based on increased liver weight with associated histopathology in both sexes, resulting from 200 ppm (equal to 32 mg/kg bw per day).

In a 90-day study in mice, dietary doses of 0, 40, 400 and 4000 ppm (equal to 0, 5.3, 51, and 505 mg/kg bw per day in males, 0, 6.4, 64, and 596 mg/kg bw per day in females) were administered. The NOAEL was 400 ppm (equal to 51 mg/kg bw per day), based on liver toxicity (increased liver weight with associated histopathology and clinical-chemistry parameters), slight effects on red blood parameters with an increase in spleen weight, follicular cell hypertrophy of the thyroid and eosinophilic changes in the zona fasciculata of the adrenals at 4000 ppm (equal to 505 mg/kg bw per day).

In a 28-day study in the rat, dietary dose levels of 0, 200 and 2000 ppm (equal to 0, 17, and 137 mg/kg bw per day in males, 0, 17, and 140 mg/kg bw per day in females) were fed to the animals. A further group receiving 20 000 ppm was prematurely terminated due to excessive toxicity. Treatment-related and adverse effects were seen at all dose levels, with effects on liver, heart and thyroid from the lowest dose of 200 ppm. A NOAEL could not be identified and the LOAEL was 200 ppm (equal to 17 mg/kg bw per day).

In a subsequent 90-day study in rats, animals were administered dietary doses of 0, 20, 200 and 1200 ppm (equal to 0, 1.2, 12, and 72 mg/kg bw per day in males, 0, 1.4, 14, and 81 mg/kg bw per day in females). An additional control group and second high-dose group were included to assess their recovery when fed an untreated diet for four weeks after dosing had ceased. The NOAEL was 20 ppm (1.2 mg/kg bw per day) based on increased heart weights in both males and females at 200 ppm (equal to 12 mg/kg bw per day). The adverse findings were only partly reversible during the recovery period.

In a 90-day feeding study in dogs, the dose levels were 0, 40, 300 and 2500 ppm (equal to 0, 1.2, 9.1, and 77 mg/kg bw per day in males, 0, 1.3, 9.5, and 75 mg/kg bw per day in females). The NOAEL was 300 ppm (equal to 9.1 mg/kg bw per day). Adverse, treatment-related effects were confined to the top dose of 2500 ppm (equal to 75 mg/kg bw per day) and consisted of cardiotoxicity (increased heart weights with associated histopathology and functional changes), increased liver weights with associated histopathology, clinical-chemistry parameters and rare histological kidney findings.

A one-year study was performed in dogs using dietary dose levels of 0, 40, 300 and 2000 ppm (equal to 0, 1.1, 8.0, and 54 mg/kg bw per day in both sexes). The NOAEL was 40 ppm (equal to 1.1 mg/kg bw per day) based on histopathological changes in the adrenals (hypertrophy, lipid depletion and thickening of the zona fasciculata) at 300 ppm (equal to 8 mg/kg bw per day).

In the 18-month study on mice, pyflubumide was administered at dietary doses of 0, 40, 400 or 1600 ppm (equal to 0, 4.4, 45, and 176 mg/kg bw per day in males, 0, 4.0, 43, and 178 mg/kg bw per day in females). The NOAEL was 400 ppm (equal to 43 mg/kg bw per day) based on lower body weight in females, on increased organ weights of liver and spleen and on histopathological findings in liver, adrenals, spleen and thyroid, which were observed either in one or both sexes at 1600 ppm (equal to 176 mg/kg bw per day). Increased tumour incidences were noted for the liver and the lymph nodes at the same maximum dose. Benign liver adenomas were increased in males only, with no progression to carcinoma noted. A possible mode of action has not been investigated. Marginal increases in haemangiosarcomas of mesenteric lymph nodes (statistically significant in a test for trend in males, and above laboratory historical control data in both sexes) were observed at 1600 ppm. Relevance to human risk of haemangiosarcoma in mice is generally considered low. On the other hand, no mode of action has been proposed and/or investigated. Additional uncertainty comes from the small number of animals in the low- and mid-dose groups in which mesenteric lymph nodes had been examined microscopically. Overall, pyflubumide was carcinogenic in mice and a NOAEL for carcinogenicity of 400 ppm (43 mg/kg bw per day) was indicated by the study.

In a one-year chronic toxicity study in rats, pyflubumide was administered at dietary concentrations of 0, 10, 20, 120, and 600 ppm (equal to 0, 0.4, 0.9, 5.1 and 26 mg/kg bw per day in males, 0, 0.5, 1.1, 6.4, 32 mg/kg bw per day in females). The NOAEL was 20 ppm (equal to 0.9 mg/kg bw per day), based on the effects on heart (weight), liver (bile duct hyperplasia), red blood

cell parameters, kidney (urinary casts and tubular basophilic changes), ovary (weight) and skin (loss of fur) at 120 ppm (equal to 5.1 mg/kg bw per day).

In a separate two-year carcinogenicity study in rats, pyflubumide was administered at dietary concentrations of 0, 10, 20, 120 and 600 ppm (equal to 0, 0.4, 0.7, 4.5, and 23 mg/kg bw per day in males, 0, 0.5, 0.9, 6, and 29 mg/kg bw per day in females). The NOAEL for chronic toxicity in this study was 20 ppm (0.7 mg/kg bw per day) based on effects on liver (weight with associated bile duct hyperplasia), heart (weight, with associated fibrosis), adrenals (medullary hyperplasia) at 120 ppm (equal to 4.5 mg/kg bw per day). No evidence of carcinogenicity was obtained in the rat and the NOAEL for carcinogenicity was 600 ppm (equal to 23 mg/kg bw per day), the highest dose tested.

The Meeting concluded that pyflubumide is carcinogenic in mice but not in rats.

Pyflubumide was tested for genotoxicity in an adequate range of studies *in vitro* and *in vivo* which were all negative.

The Meeting concluded that pyflubumide is unlikely to be genotoxic.

In the view of the lack of genotoxicity, in the absence of carcinogenicity in the rat and since the higher incidence of tumours in the mouse was confined to the highest dose, far above expected human exposure, the Meeting concluded that pyflubumide is unlikely to pose a carcinogenic risk to humans via exposure from the diet.

In a two-generation study, pyflubumide was administered to rats at dietary dose levels of 0, 7.5, 15, 100 or 500 ppm (equal to 0, 0.4, 0.8, 5.3, and 26 mg/kg bw per day for males, 0, 0.7, 1.3, 8.6, and 42 mg/kg bw per day for females). The NOAEL for parental effects was 15 ppm (equal to 0.8 mg/kg bw per day), based on increased organ weights of heart, thyroid, liver, and ovaries and histopathological findings in the heart at the dose levels above. A reproductive toxicity NOAEL of 100 ppm (equal to 5.3 mg/kg bw per day) was established because of prolonged gestation and a lower pup viability index on the day of birth at the maximum dose level of 500 ppm (equal to 26 mg/kg bw per day) even though these effects were confined to the first generation. The offspring NOAEL was 15 ppm (equal to 0.8 mg/kg bw per day), based on gross and histological lung lesions in F<sub>1</sub> and F<sub>2</sub> pups from 100 ppm (equal to 5.3 mg/kg bw per day).

In a developmental study in rats, pyflubumide was administered by oral gavage at dose levels of 0, 5, 30, and 200 mg/kg bw per day. The maternal NOAEL was 30 mg/kg bw per day since body weight gain and food consumption were reduced at the top dose level. A few of the dams even lost some body weight. In addition, placenta weights were increased. The developmental NOAEL of 30 mg/kg bw per day was based on a significantly higher mean fetal weight at the next higher dose. There was no increase in malformations or individual variations.

In a developmental study in rabbits, pyflubumide was administered by oral gavage at doses of 0, 5, 20, and 80 mg/kg bw per day. The maternal NOAEL was 20 mg/kg bw per day, based on abortions and premature delivery, lower body weight gain (or even body weight loss), reduced food intake and higher placenta weights in the high-dose group. No effects on the fetuses were observed in rabbits up to the highest dose of 80 mg/kg bw per day which was therefore considered the developmental NOAEL.

The Meeting concluded that pyflubumide is not teratogenic.

In an acute neurotoxicity study in rats in which gavage doses of 0, 500, 1000, and 2000 mg/kg bw were administered, a systemic NOAEL could not be established since body temperature on the day of dosing was reduced in all treated male and female groups, from the lowest dose onwards. In addition, body weight gain was decreased in all male groups over the first week of the post-observation period even though no clear dose response was observed. However, the maximum dose of 2000 mg/kg bw was considered the NOAEL for neurotoxicity. A separate neurotoxicity study with repeated administration was not submitted, but no concern was identified from the available studies.

The Meeting concluded that pyflubumide is not neurotoxic.

An immunotoxicity study was not submitted but no concern was identified from the available studies.

The Meeting concluded that pyflubumide is not immunotoxic.

A number of mechanistic studies were performed to further investigate the effects on the heart and thyroid as observed in many studies in different species, and effects on lungs seen in rat offspring.

With regard to the heart gross and histopathological findings as well as the higher organ weight and clinical signs (tachycardia, lower blood pressure) observed in various studies in rats and/or dogs, mechanistic studies in the rat were carried out by single intravenous administration and on excised rat tissue. These suggested a mode of action that is considered plausible: pyflubumide or its metabolites cause vasodilatation with subsequent decrease in blood pressure. As a reflex response, heart action is increased, resulting in tachycardia and, following long-lasting maintenance of these pathophysiological conditions, morphological heart changes may ensue. This mechanism was considered relevant to humans.

Thyroid effects such as organ weight increase or follicular cell hyperplasia could be clearly attributed to inhibition of thyroid peroxidase (TPO) resulting in a lower availability of iodine, reduced concentrations of circulation triiodothyronine (T<sub>3</sub>) and thyroxine (T<sub>4</sub>) and, because of hormonal feedback regulation, an increase in thyroid stimulating hormone (TSH) release.

It could be demonstrated that pyflubumide and a number of its metabolites are excreted by lactating rat females to a significant extent via the milk. In cross-fostering experiments, it was shown that the lung lesions in rat pups, as observed in the two-generation study, can be clearly attributed to postnatal exposure via the milk but were not due to in utero exposure. Young pups exhibited similar lung changes after repeated gavage application of a dose of 10 mg/kg bw per day or above from PND four to 13. It seems that there is a critical window of sensitivity for this effect. Alveolar dilatation was already observed when the test substance was applied by oral gavage administration of pups at a dose level of 50 mg/kg bw on two consecutive days, provided the pups were not older than seven days.

#### ***Toxicological data on metabolites and/or degradates***

The pyflubumide plant metabolites 1,3,5-trimethylpyrazole-4-carboxylic acid (Metabolite H) and 3'-isobutyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]isobutylanilide (Metabolite L) were of low acute oral toxicity since the LD<sub>50</sub> in rats, in both cases, was greater than 2000 mg/kg bw. In addition, these two metabolites proved negative in the Ames test. If an evaluation of these metabolites becomes necessary, the TTC approach (Cramer class III) is considered appropriate and applicable.

A mechanistic study revealed that the metabolite pyflubumide-NH-RfOH (Metabolite D) had a higher potency than the parent compound in causing vasodilatation of aorta specimens in vitro. When administered by oral gavage to rat pups from PND 4–13 at a dose level of 50 mg/kg bw per day, it caused alveolar dilatation, similar to the parent compound. In ADME studies, this metabolite was detected following single oral application of 100 mg/kg bw of pyflubumide, at a rate of up to 8.4% of the applied dose in rat plasma but was not found in excreta. In addition, it accounted for up to 7% of total residues in milk following single oral administration of the same dose to rats.

The NH-form of pyflubumide (Metabolite B, that is the acaricidal compound), also caused alveolar dilatation in rat pups when administered by oral gavage from PND 4–13 at a dose level of 50 mg/kg bw per day, meaning that it was of similar potency with regard to this effect as the parent compound. This is of particular relevance since it was the main metabolite in rat milk, accounting for up to 58% of total milk residues. In the ADME studies, at a dose level of 100 mg pyflubumide/kg bw, it had been detected only in faeces at rates between 11% and 19% of the applied total dose, but not in urine, whereas it occurred in plasma only in traces. With regard to vasodilatation in vitro, Metabolite B was of similar potency to the parent. Metabolite B has a similar structure to the parent compound. On balance, it appears reasonable to apply the ADI and ARfD as established for pyflubumide to this metabolite also. With regard to its excretion via the milk it should be taken into consideration that the ARfD is based on, and the ADI at least supported by, the reproduction study. Metabolite B can be assumed to have been tested in that study.

The metabolite pyflubumide-RfOH (Metabolite U) proved a potent inhibitor of TPO in vitro, but was inactive in an in vitro test for vasodilatation. This metabolite is a proposed intermediate in rat metabolism. It was identified as a minor metabolite in plasma, accounting for up to 4.5%, but was not found in excreta or milk. Based on its very close structural similarity to the parent compound, this metabolite is assumed not to be more toxic than its parent. Accordingly, ADI and ARfD of pyflubumide are applicable to Metabolite U, too.

#### ***Microbiological data***

Not available.

#### ***Human data***

Not available since pyflubumide is a new compound.

The meeting concluded that the existing database on pyflubumide is adequate to characterize the potential hazards to the general population, including fetuses, infants and children.

#### **Toxicological evaluation**

The Meeting established an ADI for pyflubumide of 0–0.007 mg/kg bw that was derived from the NOAEL of 0.7 mg/kg bw per day based on findings in liver, heart, and adrenals in the two-year study of toxicity and carcinogenicity in rats, using a safety factor of 100. This was supported by the parental and offspring NOAELs in the two-generation study in rats (0.8 mg/kg bw per day) and by the NOAEL in the one-year study in dogs (1.1 mg/kg bw per day).

The upper range of the ADI provides a margin of over 25 000 to the LOAEL for liver adenomas and haemangiosarcomas in mice.

The Meeting established an ARfD of 0.008 mg/kg bw on the basis of the offspring NOAEL of 0.8 mg/kg bw per day for lung lesions which have been shown to occur as an acute effect in the two-generation rat study, using a safety factor of 100.

The ADI and ARfD are applicable to the metabolites pyflubumide-NH (Metabolite B) and pyflubumide-RfOH (Metabolite U).

A toxicological monograph was prepared.

**Levels relevant to risk assessment of pyflubumide**

Species	Study	Effect	NOAEL	LOAEL
Mouse	90-day study of toxicity	Toxicity	400 ppm, equal to 51 mg/kg bw per day	4000 ppm, equal to 505 mg/kg bw per day
	18-month chronic/carcinogenicity study	Toxicity	400 ppm, equal to 43 mg/kg bw per day	1600 ppm, equal to 176 mg/kg bw per day
		Carcinogenicity	400 ppm, equal to 43 mg/kg bw per day	1600 ppm, equal to 176 mg/kg bw per day
Rat	Acute neurotoxicity study <sup>b</sup>	Neurotoxicity Toxicity	2000 mg/kg bwc -	- 500 mg/kg bw
	90-day study of toxicity	Toxicity	20 ppm, equal to 1.2 mg/kg bw per day	200 ppm, equal to 12 mg/kg bw per day
	One-year study of chronic toxicity <sup>a</sup>	Toxicity	20 ppm, equal to 0.9 mg/kg bw per day	120 ppm, equal to 5.1 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	20 ppm, equal to 0.7 mg/kg bw per day	120 ppm, equal to 4.5 mg/kg bw per day
		Carcinogenicity	600 ppm, equal to 23 mg/kg bw per day <sup>c</sup>	-
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	100 ppm, equal to 5.3 mg/kg bw per day	500 ppm, equal to 26 mg/kg bw per day
		Parental toxicity	15 ppm, equal to 0.8 mg/kg bw per day	100 ppm, equal to 5.3 mg/kg bw per day
Offspring toxicity		15 ppm, equal to 0.8 mg/kg bw per day	100 ppm, equal to 5.3 mg/kg bw per day	
Developmental toxicity study <sup>b</sup>	Maternal toxicity	30 mg/kg bw per day	200 mg/kg bw per day	
	Embryo/foetal toxicity	30 mg/kg bw per day	200 mg/kg bw per day	
Rabbit	Developmental toxicity study <sup>b</sup>	Maternal toxicity Embryo/foetal toxicity	20 mg/kg bw per day 80 mg/kg bw per day <sup>c</sup>	80 mg/kg bw per day
Dog	Thirteen-week study of toxicity <sup>a</sup>	Toxicity	300 ppm, equal to 9.1 mg/kg bw per day	2500 ppm, equal to 77 mg/kg bw per day
	One-year study of toxicity <sup>a</sup>	Toxicity	40 ppm, equal to 1.1 mg/kg bw per day	300 ppm, equal to 8.0 mg/kg bw per day

a Dietary administration.

b Gavage administration.

c Highest dose tested in study.

*Acceptable daily intake (ADI) for pyflubumide, pyflubumide-NH and pyflubumide-RfOH expressed as pyflubumide*

0–0.007 mg/kg bw

*Acute reference dose (ARfD) for pyflubumide, pyflubumide-NH and pyflubumide-RfOH expressed as pyflubumide*

0.008 mg/kg bw

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

Epidemiological, occupational health or other human observational data if they become available.



**Critical end-points for setting guidance values for exposure to pyflubumide**

<b>Absorption, distribution, excretion and metabolism in mammals</b>	
Rate and extent of oral absorption	Rapid ( $T_{max}$ , 6 h) but incomplete (52% at low dose of 1 mg/kg bw)
Dermal absorption	No data
Distribution	Widely distributed, highest residues in liver, kidney, adrenals, bone marrow and fat
Potential for accumulation	Limited evidence for retention in fat
Rate and extent of excretion	Nearly complete within 7 days, mainly via faeces ( $\geq 90\%$ ); biliary excretion accounting for main part of absorbed dose (43%), urine less important ( $< 6\%$ ); excretion via milk also proven (milk:plasma ratio about 10:1)
Metabolism in animals	Extensive with 8–12 (some unique) metabolites occurring in the different matrices
Toxicologically significant compounds in animals and plants	Pyflubumide, <i>N</i> -deisobutylated pyflubumide (P-NH, “NH- form”, Metabolite B), Pyflubumide-RfOH (Metabolite U)
<b>Acute toxicity</b>	
Rat, LD <sub>50</sub> , oral	> 2000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	> 2000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	> 5.23 mg/L (four-hour nose-only exposure)
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Dermal sensitization	Not sensitizing (local lymph node action)
<b>Short-term studies of toxicity</b>	
Target/critical effect	Adrenals (histopathological lesions in cortex and medulla)
Lowest relevant oral NOAEL	1.1 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	No data
Lowest relevant inhalation NOAEC	No data
<b>Long-term studies of toxicity and carcinogenicity</b>	
Target/critical effect	Heart (organ weight, histopathology); thyroid (organ weight, histopathology); adrenals (histopathology); liver (histopathology, organ weight); bw increase in rats
Lowest relevant NOAEL	0.7 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in mice <sup>a</sup>
<b>Genotoxicity</b>	No evidence of genotoxicity in vitro or in vivo <sup>a</sup>
<b>Reproductive toxicity</b>	
Target/critical effect	Reproductive toxicity: prolonged gestation and lower viability index at birth Offspring toxicity: histological lung lesions in rat pups due to lactational exposure Parental toxicity: increased weight of heart, liver, thyroid and ovary, myocardial fibrosis, increased body weight gain and food intake
Lowest relevant parental NOAEL	0.8 mg/kg bw per day
Lowest relevant offspring NOAEL	0.8 mg/kg bw per day
Lowest relevant reproductive NOAEL	5.3 mg/kg bw per day
<b>Developmental toxicity</b>	
Target/critical effect	Maternal: higher placenta weight in rats and rabbits, reduced body weight and food intake in rats and rabbits, abortions in rabbits Developmental: higher fetal weight in rats; none in rabbits
Lowest relevant maternal NOAEL	20 mg/kg bw per day (rabbit)
Lowest relevant embryo/fetal NOAEL	30 mg/kg bw per day (rat)
<b>Neurotoxicity</b>	

Acute neurotoxicity NOAEL	2000 mg/kg bw (i.e. no specific neurotoxic potential up to highest dose tested); not established for systemic effects (LOAEL 500 mg/kg bw)
Subchronic neurotoxicity NOAEL	No data, no evidence from routine studies
Developmental neurotoxicity NOAEL	No data
<b>Immunotoxicity</b>	No data; no concern from routine studies
Studies on toxicologically relevant metabolites	
Pyflubumide-NH (Metabolite B)	Alveolar dilatation in very young rat pups after gavage application of 50 mg/kg bw per day from PND 4–13; NOAEL 2 mg/kg bw per day
Pyflubumide-RfOH (Metabolite U)	Significant excretion via milk demonstrated in rats
Human data	Inhibition of TPO but no vasodilatation in vitro
Not available for this new compound	
a Unlikely to pose a carcinogenic risk to humans via exposure from the diet	

### Summary

	Value	Study	Safety factor
ADI <sup>a</sup>	0–0.007 mg/kg bw	Two-year, (rat)	100
ARfD <sup>a</sup>	0.008 mg/kg bw	Two-generation study; offspring toxicity (rat)	100

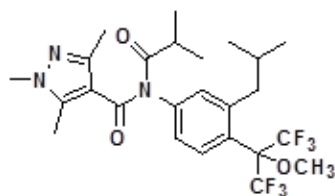
<sup>a</sup> Applies to pyflubumide, pyflubumide-NH, pyflubumide-RfOH, expressed as pyflubumide

## RESIDUE AND ANALYTICAL ASPECTS

Pyflubumide(3'-isobutyl-N-isobutyryl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl) ethyl]-pyrazole-4-carboxanilide) (IUPAC name) is a new pyrazole carboxamide acaricide used for control of mites. It inhibits mitochondrial electron transport system complex II (succinic dehydrogenase complex).

Pyflubumide was scheduled by the Forty-eighth Session of the CCPR in 2016 for toxicological and residue evaluation by the 2019 JMPR as a new compound. No specification has been established by the Joint FAO/WHO Meeting on Pesticide Specifications for pyflubumide.

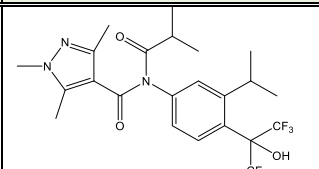
The Meeting received information on identity, physical and chemical properties, metabolism and environmental fate, residue analysis and storage stability, use pattern, supervised trials on apple and tea, and processing studies on apple and tea.



The following abbreviated names were used for the metabolites referred to in this appraisal.

Table 1 List of compounds appearing in this appraisal

Compound Name/Codes	IUPAC name	Structure
Pyflubumide/ NNI-0711	3'-isobutyl- <i>N</i> -isobutyryl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide	
P-NH/ NNI-0711-NH Pyflubumide-NH	3'-isobutyl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide	
P-acid/ NNI-0711-acid Pyflubumide-acid	1,3,5-trimethylpyrazole-4-carboxylic acid	
P-NH-RfOH/ NNI-0711-NH-RfOH Pyflubumide-NH-RfOH	3'-isobutyl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-hydroxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide	
P-aniline-isobutyryl/ NNI-0711-aniline-isobutyryl Pyflubumide-aniline-isobutyryl	3'-isobutyl-4-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)-ethyl]phenyl]isobutyranilide	
P-NH-5-CH2OH/ NNI-0711-NH-5-CH2OH Pyflubumide-5-CH2OH	5'-hydroxymethyl)-3'-isobutyl-1,3-dimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide	
P-NH-3-CH2OH/ NNI-0711-NH-3-CH2OH Pyflubumide-3-CH2OH	3-(hydroxymethyl)-3'-isobutyl-1,5-dimethyl-4'-[2,2,2-trifluoro-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide	
P-NH-1-H/ NNI-0711-NH-1-H Pyflubumide- NH-1-H	3'-isobutyl-3,5-dimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide	
P-acid-1-H/ NNI-0711-acid-1-H Pyflubumide- acid-1-H	3,5-dimethylpyrazole-4-carboxylic acid	
P-amide/ NNI-0711-amide Pyflubumide-amide	1,3,5-trimethylpyrazole-4-carboxamide	
P-aniline/ NNI-0711-aniline Pyflubumide-aniline	3-isobutyl-4-[2,2,2-trifluoro-1-methoxy-(trifluoromethyl)ethyl] aniline	

Compound Name/Codes	IUPAC name	Structure
Pyflubumide-RfOH NNI-0711-RfOH	3'-Isobutyl-N-isobutyryl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-hydroxy-1-(trifluoromethyl)ethyl] pyrazol-4-carboxanilide	

Based on the information on physical and chemical properties, pyflubumide is not volatile and much more soluble in organic solvents than in water with a  $\text{LogP}_{\text{ow}}$  of 5.34 indicating that translocation of pyflubumide in plants is unlikely to be significant. Photolysis seemed to be the major degradation pathway of pyflubumide.

### Plant metabolism

The Meeting received information on the fate of pyflubumide in apple, eggplant and spinach after one foliar spray application. For the studies, pyflubumide labelled with  $^{14}\text{C}$  at the phenyl ring ([U-phenyl- $^{14}\text{C}$ ]-pyflubumide; abbreviated as phenyl-label hereafter) and at position 3 or 5 of the pyrazole ring ([pyrazole-3(5)- $^{14}\text{C}$ ]-pyflubumide; abbreviated as pyrazole-label hereafter) were used. In metabolism studies, total radioactive residues (TRR) are expressed in mg pyflubumide equivalents/kg.

### Apple

Phenyl- or pyrazole-labelled pyflubumide was applied to apple plants, grown outdoors, as a foliar spray once at a rate of 360 or 350 g ai/ha, (concentration: ca. 10 g ai/hL). Fruit and leaf samples were collected 0–51 days after the application.

TRR after the treatment with either of the labelled pyflubumide decreased in the fruit from 0.16–0.19 mg eq/kg at 0 DAT to 0.090–0.096 mg eq/kg at 7 DAT and then to 0.058–0.068 mg eq/kg at 51 DAT. In leaves, TRR decreased from 17 mg eq/kg at 0 DAT to 12 mg eq/kg at 7 DAT and then to 5.1–5.4 mg eq/kg at 51 DAT.

Distribution of radioactivity in fruits and leaves was similar between the two  $^{14}\text{C}$ -labelled pyflubumide treatments. Most of the radioactivity was recovered in the acetone surface wash of fruits and leaves, accounting for 77–98% TRR and 86–98% TRR, respectively at 0–7 DAT, decreasing to 54–65% TRR at 51 DAT. Acetone, acetone/water, and acetone/1 M HCl (1:1, v/v) further extracted additional radioactivity. Total extractability was 86–100% TRR throughout the study period.

The most abundant radioactive residue in the surface wash and extracts was the parent pyflubumide accounting for 88–92% TRR in fruits and leaves (16 mg/kg) at 0 DAT and decreased to 50–56% TRR at 7 DAT and then to 17–28% at 51 DAT. P-NH was the only identified metabolite. Its proportion increased from 1.2–2.7% TRR at 0 DAT to 13–18% TRR at 14–28 DAT and 12–16% TRR by 51 DAT. Its concentration peaked at 7–14 DAT around 0.013–0.018 mg eq/kg in fruits and 1.3–1.6 mg eq/kg in leaves. Beta-glucosidase did not release radioactive compounds from surface wash and acetone extract, suggesting that glucose conjugates were not present.

Total unidentified residues in washes and extracts increased over time accounting for up to 61% TRR at 51 DAT. They consisted of multiple (e.g. up to 23 peaks in surface washes) minor peaks in HPLC and each peak accounted for < 10% TRR and < 0.01 mg eq/kg.

Unextracted radioactivity increased from < 0.2% TRR at 0 DAT to a maximum of 14% TRR at 51 DAT, and the concentration in pyflubumide equivalents also increased. Treatments of the unextracted residues from 28 and 51 DAT leaf samples with 1 or 6 M HCl or 1 M KOH at 50 °C for 4 hours released < 1% TRR but the treatment with 24% KOH released up to 5% TRR.

### Eggplant

Phenyl- or pyrazole- labelled pyflubumide was applied as a foliar spray at a rate of 490 or 550 g ai/ha

(ca. 20 g ai/hL) to eggplants, grown in a greenhouse, equipped with a UV-transparent ceiling.

The TRR in fruits and leaves after treatment with labelled pyflubumide decreased from 0 DAT (0.76–1.4 mg eq/kg in fruits and 55–74 mg eq/kg in leaves) to 7 DAT (0.66–0.88 mg eq/kg in fruits and 31–48 mg eq/kg in leaves). Most of the radioactivity was recovered in acetone surface wash throughout the study period in fruits and leaves: 93–99% TRR for fruits, and 86–96% TRR for leaves. Acetone and acetone/water mixture further extracted additional radioactivity. A total of 95–100% TRR in fruits and leaves were recovered in washes and extracts. A very small proportion of radioactivity remained unextracted in fruits (up to 5.0% TRR) and leaves (up to 5.2% TRR). TRR of only < 0.01–0.03 mg eq/kg was found in roots (sampled only at 14 DAT) indicating that there is little transfer from the sprayed parts of the plant to the roots.

Most of the radioactivity in the surface washes and extracts was the parent pyflubumide (90–98% TRR for fruits and 90–99% TRR for leaves) with some small amounts of radioactive metabolites/components. P-NH, also found in the apple study, P-aniline-isobutyryl, P-acid, P-NH-RfOH (only on/in leaves) and P-NH-5-CH<sub>2</sub>OH (only on/in leaves at DAT 14) were detected. None of them exceeded 1.3% TRR in either fruits or leaves. In fruit samples they were found at a maximum of 0.01 mg eq/kg and in leaf samples up to 0.59 mg eq/kg.

### *Spinach*

Phenyl- or pyrazole-labelled pyflubumide was applied to spinach as a single foliar spray at a rate of 550 or 570 g ai/ha (ca. 20 g ai/hL) grown in a greenhouse equipped with a UV-transparent ceiling.

A single application of either <sup>14</sup>C-labelled pyflubumide resulted in similar total radioactive residues (TRR) in leaves, decreasing over time from 12–13 mg eq/kg at 0 DAT to the lowest of 4.7–5.8 mg eq/kg at 14 DAT. TRR in roots and new leaf growth (post-application) were < 0.01–0.03 mg eq/kg indicating that there is little translocation from the sprayed parts to roots or new leaves.

The distribution of radioactivity in leaves was similar between the two <sup>14</sup>C-labelled pyflubumide treatments. Most of the radioactivity was recovered in the chloroform surface wash of leaves, accounting for 84–92% TRR (11–12 mg eq/kg) at 0–1 DAT. The radioactivity in the surface wash decreased to 83–87% TRR (5.0–6.3 mg eq/kg) at 21 DAT.

Acetone and acetone/water further extracted additional radioactivity (8.2–17% TRR at 0–1 DAT; and 13–16% TRR at 21 DAT). Total extractability was almost 100% TRR throughout the study period.

The most abundant radioactive residue in the surface wash and extracts was the parent pyflubumide accounting for almost 100% TRR (12–13 mg/kg) at 0 DAT but decreased to 83–91% (5.0–6.4 mg/kg) at 21 DAT. Only P-NH and P-acid were identified as metabolites at 14–21 DAT at a maximum of 3.2% TRR (0.19 mg eq/kg) at 21 DAT. There was one unknown metabolite detected in the extracts, which accounted for 4.1–5.0% TRR (0.28–0.31 mg eq/kg) at 21 DAT and was suspected to be a position-isomer of the parent based on its molecular weight.

Up to 6.3% TRR remained at the origin after TLC (indicating a polar fraction). The beta-glucosidase treatment decreased the radioactivity at the TLC origin and released P-acid (1.3–1.4% TRR), indicating that a fraction of the material was possibly a glucoside of P-acid.

### *Summary of plant metabolism*

When pyflubumide was applied as a single foliar spray to apple, eggplant and spinach, metabolism of pyflubumide was qualitatively similar. Pyflubumide was the major component of the residue. Up to 6 metabolites, P-NH (apple, eggplant and spinach), P-aniline-isobutyryl (eggplant), P-acid (eggplant and spinach), P-NH-RfOH (eggplant leaf) and P-NH-5-CH<sub>2</sub>OH (eggplant leaf) were identified. However, among them, only P-NH accounted for more than 10% TRR, with a maximum of 18% TRR (0.018 mg eq/kg) in apple and lower levels up to 3.2% TRR in eggplant and spinach (< 0.01 mg eq/kg in eggplant fruit and up to 0.19 mg eq/kg in spinach leaf).

All identified metabolites, except P-NH-5-CH<sub>2</sub>OH found in eggplant leaf, were also reported in the rat metabolism study.

### ***Animal metabolism***

Metabolism studies on laboratory animals were reviewed in the framework of toxicological evaluation by the current JMPR. No other animal metabolism studies were provided to the Meeting.

### ***Environmental fate***

The Meeting received information on hydrolysis, photolysis and aerobic degradation in soil for pyflubumide.

#### ***Hydrolysis***

Pyflubumide was hydrolysed faster at pH 9 than pH 4 or 7 in buffers. Estimated half-lives at 25 °C are 32 days at pH 4, 28 days at pH 7 and 6.6 days at pH 9. Regardless of pH, major hydrolysates which increased over time and occurred > 10% AR were P-NH, P-aniline-isobutyryl and P-acid. Hydrolysis is not expected to be a significant route of degradation at environmental pH.

#### ***Photolysis in buffer and natural water***

In irradiated pH 4 buffer solution, pyflubumide was rapidly decomposed with a mean half-life of 1.2 days compared to that of about 34 days in the dark controls. Therefore, irradiation was regarded to be a significant factor contributing to environmental degradation of the compound. Major degradates occurring > 10% AR were P-NH, P-aniline-isobutyryl, P-acid and P-amide, which were further photolysed.

#### ***Aerobic degradation in soil***

Pyflubumide degraded in a clay loam soil under laboratory conditions with a half-life of 37 days. The main degradate formed was P-NH and it reached up to 82% AR after 112 days. Consequential mineralization to carbon dioxide was confirmed and a small amount of unextracted radioactivity existed. P-NH was the only degradate found above 10% AR. Pyflubumide is not persistent in soil.

#### ***Residues in succeeding or rotational crops***

No information was provided to the Meeting.

### ***Methods of analysis***

An analytical method for the determination of residues of pyflubumide in data development was provided to the current Meeting for apple and its processed commodities, as well as dry tea leaves and tea infusion.

In general, the method employs extraction by homogenization with acetone and partitioning with hexane for analysis of pyflubumide, P-NH and P-aniline-isobutyryl. The extract is cleaned up and analysed by HPLC-MS or HPLC-MS/MS. The method was validated for apple matrices and found to be suitable for data development to determine pyflubumide, P-NH, P-aniline-isobutyryl and P-acid with an LOQ of 0.01 mg/kg for apple and 0.005 mg/kg for apple processed products. The mean recoveries were within the acceptable range (71–119%). The method was also validated for tea matrices and found to be suitable for data development with LOQs of 0.01 mg/kg in dry tea leaves and tea infusion. The mean recoveries were in the acceptable range (70–114%).

A QuEChERS method was validated and found to be suitable for multi-residue analysis with LOQs of 0.005 mg/kg for pyflubumide and P-NH in apple, grapes, wheat grain, dry tea leaves and canola seeds. The mean recoveries were in the acceptable range (74–110%).

No information on analytical methods for commodities of animal origin was submitted to the Meeting.

### ***Stability of residues in stored analytical samples***

The stability of pyflubumide and P-NH during frozen storage at -20°C or below was investigated in homogenized apple and dry tea leaves. The control samples from supervised trials were spiked with pyflubumide or P-NH and stored under the same conditions as treated samples. These spiked samples were analysed after all the treated samples were analysed to confirm the stability of analytes. The Meeting considered that these compounds were stable in homogenized apple for at least 87 days (longer than the storage period of trial samples) and dry tea leaves for at least 107 days (longer than the storage period of trial samples) under frozen conditions.

### ***Definition of the residue***

#### ***Plant commodities***

The predominant residue was parent pyflubumide: 50–92% TRR in apple fruits and leaves at 0–7 DAT, > 90% TRR in eggplant fruits during 0–14 DAT and 83–100% TRR in spinach leaves during 0–21 DAT.

Suitable analytical methods are available for plant commodities to determine pyflubumide.

The Meeting considered that pyflubumide was a suitable marker for enforcement of MRLs.

For dietary risk assessment, the Meeting noted that in the plant metabolism studies, P-NH (apple, eggplant and spinach), P-aniline-isobutyryl (eggplant), P-acid (eggplant and spinach), P-NH-5-CH<sub>2</sub>OH (eggplant leaf) and P-NH-RfOH (eggplant leaf) were identified. Among them only P-NH accounted for > 10% TRR (apple). These metabolites were also found in the rat metabolism although some of them at trace levels.

P-NH occurred at up to 11–12% AR after simulated sterilization at pH 6. It increased in proportion compared to the parent during the processing of apple.

In the supervised trials, pyflubumide and P-NH were analysed. In the apple trials P-NH was below the LOQ of 0.01 mg/kg or slightly higher (up to 0.03 mg/kg). However, in the tea trials, P-NH was sometimes found at higher levels than the parent, perhaps due to the processing of fresh leaves to dry leaves. The current Meeting noted that the ADI and ARfD covers the parent, P-NH and pyflubumide-RfOH (detected in rat but not detected in plant metabolism studies).

P-aniline-isobutyryl was below the LOQ in three apple trials in which it was analysed and <LOQ (0.007 mg eq/kg) in apple processed commodities except dry pomace (0.056–0.083 mg eq/kg). It was not analysed in the tea trials or processing studies.

P-acid was <LOQ (0.04 mg eq/kg) in apple RAC and <LOQ (0.02 mg eq/kg) in apple processed commodities except dry pomace (0.08 mg eq/kg). It was not analysed in the tea trials or processing studies.

The Meeting concluded that dietary exposure to P-aniline-isobutyryl or P-acid would be insignificant and therefore decided not to include these metabolites in the residue definition for dietary risk assessment.

The Meeting considered that in addition to pyflubumide, P-NH should be included in the residue definition for risk assessment.

#### ***Animal commodities***

The Meeting did not receive information on livestock metabolism, feeding studies or analytical methods for animal commodities. There would be some dietary burden arising from the use of apple wet pomace for feed.

The Meeting considered that it is not possible to determine residue definitions for pyflubumide in animal commodities due to the lack of information.

### Conclusion

Based on the above, the Meeting recommended the following residue definitions.

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

Definition of the residue for dietary risk assessment for plant commodities: *Sum of pyflubumide and 3'-isobutyl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide (P-NH), expressed as pyflubumide.*

### Results of supervised residue trials on crops

The Meeting received supervised trial data for pyflubumide on apple and tea.

#### Apple

Critical GAP in Japan for apple allows one application at a concentration of 10 g ai/hL and a PHI of 1 day.

Ten supervised trials were conducted on apple in Japan. Pyflubumide was applied once as foliar spray at a spray concentration of 10 g ai/hL (eight trials) or 20 g ai/hL (two trials).

Pyflubumide from trials matching the critical GAP in Japan were in rank order (n = 8): 0.13, 0.23, 0.23, 0.34, 0.44, 0.45, 0.46 and 0.52 mg/kg.

Total residues (sum of pyflubumide and P-NH expressed in pyflubumide) from trials matching the critical GAP in Japan were in rank order (n = 8): 0.15, 0.25, 0.25, 0.36, 0.46, 0.47, 0.48 and 0.55 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg, STMR of 0.41 mg/kg and HR of 0.55 mg/kg for apple.

The Meeting noted that the calculated IESTI for raw apples were up to 160% of the ARfD for the general population and up to 390% for children. However, no alternative GAP is available.

#### Tea

Critical GAP in Japan for tea allows one application at a concentration of 10 g ai/hL and PHI of 7 days.

Eight independent supervised trials were conducted on tea in Japan. Pyflubumide was applied once as a foliar spray at a concentration of 10 g ai/hL (six trials) or 5 g ai/hL (two trials).

Pyflubumide in dried green tea leaves from trials matching the critical GAP in Japan were in rank order (n = 6): 1.7, 2.9, 6.1, 12, 19 and 23 mg/kg. In two other trials where spray concentrations were 5 g ai/ha with the same water volume, unscaled pyflubumide residues were: 0.85 and 25 mg/kg. Using a scaling factor of 2, scaled residues were: 1.7 and 50 mg/kg.

Combined pyflubumide residues were in rank order (n = 8): 1.7, 1.7, 2.9, 6.1, 12, 19, 23 and 50 mg/kg.

Total residues (sum of pyflubumide and P-NH expressed in pyflubumide) from trials matching the critical GAP in Japan were in rank order (n = 6): 3.3, 6.5, 9.1, 17, 27 and 34 mg/kg. In other trials at a concentration two times higher, unscaled total residues were: 3.1 and 34 mg/kg. Using a scaling factor of 2, scaled residues were: 6.2 and 68 mg/kg.

Combined total residues were in rank order (n = 8): 3.3, 6.2, 6.5, 9.1, 17, 27, 34 and 68 mg/kg.

The Meeting estimated a maximum residue level of 80 mg/kg and STMR of 13 mg/kg for tea, green, black (black, fermented and dried).



The calculated IESTI for tea leaves were up to 230% of the ARfD for the general population and up to 150% for children. However, the calculated IESTI for tea infusion were 2% of the ARfD for general population (no value for children). The Meeting noted that as the  $\text{Log}P_{\text{ow}}$  of pyflubumide is 5.34 and P-NH has a similar structure, it is unlikely that tea infusion would contain pyflubumide or P-NH at concentrations higher than the detection limit.

### ***Fate of residues during processing***

#### ***High temperature hydrolysis***

The hydrolysis of phenyl-labelled and pyrazole-labelled pyflubumide was studied in a sterile buffered aqueous solution under conditions simulating pasteurization, baking/brewing/boiling, and sterilization.

Pyflubumide was stable under the condition representing pasteurization (pH 4, 90 °C, 20 minutes) with 96–97% AR recovered at the end of incubation. Under baking/brewing/boiling (pH 5, 100 °C, 60 minutes) and sterilization (pH 6, 120 °C, 20 minutes) conditions, 71–74% and 82–84% AR was recovered as parent at the end of incubation, respectively. Degradation products identified were: pasteurization, P-NH (3.0–4.4% AR); baking/brewing/boiling, P-NH (18–19% AR), P-aniline-isobutyryl (10% AR) and P-acid (8.8% AR); sterilization, P-NH (11–12% AR), P-aniline-isobutyryl (5.3% AR) and P-acid (6.7% AR). No other degradation products were detected.

#### ***Processing***

The Meeting received information on processing of apples to pasteurized juice, wet pomace, dry pomace, pasteurized sauce and dried apples; and dry tea leaves to tea infusion. Processing factors of apple processed products and tea leaves to tea infusion are summarized below together with STMR-P values.

Table 2 Processing factors for apple processed commodities and tea infusion for dietary risk assessment (sum of pyflubumide and P-NH expressed as pyflubumide)

Processed commodity	Individual processing factor	Mean or Best estimate	STMR/STMR-P	HR/HR-P
Apple			0.41	0.55
Pasteurized juice	< 0.002, 0.002, 0.004	0.003 <sup>a</sup>	0.001	-
Pasteurized sauce	< 0.02, < 0.02, < 0.02	< 0.02	0.008	-
Dried apple	0.029, 0.039, 0.08	0.05	0.02	0.028
Tea leaves, dry			13	-
Tea infusion	0.00006, 0.00015, 0.00021, 0.00021, 0.00027, 0.00034, 0.00042, < 0.00072	0.0003	0.004	-

<sup>a</sup> Mean of two finite processing factors

Table 3 Processing factors for apple processed commodities for animal dietary burden calculation (pyflubumide only)

Processed commodity	Individual processing factor	Mean or Best estimate	Median residue
Apple			0.39
Wet pomace	2.4, 3.4, 3.7	3.2	1.2
Dry pomace	11.7, 15.8, 18.2	15.2	5.9

Using the best estimates of processing factors and the STMR values for apple and dry tea leaves, the STMR-P values were calculated for processed commodities of apple and tea infusion.

The median residue for apple wet pomace was calculated for animal dietary burden calculation.

### ***Residues in Animal Products***

No feeding study was conducted on cattle or laying hens.

As no livestock metabolism studies or analytical method for foods of animal origin was available, the Meeting did not establish residue definitions for animal commodities. Therefore, the Meeting did not calculate animal dietary burden.

The Meeting concluded it was not possible to estimate maximum residue levels for foods of animal origin.

## **RECOMMENDATIONS**

On the basis of the data 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.

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

Definition of the residue for dietary risk assessment for plant commodities : Sum of pyflubumide and 3'-isobutyl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide, expressed as pyflubumide

## **DIETARY RISK ASSESSMENT**

### ***Long-term dietary exposure***

The current Meeting established an ADI of 0–0.007 mg/kg bw.

The International Estimated Dietary Intakes (IEDIs) of pyflubumide were calculated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the current Meeting. The results are shown in Annex 3 of the 2019 JMPR Report.

The calculated IEDIs were 3–20% of the maximum ADI (0.007 mg/kg bw). The Meeting concluded that the long-term exposure to residues of pyflubumide resulting from the uses considered by the current JMPR is unlikely to present a public health concern.

### ***Acute dietary exposure***

The current Meeting established an ARfD of 0.008 mg/kg bw.

The International Estimated Short-Term Intakes (IESTIs) of pyflubumide were calculated for commodities using the HRs and STMRs/STMR-Ps estimated by the current Meeting. The results are shown in Annex 4 of the 2019 JMPR Report.

The calculated IESTIs were 1–230% of the ARfD for the general population and 1–390% of the ARfD for children.

For apple (raw), the IESTI represents 160% of the ARfD for the general population and 390% for children. For tea (dried leaf), the IESTI represents 230% of the ARfD for the general population and 150% for children. No alternative GAPs for apple or tea were available. On the basis of the information provided to the JMPR, the Meeting concluded that the acute dietary exposure to pyflubumide from the consumption of apple and tea may present a public health concern.

The Meeting also concluded that the acute dietary exposure to pyflubumide from the consumption of apple processed commodities and tea infusion is unlikely to present a public health concern.

## 5.21 Pyridate (315)

### TOXICOLOGY

Pyridate is the ISO-approved common name for *O*-6-chloro-3-phenylpyridazin-4-yl *S*-octyl thiocarbonate (IUPAC), with CAS number 55512-33-9. It is a proherbicide of the pyridazine class that is converted to the active chemical, pyridafol (CL-9673), in the plant. Pyridafol is as an electron transport inhibitor at the photosystem II.

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

Some of the critical studies do not comply with GLP, as the data were generated before the implementation of GLP regulations. Also, many of the critical studies are old and non-compliant with current testing standards. Overall, however, the Meeting considered that the database was adequate for risk assessment.

No additional information from a literature search was identified that complemented the toxicological information submitted for the current assessment.

#### **Biochemical aspects**

The toxicokinetics and metabolism of <sup>14</sup>C-radiolabelled pyridate have been investigated in the rat and, to a lesser extent, in the dog. Studies in rats demonstrated rapid and extensive oral absorption of radioactivity following dosing at up to 200 mg/kg bw. Based on the urinary excretion of radioactivity, more than 80% of the oral dose was absorbed within 24 hours of administration. This was confirmed in studies using bile duct-cannulated rats. Following oral dosing, plasma radioactivity levels reached a maximum within 1–2 hours and decreased rapidly thereafter. Following single or repeated oral dosing, peak plasma radioactivity concentrations were dose-proportional at doses up to 200 mg/kg bw and no important sex differences were noted. Following oral dosing with radiolabelled pyridate at up to 200 mg/kg bw the highest levels of radioactivity were found in the GI tract, plasma, liver and kidneys, reflecting both the route of administration and the major routes of excretion. Low levels of radioactivity were found in other tissues with the levels in fat and brain being an order of magnitude below plasma levels. Following oral dosing the elimination of radioactivity was rapid and essentially complete 96 hours after dosing. Oral dosing at 600 mg/kg bw resulted in disproportionately high plasma and tissue radioactivity levels due to the saturation of urinary excretion.

Pyridate is almost completely metabolized in rats following oral dosing. Pyridate is initially hydrolysed to pyridafol (CL-9673, SAN 1367H) with liberation of the *n*-octylthiocarbonyl side-chain. Pyridafol is further metabolized by conjugation with either glucuronic acid or sulfate (excreted in the urine), or by hydroxylation of the phenyl group (excreted in the urine and faeces). The major metabolites in rat urine are pyridafol (14–22% of detected radioactivity) and the phenyl-hydroxylated metabolite of pyridafol (22–39% of detected radioactivity).

In contrast to the rat, the *O*- and *N*-glucuronide conjugates of pyridafol were the major metabolites found in the urine of orally-dosed dogs (70% of detected radioactivity) with free pyridafol accounting for 18–23% of the total radioactivity in urine.

#### **Toxicological data**

The acute oral toxicity LD<sub>50</sub> for pyridate in rats was greater than 2000 mg/kg bw. However, deaths occurred following oral gavage dosing at 500 mg/kg bw in the rat acute neurotoxicity study and following the first oral gavage dose of 400 mg/kg bw in the rat developmental study. This likely correlates with the saturation of urinary excretion in rats. The acute dermal LD<sub>50</sub> in rabbits was greater than 2000 mg/kg bw and the acute inhalation LC<sub>50</sub> in rats was greater than 4.37 mg/L. Pyridate was mildly irritating to the skin of rabbits. Pyridate was transiently irritating to the conjunctiva in rabbits and induced skin sensitization in guinea pigs, based on both Buehler and maximization tests.

Repeated dose toxicity studies in mice, rats and dogs demonstrated the effects of pyridate on mortality, the nervous system (clinical signs consistent with neurotoxicity), reduced weight gain, changes in erythrocyte parameters, increased organ (spleen, liver and kidney) weights, the presence of debris and mineralized deposits in lymph nodes, haemosiderin deposition in the spleen and Kupffer cell pigmentation.

A 28-day toxicity study in rats used pyridate at dietary concentrations of 0, 1000, 3000 and 10 000 ppm (equivalent to 0, 100, 300 and 1000 mg/kg bw per day). The NOAEL was 1000 ppm (equivalent to 100 mg/kg bw per day) based on reduced body weight gain and food consumption in both sexes at 10 000 ppm (equivalent to 1000 mg/kg bw per day).

A 90-day toxicity study (with a 28-day recovery period) was performed in rats using gavage dose levels of 0, 62.5, 177 and 500 mg/kg bw per day with an additional study cohort initially dosed at 500 mg/kg bw per day, incrementing to 600 mg/kg bw per day after two weeks of treatment. The NOAEL was 62.5 mg/kg bw per day based on mortality, clinical signs and histopathological findings (mineralized deposits in the mesenteric lymph nodes, haemosiderin deposition in the spleen) seen at 177 mg/kg bw per day.

A 90-day toxicity study in dogs was performed using gelatine capsule dosing at levels of 0, 20, 60 and 200 mg/kg bw per day. The NOAEL was 20 mg/kg bw per day based on the presence of clinical signs (consistent with neurotoxicity) and mortality at 60 mg/kg bw per day.

A carcinogenicity study in mice was performed at dietary concentrations of 0, 400, 800 and 1200 ppm (incremented to 1400 ppm on day 91 and 1600 ppm on day 179). Additional dose cohorts of 0 ppm and 7000 ppm were also evaluated. The pyridate intakes were equal to 0, 48, 98, 170 and 853 mg/kg bw per day in males, 0, 55, 115, 204 and 1045 mg/kg bw per day in females. The NOAEL for toxicity was 800 ppm (equal to 98 mg/kg bw per day) based on lower body weights in both sexes and increased mortality in females at the dietary concentration of 1200→1400→1600 ppm (equal to 170 mg/kg bw per day). The NOAEL for carcinogenicity was 1200→1400→1600 ppm (equal to 170 mg/kg bw per day).

A combined chronic toxicity/carcinogenicity study was performed in rats with dietary exposure at concentrations of 0, 80, 400 or 2500 ppm (equivalent to 0, 4, 20, and 125 mg/kg bw per day). The NOAEL for toxicity was 400 ppm (equivalent to 20 mg/kg bw per day) based on body weight effects in both sexes and changes in erythrocyte parameters in females at 2500 ppm (equivalent to 125 mg/kg bw per day). The NOAEL for carcinogenicity was 2500 ppm (equivalent to 125 mg/kg bw per day).

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

Pyridate has been tested for genotoxicity in a battery of studies in vitro and in vivo. Many of these studies were non-compliant with current test standards. However, no clear evidence of genotoxicity was found.

The Meeting concluded that pyridate is unlikely to be genotoxic.

Due to the absence of carcinogenic effect in rats and mice and the lack of genotoxicity the Meeting concluded that pyridate is unlikely to pose a carcinogenic risk to humans.

In a three-generation toxicity study in the rat using dietary concentrations of 0, 80, 400 and 2500 ppm (equivalent to 0, 5, 26 and 165 mg/kg bw per day) no effects on fertility or reproductive capacity were observed. The reproductive NOAEL was 2500 ppm (equivalent to 165 mg/kg bw per day), the highest dose tested. The parental NOAEL was 400 ppm (equivalent to 26 mg/kg bw per day) based on the increased relative kidney weights seen at dietary concentrations of 2500 ppm (equivalent to 165 mg/kg bw per day). The offspring NOAEL was 400 ppm (equivalent to 26 mg/kg bw per day) based on reduced pup weights at the highest dose level of 2500 ppm (equivalent to 165 mg/kg bw per day).

In a rat developmental study gavage dose levels of 0, 55, 165, 400 and 495 mg/kg bw per day were used. The maternal NOAEL was 165 mg/kg bw per day based on reduced body weight gain and

mortality at the LOAEL of 400 mg/kg bw per day (correlated with saturation of urinary excretion). The embryo/fetal NOAEL was 165 mg/kg body weight based on reduced fetal weight and associated reductions in skeletal ossification seen at the LOAEL of 400 mg/kg bw per day.

In a developmental study performed in rabbits at gavage dose levels of 0, 150, 300 and 600 mg/kg bw per day the maternal NOAEL was 300 mg/kg bw per day based on abortions, reduced body weight gain, reduced body weight and reduced food consumption following dosing at 600 mg/kg bw per day. The embryo/fetal NOAEL was 300 mg/kg bw per day based on reduced fetal body weights following dosing at 600 mg/kg bw per day.

The Meeting concluded that pyridate is not teratogenic

An acute neurotoxicity study was conducted in rats using gavage doses of 0, 62.5, 177 and 500 mg/kg bw. Clinical signs and mortality occurred following dosing at 500 mg/kg bw (correlating with saturation of urinary excretion). Surviving animals dosed at 500 mg/kg body weight displayed transient behavioural effects which were considered secondary to generalized toxicity. There were no pyridate-associated microscopic anatomic pathology changes in the nervous system. The NOAEL was 177 mg/kg bw due to mortality following dosing at 500 mg/kg bw. Clinical signs consistent with neurotoxicity occurred in the 90-day repeat-dose toxicology study in dogs.

The Meeting concluded that pyridate is not acutely neurotoxic in the rat, but shows clinical signs of neurotoxicity in a 90-day study of toxicity in dogs.

No studies on immunotoxic effect were submitted.

#### **Toxicological data on metabolites and/or degradates**

Pyridafol (CL-9673, SAN 1367H), a plant metabolite and seen at significant levels in the rat, had an acute oral LD<sub>50</sub> of 1511 mg/kg bw in the rat. It was not a skin sensitizer in a Buehler assay in albino guinea pigs. Pyridafol was not mutagenic in two bacterial reverse mutation assays. Given that pyridafol is a major rat metabolite, its toxicity is considered covered by the parent compound.

Pyridafol-*N*-glucoside, a plant metabolite, had an acute oral LD<sub>50</sub> greater than 2000 mg/kg bw in rats. In a metabolism study in the rat, pyridafol-*N*-glucoside was rapidly excreted in urine as pyridafol, with minor metabolites like the glucuronic acid conjugate of pyridafol and a hydroxylated derivative of pyridafol. Given that pyridafol-*N*-glucoside is converted to pyridafol in mammals, its toxicity is considered covered by pyridafol, and thus by the parent compound.

#### **Microbiological data**

The available data indicate that pyridazines require an *N*<sup>3</sup>,*N*<sup>6</sup>-diphenylpyridazine-3,6-diamine chemical structural skeleton for antimicrobial activity. Pyridate lacks the required chemical structural skeleton and is unlikely to show antimicrobial activity relevant to humans.

#### **Human data**

In reports on manufacturing plant personnel, no adverse health effects were noted. No adverse effects have been reported in exposed users of pyridate-based products.

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

#### **Toxicological evaluation**

The Meeting established an ADI for pyridate of 0–0.2 mg/kg bw based on the NOAEL of 400 ppm (equivalent to 20 mg/kg bw per day) in the two-year study in rat, where body weight effects in both sexes, and changes in erythrocyte parameters in females occurred following dosing at 2500 ppm (equivalent to 125 mg/kg bw per day). A safety factor of 100 was applied.

The Meeting established an ARfD for pyridate of 2 mg/kg bw based on the NOAEL of 177 mg/kg bw in the rat acute neurotoxicity study where clinical signs and mortality occurred following

dosing at 500 mg/kg bw. This was supported by the maternal NOAEL value set on account of mortality, the observed adverse effect in this case following the first dose of 165 mg/kg bw per day in the rat developmental study. A safety factor of 100 was applied. A higher safety factor was not regarded as being necessary since human food exposure is unlikely to result in saturation of renal excretion.

A toxicological monograph was prepared.

#### **Levels relevant to risk assessment of pyridate**

Species	Study	Effect	NOAEL	LOAEL
Mouse	18-month study of carcinogenicity <sup>b</sup>	Toxicity	800 ppm (equivalent to 98 mg/kg bw per day)	1200→1400→1600 ppm (equivalent to 204 mg/kg bw per day)
		Carcinogenicity	1200→1400→1600 ppm (equivalent to 204 mg/kg bw per day)	-
Rat	28-day study of toxicity <sup>b</sup>	Toxicity	1000 ppm (equivalent to 100 mg/kg bw per day)	3000 ppm (equivalent to 300 mg/kg bw per day)
		Toxicity	62.5 mg/kg bw per day	177 mg/kg bw per day
	Two-year study of carcinogenicity <sup>b</sup>	Toxicity	400 ppm (equivalent to 20 mg/kg bw per day)	2500 ppm (equivalent to 125 mg/kg bw per day)
		Carcinogenicity	2500 ppm (equivalent to 125 mg/kg bw per day) <sup>d</sup>	-
	Multigeneration study of reproduction <sup>b</sup>	Reproductive toxicity	2500 ppm (equivalent to 165 mg/kg bw per day) <sup>d</sup>	-
		Parental toxicity	400 ppm (equivalent to 26 mg/kg bw per day)	2500 ppm (equivalent to 125 mg/kg bw per day)
		Offspring toxicity	400 ppm (equivalent to 26 mg/kg bw per day)	2500 ppm (equivalent to 125 mg/kg bw per day)
	Developmental toxicity study <sup>a</sup>	Maternal toxicity	165 mg/kg bw per day	400 mg/kg bw per day
		Embryo and fetal toxicity	165 mg/kg bw per day	400 mg/kg bw per day
	Acute neurotoxicity study <sup>a</sup>	Toxicity	177 mg/kg bw per day	500 mg/kg bw per day
Rabbit	Developmental toxicity study <sup>a</sup>	Maternal toxicity	300 mg/kg bw per day	600 mg/kg bw per day
		Embryo and fetal toxicity	300 mg/kg bw per day	600 mg/kg bw per day
Dog	90-day study of toxicity <sup>c</sup>	Toxicity	20 mg/kg bw per day	60 mg/kg bw per day

<sup>a</sup> Oral gavage administration

<sup>b</sup> Dietary administration

<sup>c</sup> Capsule administration

<sup>d</sup> Highest dose tested

*Acceptable daily intake (ADI) applies to pyridate, pyridafol and pyridafol-N-glucoside, expressed as pyridate*

0–0.2 mg/kg bw

*Acute reference dose (ARfD) applies to pyridate, pyridafol and pyridafol-N-glucoside, expressed as pyridate*

2 mg/kg bw

**Critical end-points for setting guidance values for exposure to pyridate**

<b>Absorption, distribution, excretion and metabolism in mammals</b>	
Rate and extent of oral absorption	Extensive (> 80% based on urinary and bile); saturation of oral absorption occurred at 200 mg/kg bw in dogs (but not in rats)
Dermal absorption	No data
Distribution	Widely distributed; highest amounts in the GI tract, plasma, liver and kidney
Potential for accumulation	None
Rate and extent of excretion	> 90% within 96 hours, > 80% via urine; saturation of urinary excretion in rats occurred at doses > 200 mg/kg bw
Metabolism in animals	Extensively metabolized, hydrolysis to pyridafol (main metabolite); pyridafol glucuronic acid and sulfate conjugates
Toxicologically significant compounds in animals and plants	Pyridate and pyridafol (CL-9673, SAN 1367H)
<b>Acute toxicity</b>	
Rat, LD <sub>50</sub> , oral	> 2000 mg/kg bw <b>Note:</b> mortalities occurred in other rat studies at doses ≥ 400 mg/kg bw (doses likely resulting in saturation of urinary excretion)
Rat, LD <sub>50</sub> , dermal	> 2000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	> 4.37 mg/L
Rabbit, dermal irritation	Mildly irritating
Rabbit, ocular irritation	Mildly irritating
Guinea pig, dermal sensitization	Sensitizing (guinea pig maximization and Bühler tests)
<b>Short-term studies of toxicity</b>	
Target/critical effect	Mortality, clinical (neurotoxic) signs, reduced body weight, reduced body weight gain
Lowest relevant oral NOAEL	20 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	> 1000 mg/kg bw per day
Lowest relevant inhalation NOAEC	No data
<b>Long-term studies of toxicity and carcinogenicity</b>	
Target/critical effect	Reduced body weight gain (rat)
Lowest relevant oral NOAEL	20 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic in rats and mice <sup>a</sup>
<b>Genotoxicity</b>	Unlikely to be genotoxic <sup>a</sup>
<b>Reproductive toxicity</b>	
Target/critical effect	Parental effects: increased relative kidney weight Offspring effects: reduced pup weight Reproductive effects: none
Lowest relevant parental NOAEL	26 mg/kg bw per day
Lowest relevant offspring NOAEL	26 mg/kg bw per day
Lowest relevant reproductive NOAEL	165 mg/kg bw per day (highest dose tested)
<b>Developmental toxicity</b>	
Target/critical effect	Rat (maternal effects) mortality, reduced bodyweight gain; (developmental effects) skeletal variations Rabbit (maternal effects) reduced bodyweight gain; (developmental effects) abortion, reduced fetal weight
Lowest relevant maternal NOAEL	165 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	165 mg/kg bw per day (rat)
<b>Neurotoxicity</b>	
Acute neurotoxicity NOAEL	500 mg/kg bw (highest dose tested)
Subchronic neurotoxicity NOAEL	20 mg/kg bw per day (90-day toxicity study in dog)
Developmental neurotoxicity NOAEL	No data

<i>Immunotoxicity</i>	No data
<b>Studies on toxicologically relevant metabolites</b>	
<i>Pyridafol (CL 9673, SAN 1367H)</i>	Pyridafol is well absorbed and rapidly excreted in the urine. The metabolic pathways are identical for pyridate and pyridafol Acute oral LD <sub>50</sub> : 1511/1420 mg/kg bw (males/females) Bühler test (nine induction): negative Bacterial reverse mutation test: negative
<i>Pyridafol-N-glucoside</i>	ADME (single oral dose): 32–53.4% absorbed, rapidly eliminated (32%–53.4% via urine; 45–65% via faeces) low residual radioactivity in blood and tissue, similar further metabolic steps as pyridate Acute oral LD <sub>50</sub> > 2000 mg/kg bw
<i>Human data</i>	No adverse effects reported in humans
<i>Microbiological data</i>	Unlikely to have antimicrobial effects

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet.

### Summary

	Value	Study	Safety factor
ADI	0–0.2 mg/kg bw <sup>a</sup>	Two-year study of toxicity (rat)	100
ARfD	2 mg/kg bw <sup>a</sup>	Acute neurotoxicity (rat)	100

<sup>a</sup> applies to pyridate, pyridafol and pyridafol-*N*-glucoside, expressed as pyridate



## 5.22 Pyrifluquinazon (316)

### TOXICOLOGY

Pyrifluquinazon is the ISO-approved common name for 1-acetyl-3-[(pyridin-3-ylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-3,4-dihydro-1H-quinazolin-2-one (IUPAC), which has the CAS number 337458-27-2.

Pyrifluquinazon is an insecticide for use on a wide range of crops including plums, potatoes, tree nuts and tea. Its mode of insecticidal action is by modification of the insect feeding behaviour. It acts through interaction with transient receptor potential vanilloid (TRPV) channel complexes of the chordotonal stretch receptor neurons.

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

All critical studies contained statements of compliance with GLP and were conducted in accordance with the relevant national or international test guidelines, unless otherwise specified. A literature search did not identify any toxicological information additional to that submitted for the current assessment.

#### **Biochemical aspects**

Repeated dose studies of toxicokinetics were not performed. Following administration to rats of a single gavage dose of [<sup>14</sup>C]pyrifluquinazon at 1 or 100 mg/kg bw, absorption was relatively rapid, with peak plasma concentrations after 1–3 hours and 3–12 hours, respectively. Pyrifluquinazon was relatively well absorbed from the GI tract: about 63% after a 1 mg/kg bw dose, based on bile, urine and carcass. The  $C_{max}$  values in blood and plasma for radioactivity and the AUC for radioactivity were calculated up to 168 hours post-dose, and were in general proportional to dose. Following a 1 mg/kg bw dose to bile duct-cannulated rats, 34.5% of the administered dose was excreted in the bile collected at 72 hours post-dose. Pyrifluquinazon was widely distributed, with highest levels of radioactivity in the liver, kidney, GI tract and the adrenals. In a study with pyrifluquinazon labelled on its quinazolinone phenyl, virtually no radioactivity remained in tissue after 168 hours, whereas in a study with pyridine-labelled pyrifluquinazon, 18–31% of the radiolabel was recovered from the carcass at 168 hours. As the pyridine moiety of pyrifluquinazon may be metabolized to nicotinic acid, nicotinamide and related molecules, it is hypothesized that the residual activity in the carcass at 168 hours represents residues of the compound that are incorporated into organs and tissues. The major route of excretion was the faeces (75–80%), with smaller amounts in urine (15–20%). For both sexes, elimination was biphasic and almost complete by 48 hours post-dose for the 1 mg/kg bw dose (ca 80%), and by 144 hours for the 100 mg/kg bw dose (ca 90%). In view of the rate of excretion and the distribution pattern, no potential for bioaccumulation is expected.

Pyrifluquinazon was extensively metabolized. No parent compound was found in urine and bile, and only low levels in faeces. The major routes of metabolism of pyrifluquinazon involve initial deacetylation of the nitrogen atom at the 1-position of the quinazoline ring, followed by hydroxylation of the 4-position in the quinazoline ring and conjugation by glucuronic acid, oxidation of the 1-position of pyridine ring, dehydrogenation of the amino group, hydroxylation of the 8-position in the quinazolinone ring, cleavage of the nitrogen–carbon bond, followed by acetylation of the nitrogen atom and cleavage of the quinazoline ring followed by conjugation with glucuronic acid.

In urine significant levels were found of only pyrifluquinazon-8-OH-quinazolinone (IV-211) or its glucuronide (5–6% and 3–4% of the applied dose after 1 and 100 mg/kg bw, respectively), pyrifluquinazon anthranilic acid (IV-303) or its glucuronide (7% and 5–6% of the applied dose after 1 and 100 mg/kg bw, respectively) and pyrifluquinazon methylnicotinamide (IV-405, 18–21% after 1 mg/kg bw; 21% in males after 100 mg/kg bw), along with minor amounts (< 4%) of nicotinic acid (IV-403) and pyrifluquinazon-1H-imino oxide (IV-04). In bile the main metabolites were pyrifluquinazon-1H-4-OH (IV-27) or its glucuronide (9%), IV-211-glucuronide (8% of the applied dose of 1 mg/kg bw) and pyrifluquinazon aminoquinazolinone-*N*-Ac-4-OH (IV-212; 7% of the applied dose

of 1 mg/kg bw) with lower levels of IV-303 (1.5% of the applied dose of 1 mg/kg bw). Taking into account the incomplete oral absorption of pyrifluquinazon, the metabolites IV-27, IV-211, IV-212, IV-303, IV-405 were formed in rats at more than 10% of the administered dose. The presence of metabolites in the GI of bile duct-cannulated rats suggested that microbial or chemical degradation occurs in the intestine. There were no significant differences in the toxicokinetic parameters or metabolism between the sexes.

### **Toxicological data**

The acute oral LD<sub>50</sub> in rats was 300–2000 mg/kg bw, the acute dermal LD<sub>50</sub> was greater than 2000 mg/kg bw and the acute inhalation LC<sub>50</sub> was 1.2–2.4 mg/L. Pyrifluquinazon was not irritating to the skin of rabbits, nor to the eyes of rabbits. Pyrifluquinazon was mildly sensitizing in a maximization test in guinea pigs.

In repeated-dose oral toxicity studies with pyrifluquinazon in mice, rats and dogs, various effects were observed, most notably on the nasal cavity, reproductive organs, liver, adrenals, hormone levels (indicative of an antiandrogenic potential), clinical signs and behaviour.

In a 90-day study in mice using dietary pyrifluquinazon concentrations of 0, 60, 750 or 1500 ppm (equal to 0, 7.6, 102 and 206 mg/kg bw per day for males, 0, 9.1, 119 and 202 mg/kg bw per day for females) the NOAEL was 60 ppm (equal to 7.6 mg/kg bw per day), based on clinical chemistry changes indicative of liver toxicity, and reductions in total serum protein, albumin, globulin and calcium, decreased total leukocyte and lymphocyte counts, and thyroid and epididymis weight, and increased liver weights and incidences of follicular cell hypertrophy in the thyroid and centrilobular hepatocellular hypertrophy in both sexes at 750 ppm (equal to 102 mg/kg bw per day).

In a 90-day study in rats using dietary pyrifluquinazon concentrations of 0, 50, 100, 500 or 2500 ppm (equal to 0, 2.9, 5.7, 29 and 155 mg/kg bw per day for males, 0, 3.2, 6.4, 33 and 159 mg/kg bw per day for females), the NOAEL was 500 ppm (equal to 29 mg/kg bw per day), based on effects on body weight, and a number of changes in haematology, clinical chemistry, organ weights and histopathological changes in liver, thyroid, kidney, pituitary, adrenal, bone marrow, pancreas, spleen, retina, ovary, uterus, vagina, testis and epididymis at 2500 ppm (equal to 155 mg/kg bw per day).

In a 13-week oral toxicity study in dogs pyrifluquinazon was administered by gelatine capsule at doses of dose of 0, 2, 5 or 30 mg/kg bw per day. The NOAEL was 2 mg/kg bw per day, based on reduced body weight gain in both sexes, which was considered toxicologically relevant despite lack of statistical significance, at 5 mg/kg bw per day.

In a one-year oral toxicity study in dogs administered pyrifluquinazon by gelatine capsule at a dose of dose of 0, 1.5, 5 or 15 mg/kg bw per day, the LOAEL was 1.5 mg/kg bw per day based on slight to moderate mononuclear cell infiltration of the lumina propria of the olfactory epithelium, which was considered to be an early indicator of alteration/necrosis of the olfactory epithelium observed at the mid and high doses.

In a second one-year oral toxicity study in dogs pyrifluquinazon was administered by gelatine capsule at doses of 0, 0.15, 0.5 or 5 mg/kg bw per day. The NOAEL was 0.5 mg/kg bw per day, based on mononuclear cell infiltration in the nasal cavity in both sexes at 5.0 mg/kg bw per day.

The overall NOAEL for the two one-year toxicity studies in dogs was 0.5 mg/kg bw per day, and the overall LOAEL was 1.5 mg/kg bw per day.

In an 18-month carcinogenicity study in mice using dietary pyrifluquinazon concentrations of 0, 60, 250 or 1000 ppm (equal to 0, 6.3, 27 and 122 mg/kg bw per day for males, 0, 5.8, 25, 120 mg/kg bw per day for females), the NOAEL was 60 ppm (equal to 6.3 mg/kg bw per day). This was based on an increased incidence of adrenal subcapsular cell hyperplasia in males at 250 ppm, equal to 27 mg/kg bw per day. At 1000 ppm (equal to 122 mg/kg bw per day) an increase in the incidences of interstitial cell hyperplasia and benign interstitial (Leydig) cell tumours in the testis was observed.

There were no increases in the incidence of other neoplastic lesions. The NOAEL for carcinogenicity was 250 ppm (equal to 27 mg/kg bw per day).

In a one-year study in rats using dietary pyrifluquinazon concentrations of 0, 100, 350 or 1300 ppm (equal to 0, 4.1, 14 and 56.5 mg/kg bw per day for males, 0, 5.0, 18, and 66 mg/kg bw per day for females), the NOAEL was 100 ppm, equal to 4.1 mg/kg bw per day, based on organ weight changes in both sexes and indications of kidney effects in females at 350 ppm (equal to 14 mg/kg bw per day).

In a two-year carcinogenicity study in rats using dietary pyrifluquinazon concentrations of 0, 100, 350 or 1300 ppm (equal to 0, 3.5, 13 and 49 mg/kg bw per day for males, 0, 4.5, 16, and 60 mg/kg bw per day for females) the NOAEL was 100 ppm (equal to 3.5 mg/kg bw per day, based on histopathological changes in the eyes in both sexes, organ weight changes and macroscopic and histopathological changes in the male reproductive organs, including an increase in Leydig cell tumours set against a high background incidence. In females bile duct hyperplasia and uterine horn dilatation was noted at 350 ppm (equal to 13 mg/kg bw per day). Apart from the Leydig cell tumours, there were no increases in the incidence of other neoplastic lesions. Although the high background incidence in Leydig cell tumours in this study makes it difficult to assess with confidence any carcinogenic effect of pyrifluquinazon treatment in the testis, the Meeting noted that an increased incidence in this tumour type was also observed in the 18 month study in mice. Therefore the NOAEL for carcinogenicity was 3.5 mg/kg bw per day.

Studies were performed to investigate the MOA for the observed induction of interstitial (Leydig) cell hyperplasia and tumours in the testis of mice and rats (F-344 strain). Such tumours are common in certain rat strains, including F-344, and the relevance of a substance-related induction of such tumours for humans is questionable. However, interstitial cell tumours in testis of mice are rare and a substance-related induction of these tumours could not be discounted with respect to its relevance to humans. The hypothesis proposed by the sponsor is that antiandrogenic effects mediated through the androgen receptor (AR) give rise to sustained luteinizing hormone (LH) secretion due to disruption of negative feedback regulation, leading eventually to Leydig cell overstimulation. The meeting noted that, although the tumours in the mouse in particular are a matter of concern, most of the studies to substantiate the hypothesis were performed in rats or rat tissue. Pyrifluquinazon showed antiandrogenic activity in a two-generation reproductive toxicity study and in two Hershberger assays in rats. In vitro studies showed that pyrifluquinazon has antiandrogenic potential, probably through disruption of the AR-mediated signaling pathway by decreasing the intracellular protein expression, rather than through competitive inhibition of androgen binding. In a 13-week dietary study in male mice using pyrifluquinazon concentrations of 0, 250, 500 or 1000 ppm (equal to 0, 33, 71 and 136 mg/kg bw per day) increases in LH, testosterone and dihydrotestosterone (DHT), decrease in absolute and relative epididymis weight and testicular interstitial cell hypertrophy were observed at 500 ppm and 1000 ppm. In a 13-week dietary study in male rats, using pyrifluquinazon at concentrations of 0, 50, 350, 1300 or 2500 ppm (equal to 0, 6, 21, 77 and 145 mg/kg bw per day) several effects were observed at 1300 ppm and 2500 ppm. There were increases in serum LH and testosterone values and a decrease in the weights of prostate, seminal vesicles with coagulating gland and epididymis, and an increase in testicular seminiferous tubular atrophy and of germ cell debris in the epididymis. At the high dose level, vacuolation of tubular epithelial cell of the epididymides was also observed. The Meeting noted that Leydig cell tumours in rats occurred at lower dietary levels of pyrifluquinazon than the increase in LH in the 13-week MOA study in rats. The sponsor proposes that the hormonal changes in mice and rats are a consequence of the stimulation of testosterone production in the interstitial cells by LH and that the data support the hypothesis that pyrifluquinazon may increase levels of LH that would subsequently lead to interstitial (Leydig) cell tumours in mice and rats. The Meeting noted that although a number of studies had been performed in rats, only one had been performed in mice, which was the critical species and therefore it is not possible to establish the MOA in the mouse and hence the relevance to humans. With this in mind, it is not possible to dismiss the relevance to humans of the tumours observed in the testes of rats and mice.

The Meeting concluded that pyrifluquinazon is carcinogenic in male mice and male rats.

Pyriproxyfen 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 pyriproxyfen is unlikely to be genotoxic.

In view of the lack of genotoxicity, and the fact that tumours were observed only at doses unlikely to occur in humans, by a mechanism that would exhibit a threshold, the Meeting concluded that pyriproxyfen is unlikely to pose a carcinogenic risk to humans via exposure from the diet.

In a two-generation reproductive toxicity study, rats were administered pyriproxyfen in the diet at concentrations of 0, 30, 150 and 750 ppm (equal to pre-mating doses of 0, 2.0, 10 and 52 mg/kg bw per day for F<sub>0</sub> males, 0, 2.3, 12 and 59 mg/kg bw per day for F<sub>0</sub> females; 0, 2.3, 11 and 56 mg/kg bw per day for F<sub>1</sub> males, 0, 2.4, 12 and 61 mg/kg bw per day for F<sub>1</sub> females, respectively). The NOAEL for parental toxicity was 30 ppm (equal to 2.4 mg/kg bw per day), based on increased thyroid weight in F<sub>1</sub> females at 150 ppm (equal to 12 mg/kg bw per day). The NOAEL for offspring toxicity was 30 ppm (equal to 2.3 mg/kg bw per day), based on reduced body weights in both sexes at 150 ppm (equal to 10 mg/kg bw per day). The NOAEL for reproductive toxicity was 30 ppm (equal to 2.4 mg/kg bw per day), based on a reduced anogenital distance in F<sub>2</sub> male pups at 150 ppm (equal to 12 mg/kg bw per day).

In a developmental toxicity study of pyriproxyfen in rats using gavage doses of 0, 5, 10 or 50 mg/kg bw per day from GD 6–19, the NOAEL for maternal toxicity was 10 mg/kg bw per day, based on reduced feed intake and body weight gain at 50 mg/kg bw per day. The NOAEL for embryo and fetal toxicity was 5 mg/kg bw per day, based on reduction in anogenital distance in male fetuses and increased incidences in supernumerary ribs in both sexes at 10 mg/kg bw per day.

In a developmental toxicity study in rabbits administered pyriproxyfen by gavage at a dose of 0, 5, 10 or 20 mg/kg bw per day from GD 6–27, the NOAEL for maternal and offspring toxicity was 20 mg/kg bw per day, the highest dose tested.

The Meeting concluded that pyriproxyfen is not teratogenic.

In an acute neurotoxicity study in which rats were administered pyriproxyfen by gavage at a dose of 0, 30, 100, 300 or 500 mg/kg bw, and then observed for 14 days, the NOAEL was 100 mg/kg bw, based on moribundity, clinical signs, body weight loss and changes in sensorimotor reactivity, coordination, autonomic processes and motor activity observed at 300 mg/kg bw.

An acute safety pharmacology study was conducted in which female rats received pyriproxyfen by gavage at doses of 0, 5, 50 or 500 mg/kg bw and then observed for 24 hours. The NOAEL was 50 mg/kg bw, based on mortality, body weight loss, marked clinical signs and decreased mobility observed at 500 mg/kg bw.

In a 13-week neurotoxicity study in rats using dietary pyriproxyfen concentrations of 0, 30, 150 and 750 ppm (equal to 0, 1.8, 9.4 and 47 mg/kg bw per day for males, 0, 2.2, 11 and 53 mg/kg bw per day for females), the NOAEL for systemic toxicity was 150 ppm (equal to 11 mg/kg bw per day), based on reduced body weight gain at termination, reduced feed consumption early in treatment in females at 750 ppm (equal to 53 mg/kg bw per day). The NOAEL for neurotoxicity was 750 ppm, equal to 47 mg/kg bw per day, the highest dose tested.

There were no indications of neuropathological effects of pyriproxyfen. The Meeting considered that the acute behavioural effects observed at high doses of pyriproxyfen are due to severe systemic toxicity.

The Meeting concluded that pyriproxyfen is not neurotoxic.

In a 28-day immunotoxicity study in rats using dietary pyriproxyfen concentrations of 0, 30, 150 and 750 ppm (equal to 0, 2.5, 12 and 62 mg/kg bw per day for males, 0, 2.7, 13, 63 mg/kg bw per day for females), no signs of an immunotoxic effect were observed.

The Meeting concluded that pyriproxyfen is not immunotoxic.

### ***Mechanistic studies***

In addition to studies investigating the antiandrogenic potential of pyrifluquinazon and the MOA causing the induction of interstitial cell tumours in mice and rats (as described above), studies were available in which the effects of this substance on liver enzymes and the possible secondary effect on the thyroid were investigated. The Meeting considered that these data provided no information that would impact on the evaluation of pyrifluquinazon.

### ***Toxicological data on metabolites and/or degradates***

Acute oral LD<sub>50</sub> studies and mutagenicity studies were available for some metabolites of pyrifluquinazon. The acute oral LD<sub>50</sub> values of metabolites IV-01, IV-02, IV-15, IV-17, IV-27, IV-28 and IV-203 were > 2000 mg/kg bw. For the metabolite AQW the LD<sub>50</sub> was 300–2000 mg/kg bw. For the metabolites IV-02, IV-17, IV-102, IV-203, IV-208, AQA, AQW and QUA, negative results were obtained in reverse mutation test on bacteria (Ames tests).

The major residues in crops and livestock were pyrifluquinazon and its metabolites IV-01, IV-02, IV-03, IV-04, IV-15, IV-17, IV-203, IV-208 and IV-404 (nicotinamide, vitamin B compound). For the crop and livestock metabolites IV-03, IV-04, IV-404 and IV-208 no acute toxicity studies were available and for the the crop and livestock metabolites IV-01, IV-03, IV-04, IV-15 and IV-404 no reverse mutagenicity tests were available.

Apart from acute toxicity and reverse mutation tests, no specific toxicity studies on metabolites of pyrifluquinazon were available. In toxicokinetic studies in rats using pyrifluquinazon at single gavage doses of 1 or 100 mg/kg bw, metabolite levels were generally low. Significant levels (> 10% when taking the incomplete oral absorption into account) of the rat metabolites IV-211, IV-27, IV-303 and their respective glucuronides, were found in urine and/or bile. The Meeting concluded that the toxicity of these rat metabolites would be covered by that of pyrifluquinazon. As crop and livestock metabolite IV-01 is an intermediate in the metabolic pathway leading to the formation of IV-211 or IV-27, and crop and livestock metabolite IV-203 is an intermediate in the metabolic pathway leading to the formation of IV-211 and IV-303, the toxicity of metabolites IV-01 and IV-203 would also be covered by that of pyrifluquinazon. The Meeting noted that, although the metabolites IV-02, IV-03, IV-04, IV-15, IV-17 and IV-208 retain the structural backbone of the parent and have undergone only minor structural changes when compared to pyrifluquinazon, it could not conclude on the toxicity of these compounds in view of the absence of repeated dose toxicity studies with these substances. For the metabolites IV-02, IV-17 and IV-208 the TTC approach (Cramer class III) could be applied for chronic toxicity, as reverse mutation tests on bacteria (Ames tests) were negative for these substances. For the metabolites IV-03, IV-04 and IV-15 the TTC for genotoxicity could be applied for chronic toxicity. IV-404 (nicotinamide) is a B vitamin and is not of toxicological concern.

### ***Human data***

No human data were available.

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

### **Toxicological evaluation**

The Meeting established an ADI of 0–0.005 mg/kg bw for pyrifluquinazon on the basis of an overall NOAEL of 0.5 mg/kg bw per day in two 1-year dog studies, based on a slight to moderate mononuclear cell infiltration of the lumina propria of the olfactory epithelium in both sexes at 1.5 mg/kg bw per day. A safety factor of 100 was used. The upper bound of the ADI gives a margin of about 24 000 relative to the LOAEL for the observed interstitial cell tumours in the testes of mice. The upper bound of the ADI gives a margin of about 2800 relative to the LOAEL for the observed interstitial cell tumours in the testes of rats.

The Meeting established an ARfD of 1 mg/kg bw for pyriproxyfen on the basis of a NOAEL of 100 mg/kg bw in an acute neurotoxicity study of rats, based on moribundity, clinical signs, body weight loss and changes in sensorimotor reactivity, coordination, autonomic processes and motor activity observed at 300 mg/kg bw. A safety factor of 100 was used. This is supported by findings in the LD<sub>50</sub> studies and a safety pharmacology study.

The ADI and ARfD also apply to the metabolites IV-01 and IV-203, expressed as pyriproxyfen.

A toxicological monograph was prepared.

### Levels relevant to risk assessment of pyriproxyfen

Species	Study	Effect	NOAEL	LOAEL
Mouse	13-week study of toxicity <sup>a</sup>	Toxicity	60 ppm, equal to 7.6 mg/kg bw per day	750 ppm, equal to 102 mg/kg bw per day
	18-month study of carcinogenicity <sup>a</sup>	Toxicity Carcinogenicity	60 ppm equal to 6.3 mg/kg bw/day 250 ppm, equal to 27 mg/kg bw per day	250 ppm, equal to 27 mg/kg bw per day 1000 ppm, equal to 122 mg/kg bw per day
Rat	13-week study of toxicity <sup>a</sup>	Toxicity	500 ppm, equal to 29 mg/kg bw per day	2500 ppm, equal to 155 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	100 ppm, equal to 3.5 mg/kg bw per day	350 ppm, equal to 13 mg/kg bw per day
		Carcinogenicity	100 ppm, equal to 3.5 mg/kg bw per day	350 ppm, equal to 13 mg/kg bw per day
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	30 ppm equal to 2.3 mg/kg bw per day <sup>b</sup>	150 ppm equal to 11 mg/kg bw per day <sup>b</sup>
		Parental toxicity	30 ppm equal to 2.4 mg/kg bw per day <sup>b</sup>	150 ppm equal to 12 mg/kg bw per day
		Offspring toxicity	30 ppm equal to 2.3 mg/kg bw per day	150 ppm equal to 10 mg/kg bw per day
	Developmental toxicity study <sup>b</sup>	Maternal toxicity Embryo and fetal toxicity	10 mg/kg bw per day 5 mg/kg bw per day	50 mg/kg bw per day 10 mg/kg bw per day
Acute neurotoxicity study <sup>b</sup>	Neurotoxicity	100 mg/kg bw	300 mg/kg bw	
Acute safety pharmacology study <sup>b</sup>	Neurotoxicity	50 mg/kg bw	500 mg/kg bw	
Thirteen-week neurotoxicity study <sup>a</sup>	Toxicity	150 ppm, equal to 11 mg/kg bw per day	750 ppm, equal to 53 mg/kg bw per day	
	Neurotoxicity	750 ppm, equal to 47 mg/kg bw per day <sup>c</sup>	-	
Rabbit	Developmental toxicity study <sup>b</sup>	Maternal toxicity	20 mg/kg bw per day <sup>c</sup>	-
		Embryo and fetal toxicity	20 mg/kg bw per day <sup>c</sup>	-
Dog	One-year study of toxicity <sup>d,e</sup>	Toxicity	0.5 mg/kg bw per day	1.5 mg/kg bw per day

<sup>a</sup> Dietary administration

<sup>b</sup> Gavage administration

<sup>c</sup> Highest dose tested

<sup>d</sup> Capsule administration

<sup>e</sup> Two or more studies combined

*Acceptable daily intake (ADI), applies to pyrifluquinazon, IV-01 and IV-203, expressed as pyrifluquinazon*

0–0.005 mg/kg bw

*Acute reference dose (ARfD), applies to pyrifluquinazon, IV-01 and IV-203, expressed as pyrifluquinazon*

1 mg/kg bw

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

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

**Critical end-points for setting guidance values for exposure to pyrifluquinazon**

**Absorption, distribution, excretion and metabolism in mammals**

Rate and extent of oral absorption	Relatively rapid ( $T_{max}$ 1–3 hours and 3–12 hours after 1 or 100 mg/kg bw dose, respectively) and incomplete (63% at 1 mg/kg bw, based on levels in urine, bile and carcass) (rat)
Dermal absorption	19%, 13% and 4% at 0.001, 0.01 and 0.1 mg/cm <sup>2</sup> , respectively (in vivo, rat)
Distribution	Widely distributed; highest concentrations found in liver, kidneys, GI tract and adrenals
Potential for accumulation	None
Rate and extent of excretion	Relatively rapid; 80% in 48 hours after 1 mg/kg bw
Metabolism in animals	Extensively metabolized; major metabolites are IV-27 or its glucuronide, IV-211 or its glucuronide, IV-212, IV-303 or its glucuronide, IV-405
Toxicologically significant compounds in animals and plants	Pyrifluquinazon, IV-01, IV-02, IV-03, IV-04, IV-15, IV-17, IV-203, IV-208

**Acute toxicity**

Rat, LD <sub>50</sub> , oral	> 300–2000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	> 2000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	> 1.2–2.4 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea pig, dermal sensitization	Mildly sensitizing (maximization test)

**Short-term studies of toxicity**

Target/critical effect	Olfactory epithelium
Lowest relevant oral NOAEL	0.5 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day, highest dose tested (rat)
Lowest relevant inhalation NOAEC	0.042 mg/L (rat)

**Long-term studies of toxicity and carcinogenicity**

Target/critical effect	Eyes, liver, male and female reproductive organs
Lowest relevant NOAEL	3.5 mg/kg bw per day (rat)
Carcinogenicity	Carcinogenic in mice and rats <sup>a</sup>

**Genotoxicity**

No evidence of genotoxicity<sup>a</sup>

**Reproductive toxicity**

Target/critical effect	Reduced anogenital distance in male pups
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Lowest relevant parental NOAEL	2.4 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	2.3 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	2.3 mg/kg bw per day (rat)

**Developmental toxicity**

Target/critical effect	Reduced anogenital distance in male fetuses; increased incidences in supernumerary ribs
Lowest relevant maternal NOAEL	10 mg/kg bw per day (rat)
Lowest relevant embryo/fetal NOAEL	5 mg/kg bw per day (rat)

**Neurotoxicity**

Acute neurotoxicity NOAEL	100 mg/kg bw (rat)
Subchronic neurotoxicity NOAEL	53 mg/kg bw per day, highest dose tested (rat)
Developmental neurotoxicity NOAEL	No data

**Immunotoxicity**

Lowest relevant NOAEL	62 mg/kg bw per day, highest dose tested (rats)
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**Studies on toxicologically relevant metabolites and impurities**

IV-01, IV-02, IV-15, IV-27, IV-28 and IV-203 (metabolites) and IV-17	LD <sub>50</sub> > 2000 mg/kg bw
AQW	LD <sub>50</sub> > 300–2000 mg/kg bw
IV-02, IV-17, IV-102, IV-404, IV-203, IV-208, AQA, AQW and QUA	No evidence of genotoxicity in Ames test

<b>Human data</b>	No data
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<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet

**Summary**

	Value	Study	Safety factor
ADI	0–0.005 mg/kg bw <sup>a</sup>	One-year toxicity studies in dogs <sup>b</sup>	100
ARfD	1 mg/kg bw <sup>a</sup>	Acute neurotoxicity study in rats	100

<sup>a</sup> Applies to pyriproxyfen and IV-01 and IV-203 expressed as pyriproxyfen.

<sup>b</sup> Two or more studies combined

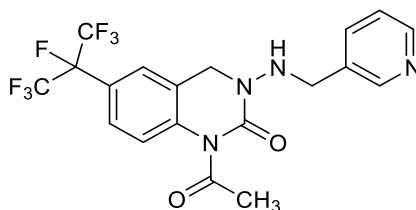
**RESIDUE AND ANALYTICAL ASPECTS**

Pyriproxyfen is a non-systemic insecticide for the control of sap-feeding insects. It acts by modification of insect feeding behaviour. Pyriproxyfen was scheduled at the Fiftieth Session of the CCPR for evaluation as a new compound by the 2019 JMPR.

The Meeting received information on the identity, physicochemical properties, metabolism of pyriproxyfen in plants and livestock, rotational crops, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials on stone fruit (cherries, peaches, plums), potato, tea and tree nuts (almonds, pecans) as well as a livestock feeding study (lactating cow).

Pyriproxyfen is 1-acetyl-1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one.





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

Table 1 Abbreviations used for the major metabolites

Code	Name	Structure
IH IV-01	1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one	
IH-imino IV-02	1,2,3,4-tetrahydro-3-[(3-pyridylmethylene)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one	
IH-oxide IV-03	1,2,3,4-tetrahydro-3-[3-(1-oxypyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one	
IH-imino-oxide IV-04	1,2,3,4-tetrahydro-3-[3-(1-oxypyridylmethylene)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one	
IH-4-oxo IV-15	1,2,3,4-tetrahydro-3-[3-(1-oxypyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2,4-dione	
IH-N-Ac IV-17	<i>N</i> -[2-oxo-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-1,4-dihydro-2 <i>H</i> quinazolin-3-yl]- <i>N</i> -(Pyr-3-ylmethyl)acetamide	
IH-4-OH IV-27	1,2,3,4-tetrahydro-4-hydroxy-3-[3-(pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one	
IH-inmino-4-OH IV-28	4-hydroxy-3-[(pyridine-3-ylmethylene)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-3,4-dihydro-1 <i>H</i> -quinazolin-2-one	
N-Ac IV-101	<i>N</i> -[1-acetyl-2-oxo-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-1,4-dihydro-2 <i>H</i> -quinazolin-3-yl]- <i>N</i> -(pyridin-3-ylmethyl)acetamide	

Code	Name	Structure
Imino IV-102	1-acetyl-3-[(pyridin-3-ylmethylene)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-3,4-dihydro-1 <i>H</i> -quinazolin-2-one	
quinazolinedione IV-203	1,2,3,4-tetrahydro-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2,4-dione	
quinazolinone IV-206	6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-3,4-dihydro-1 <i>H</i> -quinazolin-2-one	
aminoquinazolinone-N-Ac IV-208	<i>N</i> -[2-oxo-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-1,4-dihydro-2 <i>H</i> -quinazolin-3-yl]acetamide	
Nicotinic acid (niacin) IV-403	Pyridine-3-carboxylic acid	
Nicotinamide (niacinamide) IV-404	Pyridine-3-carboxylic acid amide	
Methyl-nicotinamide IV-405	3-carbamoyl-1-methylpyridinium	
Nicotinic acid N-oxide	Nicotinic acid <i>N</i> -oxide	

With respect to the physical and chemical properties of pyrifluquinazon that may impact on residues in crops and livestock, pyrifluquinazon is potentially fat soluble ( $\log P_{ow} > 3$ ), not volatile, stable to hydrolysis at physiological pH and can be degraded via photolysis.

The metabolism of pyrifluquinazon in plants, animals and soils was investigated using [quinazolinone-phenyl- $^{14}\text{C}$ ]-pyrifluquinazon (Qn-label) and [pyridine-2,6- $^{14}\text{C}$ ]-pyrifluquinazon (Pyr-label).

### Plant metabolism

The Meeting received studies on the metabolism of pyrifluquinazon after foliar application to tomato (fruiting vegetables other), lettuce (leafy vegetables) and radish (root & tuber vegetables). Plants were maintained in a greenhouse with a UV transparent quartz ceiling.

### Tomato

The metabolic fate of [ $^{14}\text{C}$ ]-pyrifluquinazon in tomato plants maintained in a greenhouse was examined following three foliar applications of 0.1 kg ai/ha each made at 7 day intervals with an WDG formulation. Fruit and leaves were harvested at 0, 1, 7 and 14 days after the last application.

TRRs in rank order were 0.05–0.16 mg eq/kg in roots, 0.67–1.3 mg eq/kg in stems, 0.41–0.76 mg eq/kg in fruit and 13–21 mg eq/kg in leaves.

The majority of  $^{14}\text{C}$  residues in fruit and leaves were associated with surface rinses (acetonitrile/ $\text{H}_2\text{O}$  rinse 49–80% TRR). Extractability of  $^{14}\text{C}$  residues with the solvent system (acetonitrile/ $\text{H}_2\text{O}$ , acetonitrile) used was > 71% in fruit (71–90% TRR), > 83% in leaves (83–94% TRR) and > 45% from roots (45–51% TRR).

Parent pyrifluquinazon was the major component observed in all samples from 0 to 14 DALA. In fruits, pyrifluquinazon ranged from 42% TRR (0.17 mg/kg) at 7 DALA to 72% TRR (0.55 mg/kg) at 1 DALA. In leaves, pyrifluquinazon ranged from 46% TRR (9.4 mg/kg) at 14 DALA to 72% TRR (13 mg/kg) at 1 DALA. Metabolite 1H (IV-01) was detected in fruits at a maximum of 11% TRR (0.039 mg eq/kg) at 0 DALA and in leaves at a maximum of 9.8% TRR (1.3 mg eq/kg) at 0 DALA.

Further metabolites were detected at low levels (< 10% TRR); 1H-imino (IV-02), 1H-oxide (IV-03), 1H-imino-oxide (IV-04), 1H-4-oxo (IV-15), 1H-N-Ac (IV-17), N-Ac (IV-101), imino (IV-102), quinazolinone (IV-203) and quinazolinone (IV-206).

PES accounted for 21 to 29% TRR in fruit at 14 DALA of which 4.8–7.8% TRR was associated with lignins.

### *Lettuce*

In a metabolism study on head lettuce, three foliar applications of a WG formulation were made at 0.2 kg ai/ha and at seven day intervals to lettuce plants grown in a greenhouse with harvest 0–14 days after the last application.

At 14 DALA, TRRs were lowest in roots (0.06 to 0.10 mg eq/kg), higher in stems (0.23–0.30 mg eq/kg) and heads (0.56–1.4 mg eq/kg) and the highest in outer leaves (17–24 mg eq/kg) demonstrating limited translocation from treated leaves to other plant parts.

The majority of  $^{14}\text{C}$  residues in leaves (outer + head) were associated with surface rinses (acetonitrile/ $\text{H}_2\text{O}$  rinse 47–92% TRR). Acetonitrile (rinse + extracts) extracted > 89% of the  $^{14}\text{C}$  in leaves (89–98% TRR) and > 23% from roots (23–34% TRR).

Parent pyrifluquinazon and metabolite 1H (IV-01) were the major components observed in all samples of heads and outer leaves. In heads pyrifluquinazon ranged from 3.0–71% TRR (0.026–2.1 mg/kg). In outer leaves, pyrifluquinazon ranged from 65–82% TRR (12–19 mg/kg). Metabolite 1H (IV-01) was detected in heads in the range 13–82% TRR (0.34–1.8 mg eq/kg), and in outer leaves in the range 2.3–21% TRR (0.48–11 mg eq/kg).

In stems a similar pattern was observed, with parent pyrifluquinazon and 1H (IV-01) being the major components of the radioactivity.

Further metabolites were detected at low levels (< 10% TRR); 1H-imino (IV-02), 1H-oxide (IV-03), 1H-imino-oxide (IV-04), 1H-4-oxo (IV-15), 1H-N-Ac (IV-17), N-Ac (IV-101), imino (IV-102), quinazolinone (IV-203) and quinazolinone (IV-206).

PES accounted for 3.8–10% TRR in outer leaves and heads at 14 DALA.

### *Radish*

The metabolism of [ $^{14}\text{C}$ ]-pyrifluquinazon in radish was studied in plants grown in a greenhouse following three foliar applications at seven day intervals of a WG formulation at 0.1 kg ai/ha and at 14 days before harvest.

TRRs were lowest in roots (0.058 to 0.17 mg eq/kg) and the highest in leaves (3.6 to 15 mg eq/kg) demonstrating limited translocation from treated leaves into the roots.

The majority of  $^{14}\text{C}$  residues in leaves were associated with surface rinses (acetonitrile/ $\text{H}_2\text{O}$  50–72% TRR). Extractability of  $^{14}\text{C}$  residues with the solvent system (acetonitrile/ $\text{H}_2\text{O}$ , acetonitrile) used was > 75% of the  $^{14}\text{C}$  in leaves (75–86% TRR) and > 36% from roots (36–74% TRR).

Parent pyrifluquinazon was a major component seen in all samples, ranging from 9.2–31% TRR (0.007–0.049 mg/kg) in roots and 49–71% TRR (4.1–8.0 mg/kg) in leaves. The other most abundant

metabolite was 1H (IV-01), which was also detected in all samples ranging from 4.1–24% TRR (0.003–0.027 mg eq/kg) in roots and 2.0–18% TRR (0.071–2.7 mg eq/kg) in leaves.

Further metabolites were detected at low levels (< 10% TRR); 1H-imino (IV-02), 1H-oxide (IV-03), 1H-imino-oxide (IV-04), 1H-4-oxo (IV-15), quinazolinone (IV-203), quinazolinone (IV-206) and imino (IV-102).

PES accounted for 57 to 63% TRR in roots of which 8–11% TRR was associated with lignins.

In summary, the metabolism of pyrifluquinazon by plants is well understood and proceeds predominantly through deacetylation of the quinazolinone nitrogen forming 1H (IV-01) and dehydrogenation to imino (IV-102), which may be hydrolysed to the deacetylated metabolite, 1H-imino (IV-02). Trace amounts of 1H-N-Ac (IV-17) and N-Ac (IV-101) were detected resulting from intra and inter molecular trans-acetylation of pyrifluquinazon. Further transformations of 1H (IV-01) occur via hydroxylation at the 4-position of the quinazoline ring and oxidation at the 1-position of the pyridine ring and N-N bond cleavage.

A number of metabolites were not observed in laboratory animal (rat) studies; these were IV-15 (radish 2% TRR, lettuce 3% TRR, tomato 2% TRR), IV-17 (radish < 1% TRR, lettuce 1% TRR, tomato < 1% TRR), IV-101 (radish, lettuce, tomato < 1% TRR), and IV-102 (radish < 1% TRR, lettuce < 1% TRR, tomato 4% TRR).

### **Environmental fate**

The Meeting received aqueous and soil photolysis, aqueous hydrolysis and aerobic soil metabolism studies for pyrifluquinazon.

The major route of pyrifluquinazon degradation is aerobic soil metabolism. Pyrifluquinazon degraded with a half-life of less than 2 days in laboratory studies on three soils and less than 6 days on additional soils tested under aerobic conditions.

Pyrifluquinazon is stable to hydrolysis (aqueous and soil). Hydrolysis of pyrifluquinazon is rapid under basic conditions and slower under acidic conditions, with a half-life ranging from less than 1 day at pH 9, 24 days at pH 7 to 95 days at pH 5.

Photolysis is not a significant route of degradation.

### **Rotational crop metabolism**

#### **Confined rotational crop studies**

In a confined rotational crop study with lettuce, radish and wheat, bare sandy loam soil was treated with [<sup>14</sup>C]-pyrifluquinazon (Pyr- and Qn-labels) at the equivalent of 206 g ai/ha (2× maximum seasonal rate) and crops sown 30, 120 and 360–390 (419–434 for lettuce) days after the soil application.

For the Pyr-label experiments, the TRRs in lettuce head were < 0.01 mg eq/kg at all PBIs. TRR in radish leaves (30 PBI: 0.004 mg eq/kg,) was similar to those in radish roots for the Pyr-label but much higher in foliage (30 PBI: 0.08 mg eq/kg) compared to roots (30 PBI: 0.014 mg eq/kg) for the Qn-label. For wheat commodities TRRs at the different PBIs followed the order 120 > 30 > 360/390 days. In wheat straw residues increased for the longer PBIs (Pyr-label 30 PBI: 0.019 mg eq/kg, 360 PBI: 0.038 mg eq/kg; Qn-label 30 PBI: 0.16 mg/kg equiv, 390 PBI: 0.30 mg eq/kg).

Parent pyrifluquinazon was not detected with either radiolabel in any matrix. No single radiolabelled residue from the Pyr-label samples at any interval contributed ≥ 0.01 mg/kg. Since the TRR for lettuce (immature, mature) and radish (foliage, roots) was < 0.01 mg/kg, there was no further analysis of residues from these Pyr-label samples. Wheat forage, hay, straw, and grain (Pyr-label) were analysed by HPLC but no metabolites at ≥ 0.01 mg/kg were extractable with acetonitrile/water.

The TRRs were generally low with the highest levels observed in the Qn-label experiment in radish leaves (30 day PBI: 0.08 mg eq/kg), wheat forage (30 day PBI: 0.11 mg eq/kg), wheat hay (30 day PBI: 0.22 mg eq/kg) and wheat straw (390 day PBI: 0.3 mg eq/kg). Parent pyrifluquinazon was not

detected with either radiolabel in any matrix. The only metabolites detected above 0.01 mg/kg were: quinazolinedione (IV-203) (radish foliage 0.025–0.034 mg eq/kg; wheat forage/hay/straw 0.010–0.047 mg eq/kg), a conjugate of quinazolinedione (radish foliage 0.013 mg eq/kg; wheat forage 0.022 mg eq/kg; wheat hay up to 0.066 mg eq/kg; wheat straw up to 0.048 mg eq/kg) and 1H-4-oxo (IV-15) (wheat forage 0.020 mg eq/kg). Residues related to pyrifluquinazon are not expected to be significant at PBIs of a year or more.

### *Field rotational crop studies*

In a field rotational crop study the magnitude of pyrifluquinazon and metabolite quinazolinedione (IV-203) was investigated outdoors in succeeding crops following three foliar applications to the primary crop of mustard greens (3× maximum seasonal rate). Follow crops of radish, leaf lettuce and sorghum were planted at PBIs of 13–14, 29–30 and 58–60 days.

Pyrifluquinazon residues were <LOQ (< 0.01 mg/kg) and IV-203 residues were <LOQ (0.01 mg/kg) in lettuce. Residues of metabolite IV-203 in radish roots were in general < 0.01 mg/kg apart from samples at 30 and 58 day PBIs where a maximum residue of 0.015 mg/kg was detected. In radish tops IV-203 residues were 0.012–0.16 mg/kg. IV-203 was detected in sorghum forage at 30 and 58 day PBIs in the range 0.010–0.014 mg/kg. IV-203 was < 0.01 mg/kg in sorghum grain except at 13 day PBI where a single residue of 0.014 mg/kg was observed. IV-203 in sorghum stover was detected at 14, 30 and 58 day PBIs where residues ranged from < 0.01–0.019 mg/kg. The possible presence of conjugates of IV-203 was not investigated.

IV-203 was detected in field rotational crop studies conducted at approximately 3× the maximum seasonal rate.

### *Animal metabolism*

The Meeting received animal metabolism studies on rats, lactating goats and laying hens.

#### *Rats*

Metabolism of pyrifluquinazon in rats was evaluated by the WHO Core Assessment Group of the 2019 JMPR. Metabolites identified in rats included IV-01, IV-02, IV-03, IV-04, IV-27, IV-203, IV206, IV-208, IV-211, IV-303, IV-403, IV-404 and IV-405.

#### *Lactating goats*

Lactating goats were orally dosed by gavage once daily for five consecutive days with [<sup>14</sup>C]-pyrifluquinazon at a dose equivalent to 12 ppm in the diet for the Pyr-label or 11 ppm in the diet for the Qn-label.

By 22 hours after the last dose, the majority of the <sup>14</sup>C residues were recovered in the excreta (Pyr-label; urine 12% AD, faeces 45% AD; Qn-label; urine 14% AD, faeces 55% AD).

For tissues, <sup>14</sup>C residues were highest in liver (14 Pyr-label, 5.4 Qn-label mg eq/kg) and kidney (2.5 Pyr-label, 0.81 Qn-label mg eq/kg) with lower levels in fat (0.31 Pyr-label, 0.23 Qn-label mg eq/kg) and muscle (0.57 Pyr-label, 0.14 Qn-label mg eq/kg) containing low residues.

Residues in milk appeared to reach plateau levels by four days after the start of dosing (0.7 Pyr-label and 2 Qn-label mg eq/kg in milk fat and 0.25 mg eq/kg both labels in skim milk). There were significant differences in <sup>14</sup>C levels between milk collected in the morning prior to dosing compared to evening milk, suggesting pyrifluquinazon residues are rapidly eliminated.

Extractability was good with > 67% TRR in kidney, liver and muscle samples extracted with acetonitrile and acetonitrile/H<sub>2</sub>O (88–95% Pyr-label, > 68–85% Qn-label). Extractability of <sup>14</sup>C from milk and fat using acetone/hexane, acetone was good with > 90% TRR extracted.

Parent pyrifluquinazon was not detected in tissues or milk.

The predominant components in both skim milk and milk fat were 1H-iminooxide (IV-04) (48–80% TRR) and 1H-oxide (IV-03) (1.8–8.4% TRR). Nicotinic acid N-oxide (11–22% TRR) was also present in Pyr-label milk, as was quinazolinedione (IV-203) (8.4–20% TRR) in Qn-label milk. Aminoquinazolinone-N-Ac (IV-208) (3.8% TRR) was only found in Qn-label milk fat. Lipid conjugates of metabolites contributed 2.2 and 28% of the TRR in milk fat (Qn and Pyr labels respectively) and showed similar properties to fatty acids after saponification (17% TRR for Pyr-label).

The main components in Pyr-label liver were nicotinamide (IV-404) (68% TRR), nicotinic acid (IV-403) (1.9% TRR) and glucuronides of 1H (IV-01), 4-oxo (IV-15) and 1H-4-oxo-imino-oxide (IV-04) found in Qn-label liver (sum 15–43% TRR, mostly IV-01). Other residues found in liver consisted of 1H (IV-01), 1H-4-oxo (IV-15), and quinazolinedione (IV-203), which is unique to the Qn-label (8.4% TRR). Qn-label liver also contained a small amount of residue (3.9% TRR), which had properties similar to fatty acids.

The major residues in kidney were similar to those of liver. Nicotinamide (IV-404) (74% TRR) and methyl nicotinamide (IV-405) (4.1% TRR) were the major residues for the Pyr-label. The same glucuronide mixture that was found in liver was also present in kidney (7.2–17% TRR mostly IV-01), as well as 1H (IV-01) (1.3–13% TRR) and 1H-oxide (IV-03) (1.9–10% TRR). Quinazolinedione (IV-203) (31% TRR), and aminoquinazolinone N-Ac (IV-208) (8.0% TRR) were also present as the major residues from the Qn-label. Qn-label kidney also contained a small amount of residue (3.8% TRR) that had properties similar to fatty acids.

In Pyr-label muscle the major residue was nicotinamide (IV-404) (92–94% TRR). Quinazolinedione (IV-203) (51–57% TRR) and aminoquinazolinone-N-Ac (IV-208) (12–15% TRR) were the major residues identified for the Qn-label, along with lower levels of 1H-oxide (IV-03), 1H (IV-01), and 1H-4-oxo (IV-15). Qn-label muscle also contained a small amount of residue (1.5–4.8% TRR), which was hydrolysed to fatty acids.

For fat the major component in the Pyr-label experiment was nicotinamide (IV-404) (46–79% TRR). Lipid conjugates of metabolites contributed to 18–38% of the TRR in fat. Base saponification of these lipid conjugates released residues that showed similar properties to fatty acids. The major components in Qn-label fat were quinazolinedione (IV-203) (53–58% TRR) and aminoquinazolinone-N-Ac (IV-208) (6.1–10% TRR). Compounds tentatively assigned to lipid conjugates of metabolites contributed to 4.1–8.5% of the TRR in fat.

### *Laying hens*

Laying hens were dosed orally, once a day for a total of seven days, with Pyr- or Qn-label pyrifluquinazon at doses equivalent to 14 ppm in the diet. Sacrifice was at 22 hours after the last dose which is longer than commercial feed curfews of 8–12 hours prior to slaughter.

Excretion of pyrifluquinazon was fast, with 63% AD (Pyr-label) and 77% AD (Qn-label) found in the excreta by 22 hours after the last dose.

TRR for the Pyr-label were highest in liver (6.4 mg eq/kg), followed by muscle (1.0 mg eq/kg), fat (0.16 mg eq/kg) and eggs (0.32 mg eq/kg). TRR for the Qn-label were greatest in liver (2.3 mg eq/kg), fat (0.38 mg eq/kg) and muscle (0.30 mg eq/kg) with residues in eggs rising to 1.6 mg eq/kg. Residues in eggs from both labels continued to increase throughout the collection period.

Extractability of  $^{14}\text{C}$  with solvents was good at 62–88% for liver (acetonitrile/water, acetonitrile), 82–91% for muscle (acetonitrile/water, acetonitrile), 86–98% for fat (acetone/hexane, acetone) and > 43–88% for eggs (acetonitrile/water, acetonitrile).

Parent pyrifluquinazon was not detected in tissues or eggs.

The major components in Pyr-label eggs were nicotinamide (IV-404) (25% TRR) and 1H-4-oxo (IV-15) (3.2% TRR). Other residues in Pyr-label eggs released by treatment with KOH are thought to be associated with fatty acids (27% TRR). Quinazolinedione (IV-203) (35% TRR), and aminoquinazolinone-N-Ac (IV-208) (50% TRR) were the major residues found in Qn-label eggs.

Additional quinazolidione (IV-203) (2.4% TRR) was released after treatment of Qn-label PES with KOH.

The major residues in Pyr-label liver were nicotinamide (IV-404) (82% TRR), and 1H-4-oxo (IV-15) (4.1% TRR). 1H-4-oxo (IV-15) was also found in Qn-label liver (11% TRR) as was quinazolidione (IV-203) (25% TRR), aminoquinazolinone-N-Ac (IV-208) (15% TRR), and two polar unknowns (3.6 and 4.6% TRR) that were unique to the Qn-label. Treatment of PES with strong base and acid released additional  $^{14}\text{C}$  thought to be associated with fatty acids (7.2% TRR).

The major components in Pyr-label breast and thigh muscle was nicotinamide (IV-404) (73–74% TRR). Nicotinic acid (IV-403) was also found in breast muscle (1.5% TRR) but not in thigh muscle. Quinazolidione (IV-203) (38–48% TRR) and aminoquinazolinone-N-Ac (IV-208) (27–35% TRR) were the major residues identified in the Qn-label muscles.

In Pyr-label fat, nicotinamide (IV-404) (64% TRR) was the major component. Lipid conjugates of metabolites contributed to 17% of the TRR in fat. Base saponification of these lipid conjugates released residues that showed similar properties to fatty acids. The major components in Qn-label fat were quinazolidione (IV-203) (75% TRR), and aminoquinazolinone-N-Ac (IV-208) (18% TRR).

The metabolism of pyrifluquinazon was similar in plants, livestock, rats, and in the environment. The primary metabolic pathway for pyrifluquinazon involves initial deacetylation at the 1-position of the quinazolinone ring, yielding metabolite IV-01. Subsequent cleavage of the N-N bond yields quinazolinone-ring metabolites (such as IV-206, IV-208, and IV-203) and nicotinic acid (IV-403), a naturally occurring compound that can be incorporated into biosynthetic pathways. Metabolite IV-01 also undergoes oxidation at the 4-position of the quinazolinone ring to yield metabolite IV-15, or at the 1-position of the pyridine ring to yield metabolite IV-03. In addition, dehydrogenation of the amino group in metabolites IV-01 and IV-03 yields the respective 1H-imino metabolites IV-02 (plants and in the environment) and IV-04.

In plants, pyrifluquinazon also undergoes acetyl group disproportionation (intra- and intermolecular trans-acetylation), yielding minor metabolites IV-101 and IV-17.

In livestock, several of the metabolites (primarily IV-01 and IV-15) also form glucuronic acid conjugates, which are major residues in liver and kidney. Further environmental degradation yields IV-15, IV-02, IV-27, and IV-28.

### **Methods of analysis**

The Meeting received information on analytical methods for pyrifluquinazon in plant and animal matrices.

An important consideration for the analysis of pyrifluquinazon and metabolites is that samples must be kept in the frozen state until addition of the extraction solvent. To achieve this samples are generally homogenised in the presence of dry ice.

The methods all involve homogenisation followed by extraction with an organic/aqueous solvent mixture, typically acidified acetonitrile. In plant commodities, pyrifluquinazon and IV-01 (or IV-203 for rotational crops) are the analytes determined while in animal commodities in addition to pyrifluquinazon, IV-01, IV-03, IV-04, IV-15, IV-203 and IV-208 may also be determined. For liver and kidney conjugates of IV-01 and IV-15 are also determined as the method employs a hydrolysis step with  $\beta$ -glucuronidase. Quantification is by LC-MS/MS. The LOQs for plant commodities are typically 0.01–0.05 mg/kg for pyrifluquinazon and IV-01 while for animal commodities they are 0.01 mg/kg for tissues and 0.005 mg/kg for milk for the individual compounds. The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure pyrifluquinazon and metabolites in plant and animal commodities.

A validated multiresidue method was not available to the Meeting.

### ***Stability of pesticide residues in stored analytical samples***

The Meeting received information on storage stability of pyrifluquinazon and IV-01 in raw/processed plant commodities.

Storage stability studies showed that pyrifluquinazon is stable from 31 to up to 377 days when stored at -20 °C in crop commodities representative of the high water, at least 158 days for high acid, up to 67 days for high starch, and up to 163 days for high oil commodity groups. There was considerable variability in the demonstrated storage intervals between different commodities.

1H (IV-01) was not stable in cauliflower and tomato but was stable from up to 31 to 377 days at -20 °C in crop commodities (other than cauliflower, tomato) representative of the high water, up to 158 days for high acid, not stable for high starch, and at least 366 days for high oil commodity groups.

The storage stability of degradate IV-203 was also studied and was stable for at least 67 days in radish root, 81 days in lettuce and 93 days in sorghum grain.

The Meeting agreed that the demonstrated storage stability on various representative plant and animal commodities generally covered the residue sample storage intervals used in the field trials considered by the current Meeting.

### ***Definition of the residue***

#### ***Plant commodities***

The metabolism of pyrifluquinazon was similar in the submitted three plant metabolism studies (radish, lettuce, and tomato).

Parent pyrifluquinazon was a major component seen in all samples (radish root 9.2–31% TRR; radish leaves 49–71% TRR; lettuce heads 3.0–71% TRR, lettuce outer leaves 65–82% TRR; tomato fruit 42–72% TRR). IV-01 was also a significant component of the residue in all samples (radish leaves 2.0–18% TRR; radish roots 4.1–24% TRR; lettuce heads 13–82% TRR, lettuce outer leaves 2.3–21% TRR; tomato fruit 2.4–11% TRR).

Further metabolites were detected but at low levels (< 10% TRR): 1H-imino (IV-02), 1H-oxide (IV-03), 1H-imino-oxide (IV-04), 1H-4-oxo (IV-15), quinazolinone (IV-203), quinazolinone (IV-206) and imino (IV-102).

With the exception of IV-203, residues derived from pyrifluquinazon are unlikely to occur in rotational (follow) crops.

Pyrifluquinazon and IV-01 are the most significant residues in all commodities and validated analytical methods are available for their determination. In field trials IV-01 was sometimes present at higher levels than pyrifluquinazon or the only residue detected.

The Meeting decided that the residue definition for compliance with MRLs in plants should be the sum of pyrifluquinazon and IV-01 (expressed as pyrifluquinazon).

In deciding which additional compounds should be included in the residue definition for risk assessment the Meeting considered the likely occurrence of the compounds present at 10% TRR of pyrifluquinazon, or for the sum of pyrifluquinazon and IV-01, and the toxicological properties of the candidates. Compounds considered are IV-01, IV-02 and IV-203.

Metabolite IV-01 is an intermediate in the metabolic pathway leading to the formation of rat metabolites IV-211 and IV-27 that occur at more than 10% in the rat metabolism study. Therefore, the toxicity of IV-01 is considered to be covered by that of pyrifluquinazon. In view of the absence of repeated dose toxicity studies with IV-02 no conclusion could be drawn on the toxicity of this metabolite. For chronic toxicity the TTC approach (Cramer class III) could be applied as a reverse mutation test on bacteria (Ames tests) was negative for this metabolite.



Metabolite IV-203 is an intermediate in the metabolic pathway leading to the formation of rat metabolites IV-211 and IV-303 that occur at more than 10% in the rat metabolism study. Therefore, the toxicity of IV-203 is considered to be covered by that of pyrifluquinazon.

IV-02 was only a significant metabolite in a Qn-label radish root sample at 14 DALA where it represented 20% of the  $^{14}\text{C}$  attributed to the sum of pyrifluquinazon and IV-01. However, the absolute level present was only 0.0025 mg eq/kg.

IV-203 is present at low levels in tomato (0.31–4.5% TRR), lettuce (0.04–1.6% TRR), radish leaves (0.27–1.2% TRR) and radish roots (0.37–3.9% TRR). The contribution of IV-203 from rotational crops would be low compared to direct treatment and also in comparison to residues of pyrifluquinazon and IV-01.

The Meeting agreed it was not necessary to include IV-02 and IV-203 in the residue definition and that the residue definition for dietary risk assessment should be the sum of pyrifluquinazon and IV-01 (expressed as pyrifluquinazon).

### *Animal commodities*

Regarding the residue definition for livestock commodities, the metabolism of pyrifluquinazon in lactating goats and laying hens was qualitatively similar. In the hen metabolism study, birds were slaughtered at 21–22 hours after the last dose compared to commercial practice of 8–12 hours after last feeding. Residues of pyrifluquinazon per se were not found in the metabolism or livestock feeding studies. Rather, the predominant residue in the lactating goat and laying hen metabolism studies was nicotinamide IV-404 (goat: muscle 68–74%, fat 46–79%, kidney 74%, liver 68%; hen: eggs 25%, muscle 73–74%, fat 64%, liver 82%). IV-404 is a vitamin and also a precursor to nicotinamide adenine dinucleotide (NAD) and unlikely to be a compound unique to pyrifluquinazon. IV-404 and other related compounds (IV-402, IV-403, IV-405 and nicotinic acid N-oxide) are not suitable for monitoring compliance.

IV-203 is present in milk (8.4% TRR skim milk, 20% TRR milk fat), eggs (32% TRR) and all tissues in the lactating goat (53–58% TRR fat, 51–57% TRR muscle, 31% TRR kidney, 8.4% TRR liver) and laying hen (75% TRR fat, 38–48% TRR muscle, 25% TRR liver) metabolism studies and would be suitable for monitoring compliance. However, in the lactating cow feeding study the only compounds detected in any tissue were IV-01 in liver and kidney and IV-203 in liver, while IV-04 was the only compound detected in milk. IV-01 and its glucuronide conjugates comprised 8.5–44.5% TRR in kidney and liver.

Methods are available for the determination of pyrifluquinazon, IV-01 and IV-203 in tissues. The method includes a  $\beta$ -glucuronidase hydrolysis step for liver and kidney and therefore determines free and conjugated forms of the metabolites in these tissues. Methods are available for the determination of pyrifluquinazon, IV-04 and IV-203 in milk.

The Meeting agreed the residue for compliance monitoring for tissues and eggs should be the sum of IV-01 (free and conjugated) and IV-203 (free and conjugated) (expressed as pyrifluquinazon). The Meeting agreed the residue definition for compliance monitoring for milk should be IV-04 (expressed as pyrifluquinazon).

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 nicotinamide IV-404, IV-01 (free and conjugated), IV-03, IV-04, IV-15, IV-17, IV-203 and IV-208.

The nicotinamide IV-404 while the predominant residue in all matrices is not toxicologically significant and the contribution to dietary exposure from natural sources is much greater than from pesticide use. The residues related to pyrifluquinazon of significance were (%TRR):

IV-01 (goat: milk 0.4%, fat 0–1.9%, kidney 8.5–29%, liver 17–45%) for kidney and liver includes glucuronide conjugates;

IV-03 (goat: milk 2.4–4.5%, muscle 3.1–3.4%, kidney 10%, liver 1.8%; hen liver 1.5%);

IV-04 (goat: milk 50–70%);

IV-15 (goat: kidney 0.1–0.4, liver 4%; hen: eggs 3.2%, liver 4.1–11%);

IV-17 (goat: fat 4.3%);

IV-203 (goat: milk 16%, muscle 51–57%, fat 53–58%, kidney 31%, liver 8.4%; hen: eggs 32%, muscle 38–48%, fat 75%, liver 25%);

IV-208 (milk 2.6%, muscle 12–15%, fat 6.1–10%, kidney 8%, liver 1.7%; hen: eggs 50%, muscle 27%, fat 18%).

The metabolites IV-01, and IV-203 are intermediates in the metabolic pathway leading to the formation of rat metabolites IV-211, IV-27 and/or IV-303 that occur at more than 10% in the rat metabolism study. Therefore, the toxicity of IV-01 and IV-203 is considered to be covered by that of pyrifluquinazon.

In view of the absence of repeated dose toxicity studies with IV-03, IV-04, IV-15, IV-17 and IV-208, no conclusion could be drawn on the toxicity of these metabolites. For the metabolites IV-17 and IV-208 the TTC approach (Cramer class III) could be applied for chronic toxicity, as reverse mutation tests on bacteria (Ames tests) were negative for these substances. For the metabolites IV-03, IV-04 and IV-15 the TTC for genotoxicity could be applied for chronic toxicity.

The predominant residues in milk are IV-04 accounting for over 70% of the residues structurally related to pyrifluquinazon. IV-04 was the only residue detected in milk in the lactating cow feeding study.

IV-203 forms the major proportion (> 75%) of the residue related to pyrifluquinazon in goat fat and muscle and chicken fat while for goat kidney, chicken eggs, chicken muscle and chicken liver IV-203 and IV-208 comprise the major proportion (> 75%).

In goat liver, IV-01, and IV-203 account for 89% of the pyrifluquinazon related residues. However as noted above, IV-01 and IV-203 out of pyrifluquinazon, IV-01 and IV-203 was detected in liver or kidney in the lactating cow feeding study.

The Meeting applied the TTC approach to assess IV-02, IV-03, IV-04, IV-15, IV-17 and IV-208. To estimate metabolite concentrations the Meeting utilized the highest ratios of metabolite to the sum of pyrifluquinazon and IV-01 observed in the plant metabolism studies at intervals after the last application relevant to the crops considered by the Meeting to derive factors for fruit, root vegetables and potato.

The maximum long-term (daily) exposures were estimated as 0.03 µg/kg bw for IV-02, 0.49 µg/kg bw for IV-17 and 0 µg/kg bw for IV-208, and are all below the TTC of 1.5 µg/kg bw per day for Cramer Class III compounds. The Meeting concluded that IV-02, IV-17 and IV-208 are unlikely to present a public health concern from the uses evaluated by the current Meeting.

However, the maximum long-term (daily) exposures were estimated as 0.022 µg/kg bw for IV-03, 0.0033 µg/kg bw for IV-04 and 0.017 µg/kg bw for IV-15, and are all above the TTC of 0.0025 µg/kg bw per day for compounds that are potential DNA-reactive mutagens and/or carcinogens. Because the Meeting was unable to conclude on the toxicological relevance of the metabolites IV-03, IV-04 and IV-15, the Meeting could not reach a conclusion on a residue definition for dietary risk assessment.

The Meeting recommended the following residue definitions for pyrifluquinazon:

Definition of the residue for compliance with the MRL for plant commodities: sum of *pyrifluquinazon and IV-01 expressed as pyrifluquinazon*.

Definition of the residue for dietary risk assessment for plant commodities: sum of *pyrifluquinazon and IV-01 expressed as pyrifluquinazon*.

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

Tissues: sum of IV-01 (free and conjugated) and IV-203 (free and conjugated) (expressed as pyriproxyfen).

Milk: IV-04 (expressed as pyriproxyfen).

In deciding whether the residue for compliance monitoring is regarded as fat-soluble, the Meeting noted that residues according to the compliance residue definitions were 0.08–0.09 mg/kg in muscle and 0.11–0.13 mg/kg in fat while residues in skim milk were 0.67 mg/kg and in milk fat 1.0 mg/kg. The Meeting considers the residue should not be classified as fat-soluble.

Definition of the residue for dietary risk assessment for animal commodities: *a conclusion could not be reached.*

**Results of supervised residue trials on crops**

Supervised trials were available for the use of pyriproxyfen on stone fruit, potatoes, tree nuts and tea.

Product labels were available from Japan and the USA.

In trials on potatoes and tree nuts, parent pyriproxyfen and 1H (IV-01) were analysed but found at levels below the LOQ (parent, IV-01). In metabolism studies and residue trials on other crops, pyriproxyfen and 1H (IV-01) are often found at similar levels. The Meeting decided when residues were <LOQ to add the LOQs.

When calculating the sum of pyriproxyfen and IV-01, values below the LOQ were assumed to be at the LOQ. Examples are shown below

Table 2 Examples for calculating the sum of pyriproxyfen and IV-01

Pyriproxyfen (mg/kg)	IV-01 (mg/kg)	Sum (mg/kg)
< 0.01	< 0.01	< 0.02
< 0.01	0.02	< 0.03
0.02	0.02	0.04

**Stone fruit**

The GAP for pyriproxyfen on stone fruit in the USA is applications at 39–53 g ai/ha with a minimum interval between sprays of 7 days, a maximum annual rate of 78 g ai/ha and a PHI of 7 days. The Meeting considered critical GAP to be two sprays, the first at 25 g ai/ha and the second at 53 g ai/ha.

No trials on cherries or peaches from the USA matched the critical GAP for the USA.

In seven trials on plums conducted in the USA, at exaggerated rates compared to critical GAP in the USA, where three applications were made at 50 g ai/ha at 7 day intervals, residues at harvest 7 days after the last application were: < 0.02 (6) mg/kg. In some trials, residues were above the LOD but below the LOQ.

The Meeting estimated a maximum residue level of 0.02(\*) mg/kg, a STMR of 0.02 mg/kg and a HR of 0.02 mg/kg for pyriproxyfen (total) in the sub-group of plums.

**Tuberous and corm vegetables**

In the USA, critical GAP for pyriproxyfen on tuberous and corm vegetables is 2 × 53 g ai/ha with a minimum interval between sprays of 14 days, a maximum annual rate of 105 g ai/ha and a PHI of 14 days.

In fifteen trials on potatoes from the USA conducted at exaggerated rates (3 × 100 g ai/ha at 14 day intervals) residues at harvest 14 days after the last application were: < 0.02 (15) mg/kg.

In storage stability trials on potato, IV-01 levels declined such that only 64% remained after one month of freezer storage and thereafter was relatively stable with 55 to 69% remaining at freezer storage intervals up to one year. The Meeting agreed that considering the exaggerated application rate in the residue trials and a potential decline of residues by 31 to 45%, it can be concluded that residues of IV-01 would have been detected if present and that residues of IV-01 above the LOQ are not expected in trials conducted according to GAP.

Potatoes are a representative commodity for the subgroup tuberous and corm vegetables and the Meeting estimated a maximum residue level of 0.02(\*) mg/kg, a STMR of 0.02 mg/kg and a HR of 0.02 mg/kg for pyrifluquinazon (total) in the subgroup tuberous and corn vegetables based on data for potatoes.

### *Tree nuts*

The Meeting received supervised residue trials conducted in the USA on tree nuts. The GAP for pyrifluquinazon on tree nuts in the USA is applications at 39–53 g ai/ha with a minimum interval between sprays of 7 days, a maximum annual rate of 78 g ai/ha and a PHI of 7 days. The Meeting considered critical GAP to be two sprays, the first at 25 g ai/ha and the second at 53 g ai/ha.

In five trials on almonds and five trials on pecans conducted at exaggerated rates ( $3 \times 100$  g ai/ha at 7 day intervals) residues at harvest 7 days after the last application were: < 0.02 (10) mg/kg. In some trials, residues were above the LOD but below the LOQ.

Almond and pecans are representative crops for tree nuts and the Meeting estimated a maximum residue level of 0.02(\*) mg/kg, an STMR of 0.02 mg/kg and an HR of 0.02 mg/kg for pyrifluquinazon (total) in tree nuts.

### *Tea, Green, Black (black, fermented and dried)*

The Meeting received supervised residue trials conducted in Japan on green tea. In Japan, critical GAP for pyrifluquinazon on tea is 10 g ai/hL with a PHI of 7 days. In six trials approximating cGAP in Japan, residues in green tea (dry) were: 1.2, 2.5, 5.1, 5.7, 6.1 and 14 mg/kg.

The Meeting estimated a maximum residue level of 30 mg/kg and a STMR of 5.4 mg/kg for pyrifluquinazon (total) in tea green, black (black, fermented and dried).

## **Residues in animal feeds**

### *Almond hulls*

The Meeting received supervised residue trials on almonds. The GAP for pyrifluquinazon on tree nuts in the USA is applications at 39–53 g ai/ha with a minimum interval between sprays of 7 days, a maximum annual rate of 78 g ai/ha and a PHI of 7 days. The Meeting considered critical GAP to be two sprays, the first at 25 g ai/ha and the second at 53 g ai/ha.

None of the trials matched critical GAP.

### **Fate of residues during processing**

The Meeting received information on the fate of pyrifluquinazon residues during processing in plums, potatoes and infusions of green tea. For potatoes no residues were detected in the RAC or processed commodities. No hydrolysis study simulating processing was made available to the Meeting.

Table 3 Estimated processing factors for the commodities considered at this Meeting are summarized

below (residues are for total pyriproxyfen).

Processed commodity	Raw commodity [STMR/HR]	Individual processing factors	Mean or best estimate processing factor	STMR-P = STMR <sub>RAC</sub> × PF (mg/kg)	HR-P = HR <sub>RAC</sub> × PF (mg/kg)
Prune	0.02	1.5	1.5	0.03	0.03
Green tea infusion	5.4	0.0018 0.0026	0.0022	0.012	

Using the estimated maximum residue level of 0.02\* mg/kg for plums and applying the processing factor of 1.5, the Meeting estimated a maximum residue level of 0.03 mg/kg for pyriproxyfen (total) in prunes.

**Residues in animal commodities**

**Farm animal feeding studies**

The Meeting received information on the residue levels in tissues and milk of dairy cows dosed with pyriproxyfen at the equivalent of 0.5, 1.5 and 5.1 ppm in the feed for 28 consecutive days.

In milk, residues of pyriproxyfen, IV-04 and IV-203 were measured. No residues of pyriproxyfen or IV-203 above the LOQ of 0.005 mg/kg were detected in any sample. In the 5.1 ppm group residues of IV-04 were detected between 0.005 and 0.008 mg/kg. No residues of pyriproxyfen or IV-04 or IV-203 were detected in skim milk above the LOQ. In cream samples all residues were < LOQ, apart from the day 13 and 28 samples of cream in the highest treatment group (5.1 ppm diet), which were detected at 0.005 mg/kg.

In tissues, residues of pyriproxyfen, IV-01, IV-03, IV-15, IV-203 and IV-208 were measured. The only residues detected were IV-01 in liver, at mean levels of < 0.011 (max 0.013), 0.026 (max 0.034) and 0.062 (max 0.074) mg/kg for the 0.5, 1.5 and 5.1 ppm dose groups respectively, IV-01 in kidney of the 5.1 ppm dose group at a mean level of < 0.01 (max 0.01) mg/kg and IV-203 in liver of the 5.1 ppm dose group at a mean level of 0.011 (max 0.013) mg/kg.

A laying hens transfer study was not made available to the Meeting.

**Farm animal dietary burden**

Potato processing waste was used in estimating livestock dietary burdens.

Dietary burdens were calculated for beef cattle, dairy cattle, broilers and laying poultry based on feed items evaluated by the current Meeting. As there were no feed items relevant to poultry, dietary burdens for poultry are not calculated. 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 summarised below.

Table 4 Estimated maximum and mean dietary burdens of farm animals

	Animal dietary burden: pyriproxyfen (total), ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	max	Mean	max	Mean	max	Mean	max	Mean
<b>Beef cattle</b>	0.08	0.08	0.0967 <sup>a</sup>	0.0967 <sup>c</sup>	0.0183	0.0183		
<b>Dairy cattle</b>	0.027	0.027	0.08 <sup>b</sup>	0.08 <sup>d</sup>	0.01	0.01		

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

<sup>c</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

<sup>d</sup> Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

**Animal commodity maximum residue levels****Cattle**

The calculations used to estimate highest total residues for use in estimating maximum residue levels are shown below.

Table 5 Calculations used to estimate highest total residues for use in estimating maximum residue levels

	Feed Level (ppm) for milk residues	Total residues (mg equiv/kg) in milk	Feed Level (ppm) for tissue residues	Total residues (mg equiv/kg)			
				Muscle	Liver	Kidney	Fat
<b>Highest residue determination (beef or dairy cattle)</b>							
<b>Feeding Study</b>	0.5	< 0.005	0.5	< 0.03	< 0.03	< 0.03	< 0.03
<b>Dietary burden and estimate of highest residue</b>	0.08	< 0.005	0.0967	< 0.03	< 0.03	< 0.03	< 0.03

The Meeting estimated the following maximum residue levels: milk 0.005(\*) mg/kg; meat (mammalian except marine mammals) 0.03(\*) mg/kg, mammalian fat (except milk fat) 0.03(\*) mg/kg and edible offal 0.03(\*) mg/kg.

No feed items relevant to poultry were considered by the current Meeting and therefore there was no dietary burden for poultry. The Meeting estimated the following maximum residue levels for poultry commodities: eggs, poultry meat, poultry edible offal and poultry fat 0.03(\*) mg/kg.

**RECOMMENDATIONS**

The Meeting concluded on the following residue definitions.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: sum of pyrifluquinazon and 1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-01) expressed as pyrifluquinazon.

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

Tissues: sum of 1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-01) and 1,2,3,4-tetrahydro-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2,4-dione (IV-203) and their conjugates (expressed as pyrifluquinazon)

Milk: 1,2,3,4-tetrahydro-3-[3-(1-oxy-pyridylmethylene)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-04) (expressed as pyrifluquinazon).

The residue is not fat-soluble.

Definition of the residue for dietary risk assessment for animal commodities: *a conclusion could not be reached.*

**Desirable**

Data to clarify potential for residues of IV-203 and its conjugates in rotational Brassica leafy vegetable and cereal (forages, fodder, grain) crops.

**DIETARY RISK ASSESSMENT**

Because the Meeting was unable to conclude on the toxicological relevance of the metabolites IV-03, IV-04 and IV-15, the Meeting could not reach a conclusion on a residue definition for dietary risk assessment.

As a result long-term and acute dietary risk assessments could not be conducted.





## 5.23 Pyriofenone (310)

### RESIDUE AND ANALYTICAL ASPECTS

Pyriofenone was first evaluated for toxicology and residues by the JMPR in 2018. An acceptable daily intake (ADI) of 0–0.09 mg/kg bw was established. An acute reference dose (ARfD) was considered unnecessary. The residue definition for compliance with the MRL and dietary risk assessment for plant and animal commodities is: *Pyriofenone*. The 2018 Meeting considered that information was insufficient for determining fat solubility of pyriofenone in commodities of animal origin. The 2018 Meeting indicated that it may revisit the definition of the residue for animal commodities when information on the analytical method(s) for animal commodities becomes available.

Pyriofenone was scheduled at the Fiftieth Session of the CCPR (2018) for evaluation of additional uses by the 2019 JMPR. The Meeting received additional analytical methods on plant and animal matrices, storage stability studies, GAP information and supervised residue trials for uses on tomatoes and peppers and processing data for tomatoes.

#### **Methods of analysis**

The Meeting received additional validation data for lettuce, peppers, tomatoes and tomato processed commodities for LC-MS/MS method ISK0341, which was already evaluated by the 2018 JMPR.

Furthermore, the Meeting received an analytical method for the determination of pyriofenone in liver, kidney, muscle, fat, milk and eggs. The method employed extraction with acetonitrile:water:hydrochloric acid (50:50:1, v:v:v) and clean-up with solid phase extraction. The resulting extract was analysed by LC-MS/MS with an LOQ of 0.01 mg/kg.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure pyriofenone in the matrices indicated.

#### **Stability of pesticide residues in stored analytical samples**

The Meeting received additional information on storage stability of pyriofenone in lettuce, tomato, tomato puree, tomato paste, tomato juice and tomato wet and dry pomace, demonstrating a storage stability of at least 18 months at -10 °C.

The Meeting agreed that the demonstrated storage stability on lettuce, tomatoes and tomato processed commodities covered the residue sample storage intervals used in the field trials and processing studies considered by the current Meeting.

#### **Definition of the residue for animal commodities**

The Meeting noted that a sufficiently validated analytical method was available for the analysis of parent pyriofenone in animal tissues, milk and eggs. The Meeting confirmed its conclusion from the 2018 Meeting that pyriofenone is a suitable marker for enforcement of MRLs and for dietary risk assessment for commodities of animal origin. Should the livestock dietary burden increase for ruminants or a dietary burden for poultry be required for pyriofenone, the Meeting may revisit the residue definition for dietary risk assessment.

#### **Results of supervised residue trials on crops**

The Meeting received additional supervised trials for the use of pyriofenone on tomatoes and peppers. Product labels were available from the USA.

#### **Fruiting vegetables other than cucurbits**

Pyriofenone is registered in the USA for use on fruiting vegetables. The critical GAP is a maximum of 0.35 kg ai/ha per year with a maximum of 0.11 kg ai/ha per application and a minimum re-treatment

interval of 7 days and a 0-day PHI. This leads to a critical GAP of 3 applications at 0.11 kg ai/ha, with a minimum re-treatment interval of 7 days and a PHI of 0 days.

Trials were conducted in the USA on tomatoes and peppers. None of these trials matched the critical GAP, since all trials were conducted at a lower dose rate of 0.090 kg ai/ha and a higher number of applications (4 applications). The Meeting was unable to estimate maximum residue levels for tomatoes and peppers.

### ***Fate of residues during processing***

The Meeting received new information on the fate of pyriofenone residues during the processing of tomatoes into juice, puree and paste. The preliminary results suggest that concentration of pyriofenone occurs in tomato wet and dry pomace, while no concentration occurs in tomato juice, tomato puree and tomato paste.

### ***Residues in animal products***

#### ***Feeding studies***

No feeding studies were received by the 2018 or 2019 Meetings. The Meeting decided to use the lactating goat metabolism study evaluated by the 2018 Meeting.

In this metabolism study a lactating goat received a dose equivalent to 10 ppm in the diet (nominal; actual levels were 7.8–13 ppm) for five consecutive days. Total radioactive residues (TRR) in milk reached a plateau concentration of 0.004 mg eq/kg after the third day of dosing. The goat was slaughtered 23 hours after the last dose. Parent compound was found at 0.005–0.007 mg/kg in liver and 0.001–0.002 mg/kg in kidney. TRR in milk, muscle and fat were all at or below 0.004 mg eq/kg and were not further characterized.

#### ***Estimation of livestock dietary burdens***

A maximum dietary burden of 0.61 ppm for beef and dairy cattle was estimated by the 2018 JMPR. As no maximum residue levels were estimated for plant commodities at the current Meeting, the dietary burden remains unchanged.

#### ***Animal commodities maximum residue levels***

As a valid analytical method on animal commodities is available, the Meeting decided to estimate maximum residue levels for animal commodities.

Based on the goat metabolism study, parent pyriofenone is not expected above the LOQ of 0.01 mg/kg in mammalian tissues or milk at a maximum dietary burden of 0.61 ppm. The Meeting recommended maximum residue levels of 0.01(\*) mg/kg and STMRs of 0 mg/kg in mammalian meat (muscle, fat), mammalian fat, mammalian edible offal and milk.

Since poultry is not exposed and residues of pyriofenone are not expected in eggs and poultry tissues, the Meeting recommended maximum residue levels of 0.01(\*) mg/kg in eggs, poultry meat (muscle, fat), poultry fat and poultry edible offal with STMRs of 0 mg/kg in eggs, poultry meat (muscle, fat), poultry fat and poultry edible offal.

## **RECOMMENDATIONS**

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

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

**DIETARY RISK ASSESSMENT*****Long-term dietary exposure***

The 2018 JMPR established an ADI for pyriofenone of 0–0.09 mg/kg bw and estimated International Estimated Daily Intakes (IEDIs) for pyriofenone ranging from 0–0.5% of the maximum ADI. As no maximum residue levels were recommended for plant commodities at the current Meeting and there is no contribution from animal commodities, the IEDIs remain unchanged. The Meeting concluded that the long-term dietary exposure to residues of pyriofenone from uses considered by the JMPR is unlikely to present a public health concern.

***Acute dietary exposure***

The 2018 JMPR decided that an ARfD for pyriofenone was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of pyriofenone from the uses considered is unlikely to present a public health concern.



## 5.24 Pyriproxyfen (200)

### RESIDUE AND ANALYTICAL ASPECTS

Pyriproxyfen is classified as a juvenile hormone mimic that interferes with normal insect development and reproduction. Metamorphosis of immature life stages is affected, but adults are not directly controlled, although production of viable eggs is affected by transovarial activity. Pyriproxyfen is absorbed through the insect cuticle but may also act by ingestion.

Pyriproxyfen was first evaluated by the JMPR in 1999 and then in 2000 and 2001. In the 1999 evaluation for toxicity and residues an ADI of 0–0.1 mg/kg bw was established. The Meeting concluded that it was not necessary to establish an ARfD due to the low acute toxicity of pyriproxyfen.

The 1999 JMPR recommended the following residue definition for pyriproxyfen:

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

The residue is fat-soluble.

At the 2018 JMPR, where new uses of pyriproxyfen were evaluated, the Meeting considered the banana and mango trials approximating the critical GAPs insufficient to estimate maximum residue levels.

Pyriproxyfen was scheduled by the fiftieth session of the CCPR for the reassessment of the banana and mango trials reviewed in 2018 against new GAP information, for bananas from Costa Rica and for mangoes from Malaysia, received by the current Meeting.

#### **Results of supervised residue trials on crops**

##### **Banana**

The critical GAP for bananas is in Costa Rica with four foliar sprays of 0.12 kg ai/ha/application with a 20-day re-treatment interval (RTI) and a PHI of 0 days.

As none of the trials conducted in Costa Rica and Guatemala reflected the critical GAP, in regards to application rate and number of applications, and the proportionality approach could not be considered, the Meeting was unable to estimate a maximum residue level or STMR for banana.

##### **Mango**

The critical GAP for mangoes is in Malaysia with two foliar sprays of 0.005 kg ai/hL/application with a 2-week RTI and a PHI of 14 days.

Residues of parent pyriproxyfen in whole mango fruits treated in accordance with the critical GAP were (n = 6): < 0.02 mg/kg.

The Meeting estimated a maximum residue level of 0.02(\*) mg/kg and a STMR of 0.02 mg/kg.

#### **Residues in animal commodities**

The Meeting noted that no commodities considered by the current Meeting are relevant for livestock animal feeding.

### 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 and dietary risk assessment for plant and animal commodities: *pyriproxyfen*

The residue is fat-soluble.

## DIETARY RISK ASSESSMENT

### ***Long-term dietary exposure***

The ADI for pyriproxyfen is 0–0.1 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for pyriproxyfen 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 2019 Extraordinary JMPR Report.

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

### ***Acute dietary exposure***

The 1999 JMPR decided that an ARfD for pyriproxyfen was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of pyriproxyfen from the uses considered is unlikely to present a public health concern.

## 5.25 Spices – Pesticide residues

### RESIDUE AND ANALYTICAL ASPECTS

The Thirty-sixth Session of CCPR decided to schedule the JMPR to review the monitoring data available for the elaboration of MRLs on spices for pesticides already in the Codex system. The Committee also recommended that governments and the spice trade industry continue to collect monitoring data for pesticides on spices on a regular basis, following agreed criteria and other JMPR guidelines on the conduct of selective surveys, in order to keep the database updated for future review.

General principles for the evaluation of monitoring data for recommending maximum residue levels, median and high residues for spices were developed by the JMPR in 2004.

The Fiftieth Session of the CCPR scheduled the evaluation of monitoring data in support of maximum residue levels in spices by the 2019 JMPR. India submitted monitoring data for the following spices: black pepper, cardamom, cumin, dried ginger, fennel seeds and fenugreek seeds. Monitoring data were also provided for curry leaves and dried chilli pepper.

#### ***Sampling and residues analysis***

Samples were collected from market and retail outlets.

Residues were extracted from the herbs and spices using acetonitrile or a mixture of acetonitrile and water. The extracts were purified with final identification and quantification by GC-MS/MS or LC-MS/MS. For all pesticide/commodity combinations the recovery data were acceptable and the supported LOQ was either 0.01 mg/kg or 0.1 mg/kg.

#### ***Agricultural practices***

The herbs and spices are grown throughout India and are susceptible to a number of pests and diseases. No information was provided on registered uses of the pesticides.

#### ***Principles of evaluation of residues derived from monitoring programmes***

The principles for using monitoring data to derive maximum residue levels are outlined in the FAO manual (Third edition, 2016).

#### ***Analytical results***

For imidacloprid, the residue definition for plants for both compliance with MRLs and for estimation of dietary exposure is the sum of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as imidacloprid. In the monitoring data provided, total residues, converted to the common moiety, were not analysed. The Meeting concluded that as the data did not comply with the residue definitions, it was not sufficient to estimate maximum residue levels.

For propiconazole and trifloxystrobin residues data were only provided in compliance with the residue definition for MRLs and not in accordance with the residue definition for dietary risk assessments. The Meeting noted that for these active/ commodity combinations there were less than 59 samples that contained positive residues. The Meeting also concluded that the LOQ of 0.1 mg/kg validated was higher than the level that can be achieved using current analytical techniques. Consequently, the Meeting decided to not consider the data further.

#### ***Commodities***

##### ***Herbs and dried chili peppers***

Monitoring data were provided for curry leaves and dried chili peppers. The Meeting concluded that maximum residue levels could not be estimated on the basis of monitoring data for these commodities. Further information is outlined in Chapter 2.8 of the 2019 JMPR report.

## Spices

### *Black pepper*

A total of 317 samples were analysed for imidacloprid and only 11 samples contained quantified residues. As the residues determined did not comply with the residue definition (for both compliance with the MRL and dietary risk assessment) and the LOQ validated was 0.1 mg/kg the Meeting decided that the data were not suitable to estimate a maximum residue level.

### *Cardamom*

A total of 320 cardamom samples were analysed. The number of samples containing quantified residues was 15 for fenpropathrin, 12 for metalaxyl and 10 for tebuconazole. The Meeting concluded that the LOQ of 0.1 mg/kg validated was higher than the level that can be achieved using current analytical techniques. Consequently, the Meeting concluded that maximum residue levels at the LOQ could not be estimated.

### *Cumin*

For cumin a total of 357 samples were analysed. The number of samples with quantified residues was 13 for azoxystrobin, 13 for bifenthrin, 14 for carbofuran, 18 for clothianidin, 33 for cypermethrin, 12 for fenpropathrin, 29 for propiconazole, 24 for tebuconazole, 41 for thiamethoxam and 11 for trifloxystrobin. The Meeting concluded that the LOQ of 0.1 mg/kg validated was higher than the level that can be achieved using current analytical techniques. Consequently, the Meeting concluded that maximum residue levels at the LOQ could not be recommended.

### *Acetamiprid*

Cumin samples were analysed for acetamiprid.

Of the 357 samples analysed, 123 samples contained quantified residues. The residues in rank order were:

0.11, 0.12, 0.14, 0.15, 0.16, 0.17, 0.17, 0.19, 0.19, 0.20, 0.20, 0.20, 0.20, 0.22, 0.23, 0.23, 0.23, 0.24, 0.24, 0.24, 0.27, 0.27, 0.30, 0.30, 0.30, 0.30, 0.30, 0.32, 0.32, 0.36, 0.36, 0.37, 0.40, 0.40, 0.40, 0.41, 0.41, 0.42, 0.42, 0.44, 0.44, 0.45, 0.45, 0.45, 0.45, 0.46, 0.46, 0.46, 0.46, 0.48, 0.49, 0.50, 0.50, 0.51, 0.51, 0.52, 0.54, 0.54, 0.54, 0.55, 0.56, **0.57**, 0.58, 0.58, 0.59, 0.60, 0.65, 0.65, 0.65, 0.69, 0.70, 0.70, 0.70, 0.73, 0.74, 0.74, 0.75, 0.79, 0.79, 0.80, 0.81, 0.81, 0.83, 0.83, 0.84, 0.86, 0.90, 0.94, 0.96, 1.00, 1.00, 1.00, 1.01, 1.05, 1.06, 1.08, 1.09, 1.11, 1.11, 1.12, 1.13, 1.13, 1.15, 1.17, 1.23, 1.27, 1.31, 1.31, 1.31, 1.34, 1.40, 1.53, 1.60, 1.63, 1.66, 1.69, 1.70, 1.74, 1.82, 2.00, 2.07 and 2.40 mg/kg

The upper 95% one tailed confidence limit of the 95th percentile of the detected residues is 2 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg and a median residue of 0.57 mg/kg for acetamiprid in cumin. Any of the commodities included in the Subgroup spices, seeds, can be regarded as a representative commodity. The Meeting therefore agreed that the maximum residue level and median residue could be extrapolated to the Subgroup of spices, seeds. The Meeting withdraws its previous recommendation of 0.1 mg/kg for cardamom seeds.

### *Carbendazim*

Residues were reported in cumin samples as the sum of carbendazim, benomyl and thiophanate-methyl expressed as carbendazim.

Of the 357 samples analysed, 172 samples contained quantified residues. The residues in rank order were:

0.12, 0.12, 0.15, 0.15, 0.15, 0.15, 0.16, 0.16, 0.16, 0.16, 0.16, 0.16, 0.17, 0.18, 0.18, 0.19, 0.19, 0.19, 0.20, 0.20, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.21, 0.22, 0.22, 0.22, 0.23, 0.23, 0.23, 0.23, 0.23, 0.23,



0.24, 0.24, 0.24, 0.25, 0.25, 0.25, 0.26, 0.26, 0.27, 0.27, 0.27, 0.27, 0.28, 0.29, 0.30, 0.30, 0.30, 0.31, 0.31, 0.33, 0.34, 0.35, 0.36, 0.36, 0.36, 0.37, 0.38, 0.40, 0.40, 0.41, 0.41, 0.41, 0.41, 0.42, 0.42, 0.42, 0.44, 0.46, 0.46, 0.46, 0.46, 0.47, 0.47, 0.48, 0.48, 0.49, 0.49, 0.50, 0.50, 0.50, 0.52, 0.53, 0.55, 0.55, 0.56, 0.57, 0.57, 0.59, 0.60, 0.63, 0.64, 0.64, 0.65, 0.66, 0.68, 0.70, 0.72, 0.73, 0.73, 0.74, 0.78, 0.80, 0.80, 0.80, 0.81, 0.83, 0.87, 0.87, 0.90, 0.91, 0.91, 0.92, 0.95, 0.95, 0.95, 0.97, 0.99, 0.99, 1.00, 1.00, 1.04, 1.05, 1.07, 1.09, 1.10, 1.11, 1.13, 1.13, 1.13, 1.24, 1.30, 1.30, 1.30, 1.30, 1.32, 1.33, 1.46, 1.54, 1.54, 1.54, 1.64, 1.70, 1.71, 1.83, 1.84, 1.85, 1.90, 2.13, 2.20, 2.31, 2.42, 2.70, 3.40, 3.80, 3.80, 4.00, 4.20, 4.20, 4.50, 4.50, 4.53, 4.56, 4.80, 4.86, 5.01, 5.01, 5.22 mg/kg

The upper 95% one tailed confidence limit of the 95th percentile of the detected residues is 4.86 mg/kg.

The Meeting estimated a maximum residue level of 5 mg/kg and a median residue of 0.525 mg/kg for carbendazim in cumin. Any of the commodities included in the Subgroup spices, seeds, can be regarded as a representative commodity. The Meeting therefore agreed that the maximum residue level and median residue could be extrapolated to the Subgroup of spices, seeds.

#### ***Dried ginger, Fennel seeds and Fenugreek seeds***

For these commodities the number of samples containing quantified residues was less than 59. The Meeting concluded that the LOQ of 0.1 mg/kg validated was higher than the level that can be achieved using current analytical techniques. Consequently, the Meeting concluded that maximum residue levels at the LOQ could not be recommended for these commodities.

### **RECOMMENDATIONS**

On the basis of the monitoring data submitted the Meeting concluded that the residue levels listed in Annex 1 are appropriate for establishing maximum residue levels and for IEDI and IESTI assessments.

### **DIETARY RISK ASSESSMENT**

#### ***Long-term dietary exposure***

For acetamiprid, the ADI is 0–0.07 mg/kg bw and for carbendazim, the ADI is 0–0.03 mg/kg bw.

The International Estimated Daily Intakes (IEDIs) for acetamiprid and carbendazim were estimated for the 17 GEMS/Food Consumption Cluster Diets using the median values estimated by the JMPR for the Subgroup of spices, seeds only. The results are shown in Annex 3 of the 2019 JMPR Report.

For acetamiprid and carbendazim, the contribution of residues in the Subgroup of spices, seeds, to long-term dietary exposures were negligible.

The Meeting concluded that the long-term dietary exposure to residues of acetamiprid and carbendazim resulting from the uses on spices are unlikely to present a public health concern.

#### ***Acute dietary exposure***

For acetamiprid, the ARfD is 0.1 mg/kg bw and carbendazim, the ARfD is 0.5 mg/kg bw for the general population, including children and 0.1 mg/kg bw for women of childbearing age.

The International Estimate of Short Term Intakes (IESTIs) for acetamiprid and carbendazim were calculated for the food commodities and their processed commodities for which median values were estimated by the present Meeting and for which consumption data were available. The results are shown in Annex 4 of the 2019 JMPR Report.

The IESTIs were 0% of the ARfD for acetamiprid and carbendazim.

The Meeting concluded that acute dietary exposure to residues of acetamiprid and carbendazim resulting from the uses on spices are unlikely to present a public health concern.

## 5.26 Tolclofos-methyl (191)

### TOXICOLOGY

Tolclofos-methyl is the ISO-approved common name for *O*-2,6-dichloro-*p*-tolyl *O,O*-dimethyl phosphothioate (IUPAC) with the CAS number 57018-04-9.

Tolclofos-methyl is used for the control of soil-borne fungal diseases of potatoes but may also be used for the treatment of lettuce and other crops. Unlike other organophosphorous pesticides that are used as insecticides, tolclofos-methyl is a fungicide and its pesticidal MOA is via inhibition of phospholipid biosynthesis.

Tolclofos-methyl was last evaluated by JMPR in 1994. At that time, an ADI of 0–0.07 mg/kg bw was established on the basis of reduced brain cholinesterase activity in a two-year study of toxicity and carcinogenicity in mice. New studies submitted since the last JMPR evaluation include *in vitro* comparative metabolism (human and rat microsome), one-generation reproduction toxicity, neurotoxicity, immunotoxicity, phototoxicity, and *in vitro* endocrine toxicity studies.

Tolclofos-methyl was re-evaluated by the present Meeting within the periodic review programme of CCPR. The majority of studies considered by the current Meeting were evaluated during the 1994 JMPR meeting and, where appropriate, the text from the previous monograph has been adopted here verbatim. Some of the critical studies do not comply with GLP, as the data were generated before the implementation of GLP regulations. Overall, however, the database was considered adequate for the risk assessment.

#### **Biochemical aspects**

After oral administration [<sup>14</sup>C-4-methyl]-tolclofos-methyl was rapidly absorbed from the GI tract of mice and rats and was extensively distributed throughout the body.

In mice exposed to a single dose of tolclofos-methyl at 5 mg/kg bw, 74–83% of the administered radiolabel was recovered in urine, faeces, and expired air within the first day of exposure. The major route of excretion was the urine, accounting for 69–76% of the administered dose, while faecal excretion accounted for < 6%.

In a study in rats exposed to a single 5 mg/kg bw dose of [<sup>14</sup>C-4-methyl]-tolclofos-methyl, absorption and elimination was rapid with radioactivity recovery reaching 83% one day after exposure. The majority of the radioactivity was recovered in the urine (> 62%) followed by faeces (> 16%). For most tissues, peak concentration was reached within two hours of administration. The oral absorption was at least 63% within 48 hours. The highest concentration of radioactivity was localized to the kidney (3–5 times higher than plasma and liver). For the remainder of the tissues, radioactivity concentration was < 29% of plasma. By 72 hours post-exposure, < 3% of the administered dose remained in the tissues and carcass.

Tolclofos-methyl undergoes extensive metabolism in mammals, proceeding through a pathway involving stepwise oxidative desulfuration to an oxon and related derivatives, oxidation of the 4-methyl group to alcohols and acids, cleavage of P–O–aryl and P–O–methyl linkages, and conjugation of the resultant acid with glycine. In rats, the major metabolites were Ph-CH<sub>3</sub> (12%) and Ph-COOH (29%). In mice, the major metabolites were Ph-COOH (12%), Ph-CO-glycine (13% ; unique to mice) and DM-TMO-COOH (12%). An *in vitro* metabolism study comparing the metabolic profile of rat microsomes to human microsome preparations, indicated that the rodent and human metabolic pathways are virtually identical with only two unique minor metabolites (< 5% of radioactivity) identified in rat, but not in human microsome preparations.

#### **Toxicological data**

The acute LD<sub>50</sub> of tolclofos-methyl was > 5000 mg/kg bw in rats, > 3500 mg/kg bw in mice and

> 1000 mg/kg bw in dogs. The dermal LD<sub>50</sub> was > 5000 mg/kg bw in rats and mice and > 2000 mg/kg bw in rabbits. The LC<sub>50</sub> for inhalation in rats was > 2.07 mg/L. No signs of ocular irritation were noted. Slight dermal irritation in rabbits was observed at 500 mg/kg bw. There was evidence of dermal sensitization as assessed by the Magnusson and Kligman methodology.

In general, tolclofos-methyl exhibited relatively low toxicity. Body weight decrements, decreases in cholinesterase activity and liver weight changes were the most commonly observed effects.

In a 32–34-day toxicity study in rats exposed to dietary concentrations of 0, 200, 1000, 5000, or 20 000 ppm (equal to 0, 16, 79, 414, and 1635 mg/kg bw per day for males, 0, 18, 88, 452, and 1830 mg/kg bw per day for females), the NOAEL was 1000 ppm, (equal to 79 mg/kg bw per day), on the basis of increased relative kidney weights and reduced brain cholinesterase activity at 5000 ppm, (equal to 414 mg/kg bw per day).

In rats exposed for 13 weeks to tolclofos-methyl at dietary concentrations of 0, 100, 1000 or 10 000 ppm (equal to 0, 6.5, 66 or 653 mg/kg bw per day for males, 0, 7.1, 71 or 696 mg/kg bw per day for females), the NOAEL was 1000 ppm (equal to 66 mg/kg bw per day), based on marginal reduction in erythrocyte cholinesterase activity and changes in clinical chemistry parameters at 10 000 ppm (equal to 653 mg/kg bw per day).

In a 26-week study, dogs were exposed to tolclofos-methyl at dietary concentrations of 0, 200, 600 or 2000 ppm (equal to 0, 7.4, 23 or 69 mg/kg bw per day in males, 0, 4.1, 21 or 65 mg/kg bw per day in females). The NOAEL was 600 ppm (equal to 21 mg/kg bw per day), on the basis of reduced body weight gain at 2000 ppm (equal to 65 mg/kg bw per day).

In a 52-week study, dogs were exposed to tolclofos-methyl at dietary concentrations of 0, 80, 400 or 2000 ppm (equal to 0, 2.2, 11 or 59 mg/kg bw per day for males, 0, 2.6, 11.2, or 62 mg/kg bw per day for females). The NOAEL was 400 ppm (equal to 11 mg/kg bw per day), on the basis of reduced body weight gain at 2000 ppm, equal to 59 mg/kg bw per day.

The overall NOAEL for dogs after short-term exposure was 600 ppm (equal to 21 mg/kg bw per day), on the basis of reduced body weight gain at 2000 ppm (equal to 59 mg/kg bw per day).

In a nine-month study, mice were exposed to tolclofos-methyl at dietary concentrations of 0, 10, 30, 100 or 3000 ppm (equal to 0, 1.2, 3.8, 12 and 510 mg/kg bw per day for males, 0, 1.4, 4.1, 14 and 560 mg/kg bw per day for females), the NOAEL was 100 ppm (equal to 12 mg/kg bw per day), based on decreased body weight as well as decreased erythrocyte and brain cholinesterase activity at 3000 ppm (equal to 510 mg/kg bw per day).

In a 104-week toxicity study, mice were exposed to tolclofos-methyl at dietary concentrations of 0, 10, 50, 250 or 1000 ppm (equal to 0, 1.3, 6.5, 32 and 134 mg/kg bw per day in males, 0, 1.3, 6.8, 34 and 137 mg/kg bw per day in females). The NOAEL was identified at 50 ppm (equal to 6.5 mg/kg bw per day), based on reduced brain and erythrocyte cholinesterase activity and an increase in kidney weights at 250 ppm (equal to 32 mg/kg bw per day). The carcinogenicity NOAEL was 1000 ppm (equal to 134 mg/kg bw per day), the highest dose tested.

In rats exposed to tolclofos-methyl for 28 weeks at dietary concentrations of 0, 10, 30, 1000, 3000 or 10 000 ppm (equal to 0, 16, 51, 164 and 540 mg/kg bw per day for males, 0, 18, 65, 184, and 623 mg/kg bw/day for females), the NOAEL was 1000 ppm (equal to 51 mg/kg bw per day) on the basis of bile duct proliferation and oval cell proliferation at 3000 ppm (equal to 164 mg/kg bw per day).

In a two-year chronic and carcinogenicity toxicity study rats were exposed to dietary concentrations of 0, 100, 300 or 1000 ppm (equal to 0, 4.2, 12, and 42 mg/kg bw for males, 0, 4.8, 15, and 49 mg/kg bw for females) for either 122 weeks (males) or 129 weeks (females). A systemic NOAEL could not be identified due to the variability in the cholinesterase activity data. Although an increase in the incidence of follicular cell carcinomas was noted at 1000 ppm (equal to 42 mg/kg bw per day), in the absence of any indication of thyroid toxicity at higher doses in the remainder of the tolclofos-methyl database this observation was considered to be a spurious finding, based on the weight of the evidence. The carcinogenicity NOAEL was 1000 ppm (equal to 42 mg/kg bw per day), the highest dose tested.

In a two-year study in rats with concentrations of 0, 100, 300, or 1000 ppm (equivalent to 0, 5, 15, or 50 mg/kg bw per day), the systemic NOAEL was 1000 ppm (equivalent to 50 mg/kg bw per day), the highest dose tested. The carcinogenic NOAEL was 1000 ppm (equivalent to 50 mg/kg bw per day), the highest dose tested.

The Meeting concluded that tolclofos-methyl is not carcinogenic in rats or mice.

Tolclofos-methyl 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 tolclofos-methyl 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 tolclofos-methyl is unlikely to pose a carcinogenic risk to humans.

In a multigeneration toxicity study of rats exposed to dietary concentrations of 0, 100, 300, or 1000 ppm (equal to 0, 6.9, 20.5, and 70.6 mg/kg bw per day for F<sub>0</sub> males, 0, 8.9, 26.2, and 90.5 mg/kg bw per day for F<sub>0</sub> females) no evidence of parental, reproductive, or offspring toxicity was observed at any dose. The parental, offspring, and reproductive NOAEL was 1000 ppm (equal to 70.6 mg/kg bw per day), the highest dose tested.

In a one-generation reproduction toxicity study rats were exposed to dietary concentrations of 0, 2500, 5000, or 10 000 ppm (equal to 0, 173, 338, and 680 mg/kg bw per day for males, 0, 178, 353, or 668 mg/kg bw per day for females). The parental NOAEL was 5000 ppm (equal to 338 mg/kg bw per day) on the basis of body, ovarian, uterine, and liver weight changes at 10 000 ppm (equal to 680 mg/kg bw per day). The reproductive NOAEL was 10 000 ppm (equal to 680 mg/kg bw per day), the highest dose tested. The offspring NOAEL was 2500 ppm (equal to 173 mg/kg bw per day), on the basis of decreased body weight, body weight gain, and food consumption at 5000 ppm (equal to 338 mg/kg bw per day).

In a developmental toxicity study in rats, tolclofos-methyl was administered via gavage at doses of 0, 100, 300 or 1000 mg/kg bw per day from GD 6–15. The NOAEL for maternal toxicity was 300 mg/kg bw per day based on decreased body weight gain at 1000 mg/kg bw per day. The embryo/fetal NOAEL was 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study, rabbits were administered 0, 300, 1000 or 3000 mg/kg bw per day tolclofos-methyl via gavage on days GD 6–18. The maternal toxicity NOAEL was 300 mg/kg bw per day on the basis of decreased body weight gain and food consumption at 1000 mg/kg bw per day. The embryo/fetal NOAEL was 3000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that tolclofos-methyl is not teratogenic.

The neurotoxic potential of tolclofos-methyl was evaluated in a series of neurotoxicity studies including a time-to-peak-effect study for cholinesterase activity, acute and subchronic neurotoxicity studies in rats, and a delayed neuropathology study in hens.

In a time-to-peak-effect study designed to investigate the effects of tolclofos-methyl exposure on cholinesterase activity, tolclofos-methyl was administered by gavage at a single dose of 0 or 2000 mg/kg bw. The NOAEL was 2000 mg/kg bw, the highest dose tested. As a result of this study, cholinesterase activity was not assessed in a subsequent acute neurotoxicity study.

In an acute neurotoxicity study, rats were given a single oral dose of 0, 200, 700, or 2000 mg/kg bw tolclofos-methyl by gavage. The systemic NOAEL was 200 mg/kg bw on the basis of decreased motor activity at 700 mg/kg bw.

In a subchronic neurotoxicity study tolclofos-methyl was administered to rats in their diet for 90 days at concentrations of 0, 300, 1800, or 10 000 ppm (equal to 0, 20.6, 122, 736 mg/kg bw per day for males, 0, 23.1, 136, and 763 mg/kg bw per day for females). The Meeting noted that at 10 000 ppm erythrocyte cholinesterase activity was slightly reduced from week five onwards, while brain cholinesterase activity was slightly, and inconsistently, reduced at certain time points only. The systemic NOAEL was 1800 ppm (equal to 122 mg/kg bw per day) on the basis of decreased body

weight, body weight gain, and food utilization as well as decreases in motor activity at 10 000 ppm (equal to 736 mg/kg bw per day).

In a delayed neuropathy study, Leghorn hens were administered 0 or 8000 mg/kg bw tolclofos-methyl. Hens treated with tolclofos-methyl had no signs of leg weakness or paralysis and no histopathological changes to their nervous tissues.

The Meeting noted that the small decreases in cholinesterase activity recorded in several studies, particularly in mice, were never associated with the typical signs of the cholinergic syndrome. Even at high single doses, from 1500 mg/kg bw to > 3500 mg/kg bw (the LD<sub>50</sub> for mice), which caused lethality, such signs were not observed.

Therefore, the Meeting concluded that the clinical observations in these studies are not indicative of specific toxicity to the nervous system but rather a generalized toxic effect, and that the slightly reduced erythrocyte and brain cholinesterase activity observed at doses above the LOAEL in repeated dose studies is likely not due to direct inhibition by tolclofos-methyl.

The immunotoxic potential of tolclofos-methyl was investigated in an immunotoxicity study with mice exposed to concentrations of 0, 500, 1500, or 4500 ppm (equal to 0, 91, 273, and 811 mg/kg bw per day) for 28 days. The immunotoxicity NOAEL was 4500 ppm (equal to 811 mg/kg bw per day), the highest concentration tested. The systemic NOAEL was 1500 ppm (equal to 273 mg/kg bw per day) on the basis of decreased body weight, body weight gain, and food consumption at 4500 ppm (equal to 811 mg/kg bw per day).

The Meeting concluded that tolclofos-methyl is not immunotoxic.

Four in vitro assays were conducted to evaluate tolclofos-methyl's potential impact on estrogen activity or pregnane X receptor (PXR) agonism. None of the assays suggested endocrine activity in relation to estrogen or PXR.

#### ***Toxicological data on metabolites and/or degradates***

No toxicological data specific to the metabolites or degradates identified as residues in crops or livestock (goat) are available. However, all the residues identified (ph-CH<sub>3</sub>, TMO-COOH, ph-COOH, TMO, TM-CH<sub>2</sub>OH, DM-TM, DM-TM-CH<sub>2</sub>OH and TMO-CH<sub>2</sub>OH) are also major rat metabolites (> 10%). Hence, the Meeting concluded that the toxicity of these metabolites would be covered by that of tolclofos-methyl.

#### ***Microbiological data***

No data are available to assess the potential impact of tolclofos-methyl exposure on the microbiome.

#### ***Human data***

In reports on manufacturing plant personnel, no adverse health effects were noted. There are no reports of poisoning incidents and no epidemiological studies available for tolclofos-methyl.

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

### **Toxicological evaluation**

The Meeting reaffirmed the ADI for tolclofos-methyl of 0–0.07 mg/kg bw based on a NOAEL of 6.5 mg/kg bw per day based on reduced erythrocyte and brain cholinesterase activity along with increased kidney weights in a two-year study of toxicity and carcinogenicity in mice.

The Meeting concluded that it was not necessary to establish an ARfD for tolclofos-methyl in view of its low acute oral toxicity and the absence of developmental toxicity and any other toxicological effects that would be likely to be elicited by a single dose. The Meeting noted that although brain cholinesterase activity is decreased in mice after 28 weeks of exposure, the oral LD<sub>50</sub> for mice is > 3500 mg/kg bw suggesting that acute exposure would not elicit a decrease in cholinesterase activity.

Furthermore, the toxic effects reported (for example, decreased motor activity, dyspnea, irregular respiration) were not typical of a cholinergic syndrome and were only noted at doses  $\geq 1500$  mg/kg bw.

A toxicological monograph was prepared.

### **Levels relevant to risk assessment of tolclofos-methyl**

<b>Species</b>	<b>Study</b>	<b>Effect</b>	<b>NOAEL</b>	<b>LOAEL</b>
Mouse	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	50 ppm, equal to 6.5 mg/kg bw per day	250 ppm, equal to 32 mg/kg bw per day
		Carcinogenicity	1000 ppm, equal to 134 mg/kg bw per day <sup>b</sup>	-
Rat	13-week toxicity study <sup>a</sup>	Toxicity	1000 ppm, equal to 66 mg/kg bw per day	10 000 ppm, equal to 653 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity <sup>a,c</sup>	Toxicity	1000 ppm, equivalent to 50 mg/kg bw per day <sup>b</sup>	-
		Carcinogenicity	1000 ppm, equivalent to 50 mg/kg bw per day <sup>b</sup>	-
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	1000 ppm, equal to 70.6 mg/kg bw per day <sup>b</sup>	-
		Parental toxicity	1000 ppm, equal to 70.6 mg/kg bw per day <sup>b</sup>	-
		Offspring toxicity	1000 ppm, equal to 70.6 mg/kg bw per day <sup>b</sup>	-
	One-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	10 000 ppm, equal to 680 mg/kg bw per day <sup>b</sup>	-
		Parental toxicity	5000 ppm, equal to 338 mg/kg bw per day	10 000 ppm, equal to 680 mg/kg bw per day
		Offspring toxicity	2500 ppm, equal to 173 mg/kg bw per day	5000 ppm, equal to 338 mg/kg bw per day
	Developmental toxicity study <sup>d</sup>	Maternal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
Embryo and fetal toxicity		1000 mg/kg bw per day <sup>b</sup>	-	
Acute neurotoxicity study <sup>d</sup>	Toxicity <sup>e</sup>	200 mg/kg bw	700 mg/kg bw	
Subchronic neurotoxicity <sup>a</sup>	Toxicity <sup>e</sup>	1800 ppm, equal to 122 mg/kg bw per day	10 000 ppm, equal to 736 mg/kg bw per day	
Immunotoxicity study <sup>a</sup>	Immunotoxicity	4500 ppm, equal to 811 mg/kg bw per day <sup>b</sup>		
Rabbit	Developmental toxicity study <sup>d</sup>	Maternal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
		Embryo and fetal toxicity	3000 mg/kg bw per day <sup>b</sup>	
Dog	26-week toxicity study <sup>a</sup>	Toxicity	600 ppm, equal to 21 mg/kg bw per day	2000 ppm, equal to 59 mg/kg bw per day

One-year study of toxicity <sup>a</sup>	Toxicity	400 ppm, equal to 11 mg/kg bw per day	2000 ppm, equal to 59 mg/kg bw per day
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<sup>a</sup> Dietary administration

<sup>b</sup> Highest dose tested

<sup>c</sup> Three studies combined

<sup>d</sup> Gavage administration

<sup>e</sup> Generalized toxicity not associated with neurotoxicity

*Acceptable daily intake (ADI), applies to tolclofos-methyl, ph-CH<sub>3</sub>, TMO-COOH, ph-COOH, TMO, TM-CH<sub>2</sub>OH, DM-TM, DM-TM-CH<sub>2</sub>OH and TMO-CH<sub>2</sub>OH, expressed as tolclofos-methyl*

0–0.07 mg/kg bw

*Acute reference dose (ARfD)*

Unnecessary

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

Results from epidemiological studies of human exposure.

### **Critical endpoints for setting guidance values for exposure to tolclofos-methyl**

#### ***Absorption, distribution, excretion and metabolism in mammals***

Rate and extent of oral absorption	Rapid; > 75% at 5 mg/kg bw (mouse and rat)
Dermal absorption	No data
Distribution	Extensive; highest concentration found in the kidney
Potential for accumulation	Low
Rate and extent of excretion	Rapid; largely complete within the first 24 h after dose administration
Metabolism in animals	Converted primarily to Ph-CH <sub>3</sub> (12%) and Ph-COOH (29%) in rats and Ph-COOH (12%), Ph-CO-glycine (13%, unique to mice), and DM-TMO-COOH (12%) in mice
Toxicologically significant compounds in animals and plants	Tolclofos-methyl

#### ***Acute toxicity***

Mouse LD <sub>50</sub> , oral	≥ 3500 mg/kg bw
Rat LD <sub>50</sub> , oral	> 5000 mg/kg bw
Rat LD <sub>50</sub> , dermal	> 5000 mg/kg bw
Rat LC <sub>50</sub> , inhalation	> 3.32 mg/L after 4 h exposure
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Slightly irritating
Guinea pig, dermal sensitization	Sensitizer (Magnusson & Kligman assay)

#### ***Short-term studies of toxicity***

Target/critical effect	Decreased body weight gain (dog)
Lowest relevant oral NOAEL	11 mg/kg bw per day
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rabbit; highest dose tested)
Lowest relevant inhalation NOAEC	No data

#### ***Long-term studies of toxicity and carcinogenicity***

Target/critical effect	Reduced erythrocyte and brain cholinesterase activity and increased kidney weights
Lowest relevant NOAEL	6.5 mg/kg bw per day (mouse)



Carcinogenicity	Not carcinogenic in rat or mouse <sup>a</sup>
<b>Genotoxicity</b>	Not genotoxic <sup>a</sup>
<b>Reproductive toxicity</b>	
Target/critical effect	Decreased body, thymus, kidney, brain, ovarian, uterine, seminal vesicles, epididymal, and liver weights
Lowest relevant parental NOAEL	338 mg/kg bw per day (rat)
Lowest relevant offspring NOAEL	173 mg/kg bw per day (rat)
Lowest relevant reproductive NOAEL	680 mg/kg bw per day (rat; highest dose tested)
<b>Developmental toxicity</b>	
Target/critical effect	No embryo/fetal effects; decreased body weight gains in maternal animals (rats and rabbits)
Lowest relevant maternal NOAEL	300 mg/kg bw per day (rats and rabbits)
Lowest relevant embryo/fetal NOAEL	1000 mg/kg per day (rat; highest dose tested)
<b>Neurotoxicity</b>	
Acute neurotoxicity NOAEL	Not neurotoxic
Subchronic neurotoxicity NOAEL	Not neurotoxic
Developmental neurotoxicity NOAEL	No data
<b>Immunotoxicity</b>	
Immunotoxicity NOAEL	811 mg/kg bw per day (rat; highest dose tested)
<b>Human data</b>	No poisoning incidents or adverse effects have been reported as part of the medical surveillance data collection

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet

### Summary

	Value	Study	Safety Factor
ADI	0–0.07 mg/kg bw <sup>a</sup>	Two-year study of toxicity and carcinogenicity (mouse)	100
ARfD	Unnecessary		

<sup>a</sup> applies to tolclofos-methyl, ph-CH<sub>3</sub>, TMO-COOH, ph-COOH, TMO, TM-CH<sub>2</sub>OH, DM-TM, DM-TM-CH<sub>2</sub>OH and TMO-CH<sub>2</sub>OH, expressed as tolclofos-methyl

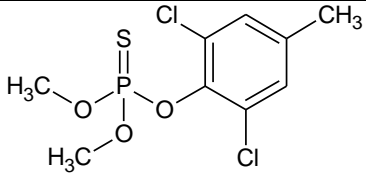
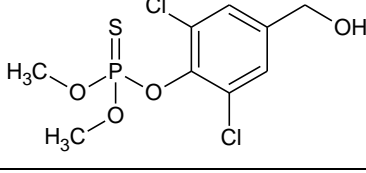
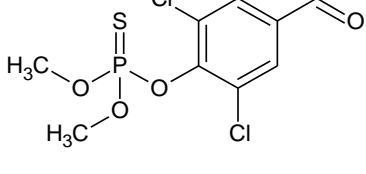
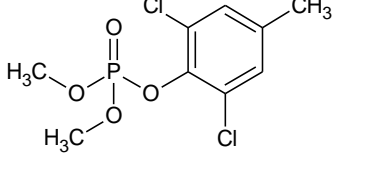
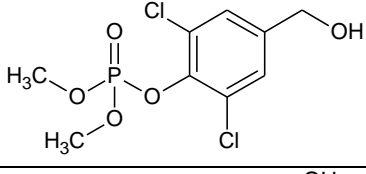
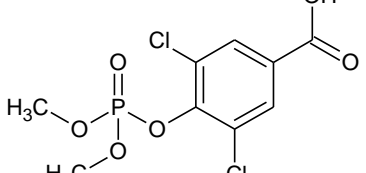
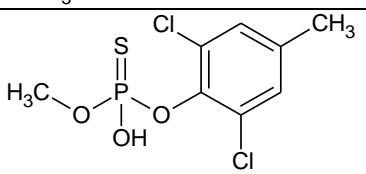
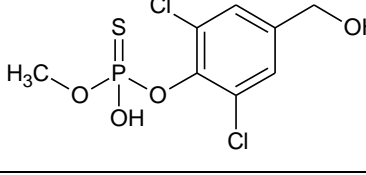
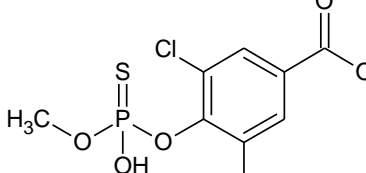
## RESIDUE AND ANALYTICAL ASPECTS

Tolclofos-methyl is a non-systemic contact organophosphorus fungicide used for control of soil-borne diseases caused by *Rhizoctonia solani*. The IUPAC name for tolclofos-methyl is *O*-2,6-dichloro-*p*-tolyl *O,O*-dimethyl phosphorothioate. Tolclofos-methyl was first evaluated for toxicology and residues by the JMPR in 1994.

Tolclofos-methyl was scheduled at the Fiftieth Session of the CCPR for periodic review by the 2019 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 and supervised trials.

The following abbreviated names were used for the metabolites referred to in this appraisal.

Table 1 Abbreviated names used for the metabolites referred to in this appraisal

Abbreviation	Matrix found	Structure
Tolclofos-methyl TM (parent)	Goat (liver, kidney), Hen (egg yolk, liver, fat, skin, muscle), Sugar beet (leaves, shoots, roots) Peanut (leaves, hull), Potato (foliage, shoots, roots, parent tubers, daughter tubers), Lettuce (plants)	
TM-CH <sub>2</sub> OH	Sugar beet (leaves), Peanut (leaves, stem), Potato (foliage, roots, parent tubers, daughter tubers)	
TM-CHO	Hen (liver)	
TMO	Goat (milk), Sugar beet (leaves, shoots, roots), Peanut (leaves, stem)	
TMO-CH <sub>2</sub> OH	Goat (kidney), Hen (liver), Sugar beet (leaves) Peanut (stem)	
TMO-COOH	Goat (kidney, milk), Hen (liver, muscle, skin) Sugar beet (leaves, shoots, roots), Peanut (stem)	
DM-TM	Goat (kidney), Sugar beet (leaves), Potato (foliage, shoots, roots, parent tubers, daughter tubers)	
DM-TM-CH <sub>2</sub> OH	Goat (, kidney), Potato (foliage, shoots, roots, parent tubers, daughter tubers)	
DM-TM-COOH	Goat (milk), Potato (foliage, roots, parent tubers, daughter tubers)	

Abbreviation	Matrix found	Structure
DM-TMO	Goat (kidney), Sugar beet (leaves) Peanut (hull), Potato (foliage, roots, parent tubers, daughter tubers)	
ph-CH <sub>3</sub>	Goat (liver), Hen (liver), Sugar beet (leaves, roots), Peanut (leaves)	
ph-CH <sub>2</sub> OH	Goat (liver, kidney), Hen (skin), Sugar beet (leaves), Peanut (leaves, stem)	
ph-CHO	Goat (liver), Peanut (leaves)	
ph-COOH	Goat (milk, kidney, liver), Hen (liver, kidney, muscle, fat, skin), Potato (foliage, shoots, roots, parent tubers, daughter tuber)	
Glucose conjugate of ph-CH <sub>3</sub>	Lettuce	
Malonylglucose conjugate of ph-CH <sub>3</sub>	Lettuce	
Glucose conjugate of TM-CH <sub>2</sub> OH	Lettuce	

Tolclofos-methyl is of low volatility (0.88 mPa at 20 °C). The log  $K_{ow}$  value (3.8 at 25 °C) suggests that tolclofos-methyl has the potential to partition into fat. Hydrolysis is unlikely to be a significant route of degradation in the environment, but may be significant at higher temperatures during food processing.

### **Plant metabolism**

The Meeting received plant metabolism studies for tolclofos-methyl radiolabelled in the phenyl ring after foliar, soil, or seed tuber application on leafy vegetables (lettuce), root and tuber vegetables (sugar beet, potato) and oilseeds (cotton, peanut).

#### **Lettuce**

[phenyl-<sup>14</sup>C]-Tolclofos-methyl was applied once to lettuce seedlings (3–4 leaf stage; BBCH 14) and soil in crates grown in a greenhouse at rates of 2 or 10 kg ai/ha. Lettuce grown to maturity in a greenhouse was harvested 34 days after the application.

TRRs in mature lettuce were 0.23 and 0.77 mg eq/kg for the 2 and 10 kg ai/ha experiments, respectively. Aqueous acetone extracted 66% of the total radioactivity from the lettuce matrices, and a subsequent extraction with methanol added 16–20%, thus, total extractability was 82–86% TRR. After hydrolyses of PES with acid and base, only 0.5–1.7% TRR remained in the solids.

Parent was a major component of the residue, accounting for 37–40% TRR (0.084–0.30 mg/kg). The malonylglucose conjugate of ph-CH<sub>3</sub> (M22 fraction) was found at 20–23% TRR (0.052–0.15 mg eq/kg). Glucose conjugate of TM-CH<sub>2</sub>OH (M35 fraction) was found at 14–15% TRR (0.032–0.11 mg eq/kg). These metabolites were found in aqueous acetone extracts. In addition, unidentified fractions of 8–9% TRR (0.020–0.059 mg eq/kg) in total were present in the extracts. In the acid and base hydrolysates, unidentified fractions were present at 14% TRR (0.031–0.11 mg eq/kg) in total. Meanwhile, it was observed that TM-CH<sub>2</sub>OH sugar conjugate may be transformed to TMO-COOH under acidic conditions (1 M HCl at 80 °C for 2 hours).

The conjugates were further identified in another study, where the radiolabelled substance was topically applied once to lettuce leaves grown in a greenhouse at rates of 75 g ai/ha and 750 g ai/ha. Lettuce leaves were harvested at 2 and 7 days after the application. In the study, the major conjugated metabolite was identified as a malonylglucose conjugate of ph-CH<sub>3</sub>.

#### **Sugar beet foliar treatment**

A metabolism study was performed on sugar beet plants in a greenhouse with foliar treatment. The radiolabelled substance was topically applied to the third leaf of potted six-month old sugar beets grown in a greenhouse at a rate equivalent to 3.3 kg ai/ha. Sugar beet plants harvested at 3, 7, 14, 21, 28, 35 and 50 days after treatment (DAT; 28, 35 and 50 DAT, relevant to harvest practice) were sectioned into treated leaf, untreated leaves, and root portions. The treated leaves were rinsed with methanol.

Total recovery of applied radiocarbon (AR) from leaves and roots was in the range of 8.4–40% AR over the study period. The radioactivity comprised 7.1–40% AR in treated leaves, 0.3–1.6% AR in untreated leaves and 0.3–0.6% AR in roots, indicating limited translocation of radiocarbon into untreated leaves and roots.

At 28–50 DAT, surface wash accounted for 3.9–4.2% of total radioactivity in the treated leaves. Organic solvents (MeOH/chloroform) extracted 60–83% of the total radioactivity in washed leaves, untreated leaves and roots at 28–50 DAT. Partitioning with acidified solvents may result in conversion of TM-CH<sub>2</sub>OH to TMO-COOH.

In treated leaves (28–50 DAT), metabolite DM-TMO was a major component, accounting for 38–42% TRR. Parent was present at 8.4–9.2% TRR (including 1.4–2.6% TRR from surface wash). TMO-COOH was detected at 3.9–6.5% TRR. Other minor components (ph-CH<sub>3</sub>, ph-CH<sub>2</sub>OH, TM-CH<sub>2</sub>OH, TMO-CH<sub>2</sub>OH, TMO, DM-TM) were also found individually at up to 3.9% TRR. Unidentified fractions were present at up to 3–12% TRR in total.

In untreated leaves (28–50 DAT), parent was the predominant residue, accounting for 40–47% TRR. TMO-COOH was found at up to 13% TRR. Unidentified fractions were present at 13–20% TRR in total.

For roots (28–50 DAT), parent was found at 17–33% TRR. TMO-COOH was found at 17–33% TRR. Unidentified fractions were present at 33–50% TRR in total; no characterisation of these fractions was provided.

### *Sugar beet soil treatment*

Six-month old sugar beets were planted in loamy sand soil, grown in a greenhouse and treated at a rate of 20 mg/kg soil on a dry weight basis. Sugar beets (roots and leaves) were harvested at 3, 7, 14, 21, 28, 35 and 75 DAT (28, 35 and 75 DAT, relevant to harvest practice).

Total recovery of applied radiocarbon from leaves, roots and soil was in the range of 48–63% AR over the study period. The radioactivity comprised 0.1–1.0% AR in leaves, 0.1–1.5% AR in roots and 47–63% AR in soil, indicating very limited uptake of radioactive carbon from soil into plants.

TRRs (28–75 DAT) were 0.24–0.33 mg eq/kg in leaves and 0.44–0.49 mg eq/kg in roots. Organic solvent (MeOH/chloroform) extracted 33–75% TRR in leaves and roots.

In leaves (28–75 DAT), parent was the predominant residue, present at levels of 17–33% TRR and 0.05–0.07 mg/kg. Metabolites TMO and *ph*-CH<sub>3</sub> were found at ≤0.1% AR. Unidentified fractions were present at 17–33% TRR (0.041–0.11 mg eq/kg) in total.

For roots (28–75 DAT), parent was a major component found at residue levels of 17–50% TRR (0.07–0.18 mg/kg). TMO was also a major component found at 17–25% TRR (0.075–0.12 mg eq/kg). *ph*-CH<sub>3</sub> was found, but at < 0.1% AR. Unidentified fractions were present at < 0.1% AR in total.

### *Potato*

Seed potatoes were surface treated once with the radiolabelled substance, immediately prior to planting at a rate of 125 g ai/tonne of tubers. Potato plants were grown in a glasshouse and harvested at an immature stage (27 days after planting) and at full maturity stage (129 days after planting). The harvested plant material was separated into foliage, parent and daughter tubers (only at mature stage).

TRRs in immature potato plants were 0.25 mg eq/kg in foliage and 56 mg eq/kg in parent tubers. For mature potato plants, TRRs were 0.040 mg eq/kg in shoots, 1,890 mg eq/kg in parent tubers and 0.048 mg eq/kg in daughter tubers.

Organic solvents (acetone and aqueous acetone) extracted 76–96% TRR in foliage, 98–99% TRR in parent tubers and 66% TRR in daughter tubers (unextracted, 33% TRR; 0.016 mg eq/kg).

In foliage at the immature stage, parent was found at 1.3% TRR (0.003 mg/kg). The largest component, metabolite DM-TM-CH<sub>2</sub>OH was found at 31% TRR (0.076 mg eq/kg). Five unidentified fractions were present individually at 4.4–11% TRR (0.011–0.028 mg eq/kg). At the mature stage, parent was not detected in foliage. Metabolite *ph*-COOH (37% TRR, 0.015 mg eq/kg) was the predominant residue. One unidentified fraction (19% TRR, 0.008 mg eq/kg) was observed.

In parent tuber at immature and mature stages, parent was the predominant residue accounting for 97% TRR (55 mg/kg) and 95% TRR (1,790 mg/kg), respectively. Metabolites were not found at either the immature or mature harvest timing.

In daughter tubers, parent was not detected. Metabolite DM-TM-CH<sub>2</sub>OH was a major component found at 27% TRR (0.013 mg eq/kg). DM-TM-COOH was also found but at a lower level, 6.0% TRR (0.003 mg eq/kg). Three unidentified fractions were observed at 4.3–12% TRR (0.002–0.006 mg eq/kg).

Another study with a seed potato treatment was conducted at rates of 250 g ai/t tuber and 1,250 g ai/t tuber. A single application with the radiolabelled substance was made immediately prior to planting. Plants were grown outside in a caged enclosure and harvested at maturity (118 days after planting). At harvest, parent tubers, daughter tubers and foliage were collected.

TRRs were 40–180 mg eq/kg in parent tubers, 0.032–0.067 mg eq/kg in daughter tubers, and 0.13–0.36 mg eq/kg in foliage.

Organic solvents extracted 95–98% TRR in parent tuber, 78–79% TRR in daughter tubers (unextracted, 21–22%; 0.007–0.015 mg eq/kg) and 63–86% TRR in foliage.

In parent tubers, parent was the predominant residue, accounting for 89–96% TRR (35–172 mg/kg). Metabolites DM-TM-CH<sub>2</sub>OH, DM-TM-COOH, TM-CH<sub>2</sub>OH, ph-COOH, DM-TMO and DM-TM were found at very low levels, each up to 0.1% TRR and 0.18 mg eq/kg. Unidentified fractions were at less than 4%, in total, with individual components of  $\leq 1\%$  TRR.

In daughter tubers, parent was detected, but at very low levels of 2.6–8.3% TRR (0.002 mg/kg). The largest component was DM-TM-CH<sub>2</sub>OH present at 11–12% TRR ( $< 0.01$  mg eq/kg). Metabolite DM-TM-COOH was found at 6.0–10% TRR. Other metabolites TM-CH<sub>2</sub>OH, ph-COOH, DM-TMO and DM-TM were present at levels of less than 6% TRR each. Unidentified multiple fractions were present individually at less than 6% TRR, totaling  $< 29\%$  TRR.

Foliage contained parent residues at levels of 6.6–9.7% TRR (0.012–0.025 mg eq/kg). DM-TM-CH<sub>2</sub>OH and DM-TM-COOH were found at 5.2–15% TRR (0.018–0.019 mg eq/kg) and 8.9–13% TRR (0.017–0.032 mg eq/kg), respectively. Metabolites TM-CH<sub>2</sub>OH, ph-COOH, DM-TMO and DM-TM were found at individually less than 8% TRR ( $\leq 0.025$  mg eq/kg). Unidentified multiple fractions were observed at less than 0.06 mg eq/kg in total.

### *Cotton seed and peanuts*

Cotton and peanut plants grown under field conditions were treated with a single soil application at a rate of 5.2 or 15.7 kg ai/ha. For peanuts, an additional foliar application was made 75 days after the soil treatment, at a rate of 5.2 kg ai/ha (in total, 10 kg ai/ha) or 15.7 kg ai/ha (in total, 31 kg ai/ha). Cotton and peanut plants were harvested 150 days after the soil treatment. Cotton (bolls, squares, leaves, stems and seeds) and peanut (hull, leaves, stems and nutmeat) samples were taken. The surface of peanut leaves was rinsed with methanol.

In cotton samples, radioactivity was not detected ( $< 0.003$ – $< 0.008$  mg eq/kg), except in the stem (0.008–0.010 mg eq/kg at 5.2 kg ai/ha; 0.015–0.026 mg eq/kg at 15.7 kg ai/ha) and in the leaf (0.015 mg eq/kg at 15.7 kg ai/ha). In peanuts, TRR levels (10, 31 kg ai/ha) were 0.016–0.052 mg eq/kg in hulls, 1.4–3.8 mg eq/kg in leaves, 0.044–0.079 (10 kg ai/ha)/0.090–0.38 (31 kg ai/ha) mg eq/kg in stems and 0.010 mg eq/kg (both rates) in nutmeat. In peanut leaves, parent was detected only in the surface wash (0.1% TRR), and TM-CH<sub>2</sub>OH and ph-CH<sub>2</sub>OH and the conjugates were found. Overall, characterisation of residues was not sufficient (low extraction and low recovery in TLC analysis) to draw conclusions.

### *Conclusions*

In plants, tolclofos-methyl was non-systemic and mostly recovered in directly treated parts. Parent was present at various levels in the edible parts of the plants and the metabolite profiles were dependent on the mode of application.

In lettuce with seedling and soil treatment, major metabolites were sugar conjugates of ph-CH<sub>3</sub> and TM-CH<sub>2</sub>OH, generated via cleavage of the P-O aryl bond or oxidation of the 4-methyl group and further, their conjugation with sugar. In potato with seed tuber treatment, a major metabolite was DM-TM-CH<sub>2</sub>OH, generated via demethylation and oxidation of the 4-methyl group.

### *Environmental fate*

The Meeting received soil and aqueous photolysis, aqueous hydrolysis and aerobic soil metabolism studies for tolclofos-methyl.

### *Hydrolysis*

Hydrolytic degradation of [phenyl-<sup>14</sup>C]-tolclofos-methyl was mostly dependent on pH and temperature in the sterile aqueous buffered solution. At pH 4–9, the half-lives calculated from experiments at higher temperatures were 97–126 days at 20 °C and 50–68 days at 25 °C. A single hydrolysis product DM-TM

occurred (up to 81% AR at 62 °C, pH 7 after 50 hours). Another metabolite ph-CH<sub>3</sub>, produced only at pH 9, was observed at much lower levels (up to 13% AR at 62 °C after 50 hours).

Therefore, it was considered that hydrolysis is unlikely to be a significant route of degradation under environmental conditions.

### *Photochemical degradation*

#### *Aqueous photolysis*

Aqueous photolysis is not a significant environmental degradation pathway for tolclofos-methyl, as shown by an aqueous photolysis study which determined half-lives of 8.2–48.5 days at latitudes of 20°N–50°N.

#### *Soil photolysis*

On irradiated soil under natural sunlight, the half-life of tolclofos-methyl was 113 days. Photolysis was not a significant degradation pathway of tolclofos-methyl on soil.

#### *Aerobic soil metabolism*

In three studies, a total of 11 soils were treated with [phenyl-<sup>14</sup>C]-tolclofos-methyl. Tolclofos-methyl degraded rapidly in the tested soils. DT<sub>50</sub> values for tolclofos-methyl ranged from 2 to 30 days (geometric mean: 9.2 days). The DT<sub>90</sub> values ranged from 6.9 to 100 days. Major degradation products were DM-TM and ph-CH<sub>3</sub> (up to 13% and 8% of the applied radioactivity). Other identified metabolites ph-COOH, ph-CH<sub>2</sub>OH, TM-COOH, TMO and DM-TMO were found at low levels of < 2–7% of the applied radioactivity.

The Meeting considered that tolclofos-methyl is not persistent in soil.

#### *Rotational crop metabolism*

No information was provided.

#### *Animal metabolism*

The Meeting received animal metabolism studies on rats, lactating goats and laying hens.

##### *Rats*

The metabolism of tolclofos-methyl in rats was reviewed within the framework of the toxicological evaluation by the WHO Core Assessment Group of the 2019 JMPR.

##### *Goats*

One goat was orally dosed, once daily, for 4 consecutive days at a rate equivalent to 250 ppm in the feed (10 mg/kg bw per day). Milk was collected twice daily. The goat was sacrificed 7 hours after the final dosing.

Of the total dose, only 27% was recovered, and most (26% of the total dose) was recovered in urine and a small amount (0.6% of the total dose) was recovered from faeces. TRRs were 0.2 mg eq/kg in muscle, 1.1 mg eq/kg in fat, 3.0 mg eq/kg in liver, 4.3 mg eq/kg in kidney. For milk, the TRR was 0.41 mg eq/kg at 48 hours after the first dosing. Residue levels in milk reached an equilibrium of about 0.8 mg eq/kg within 4 days after the first dosing.

Muscle, liver and kidney samples were extracted with acidified organic solvent (diethyl ether after adjusting to pH 1) and refluxed with diethyl ether at acid and base conditions followed by extraction with water. The extraction process may hydrolyse conjugates and oxidise TM-CH<sub>2</sub>OH to TMO-COOH. For milk and fat, acidified organic solvent was not used.

Acidified organic solvent extracted 37% TRR in liver, 28% TRR in kidney, and 13% TRR in muscle. Further extractions (acid- and base-reflux followed by extraction with diethyl ether) released 13% TRR in liver, 39% TRR in kidney and 25% TRR in muscle. Water extract contained 21% TRR (0.62 mg eq/kg) in liver, 44% TRR (1.9 mg eq/kg) in kidney and 54% TRR (0.11 mg eq/kg) in muscle. Final unextracted radioactivity was 30% TRR in liver, 4% TRR in kidney and 8% TRR in muscle. For milk and fat, organic solvent extracted 74% TRR and 118% TRR, respectively; and the final unextracted radioactivity was 21% TRR and 8% TRR, respectively. For muscle and fat, further investigations for identification of metabolites were not performed.

In liver, parent was not detected. Metabolite ph-COOH was a major component found at 18% TRR (17% free+conj. form, 1.6% base released, total: 0.55 mg eq/kg). Another major component ph-CH<sub>3</sub> was found at 15% TRR (11% free+conj., 4.0% acid released, total: 0.45 mg eq/kg). Metabolite ph-CH<sub>2</sub>OH and one unknown fraction, free+conj., were present at 5.4% TRR (0.16 mg eq/kg) and 4.4% TRR (0.13 mg eq/kg), respectively. Acid- and base-released two other fractions that were observed, individually, at less than 5.1% TRR (0.15 mg eq/kg). Some 21% TRR (0.62 mg eq/kg) in water extract was not further investigated.

In kidney, parent was not detected. TMO-COOH was a major component found at 21% TRR (8.7% free+conj., 8.1% acid released, 4.4% base released, total: 0.91 mg eq/kg). Another major component ph-COOH was found at 21% TRR (5.7% free+conj., 7.4% acid released, 8.0% base released, total: 0.91 mg eq/kg). TMO-CH<sub>2</sub>OH was found at a lesser extent of 11% TRR (3.1% free+conj., 4.0% acid released, 3.9% base released, total 0.47 mg eq/kg). DM-TM-CH<sub>2</sub>OH, DM-TMO and two unknown fractions, free+conj., were present at levels of less than 3.8% TRR (0.16 mg eq/kg). Acid- and base-released four fractions that were observed individually at less than 3.2% TRR (0.14 mg eq/kg). Some 44% TRR (1.9 mg eq/kg) in water extract was not further investigated.

In milk, parent was not detected. Metabolite TMO was the predominant residue accounting for 42% TRR (0.17 mg eq/kg). Metabolite ph-COOH was found at a level of 9.0% TRR (0.037 mg eq/kg). DM-TM-COOH and one unknown fraction were present individually at less than 6.9% TRR (0.028 mg eq/kg).

In another study, a goat was dosed twice daily with [phenyl-<sup>14</sup>C]-tolclofos-methyl for 6 consecutive days at a rate equivalent to 11 ppm in the feed (0.39 mg/kg bw per day). Milk was collected twice daily. The goat was sacrificed 7 hours after the last dosing.

The majority (85%) of the radiolabelled tolclofos-methyl was excreted in urine (46% of the total dose) and faeces (39% of the total dose). Residue levels in muscle and fat were near or below the limit of quantification. TRR levels in liver and kidney were 0.25 mg eq/kg and 0.22 mg eq/kg, respectively. TRR levels in milk reached a plateau of 0.014–0.019 mg eq/kg at approximately one day after the first dosing. A ratio of 8.1% of the total radioactivity in whole milk was distributed into milk fat.

In liver, acid and base conditions were used for extraction and partitioning with organic solvents. For milk and kidney samples, extraction was conducted under neutral conditions and partitioning steps were conducted at neutral, acidic and basic conditions. The extraction conditions may hydrolyse conjugates. Further, TMO-COOH found in the matrices may be an artefact produced under acidic conditions by oxidation of TM-CH<sub>2</sub>OH.

Extraction efficiency of radioactivity was 66% TRR in liver and 93% TRR in kidney. Further treatments for liver released additional residues of 24% TRR (18% TRR by acid hydrolysis and 6.3% TRR by pronase incubation), and 9.9% TRR remained unextracted. Acetone extracted 87% TRR from the whey.

Parent was not detected in milk (milk whey). Metabolite TMO-COOH was found but at a low level of 6.7% TRR (0.001 mg eq/kg). Two unidentified fractions were observed individually at less than 12% TRR (0.002 mg eq/kg) in the organic phase. The radioactivity in the aqueous phase (66% TRR, 0.01 mg eq/kg) was not further investigated.



In liver, parent was present at 4.4% TRR (0.011 mg/kg). Metabolite ph-COOH was the largest component, accounting for 10% TRR (0.026 mg eq/kg). Five unidentified fractions were observed individually at less than 8.8% TRR (0.022 mg eq/kg) in the organic phase. The 28% TRR (0.069 mg eq/kg) in the aqueous phase consisted of nine fractions, individually at less than 8.2% TRR (0.021 mg eq/kg).

In kidney, parent was present at 12% TRR (0.029 mg/kg). Metabolite ph-COOH was the largest component, accounting for 13% TRR (0.031 mg eq/kg). TMO-COOH was found at 5.4% TRR (0.013 mg eq/kg). ph-CH<sub>2</sub>OH and DM-TM were also found but at levels of less than 2% TRR (0.005 mg eq/kg). Five unidentified fractions were observed individually at less than 5.9% TRR (0.014 mg eq/kg) in the organic phase. The 43% TRR (0.096 mg eq/kg) in the aqueous phase consisted of six fractions, individually at less than 19% TRR (0.045 mg eq/kg).

### *Laying hens*

The radiolabelled substance was orally administered to three laying hens daily for four consecutive days at a rate equivalent to 167 ppm in the diet (10 mg/kg bw per day). Eggs and excreta were collected daily. Hens were sacrificed 7 hours after the last dosing.

The majority (86%) of the administered total dose was recovered from excreta. TRR levels were 0.11 mg eq/kg in muscle, 1.0 mg eq/kg in fat, 3.4 mg eq/kg in liver, 6.0 mg eq/kg in kidney, up to 0.37 mg eq/kg in egg yolk and up to 0.07 mg eq/kg in egg white.

Liver and kidney samples were extracted with acidified organic solvent (diethyl ether after adjusting to pH 1), conditions that may hydrolyse conjugates.

Acidified organic solvent extracted 20% TRR and 40% TRR in liver and kidney, respectively. Further extractions (acid- and base-reflux followed by extraction with diethyl ether) released 8.1% TRR and 19% TRR in liver and kidney, respectively. Final unextracted radioactivity was 70% TRR and 40% TRR in liver and kidney, respectively.

In liver, parent was not detected. Metabolite TM-CHO was found at 3.4% TRR (free+conj., 0.12 mg eq/kg). Five unidentified fractions were present individually at less than 5.2% TRR (0.018 mg eq/kg). Acid- and base-released residues were not analysed.

In kidney, parent was not detected. Metabolite ph-COOH was found at 9.3% TRR (free+conj., 0.56 mg eq/kg). Eight unidentified fractions were present individually at less than 7.7% TRR (0.46 mg eq/kg). Acid- and base-released residues were not analysed.

In another study on laying hens (ten animals), the radiolabelled substance was orally administered for fourteen days at a dose level equivalent to 11 ppm in the feed (0.92 mg/kg bw per day). Eggs were collected daily prior to dosing. Hens were sacrificed 7 hours after the last dosing, and liver, muscle, fat, and skin were taken.

The majority (89%) of the radiolabelled tolclofos-methyl was eliminated in excreta. TRR levels were 0.008 (breast)–0.013 (thigh) mg eq/kg in muscle, 0.045 mg eq/kg in fat, 0.073 mg eq/kg in skin, 0.42 mg eq/kg in liver. In egg white and yolk, maximum TRR levels were 0.006 mg eq/kg and 0.059 mg eq/kg, respectively, with a plateau level of 0.057–0.059 mg eq/kg after 8–9 days in yolk.

For muscle and liver samples, acid and base conditions were used for extraction and partitioning with organic solvents. Egg yolk samples were extracted at neutral conditions with organic solvent and partitioned with organic solvent at neutral, acidic and basic conditions. Fat and skin samples were not treated with acid in extraction and partitioning. The extraction conditions used may hydrolyse conjugates. Further, TMO-COOH found in the matrices may be an artefact produced from TM-CH<sub>2</sub>OH under acidic conditions.

Extractability of the radioactivity was 60–93% TRR in muscle, liver, fat, skin and yolk. For liver with the lowest extraction efficiency, 38% of the radioactivity was further extracted by acid, base and pronase hydrolyses (unextracted residue, 1.6% TRR).

In muscle (thigh), parent was detected at a level of 5.0% TRR (0.001 mg/kg). The largest component was metabolite ph-COOH found at 12% TRR (0.001 mg eq/kg). TMO-COOH was found at a level of 2.0% TRR (< 0.001 mg eq/kg). Six unidentified fractions in the organic phase were present individually at less than 16% TRR (0.002 mg eq/kg). Some 22% TRR (< 0.01 mg eq/kg) in the aqueous phase was not further investigated.

In fat, parent was the predominant residue, accounting for 76% TRR (0.034 mg/kg). Metabolite ph-COOH was found at a level of 3.7% TRR (0.002 mg eq/kg). Four unidentified fractions were observed individually at less than 4.0% TRR (0.002 mg eq/kg). TMO-COOH was not detected.

For skin, parent was found at 29% TRR (0.021 mg/kg). Metabolite ph-COOH was found at 11% TRR (0.008 mg eq/kg). Metabolites ph-CH<sub>2</sub>OH and TMO-COOH were found at levels of less than 5.4% TRR (0.004 mg eq/kg in TMO-COOH). Four unidentified fractions were present at less than 6.8% TRR (0.005 mg eq/kg).

In liver, parent was detected at a level of 0.5% TRR (0.002 mg/kg). The largest component was ph-COOH found at 18% TRR (0.076 mg eq/kg; 15.6% TRR in the organic phase; 2.7% TRR in the aqueous phase). Other metabolites ph-CH<sub>3</sub>, TMO-CH<sub>2</sub>OH and TMO-COOH (0.7% TRR, 0.003 mg eq/kg) were found in the organic phase individually at less than 3.5% TRR (0.014 mg eq/kg). Eleven unidentified fractions in the organic and aqueous phases were present individually at less than 9.9% TRR (0.041 mg eq/kg).

In egg yolk, parent was the predominant residue, accounting for 35% TRR (0.021 mg eq/kg). TMO-COOH was not detected. Five unidentified fractions were present individually at less than 13% TRR (0.007 mg eq/kg). Some 13% TRR in the aqueous phase was not further investigated.

### **Conclusions**

In general, the metabolism between goat, hen and rat is qualitatively similar. The Meeting concluded that, in all species investigated (goats, hens and rats), the total administered radioactivity was predominantly eliminated in excreta.

The routes and products of metabolism were similar across all animals. Tolclofos-methyl undergoes oxidative desulfuration, demethylation and hydrolysis of the P-O aryl bond to form ph-CH<sub>3</sub>. The ph-CH<sub>3</sub> is further metabolized to its alcohol (ph-CH<sub>2</sub>OH) and acid analogue (ph-COOH).

### **Methods of analysis**

The Meeting received information on analytical methods for tolclofos-methyl in plant and animal matrices.

Single-residue analytical methods based on GC-NPD or GC-FPD involving extraction and partitioning with various organic solvents tested with potato or lettuce matrices were generally suitable to measure tolclofos-methyl. The multi-residue methods DFG S-19 (GC-FPD) and QuEChERS (LC-MS/MS) for the determination of tolclofos-methyl were sufficiently validated with potato in the former method and with lettuce, orange, cotton seed and dried beans in the latter method. In both single- and multi-residue methods, LOQ values were 0.01 mg/kg.

Regarding the determination of tolclofos-methyl in animal matrices, one multi-residue method was provided. This method involved use of the QuEChERS technique and LC-MS/MS, and was sufficiently validated in animal matrices (milk, bovine meat and liver, eggs and fat) with LOQs of 0.01 mg/kg. Further, the extraction efficiency for tolclofos-methyl was also validated relating with extraction of radiolabelled tolclofos-methyl in goat liver, hen's egg and fat.

The Meeting concluded that the presented methods were sufficiently validated and are suitable to measure tolclofos-methyl in animal and plant commodities.

### **Storage of pesticide residues in stored analytical samples**

The Meeting received information on storage stability of tolclofos-methyl in lettuce and potato tuber

commodities.

Tolclofos-methyl was stable for at least 18 months in lettuce and 22 months in potatoes, when stored frozen at -18 °C.

The Meeting agreed that the demonstrated storage stability in the high water and the high starch commodities covered the residue sample storage intervals used in the field trials considered by the current Meeting.

### ***Definition of the residue***

#### ***Plant commodities***

Parent tolclofos-methyl was present at various levels in the edible parts of the plants at up to 40% TRR in lettuce, up to 8.3% TRR in potato tubers and up to 50% TRR in sugar beet roots. In cotton and peanuts, the TRRs were too low to permit identification of residue components in the edible parts. Different metabolic profiles were observed for different application methods in lettuce with seedlings and soil treatment and in potato with seed tuber treatment.

In most primary crop commodities in the metabolism studies, tolclofos-methyl is found in significant proportions (8.3–40% TRR) and is a suitable marker compound. In supervised field trials on potatoes, parent was frequently found above the LOQ. The Meeting noted that suitable analytical methods exist to measure tolclofos-methyl in plant commodities. The Meeting defined the residue for compliance with the MRL in plant commodities as tolclofos-methyl.

Regarding dietary risk assessment, major metabolites were DM-TM-CH<sub>2</sub>OH found at 11–27% TRR in potatoes, ph-CH<sub>3</sub> sugar conjugate (malonylglucose conjugate) found at 20–23% TRR and TM-CH<sub>2</sub>OH sugar conjugate (glucose conjugate) found at 14–15% TRR in lettuce. DM-TM was a major processing degradate of tolclofos-methyl, which occurred at 24–87% applied radioactivity in a high temperature hydrolytic study and could be detected in heated potatoes and lettuce. The metabolites were identified in the rodent metabolism studies at significant levels (> 10% of TRR), and hence are covered by the risk assessment for parent compound. The Meeting concluded that these metabolites potentially add significantly to the dietary exposure to tolclofos-methyl in plant commodities and should be included in the residue definition for dietary risk assessment in plant commodities.

In plant commodities, the residue definition for dietary risk assessment is the sum of tolclofos-methyl, ph-CH<sub>3</sub> (including conjugates), TM-CH<sub>2</sub>OH (including conjugates), DM-TM-CH<sub>2</sub>OH and DM-TM, expressed as tolclofos-methyl.

To convert residues of tolclofos-methyl from the supervised trials to values for total residue (sum of tolclofos-methyl and the metabolites), the Meeting derived the following adjustment factors from the ratios of total residue to parent residues observed in the metabolism studies (lettuce, potato).

Leafy greens (seedlings and soil treatment): 2.0 (lettuce).

Potato (seed tuber treatment): 6.0 (potato seed tuber).

#### ***Animal commodities***

Metabolism studies in lactating goats and laying hens were conducted at two dose levels (250 ppm and 11 ppm in goats; 167 ppm and 11 ppm in hens). The Meeting noted that the livestock dietary burden based on uses considered by the Meeting was very low and considered the lower dose level more representative. The Meeting decided to use the results from the metabolism study performed at the lower dose level.

In goat, tolclofos-methyl was found at 4.4% TRR (0.011 mg/kg) in liver, 12% TRR (0.029 mg/kg) in kidney and was not detected in milk. In hens, tolclofos-methyl was found at 0.5% TRR (0.002 mg/kg) in liver, 5.0% TRR (0.001 mg/kg) in muscle, 35% TRR (0.021 mg/kg) in yolk, 29% TRR (0.021 mg/kg) in skin and 76% TRR (0.034 mg/kg) in fat.

Tolclofos-methyl was found in most animal commodities, was the most significant residue in hen fat, skin and yolk and is therefore a suitable marker compound. The Meeting noted that a suitable analytical method exists to measure tolclofos-methyl in animal commodities. The Meeting defined the residue for compliance with the MRL in animal commodities as tolclofos-methyl.

The log  $K_{ow}$  value of tolclofos-methyl indicates lipophilic properties (3.8 at 25 °C). Residues of tolclofos-methyl in fatty matrices were at least 30-fold higher than residues in non-fatty matrices (egg white/egg yolk: ND/0.021 mg/kg; hens muscle/fat: 0.001/0.034 mg/kg). Therefore, the Meeting concluded that the residue is fat-soluble.

Regarding dietary risk assessment, metabolite ph-COOH (incl. conjugate) was a major metabolite found at 10% TRR (0.026 mg eq/kg) in goat liver, 13% TRR (0.031 mg eq/kg) in goat kidney, 18% TRR (0.076 mg eq/kg) in hen liver, 12% TRR (0.001 mg eq/kg) in hen muscle, 11% TRR (0.008 mg eq/kg) in hen skin and 3.7% TRR (0.002 mg eq/kg) in hen fat. The metabolite was identified at significant levels (> 10% of TRR) in the rodent metabolism studies, and hence is covered by the risk assessment for the parent compound. The Meeting concluded that the metabolite adds significantly to the dietary exposure arising from animal commodities and decided to include ph-COOH for dietary risk assessment for animal commodities.

Metabolite TMO-COOH (incl. conjugate), which can be produced by oxidation of TM-CH<sub>2</sub>OH under acidic conditions during the analytical extraction process, was also found at 5.4% TRR (0.013 mg eq/kg) in goat kidney, 6.7% TRR (0.001 mg eq/kg) in goat milk, 2.0% TRR (< 0.001 mg eq/kg) in hen muscle, 1.3% TRR (0.001 mg eq/kg) in hen skin, and 0.7% TRR (0.003 mg eq/kg) in hen liver. The Meeting noted that TMO-COOH is less than 10% of TRR in all matrices and < 0.01 mg eq/kg in all matrices except goat kidney. The Meeting further noted that the dose level in the goat metabolism study (11 ppm) is 24-fold higher than the maximum dietary burden for beef cattle calculated by the current Meeting. The interval between the last dose and sacrifice in the goat study (6–7 hours) is significantly shorter than the interval between last feeding and slaughter of mammalian livestock in normal commercial practice (typically 20–24 hours), and the Meeting therefore considered that the metabolism study is likely to overestimate the level of TMO-COOH found in animal commodities in practice. The Meeting considered that there is little possibility of significant levels of TMO-COOH being detected in animal commodities, and decided not to include TMO-COOH in the definition for dietary risk assessment for animal commodities.

The Meeting defined the residue for dietary risk assessment for animal commodities as the sum of tolclofos-methyl and 3,5-dichloro-4-hydroxybenzoic acid (ph-COOH), expressed as tolclofos-methyl.

The Meeting recommended the following residue definitions for tolclofos-methyl:

Definition of the residue for compliance with the MRL for plant commodities: *tolclofos-methyl*.

Definition of the residue for dietary risk assessment for plant commodities: *sum of tolclofos-methyl, ph-CH<sub>3</sub> (incl. conjugates), TM-CH<sub>2</sub>OH (incl. conjugates), DM-TM-CH<sub>2</sub>OH and DM-TM, expressed as tolclofos-methyl*.

Definition of the residue for compliance with the MRL for animal commodities: *tolclofos-methyl*.

Definition of the residue for dietary risk assessment for animal commodities: *sum of tolclofos-methyl and ph-COOH, expressed as tolclofos-methyl*.

The residue is fat-soluble.

### **Results of supervised residue trials on crops**

Supervised trials were available for the use of tolclofos-methyl on potato and lettuce. Product labels were available from Belgium, Germany, Italy and the Netherlands. The Meeting withdrew its previous recommendation on radish.

**Leafy vegetables****Lettuce**

The critical GAP for tolclofos-methyl on protected lettuce and other salad greens in Italy is a single spray application at a rate of 2 kg ai/ha when transplanting with a 28 days PHI. Five independent trials conducted in Belgium, France and Italy in 2000 and 2005 matched the Italian GAP.

Tolclofos-methyl residues in head lettuce were (n = 5): 0.08, 0.16, 0.18, 0.24 and 0.39 mg/kg.

As application was made at BBCH 18–19 or 12–16 (2–6 true leaves), no difference in residue levels between head lettuce and leafy lettuce is expected. Therefore, the Meeting decided to estimate a maximum residue level for head lettuce and leafy lettuce.

The Meeting estimated maximum residue levels of 0.7 mg/kg for tolclofos-methyl in head lettuce and leafy lettuce. Based on the adjustment factor of 2.0 for total residues (parent plus metabolites), the Meeting estimated STMRs of 0.36 mg/kg (0.18 mg/kg × 2.0) for head lettuce and leafy lettuce.

The GAP covers use on crops in the subgroup of leafy greens, except spinach, purslane and chard. Therefore, the Meeting estimated a maximum residue level of 0.7 mg/kg and a STMR of 0.36 mg/kg for tolclofos-methyl in the Subgroup 013A Leafy greens except spinach, purslane and chard.

**Root and tuber vegetables****Potato**

The critical GAP for tolclofos-methyl on potato seed tuber in Italy is a single seed dressing before planting at a rate of 0.25 kg ai/t tubers. Thirty-one independent trials conducted in France, Germany, Greece, Italy, Spain and the UK, conducted between 1980 and 2013, matched the Italian GAP.

Tolclofos-methyl residues in potato were (n = 31): < 0.01 (10), 0.01 (6), 0.02 (5), 0.03, 0.04, < 0.05 (2), 0.05, 0.08, 0.08, 0.12, 0.18 and 0.21 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for tolclofos-methyl in potato. Based on the adjustment factor of 6.0 for total residues, the Meeting estimated a STMR of 0.060 mg/kg (0.010 mg/kg × 6.0) for potato.

**Fate of residues during processing**

Tolclofos-methyl was converted into DM-TM under processing hydrolysis conditions. At pH 4 and 90 °C (20 min), pH 5 and 100 °C (60 min), and pH 6 and 120 °C (20 minutes) conditions, tolclofos-methyl/DM-TM occurred at 75%/24%, 47%/53% and 13%/87%, respectively.

In the processing studies on potatoes, no information was provided on the fate of tolclofos-methyl metabolites during processing.

Table 2. Tolclofos-methyl processing factors (PF) for livestock dietary burden estimation

Raw commodity	Processed commodity	Individual PF	Mean or best estimate PF
Potato	Potato wet peel	1.5, 2.0, 2.5, 2.9, 3.3, 3.6, 3.7, 4.0, 4.0, 4.1, 4.4, 4.5, 5.0, 5.3, 5.3, 6.0, 6.0, 6.6, 6.7, 7.1 and 7.2 (n = 21)	4.4

**Residues in animal commodities****Farm animal feeding studies**

No information was provided.

### Farm animal dietary burden

In the current Meeting, potato cull and potato process waste (wet peel) were feed items relevant to estimate animal dietary burdens. Based on potato field residue data, median and highest residue values for tolclofos-methyl in potatoes were 0.01 mg/kg and 0.21 mg/kg, respectively. The median residue of tolclofos-methyl in potato wet peel (potato process waste) was calculated as 0.044 mg/kg by applying the processing factor of 4.4 (0.01 mg/kg × 4.4).

Dietary burden calculations for cattle and poultry are provided below. The dietary burdens were estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual<sup>17</sup>.

To estimate maximum residue levels for tolclofos-methyl in animal commodities, maximum dietary burdens for tolclofos-methyl from potato feed items were estimated. Further, to estimate STMRs and HRs for the sum of tolclofos-methyl and ph-COOH in animal commodities, mean and maximum dietary burdens for the sum of tolclofos and the metabolites convertible to ph-COOH (DM-TM-CH<sub>2</sub>OH, DM-TM-COOH, TM-CH<sub>2</sub>OH, ph-COOH and DM-TMO found in a metabolism study on potato) were estimated by multiplying maximum and mean dietary burdens for tolclofos-methyl with a factor of 6. The factor 6 was calculated by 0.012 mg eq/kg (sum) divided by 0.002 mg/kg (parent) based on residue levels shown in a potato metabolism study: parent 0.002 mg/kg, DM-TM-CH<sub>2</sub>OH 0.004 mg eq/kg, DM-TM-COOH 0.002 mg eq/kg, TM-CH<sub>2</sub>OH 0.002 mg eq/kg, ph-COOH < 0.001 mg eq/kg and DM-TMO < 0.001 mg eq/kg.

Table 3 Estimated animal dietary burden

	Animal dietary burden: tolclofos-methyl, ppm of dry matter diet					
	US-Canada		EU		Australia	
	max	mean	max	mean	max	mean
Beef cattle	0.43	0.13	0.46 <sup>a</sup> (2.8) <sup>A</sup>	0.16 (0.97) <sup>B</sup>	0.12	0.023
Dairy cattle	0.14	0.042	0.43 <sup>b</sup> (2.6) <sup>A</sup>	0.13 (0.75) <sup>B</sup>	0.11	0.005
Poultry – broiler			0.11 <sup>c</sup> (0.63) <sup>A</sup>	0.005 (0.030) <sup>B</sup>		
Poultry – layer			0.11 <sup>d</sup> (0.63) <sup>A</sup>	0.005 (0.030) <sup>B</sup>		

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

<sup>c</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

<sup>d</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

<sup>A</sup> Values in bracket are burdens for estimates of animal HRs (6×parent)

<sup>B</sup> Values in bracket are burdens for estimates of animal STMRs (6×parent)

### Animal commodity maximum residue levels

Feeding studies (goat, hen) were not available. The Meeting decided to use the goat and hen metabolism studies conducted at a feeding level of 11 ppm to evaluate residue levels in mammalian and poultry commodities.

The residue definition for compliance with MRLs in animal commodities is tolclofos-methyl. Residues of tolclofos-methyl in the goat metabolism study were not detected in milk, < 0.01 mg/kg in fat, < 0.005 mg/kg in muscle, 0.011 mg/kg in liver and 0.029 mg/kg in kidney. When scaled to the dietary burden for estimating maximum residue levels (0.46 ppm beef cattle, 24-fold lower than the dose in the metabolism study/0.43 ppm dairy cattle), the anticipated residues are < 0.01 mg/kg in all

<sup>17</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

commodities. The Meeting estimated maximum residue levels of 0.01(\*) mg/kg for all mammalian commodities.

The residue definition for dietary risk assessment in animals is the sum of tolclofos-methyl and ph-COOH, expressed as tolclofos-methyl. Residues corresponding to the risk assessment definition from the goat metabolism study were: not detected in milk, < 0.01 mg/kg in fat, < 0.005 mg/kg in muscle, 0.037 mg/kg in liver and 0.060 mg/kg in kidney. When scaled to the dietary burden for risk assessment (mean 0.97 ppm in beef cattle; mean 0.75 ppm in dairy cattle STMR estimates are 0 mg/kg for fats (except milk fats), 0 mg/kg for meat (from mammals other than the marine mammals), 0.0055 mg/kg for edible offal (mammalian; based on kidney) and an STMR of 0 mg/kg in milks.

For poultry, residues of tolclofos-methyl in the metabolism study were 0.001 mg/kg in muscle, 0.034 mg/kg in fat, 0.021 mg/kg in skin, 0.002 mg/kg in liver and 0.021 mg/kg in yolk. When scaled to the dietary burden for estimating maximum residue levels (0.11 ppm poultry, broiler and layer, 105-fold lower than the dose of the metabolism study), the anticipated residues are < 0.01 mg/kg in all commodities. The Meeting estimated maximum residue levels of 0.01(\*) mg/kg for all poultry commodities.

Residues corresponding to the risk assessment definition from the hen metabolism study were: 0.002 mg/kg in muscle, 0.036 mg/kg in fat, 0.029 mg/kg in skin, 0.078 mg/kg in liver and 0.021 mg/kg in yolk. When scaled to the dietary burden for risk assessment (mean 0.030 ppm in poultry broiler and layer), STMR estimates are 0 mg/kg for muscle, 0 mg/kg for fat, 0 mg/kg in skin, 0 mg/kg for edible offal (based on liver) and 0 mg/kg in egg yolk.

## 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 assessment.

Definition of the residue for compliance with the MRL for plant and animal commodities: *tolclofos-methyl*

Definition of the residue for dietary risk assessment for plant commodities: *sum of tolclofos-methyl, 2,6-dichloro-4-methylphenol (ph-CH<sub>3</sub>, incl. conjugates), O,O-dimethyl O-2,6-dichloro-4-(hydroxymethyl) phenylphosphorothioate (TM-CH<sub>2</sub>OH, incl. conjugates), O-methyl O-hydrogen O-2,6-dichloro-4-(hydroxymethyl) phenylphosphorothioate (DM-TM-CH<sub>2</sub>OH) and O-methyl O-hydrogen O-(2,6-dichloro-4-methylphenyl) phosphorothioate (DM-TM), expressed as tolclofos-methyl*

Definition of the residue for dietary risk assessment for animal commodities: *sum of tolclofos-methyl and 3,5-dichloro-4-hydroxybenzoic acid (ph-COOH), expressed as tolclofos-methyl*

*The residue is fat-soluble.*

## DIETARY RISK ASSESSMENT

### **Long-term dietary exposure**

The ADI for tolclofos-methyl is 0–0.07 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for tolclofos-methyl 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 2019 JMPR Report.

The IEDIs ranged from 0–1% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of tolclofos-methyl from uses considered by the JMPR is unlikely to present a public health concern.

### **Acute dietary exposure**

The 2019 JMPR decided that an ARfD for tolclofos-methyl was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of tolclofos-methyl from the uses considered is

unlikely to present a public health concern.



## 5.27 Tolfenpyrad (269)

### RESIDUE AND ANALYTICAL ASPECTS

Tolfenpyrad is a pyrazole insecticide first evaluated by JMPR for toxicology and residues in 2013 when an ADI of 0–0.006 mg/kg bw and an ARfD of 0.01 mg/kg bw were established. The residue definition for plant commodities for compliance with the MRL and dietary risk assessment is *tolfenpyrad*. The residue definition for animal commodities for compliance with the MRL and dietary risk assessment is the *sum of tolfenpyrad and PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylamino]methyl] phenoxy] benzoic acid; free and conjugated) and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonyl amino]methyl] phenoxy] benzoic acid; released with alkaline hydrolysis) expressed as tolfenpyrad*. The residue is not fat soluble.

Tolfenpyrad was scheduled at the Fiftieth Session of the CCPR for the evaluation of additional uses by the 2019 JMPR.

#### **Residues in supervised residue trials on crops**

The Meeting received supervised residue trials for application of tolfenpyrad to citrus, dry bulb onion, green onion, cucumber, tomatoes, and peppers. Residues from the trials were analysed by a suitable analytical method, and the results are supported by adequate storage stability data; both previously evaluated by the 2013 Meeting.

#### *Citrus*

The critical GAP for citrus in the USA is a single application at 0.31 kg ai/ha, with a 3-day PHI.

Field trials were available from the USA in grapefruit, lemon, and orange, approximating the US GAP. In the processing studies discussed below, the best estimate processing factor for citrus flesh was 0.32, which was used to derive the STMR and HR values for citrus fruits. Residues in whole fruits were as follows:

Lemon (n = 8): 0.13, 0.16, 0.24, 0.26, 0.27, 0.32, 0.33, and 0.48, mg/kg (highest single value = 0.57 mg/kg).

Lemons are representative of the subgroup of lemons and limes. The Meeting estimated a maximum residue level of 0.9 mg/kg for tolfenpyrad in the Subgroup of Lemons and Limes, an STMR of 0.085 mg/kg, and an HR of 0.18 mg/kg.

Orange (n = 11): 0.043, 0.058, 0.14, 0.15, 0.16, 0.19, 0.21, 0.23, 0.25, 0.31, and 0.35 mg/kg (highest single value = 0.42 mg/kg).

Oranges are representative of the subgroup of oranges. The Meeting estimated a maximum residue level of 0.6 mg/kg for tolfenpyrad in the Subgroup of Oranges, Sweet, Sour, an STMR of 0.061 mg/kg, and an HR of 0.13 mg/kg.

Grapefruit (n = 6): 0.017, 0.087, 0.12, 0.14, 0.15, and 0.30 mg/kg (highest single value = 0.31 mg/kg).

Grapefruit are representative of the subgroup of pummelo and grapefruits. The Meeting estimated a maximum residue level of 0.6 mg/kg for tolfenpyrad in the Subgroup of Pummelo and Grapefruits, an STMR of 0.042 mg/kg, and an HR of 0.099 mg/kg.

The GAP covers the group of citrus fruits, including use on mandarins. Although trials were not provided for mandarins, the Meeting noted that residues in lemons/limes have been shown to be similar to or greater than residues in mandarins. Therefore, the Meeting decided to extrapolate the residues from lemon and estimated a maximum residue level of 0.9 mg/kg for tolfenpyrad in the Subgroup of Mandarins, an STMR of 0.085 mg/kg, and an HR of 0.18 mg/kg.

### *Bulb vegetables*

The critical GAP for bulb vegetables in the USA is a single application at 0.28 kg ai/ha, with a 7-day PHI.

#### *Bulb onion*

Field trials in bulb onion were available from the USA approximating the US GAP. Residues in bulb onion were (n = 6): < 0.01 (2), 0.012, 0.013, 0.036, and 0.047 mg/kg (highest single value = 0.057 mg/kg).

The Meeting estimated a maximum residue level of 0.09 mg/kg of tolfenpyrad in the Subgroup of Bulb Onions, an STMR of 0.0125 mg/kg, and an HR of 0.057 mg/kg.

#### *Green onion*

Field trials in green onion were available from the USA approximating the US GAP. Residues in green onion were (n = 4): 0.65, 1.3, 2.0, and 4.9 mg/kg (highest single value = 4.9 mg/kg).

Five trials are considered necessary to estimate maximum residue levels for green onions; therefore, the Meeting did not make any recommendations for green onion.

#### *Cucumber*

The critical GAP for greenhouse-grown cucumber in the USA is four applications, each at 0.31 kg ai/ha on a 14-day interval, with a 1-day PHI.

Trials in greenhouse-grown cucumber were available from the USA approximating the US GAP. Residues in cucumber (n = 4) were: 0.10, 0.14, 0.19, and 0.21 mg/kg (highest single value = 0.25 mg/kg).

Six trials are considered necessary to estimate maximum residue levels for cucumbers; therefore, the Meeting did not make any recommendations for cucumber.

### *Fruiting vegetables, other than cucurbits*

Field trial data for tolfenpyrad in fruiting vegetables, other than cucurbits were evaluated by the 2013 JMPR; however, GAP information for those crops was not available and no recommendations were made. New GAP information for use of tolfenpyrad on these crops was provided to the present Meeting.

The critical GAP for fruiting vegetables, other than cucurbits, in the USA is two applications, each at 0.25 kg ai/ha on a 14-day interval, with a 1-day PHI.

#### *Tomato*

Field trials in tomato were available from the USA approximating the US GAP. Residues in tomato (including cherry tomato) were (n = 12): 0.064, 0.084, 0.092, 0.099, 0.12, 0.13 (3), 0.14, 0.21, 0.23, and 0.50 mg/kg (highest single value = 0.50 mg/kg).

The Meeting estimated a maximum residue level of 0.7 mg/kg of tolfenpyrad in the Subgroup of Tomatoes, an STMR of 0.13 mg/kg, and an HR of 0.5 mg/kg.

Acute dietary exposure assessment indicated that residues in tomato may exceed the acute reference dose (ARfD) of 0.01 mg/kg bw, at 110 to 190% for different commodities (i.e. raw with peel, cooked, and canned) and multiple populations. No alternative GAP was available.

#### *Peppers*

Field trials in peppers were available from the USA approximating the US GAP. Residues in peppers ([CH] = chili peppers) were (n = 9): 0.060, 0.063, 0.077, 0.080, 0.11, 0.12<sup>[CH]</sup>, 0.16, 0.28<sup>[CH]</sup>, and 0.29<sup>[CH]</sup> mg/kg (highest single value = 0.32<sup>[CH]</sup> mg/kg).

The Meeting estimated a maximum residue level of 0.5 mg/kg of tolfenpyrad in the Subgroup of Peppers (except okra, martynia, and roselle), an STMR of 0.11 mg/kg, and an HR of 0.32 mg/kg.

Using the default concentration factor of 10 for deriving residues in dried chili pepper from peppers, the Meeting estimated a maximum residue level of 5 mg/kg for tolfenpyrad in dried chili pepper, an STMR of 1.1 mg/kg, and an HR of 3.2 mg/kg.

### *Eggplant*

The Meeting noted that the registration is for the US fruiting vegetables group and decided to extrapolate the residue data to the Subgroup of Eggplants. As noted by the 2018 JMPR, residues in tomatoes and peppers may be equally suitable for extrapolation to eggplant and the extrapolation resulting in the higher maximum residue recommendation should be used. Therefore, the Meeting extrapolated from tomato and estimated a maximum residue level of 0.7 mg/kg of tolfenpyrad in the Subgroup of Eggplants, an STMR of 0.13 mg/kg, and an HR of 0.5 mg/kg.

Acute dietary exposure assessment indicated that residues in eggplant may exceed the acute reference dose (ARfD) of 0.01 mg/kg bw, at 130% for the general population and 240% for children in China. No alternative GAP was available.

### **Residues in processed commodities**

Processing factors based on data reviewed by the 2013 and 2019 Meetings are summarized below, as well as estimates of maximum residue levels, STMR-P and HR-P, as needed. The Meeting decided to extrapolate processing factors from orange to citrus.

Table 1 Summary of processing factors, maximum residue levels, STMRs and HRs for tolfenpyrad in processed commodities

Crop	Commodity	Processing factor [best estimate]
Citrus	Flesh	0.03, 0.32 [0.32]
	Peel (fresh)	3.0, 6.5 [4.8]
	Dried pulp	8.9 (2013, single value)
	Juice (pasteurised)	0.018 (2013), 0.12, 0.32, [0.22] <sup>a</sup>
	Marmalade	0.09, 0.15 [0.12]
	Oil	83 (2013, single value)
Tomato	Puree	0.34
	Paste	1.1

<sup>a</sup> Mean of 0.12 and 0.32.

Table 2 Summary of residue estimates for processed commodities

RAC	Residue, mg/kg			Processed commodity	Processing factor	Residue, mg/kg		
	Max. level	STMR	HR			Max. level	STMR-P	HR-P
Lemon/mandarin	0.9	0.265 (wf)	0.57 (wf)	Peel (fresh)	4.8	--	1.3	2.7
				Juice	0.22	--	0.058	--
				Marmalade/Jam	0.12	--	0.032	0.068
				Oil	83	80	22	--
Orange	0.6	0.19 (wf)	0.42 (wf)	Peel (fresh)	4.8	--	0.91	2.0
				Juice	0.22	--	0.042	--
				Pulp (dried)	8.9	6	1.7	--
				Marmalade/Jam	0.12	--	0.023	0.050
				Oil	83	50	16	--
Grapefruit	0.6	0.13 (wf)	0.31 (wf)	Peel (fresh)	4.8	--	0.62	1.5
				Juice	0.22	--	0.029	--
Tomato	0.7	0.13	0.5	Puree	0.34	--	0.044	--
				Paste	1.1	--	0.14	--

(wf) = whole fruit

For citrus, dried pulp, the Meeting estimated a maximum residue level of 6 mg/kg and a median residue of 1.7 mg/kg.

For citrus oil, the Meeting estimated a maximum residue level of 80 mg/kg and an STMR-P of 22 mg/kg based on residue estimates for lemon oil.

### **Residues in animal commodities**

The Meeting estimated dietary burdens for livestock based on residues in potato (STMR and HR = 0; 2016 Meeting) tomato wet pomace (using residue estimates for tomato), and dried citrus pulp. The dietary burdens were estimated using the 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual<sup>18</sup>. The burdens are summarized below.

Table 3 Summary of livestock dietary burdens, as ppm of dry matter, for tolfenpyrad

Livestock	Canada and US		European Union		Australia		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	0.19	0.19	0.093	0.093	0.56	0.56	--	--
Dairy cattle	0.19	0.19	0.37	0.37	0.56 <sup>a, b</sup>	0.56 <sup>c, d</sup>	--	--
Broiler chickens	No feed items							
Layer hens	No feed items							

<sup>a</sup> Highest maximum dietary burden for beef or dairy cattle; suitable for estimating the maximum residue levels for mammalian meat, fat, and offal.

<sup>b</sup> Highest maximum dietary burden for dairy cattle; suitable for estimating the maximum residue levels for milk.

<sup>c</sup> Highest mean dietary burden for beef or dairy cattle; suitable for estimating STMRs for mammalian meat, fat, and offal.

<sup>d</sup> Highest mean dietary burden for dairy cattle; suitable for estimating the STMR for milk.

The dietary burden for estimating maximum residue levels, STMRs and HRs for cattle is 0.56 ppm. A lactating-cattle feeding study conducted at feeding levels of 2.5, 7.5, and 25 ppm in the diet was evaluated by the 2013 Meeting. The results from the 2.5-ppm dose level are summarized below. In calculating the total residues (tolfenpyrad + PT-CA + OH-PT-CA), the current Meeting assumed a residue component was zero if it was <LOQ (0.01 mg/kg) at all dose levels. Residues reported as <LOQ at the 2.5-ppm dose were assumed to be 0.01 mg/kg if a quantifiable residue was found at a higher dosing level. Molecular-weight conversion factors were 0.96 for PT-CA (400 g/mol) and 0.93 for OH-PT-CA (414 g/mol).

Table 4 Residues of tolfenpyrad reported in the dairy cattle feeding study (2.5 ppm feeding level only; 2013 JMPR)

Matrix	Maximum total residue at 2.5 ppm	Mean total residue at 2.5 ppm
Milk	0.017 mg eq./kg	0.017 mg eq./kg
Muscle	0.019	0.019
Liver	1.7	1.3
Kidney	0.18	0.14
Fat	0.0096	0.0096

### **Animal commodity maximum residue levels**

Estimated residues in tissues and milk at the dietary burden summarized above are shown in the table below.

<sup>18</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

Table 5 Anticipated residues of tolfenpyrad in cattle commodities

Tolfenpyrad feeding study	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
MRL beef or dairy cattle							
Feeding study <sup>a</sup>	2.5	0.017	2.5	0.019	1.7	0.18	0.0096
Dietary burden and high residue	0.56	0.0038	0.56	0.0043	0.38	0.040	0.0022
STMR beef or dairy cattle							
Feeding study <sup>b</sup>	2.5	0.017	2.5	0.019	1.3	0.14	0.0096
Dietary burden and residue estimate	0.56	0.0038	0.56	0.0043	0.29	0.031	0.0022

<sup>a</sup> Highest residues for tissues and mean residues for milk

<sup>b</sup> Mean residues for tissues and mean residues for milk

The Meeting estimated the following maximum residue levels, STMRs, and HRs: Milks = 0.01(\*), 0.0038 mg/kg (STMR only); mammalian fats except milk fats = 0.01(\*), 0.0022, and 0.0022 mg/kg; meat (from mammals other than marine mammals) = 0.01(\*), 0.0043, and 0.0043 mg/kg; and edible offal (mammalian) = 0.4, 0.29, and 0.38 mg/kg.

For poultry, the dietary burden is currently zero; therefore, the Meeting estimated maximum residue levels of 0.01(\*) mg/kg for all poultry commodities, with STMRs and HRs of 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 and for dietary risk assessment for plant commodities: *Tolfenpyrad*.

Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: The sum of tolfenpyrad, PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonyl aminomethyl] phenoxy] benzoic acid; free and conjugated) and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonyl aminomethyl] phenoxy] benzoic acid; released with alkaline hydrolysis) expressed as tolfenpyrad.

The residue is not fat-soluble.

## DIETARY RISK ASSESSMENT

### **Long-term dietary exposure**

The ADI for tolfenpyrad is 0–0.006 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for tolfenpyrad 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 2019 JMPR Report.

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

### **Acute dietary exposure**

The ARfD for tolfenpyrad is 0.01 mg/kg bw. The International Estimate of Short-Term Intakes (IESTIs) for tolfenpyrad 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 2019 JMPR Report.

The IESTIs were 0–100% of the ARfD for children and for the general population for all commodities except tomato and eggplant. The Meeting concluded that acute dietary exposure to residues of tolfenpyrad from the uses other than tomato and eggplant is unlikely to present a public health concern.

The IESTIs exceeded the ARfD for tomato (up to 190%, children 1–6 years in China), and eggplant (up to 240%, children 1–6 years in China). The Meeting concluded that acute dietary exposure to residues of tolfenpyrad may present a public health concern for those commodities.

## 5.28 Triflumuron (317)

### TOXICOLOGY

Triflumuron is the ISO-approved common name for 2-chloro-*N*-[[4-(trifluoromethoxy)phenyl]carbamoyl]benzamide (IUPAC), for which the CAS number is 64628-44-0.

Triflumuron is a synthetic insecticide from the active ingredient group of chitin biosynthesis inhibitors (chitin inhibitors) type 0. Triflumuron acts primarily as a feeding poison for biting and sucking pests. It disturbs the chitin biosynthesis of insects, particularly in immature life stages. It is used in a wide range of crops, including apple, pear, cabbage, citrus, cotton, potato and tea. It is also used as a veterinary drug.

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

The majority of the studies were conducted prior to the implementation of GLP regulation. GLP-compliant studies are identified in the monograph. Many studies were not conducted in accordance with national or international test guidelines since at the time the studies were performed no particular guideline had been agreed. However, the Meeting considered that overall the database was adequate for the risk assessment.

A search of the open literature did not reveal any relevant information additional to that submitted by the sponsor.

#### **Biochemical aspects**

Absorption, distribution and excretion of triflumuron[[4-(trifluoromethoxy)aniline-UL-<sup>14</sup>C] was studied in rats at a single gavage dose of 1.98 mg/kg bw (low-dose male), 318 mg/kg bw (high-dose male), unlabelled triflumuron at 3.74 mg/kg bw per day for 14 days, followed by a single oral dose of [<sup>14</sup>C]triflumuron at 3.74 mg/kg bw by gavage (multiple dose) and 2.59 mg/kg bw in bile-cannulated rats. Oral absorption of triflumuron was estimated to be greater than 77% based on excretion of 41% in bile and 32% in urine, together with 4% in blood and carcass at 48 hours in bile-cannulated rats. The radioactivity was distributed within the body at low concentrations, with the highest levels found in the liver, kidney, spleen, lung and in fatty tissues. No significant differences were seen between the distribution pattern of [chlorophenyl-UL-<sup>14</sup>C]-triflumuron and that of [(trifluoromethoxy)aniline-UL-<sup>14</sup>C]-triflumuron.

Following a single oral administration of 2 mg/kg bw in males, the maximum plasma concentration of radioactivity was reached after 4.9 hours. Elimination was biphasic with half-lives of three and 13 hours in males. Excretion via urine and faeces was essentially complete 96 hours after dosing, with similar amounts excreted in urine and faeces, although female rats excreted slightly less of the radioactivity in urine over a longer period than males.

The half-life in the rat of radiolabelled [2-chlorophenyl-UL-<sup>14</sup>C]triflumuron following oral dosing was relatively long in erythrocytes (ca 17 days); the radioactivity was primarily present in the globin fraction (76.2%). Triflumuron was rapidly metabolized in rats. A total of 17 components were detected in urine. Unchanged triflumuron was present at only low levels (1–2% of dose) in urine. The main metabolites in urine were identified as 2-hydroxy-4-(trifluoromethoxy)aniline (M09) and 3-hydroxy-4-(trifluoromethoxy)aniline (M10) and their sulfate conjugates (M16 and M17 respectively). A total of five components were observed in faecal extracts with the majority of the residue (19% at 3.7 mg/kg bw multiple doses; 91% at 318 mg/kg bw of the administered dose) remaining as unchanged triflumuron. A total of 26 components were observed in bile, with unchanged triflumuron present at only very low levels (< 1% of dose).

In rats, the major detoxification pathway proceeds initially through hydrolysis of triflumuron's urea moiety to yield 4-(trifluoromethoxy)aniline and chlorobenzoic acid. Minor metabolic pathways include hydrolysis of the 2-chlorobenzamide and direct hydroxylation of the trifluoromethoxyaniline ring prior to excretion. Parent and metabolites may also be conjugated.

### **Toxicological data**

The acute LD<sub>50</sub> by the oral and dermal routes in the rat was > 5000 mg/kg bw. The acute inhalation LC<sub>50</sub> in rats was > 5.03 mg/L. Triflumuron is non-irritating to the skin and eyes of rabbits. Triflumuron was not sensitizing to the skin of guinea pigs, as determined by the Magnusson and Kligman test. In a single-dose oral toxicity study, rats were administered triflumuron via gavage at a dose of 0, 10, 70 or 500 mg/kg bw. The NOAEL was 500 mg/kg bw, the highest dose tested.

The main target organ of toxicity in short- and long-term studies in mice, rats and dogs was the haematopoietic system (erythrocyte damage). Compensation or regeneration processes (highly active bone marrow, extramedullary haematopoiesis in the spleen and frequent appearance of immature erythrocytes in the peripheral blood) were observed as a result of the erythrocyte damage. Enlarged spleen and haemosiderosis in spleen, liver and kidneys represented secondary effects.

In a 28-day toxicity study in rats, triflumuron was administered once daily via gavage at doses of 0, 30, 100 and 300 mg/kg bw per day. The NOAEL was 100 mg/kg bw per day based on decreases in erythrocytes and elevated reticulocytes and thrombocytes counts, and extramedullary haematopoiesis (splenic) seen in females at the LOAEL of 300 mg/kg bw per day.

In a 90-day toxicity study in rats, triflumuron was administered via diet at concentrations of 0, 50, 500 and 5000 ppm (equal to 0, 3.6, 35.5, and 349 mg/kg bw per day for males, 0, 4.5, 47.0 and 449 mg/kg bw per day for females). The NOAEL was 50 ppm (equal to 3.6 mg/kg bw per day) based on increased spleen weight in females, and slight declines in haemoglobin and erythrocytes seen at the LOAEL of 500 ppm (equal to 35.5 mg/kg bw per day) in both sexes.

In another 90-day toxicity study in rats, triflumuron was administered via diet at concentrations of 0, 5, 15 and 45 ppm (equal to 0, 0.34, 1.02 and 3.12 mg/kg bw per day for males, 0, 0.39, 1.18 and 3.63 mg/kg bw per day for females), the NOAEL was 45 ppm (equal to 3.12 mg/kg bw per day), the highest dose tested.

In a separate 90-day toxicity study in rats, triflumuron was administered via diet at concentrations of 0, 20, 200 and 2000 ppm (equal to 0, 1.34, 13.9 and 142 mg/kg bw per day for males, 0, 1.52, 15.9 and 149 mg/kg bw per day for females), the NOAEL was 20 ppm (equal to 1.34 mg/kg bw per day) based on decrease in erythrocytes, haemoglobin, haematocrit, mean corpuscular haemoglobin (MCH), mean corpuscular volume (MCV) and increase in reticulocytes (females only) seen at the LOAEL of 200 ppm (equal to 13.9 mg/kg bw per day).

The overall NOAEL for triflumuron in 90-day toxicity studies in rats was 50 ppm (equal to 3.6 mg/kg bw per day), on the basis of haematological effects (decreased haemoglobin and erythrocytes) seen at 200 ppm (equal to 13.9 mg/kg bw per day).

In a 90-day toxicity study in dogs, triflumuron was administered in the diet at concentrations of 0, 100, 500 or 2500 ppm (equal to 0, 3.21, 17.3 or 85.2 mg/kg bw per day for males, 0, 3.66, 17.1 or 87.7 mg/kg bw per day for females). The NOAEL was 100 ppm (equal to 3.21 mg/kg bw per day) based on decreased haemoglobin and erythrocytes, increased methaemoglobin, reticulocytes and thrombocytes and histological findings (increase in bone marrow cells and extramedullary erythropoiesis in the spleen) at 500 ppm (equal to 17.1 mg/kg bw per day).

In a 12-month toxicity study in dogs, triflumuron was administered at concentrations of 0, 40, 200 or 1000 ppm in the diet (equal to 0, 1.42, 7.1 or 35.3 mg/kg bw per day for males, 0, 1.50, 7.3 or 37.9 mg/kg bw per day for females), the NOAEL was 40 ppm (equal to 1.42 mg/kg bw per day) based on haematological changes (increased reticulocytes), increased absolute spleen weight, pigmentation in liver, kidney and spleen seen at the LOAEL of 200 ppm (equal to 7.1 mg/kg bw per day).

In a separate 12-month toxicity study in dogs, triflumuron was administered at concentrations of 0 or 20 ppm in the diet (equivalent to 0 and 0.72 mg/kg bw per day) for a period of 12 months. The NOAEL was 20 ppm (equivalent to 0.72 mg/kg bw per day), the highest dose tested.

The overall NOAEL for 90-day and 12-month toxicity studies in dogs was 100 ppm (equal to 3.2 mg/kg bw per day). The LOAEL was 200 ppm (equal to 7.1 mg/kg bw per day).



Fluoride levels were elevated in the bones and teeth of rats and mice in chronic studies. No macroscopic or microscopic alterations of the bones or teeth were observed.

In a study of carcinogenicity in mice, triflumuron was administered via diet for 24 months at a concentration of 0, 20, 200 or 2000 ppm (equal to 0, 5.19, 49.0 and 523 mg/kg bw per day in males, 6.68, 67.9 and 692 mg/kg bw/day in females). The NOAEL for systemic toxicity was 20 ppm (equal to 5.19 mg/kg bw per day) based on haematological changes (reduced thrombocytes, increased Heinz bodies in males; reticulocytes, Heinz bodies, MCV and MCH values increased in females) and histopathological findings (increased haemosiderin pigment storage in the spleen in both sexes) seen at the LOAEL of 200 ppm (equal to 49.0 mg/kg bw per day). The NOAEL for carcinogenicity was 2000 ppm (equal to 523 mg/kg bw per day), the highest dose tested.

In a study of chronic carcinogenicity in rats, triflumuron was administered for 24 months via diet at a concentration of 0, 20, 200 or 2000 ppm (equal to 0, 0.82, 8.45 and 86.1 mg/kg bw per day in males, 0, 1.11, 11.2 and 110 mg/kg bw/day in the females). The NOAEL for systemic toxicity was 20 ppm (equal to 0.82 mg/kg bw per day) based on haematological effects (reticulocytes increased in males; leukocytes, erythrocytes, haemoglobin and haematocrit values reduced in females), and increased spleen weights seen at the LOAEL of 200 ppm (equal to 8.45 mg/kg bw per day). The NOAEL for carcinogenicity was 2000 ppm (equal to 86.1 mg/kg bw per day), the highest dose tested.

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

Triflumuron was tested for genotoxicity in a range of in vitro and in vivo assays. Although there were some deficiencies in the studies, no concerns were identified.

The Meeting concluded that triflumuron is unlikely to be genotoxic in vivo.

In view of the lack of carcinogenicity in mice and rats, and that it is unlikely to be genotoxic, the Meeting concluded that triflumuron is unlikely to pose a carcinogenic risk to humans from the diet.

In a multigeneration reproduction study in rats, triflumuron was administered via diet at a nominal dose of 0, 20, 200 or 2000 ppm (equivalent to 0, 1.32, 13.2 or 132 mg/kg bw per day) for three generations. The NOAEL for parental systemic toxicity, reproductive toxicity and offspring toxicity was 2000 ppm (equivalent to 132 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats, triflumuron was administered once daily by gavage at 0, 10, 30 or 100 mg/kg bw per day during GD 6–15. The NOAEL for maternal and embryo toxicity was 100 mg/kg bw per day, the highest dose tested.

In a separate developmental toxicity study in rats, triflumuron was administered once daily by gavage at 0, 100, 300 or 1000 mg/kg bw per day during GD 6–15. At 1000 mg/kg bw per day haematological effects were seen in maternal animals, however, a NOAEL for maternal toxicity could not be identified as no haematological measurements were conducted at 100 and 300 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 300 mg/kg bw per day based on a slight increase in skeletal variations (delayed ossifications) seen at the LOAEL of 1000 mg/kg bw per day, the highest dose tested.

In a developmental toxicity study in rabbits, triflumuron was administered once daily by gavage at 0, 10, 30 or 100 mg/kg bw per day during GD 6–18. The NOAEL for maternal and embryo/foetal toxicity was 100 mg/kg bw per day, the highest dose tested.

In a separate developmental toxicity study in rabbits, triflumuron was administered once daily by gavage at 0, 100, 300 or 1000 mg/kg bw per day during GD 6–18. At 1000 mg/kg bw per day haematological effects were observed in maternal animals, however, a NOAEL for maternal toxicity cannot be identified as no haematological measurements were conducted at 100 and 300 mg/kg bw per day. The NOAEL for embryo/fetal toxicity was 300 mg/kg bw per day based on increased resorption rate (late) seen at the LOAEL of 1000 mg/kg bw per day.

The Meeting concluded that triflumuron is not teratogenic.

No neurotoxicity studies are available, however, no evidence of neurotoxicity or neuropathology was observed in any of the studies of systemic toxicity.

The Meeting concluded that triflumuron is unlikely to be neurotoxic.

No evidence of direct immunotoxic effects were observed in the available toxicity studies.

The Meeting concluded that triflumuron is unlikely to be immunotoxic.

### **Toxicological data on metabolites and/or degradates**

The compound 4-(trifluoromethoxy)aniline (M07; *p*-aminotrifluoroanisole; trifluoromethyl-4-aminophenyl ether; KLU 2996B) is a plant and rat metabolite. It was detected in a rat metabolism study at a trace level.

The LD<sub>50</sub> of 4-(trifluoromethoxy)aniline in rats was 63 mg/kg bw. The acute dermal LD<sub>50</sub> of 4-(trifluoromethoxy)aniline in rats was 25–50 mg/kg bw. The four hour inhalation LC<sub>50</sub> in rats was 0.86–0.95 mg/L. It was non-irritating to the skin of rabbits and moderately irritating to the eyes of rabbits. In a limited study, cats were orally administered (gavage) 4-(trifluoromethoxy)aniline at 0, 0.5, 1.0 and 2.5 mg/kg bw (two cats/dose) and methaemoglobin formation was measured at 0, 3, 6, 24 and 48 hours post dosing. Methaemoglobin formation was observed at a single gavage dose of 1 mg/kg bw and above.

The compound 4-(trifluoromethoxy)aniline did not have any methaemoglobin-forming effect following single-dose administration of 500 mg/kg bw to male domestic cats.

Following administration of a 0.1 mg/kg bw per day gavage dose (total of 10 doses) no haemotoxic effects or methaemoglobin formation were detected in female domestic cats. After 2.5 mg/kg bw per day gavage dose (total of eight doses) 4-(trifluoromethoxy)aniline caused haemotoxic effects resulting in methaemoglobin formation and destruction of haemoglobin (Heinz body formation) in female domestic cats.

In a toxicity study in rats, 4-(trifluoromethoxy)aniline was administered as a single oral gavage dose at concentrations of 0, 0.5, 2 and 10 mg/kg bw per day. Animals from one group were killed 24 hours post-dosing and another group at five days post-dosing. The NOAEL of 0.5 mg/kg bw was based on clinical signs, chocolate brown coloration of the blood, higher methaemoglobin levels in both sexes, a slight increase in mean absolute reticulocyte counts in females (not statistically significant), observed one hour post-dosing, and increases in both absolute and relative weight in females and a slightly higher severity grade of diffuse extramedullary haematopoiesis in the spleen of females (termination) seen at the LOAEL of 2 mg/kg bw.

Investigations using the Ames test, an in vitro DNA test and an in vivo micronucleus test 4-(trifluoromethoxy)aniline was negative for genotoxicity.

*N,N'*-bis(trifluoromethoxyphenyl)urea (technical impurity) has an acute oral LD<sub>50</sub> to rats of 133 mg/kg bw. The acute oral LD<sub>50</sub> to domestic cats was > 1000 mg/kg bw and no haemotoxic effects were observed.

The Meeting concluded that metabolite M02 and metabolite M03 are major rat metabolites and would be covered by the toxicity of the parent compound. No data are available for metabolite M01 and M04 and these metabolites were not detected in rat metabolism studies, therefore the Meeting concluded that the genotoxic TTC value is appropriate for M01 and M04 for dietary exposure assessment. The Meeting also concluded that metabolite M08 would be covered by the toxicity of metabolite M07.

### **Microbiological data**

No data are available.

### **Human data**

Occupational medical surveillance of workers exposed to triflumuron during manufacturing indicate no health hazard to workers.

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

### Toxicological evaluation

The Meeting established an ADI for triflumuron of 0–0.008 mg/kg bw, based on the NOAEL of 20 ppm (equal to 0.82 mg/kg bw per day) based on haematological effects and increase in spleen weights seen at the LOAEL of 200 ppm (equal to 8.45 mg/kg bw per day), observed in the two-year carcinogenicity study in rats and using a safety factor of 100.

The Meeting concluded that it was not necessary to establish an ARfD for triflumuron in view of its low acute oral toxicity, lack of systemic toxicity in a single-dose study at doses up to 500 mg/kg bw, lack of methaemoglobin formation in cats at doses up to 500 mg/kg bw and the absence of any other toxicological effects, including developmental toxicity, that are likely to be elicited by a single dose.

The Meeting established an ADI and ARfD of 0.02 mg/kg bw for 4-(trifluoromethoxy)aniline (M07) on the basis of the NOAEL of 0.5 mg/kg bw based on clinical signs, chocolate brown coloration of the blood, higher methaemoglobin levels in both sexes, and a slight increase in mean absolute reticulocyte counts in females, observed one hour post-dosing, and increase in both absolute and relative spleen weight in females and a slightly higher severity grade of diffuse extramedullary haematopoiesis in the spleen in females (termination) seen at the LOAEL of 2 mg/kg bw observed in single dose oral (gavage) toxicity study. A safety factor of 25 was used as the effect was  $C_{\max}$ -dependent. The Meeting concluded that the ADI and ARfD also cover the toxicity of metabolite M08.

A toxicological monograph was prepared.

**Levels relevant to risk assessment of triflumuron**

Species	Study	Effect	NOAEL	LOAEL
Mouse	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	20 ppm, equal to 5.19 mg/kg bw per day	200 ppm, equal to 49.0 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 523 mg/kg bw per day <sup>c</sup>	-
Rat	Single-dose studies of toxicity <sup>b</sup>	Toxicity	500 mg/kg bw <sup>c</sup>	-
	90-day studies of toxicity <sup>d</sup>	Toxicity	50 ppm, equal to 3.6 mg/kg bw per day	200 ppm, equal to 13.9 mg/kg bw per day
	Two-year studies of toxicity and carcinogenicity <sup>a</sup>	Toxicity	20 ppm, equal to 0.82 mg/kg bw per day	200 ppm, equal to 8.45 mg/kg bw per day
		Carcinogenicity	2000 ppm, equal to 86.1 mg/kg bw per day <sup>c</sup>	-
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	2000 ppm, equal to 132 mg/kg bw per day <sup>c</sup>	-
		Parental toxicity	2000 ppm, equal to 132 mg/kg bw per day <sup>c</sup>	-
		Offspring toxicity	2000 ppm, equal to 132 mg/kg bw per day <sup>c</sup>	-
Developmental toxicity study <sup>b</sup>	Maternal toxicity	-	1000 mg/kg bw per day <sup>f</sup>	
	Embryo and fetal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day	
Rabbit	Developmental toxicity study <sup>b</sup>	Maternal toxicity	-	1000 mg/kg bw per day <sup>f</sup>
		Embryo/fetal toxicity	300 mg/kg bw per day	1000 mg/kg bw per day
Dog	13-week and one-year studies of toxicity <sup>d,e</sup>	Toxicity	100 ppm, equal to 3.2 mg/kg bw per day	200 ppm, equal to 7.1 mg/kg bw per day
<b>Metabolite M07</b>				
Rat	Single dose study of toxicity	Toxicity	0.5 mg/kg bw	2.0 mg/kg bw

<sup>a</sup> Dietary administration<sup>b</sup> Gavage administration<sup>c</sup> Highest dose tested<sup>d</sup> Two or more studies combined<sup>e</sup> Capsule administration<sup>f</sup> NOAEL for maternal toxicity could not be identified as no haematological measurements were taken at lower doses

Acceptable daily intake (ADI), applies to triflumuron, M02, M03, expressed as triflumuron

0–0.008 mg/kg bw

Acute reference dose (ARfD), applies to triflumuron, M02, M03, expressed as triflumuron

Unnecessary

Acceptable daily intake (ADI) applies to 4-(trifluoromethoxy)aniline (M07) and M08, expressed as M07

0–0.02 mg/kg bw

Acute reference dose (ARfD), applies to 4-(trifluoromethoxy)aniline (M07) and M08, expressed as M07

0–0.02 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. Toxicity studies on plant metabolites and new genotoxicity studies on triflumuron.

**Critical end-points for setting guidance values for exposure to triflumuron**

<b>Absorption, distribution, excretion and metabolism in mammals</b>	
Rate and extent of oral absorption	Rapidly absorbed and eliminated in urine and faeces, oral absorption $\geq 77\%$ within 48 hours (based on urine, bile and carcass)
Dermal absorption	No data provided
Distribution	Widely distributed (fatty tissue, blood, liver, kidney, lung and spleen)
Potential for accumulation	No potential for accumulation
Rate and extent of excretion	Almost completely excreted via urine and faeces within 72 h
Metabolism in animals	In rats, metabolites were formed through hydrolysis followed by subsequent conjugation, or by hydroxylation of the parent compound followed by hydrolysis and/or conjugation
Toxicologically significant compounds in animals and plants	Triflumuron, M07, M08, M01, M02, M03 and M04
<b>Acute toxicity</b>	
Rat, LD <sub>50</sub> , oral	> 5000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	> 5000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	> 5.03 mg/L
Rabbit, dermal irritation	Not irritant
Rabbit, ocular irritation	Not irritant
Guinea pig, dermal sensitization	Not a sensitizer (Magnusson and Kligman test)
<b>Short-term studies of toxicity</b>	
Target/critical effect	Haematopoietic system (reduced erythrocytes count, haemoglobin and haematocrit)
Lowest relevant oral NOAEL	3.6 mg/kg bw per day (rat) 3.21 mg/kg bw per day (dog)
Lowest relevant dermal NOAEL	100 mg/kg bw per day
Lowest relevant inhalation NOAEC	0.0045 mg/L (rat, three-week study)
<b>Long-term studies of toxicity and carcinogenicity</b>	
Target/critical effect	Haematopoietic system (haemolytic anaemia)
Lowest relevant NOAEL	0.82 mg/kg bw per day (rat)
Carcinogenicity	Not carcinogenic in mice and rats <sup>a</sup>
<b>Genotoxicity</b>	Unlikely to be genotoxic <sup>a</sup>
<b>Reproductive toxicity</b>	
Target/critical effect	None
Lowest relevant parental NOAEL	132 mg/kg bw per day, highest dose tested
Lowest relevant offspring NOAEL	132 mg/kg bw per day, highest dose tested
Lowest relevant reproductive NOAEL	132 mg/kg bw per day, highest dose tested
<b>Developmental toxicity</b>	
Target/critical effect	Delayed ossification (rat) and late resorptions (rabbit)
Lowest relevant maternal NOAEL	None (no assessment of haematological parameters at lower doses)
Lowest relevant embryo/fetal NOAEL	300 mg/kg bw per day (rat, rabbit)

<b>Neurotoxicity</b>	
Acute neurotoxicity NOAEL	No specific studies, no evidence of neurotoxicity in the database
Subchronic neurotoxicity NOAEL	No specific studies, no evidence of neurotoxicity in the database
Developmental neurotoxicity NOAEL	No specific studies, no evidence of developmental neurotoxicity in the database
<b>Immunotoxicity</b>	
No data provided	
<b>Studies on toxicologically relevant metabolites</b>	
<b>Acute toxicity</b>	
<b>4-(trifluoromethoxy)aniline (metabolite M07)</b>	
Rat, LD <sub>50</sub> , oral	63 mg/kg bw
Rat, LD <sub>50</sub> , dermal	25–50 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	0.008–0.009 mg/L
Rabbit, dermal irritation	Not irritant
Rabbit, ocular irritation	Moderately
<b>Genotoxicity</b>	
<b>4-(trifluoromethoxy)aniline (metabolite M07)</b>	Negative for genotoxicity in the Ames test, DNA damage test and in vivo micronucleus test
<b>Human data</b>	No adverse effects in workers

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet

### Summary

	Value	Study	Safety factor
ADI	0–0.008 mg/kg bw <sup>a</sup>	Two-year study of toxicity and carcinogenicity (rat)	100
ARfD	Unnecessary		
<b>4-(trifluoromethoxy)aniline (metabolite M07)</b>			
ADI	0.02 mg/kg bw <sup>b</sup>	Single dose study of toxicity (rat)	25
ARfD	0.02 mg/kg bw <sup>b</sup>	Single dose study of toxicity (rat)	25

<sup>a</sup> Applies to triflumuron, and M02, M03, expressed as triflumuron

<sup>b</sup> Applies to 4-(trifluoromethoxy)aniline (M07), and M08, expressed as M07

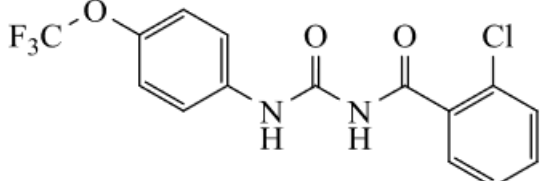
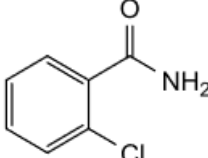
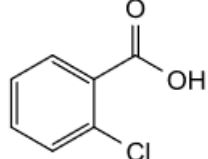
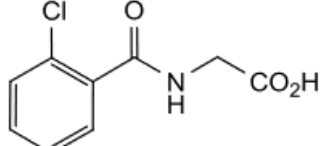
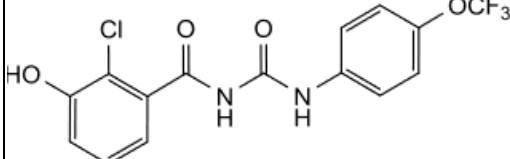
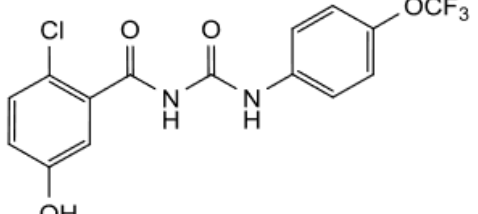
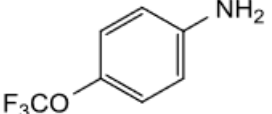
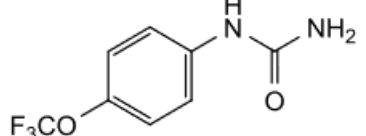
## RESIDUE AND ANALYTICAL ASPECTS

Triflumuron is a benzoylurea insecticide. The mode of action is insect growth regulation by inhibiting the synthesis of chitin in insect larvae that are about to moult and interfering with the moulting hormone system. The IUPAC name for triflumuron is 1-(2-chlorobenzoyl)-3-[4-trifluoromethoxyphenyl]urea.

Triflumuron was scheduled at the Fiftieth Session of CCPR (2018) for evaluation as a new compound by the 2019 JMPR. The Meeting received information on identity, physical and chemical properties, plant and animal metabolism, environmental fate, methods of analysis, use pattern and supervised trials on soya bean, fate of residues in storage and processing and an animal feeding study.

The code numbers, chemical names and chemical structures of the compounds are as follows:

Table 1 Triflumuron and its metabolites referred to in this appraisal

Compound Code number, Chemical name	Structure
Triflumuron	
M01 2-Chlorobenzamide	
M02 2-Chlorobenzoic acid	
M03 2-Chlorohippuric acid	
M04 1-(2-chloro-3-hydroxybenzoyl)-3-[4-trifluoromethoxyphenyl]urea	
M05 1-(6-chloro-3-hydroxybenzoyl)-3-[4-trifluoromethoxyphenyl]urea	
M07 4-Trifluoromethoxyaniline	
M08 4-Trifluoromethoxyphenyl urea	

With respect to the physical and chemical properties that may impact on residues in crops, triflumuron is not regarded as volatile and the log  $P_{ow}$  is 3.5–3.6.

### **Plant metabolism**

The Meeting received information on the fate of triflumuron in apples after direct treatment or soaking and in tomatoes, soya beans and potatoes after foliar applications. In the studies, triflumuron labelled with  $^{14}\text{C}$  at the chlorophenyl group ([2-chlorophenyl-UL- $^{14}\text{C}$ ] triflumuron) and the 4-trifluoromethoxyaniline group ([4-trifluoromethoxy-phenyl-UL- $^{14}\text{C}$ ] triflumuron) were used. In the metabolism studies, total radioactive residues (TRR) are expressed in mg triflumuron equivalents/kg.

In a translocation study on apples, shoots cut from apple tree were placed into a beaker filled with an aqueous solution of labelled triflumuron. The apple cuttings absorbed 7.5–7.7% of the labelled triflumuron over a 13-day period. In another treatment, ten leaves of apple trees were treated with labelled triflumuron and, 13 days after treatment 0.05% of the applied radioactivity was translocated into upper plant parts.

In a metabolism study on apples conducted over two years, chlorophenyl-label or 4-trifluoromethoxyaniline-label triflumuron was applied topically to three individual apples on a tree under outdoor conditions, at rates equivalent to spray concentrations of 10 g ai/L in the first year and 0.2 or 1.0 g ai/L in the second year. Harvested apples 5–35 DAT were washed with acetone (acetone wash) and peeled. Peel and pulp were extracted with acetone. Surface wash accounted for 90–99% TRR. Most of the radioactivity in apples was present as triflumuron ( $\geq 98\%$  of TRR at 31 DAT).

In a metabolism study on tomatoes, chlorophenyl-label or 4-trifluoromethoxyaniline-label triflumuron was applied to tomato plants grown in a greenhouse, with two foliar applications (21-day interval) at 0.38–0.39 kg ai/ha. Tomatoes were harvested 7 DALA and thereafter. Ripe tomatoes were washed with dichloromethane and then homogenized and extracted with acetonitrile/water (80:20) and then acetonitrile. Of the total radioactivity for whole tomatoes (1.1–1.4 mg/kg), 97–98% was found in surface wash. Almost 100% TRR in tomato was present as triflumuron.

In a translocation study on soya bean, labelled triflumuron was painted on the leaf surface of soya bean. About 0.02% of the AR was recovered in mature soya beans harvested 101 DAT. When 5 mg of labelled triflumuron was injected into the stem, 0.10–0.11% of the applied radioactivity was recovered in mature soya beans 101 DAT.

In a metabolism study on soya bean, chlorophenyl- or 4-trifluoromethoxyaniline-label triflumuron was applied to soya beans under field conditions at full bloom, with a foliar spray at an application rate of 1.12 kg ai/ha. Radioactive residues in foliage decreased over time during the study period (84 mg eq/kg at 0 DAT to 5.8 mg eq/kg at 77 DAT for the chlorophenyl-label; 41 mg eq/kg at 0 DAT to 11 mg eq/kg at 70 DAT for the 4-trifluoromethoxyaniline-label). TRR were higher in foliage (5.8–84 mg eq/kg, 0–77 DAT) and pods (0.4–9.0 mg eq/kg, 0–77 DAT) than in mature beans (0.21–0.31 mg eq/kg, 60–77 DAT).

In mature soya bean seed (60–77 DAT), 29–55% TRR was extracted by methanol, of which 14–15% TRR was partitioned into hexane and 13–41% TRR was in the aqueous phase. The majority of radioactivity was unextracted (45% or 71%). In the hexane phase, triflumuron was predominant (14% TRR, 0.03–0.04 mg eq/kg), followed by M01 (0–0.4% TRR, 0–0.001 mg eq/kg) and M02 (0–0.4% TRR, 0–0.001 mg eq/kg). Acid hydrolysis (6 M HCl, reflux for 16 hours) of PES released further parent triflumuron (2.1% of TRR, 0.004 mg eq/kg) and M02 (30% of TRR, 0.063 mg eq/kg) for the chlorophenyl-label and M07 (33% of TRR, 0.10 mg eq/kg) for the 4-trifluoromethoxyaniline-label.

In foliage and pods of soya bean (0–77 DAT), the major portion of radioactivity was extracted by methanol (73–99% TRR), of which 72–99% TRR and 58–98% TRR, respectively, was partitioned into hexane and 0.4–17% TRR and 2.1–17% TRR, respectively, in the aqueous phase. Triflumuron accounted for the majority of the residue in the hexane phase of foliage and pods at 72–99% TRR and 69–98% TRR, respectively. M01, M02 and M08 were also found ( $\leq 1.3\%$  TRR). TRR in the water phase was not identified. Acid hydrolysis (6 M HCl, reflux for 16 hours) of the unextracted residue of foliage (60 DAT) released M07 (0.4% TRR).

In a translocation study on potatoes, the leaf surface of four potato plants was treated with chlorophenyl- or 4-trifluoromethoxyaniline-label triflumuron. The potato tubers harvested 42 days post-



treatment contained 0.005–0.008% of the AR. Another treatment with chlorophenyl- or 4-trifluoromethoxyaniline-label triflumuron was injected into the stems of two potato plants. Stem injection resulted in low levels of residue in the tubers (up to 0.7% AR, 12 DAT).

In a metabolism study on potatoes, chlorophenyl- or 4-trifluoromethoxyaniline-label triflumuron was applied to potatoes grown outdoors or in the greenhouse, respectively, at bloom as a foliar spray at an application rate of 1.12 kg ai/ha. Radioactive residues in tubers after application of 2-chlorophenyl-label increased from 0.01 mg eq/kg (7 DAT) to 0.08 mg eq/kg (42 DAT) and TRR in foliage or pods (23–98 mg eq/kg between 0–42 DAT) was always higher than that in tubers.

After treatment with 2-chlorophenyl-label triflumuron, in mature potato tubers (42 DAT), acetone and dichloromethane extracted 46–78% TRR, with a further 14% extracted by water. In the organic-solvent extract, triflumuron and M02 accounted for 26% TRR (0.037 mg eq/kg) and 14% TRR (0.011 mg eq/kg), respectively. Hydrolysis of the organic-solvent extract with HCl (1 M, reflux for 6 hours) released further triflumuron (8.3% TRR, 0.007 mg eq/kg). Acid hydrolysis (1 M HCl, reflux for 6 hours) of PES released additional parent triflumuron (15% TRR, 0.012 mg eq/kg), M01 (2.9% TRR, 0.002 mg eq/kg) and M02 (14% TRR, 0.011 mg eq/kg).

After treatment with 4-trifluoromethoxyaniline-label triflumuron, 0.01 mg eq/kg TRR was found in mature potato tubers (42 DAT), from which 78% TRR was extracted with methanol (0.008 mg eq/kg). In the methanol extract, triflumuron (42% TRR, 0.004 mg eq/kg) and M08 (14% TRR, 0.001 mg eq/kg) was identified. Further extraction or hydrolysis was not conducted.

### ***Summary of plant metabolism***

Translocation studies on apples, soya bean and potatoes indicated limited translocation of triflumuron within the plant.

When triflumuron was applied to apples and tomatoes, most residues were at the surface of the fruits (> 96% TRR in surface wash). When triflumuron was applied to soya beans and potatoes, residues were at lower concentrations in edible parts of the plants than inedible parts. In all of the plants tested, the majority of the triflumuron remained unmetabolized.

Triflumuron is the main residue in apples (> 98% TRR, free), tomatoes (> 99% TRR, free), soya bean foliage and pods (> 69% TRR, free and conjugated), soya bean seeds (16% TRR, 0.03–0.04 mg/kg, free and conjugated), and potato tubers (42 DAT, 42–49% of TRR, free and conjugated).

Major metabolites in soya bean seeds were M02 (30% TRR, 0.063 mg eq/kg) and M07 (33% TRR, 0.10 mg eq/kg), and in potato tubers M08 (14% TRR, 0.001 mg eq/kg) and M02 (14% TRR, 0.011 mg eq/kg) (all metabolites were totals of free and conjugated).

The Meeting concluded that the metabolic profiles between the species were qualitatively similar. All of the plant metabolites identified are also observed in the metabolism in rat.

### ***Environmental fate***

#### ***Aerobic degradation in soil***

Triflumuron is not persistent in soil (DT<sub>50</sub> 1.7–19 days).

#### ***Hydrolysis***

Triflumuron is stable to hydrolysis at pH 5 and 7. It is hydrolysed at pH 9 (DT<sub>50</sub> = 57 days at 25 °C) resulting in M02 at 29% AR after 30 days.

#### ***Soil photolysis***

Triflumuron is stable to photolysis.

### *Rotational crop studies (confined)*

All the metabolites of triflurumuron found in succeeding crops (kale, red beet and wheat) were also found in the plant metabolism studies. At an application rate 7.3 times higher than the maximum seasonal rate in the Colombian GAP, TRR were 0.25–0.66 mg eq/kg at 1-month PBI and decreased to  $\leq 0.08$  mg eq/kg at longer PBI (4 or 9 months). At 1-month PBI, M02 (13–20% TRR, 0.03–0.12 mg eq/kg) was predominant, followed by M01 (1.1–20% TRR, 0.01–0.11 mg eq/kg) and triflurumuron (1.4–5.7% TRR,  $< 0.01$ –0.02 mg eq/kg). The Meeting, however, concluded that it was unlikely that triflurumuron used according to the GAP rate would carry over to follow-on crops at longer PBI (4 or 9 months).

### **Animal metabolism**

Information was available on the metabolism of triflurumuron in laboratory animals, lactating goats and laying hens. The evaluation of metabolism studies in rats was carried out by the WHO group.

In lactating goats, the metabolic fate of triflurumuron was investigated using chlorophenyl- or 4-trifluoromethoxyaniline-label triflurumuron.

For the chlorophenyl-label, triflurumuron was administered once orally at 3.0 mg/kg bw and then 56 hours later at 25.1 mg/kg bw (equivalent to 170 ppm in the feed, dry matter basis (DM)). The goat was sacrificed 20 hours after the last dose. Following the first dose, approximately 60% of AR was excreted in faeces (54% AR) and urine (6.2% AR) within 56 hours.

The TRR in edible tissues was the highest in liver (3.3 mg eq/kg), followed by fat (1.8 mg eq/kg), kidney (0.87 mg eq/kg) and muscle (0.30 mg eq/kg). In milk, the TRR was 0.43 mg eq/kg.

The tissues and milk were extracted with dichloromethane (milk), hexane (fat) or methanol (liver, kidney and muscle). In milk and fat, 96–99% TRR was extracted. In liver, kidney and muscle, extractability with methanol was 31, 71 and 83% TRR, respectively. Water extracted an additional 4.2, 50, 21 and 7.1% TRR for milk, liver, kidney and muscle.

Parent triflurumuron was a major component of the residue representing 75% TRR (0.32 mg eq/kg) in milk, 15% TRR (0.51 mg eq/kg) in liver, 20% TRR (0.18 mg eq/kg) in kidney, 58% TRR (0.18 mg eq/kg) in muscle and 96% TRR (1.8 mg eq/kg) in fat. The following metabolites were identified: M01 (free) in milk, liver, kidney, muscle and fat (0.9–20% TRR, 0.02–0.15 mg eq/kg); M03 (free and conjugated) in milk (6.2% TRR, 0.03 mg eq/kg) and kidney (36% TRR, 0.31 mg eq/kg); M04 (free and conjugated) in milk (4.1% TRR, 0.02 mg eq/kg) and kidney (0.8% TRR, 0.01 mg eq/kg); and M05 (free and conjugated) in liver (4.0% TRR, 0.13 mg eq/kg).

For the 4-trifluoromethoxyaniline-label, triflurumuron was administered orally at 18 mg/kg bw (equivalent to 440 ppm in the feed (DM)) for 3 consecutive days with sacrifice 20 hours after the final dose.

The TRR in edible tissues was the highest in liver (6.1 mg eq/kg), followed by fat (4.8 mg eq/kg), kidney (1.6 mg eq/kg) and muscle (0.18 mg eq/kg). In milk collected 20 hours after first application, the TRR was 0.76 mg eq/kg.

The tissues and milk were extracted with dichloromethane (milk), hexane (fat) or methanol (liver, kidney and muscle). In milk, kidney, muscle and fat, 86–98% TRR was extracted. In liver, 52% TRR was extracted. Additional radioactivity was extracted with water (3.0–8.8% TRR in milk, liver, kidney and muscle).

Parent triflurumuron was a major component of the residue at 60% TRR (0.45 mg eq/kg) in milk, 20% TRR (1.2 mg eq/kg) in liver, 27% TRR (0.43 mg eq/kg) in kidney, 80% TRR (0.14 mg eq/kg) in muscle and 95% TRR (4.6 mg eq/kg) in fat. The following metabolites were identified: M04 (free and conjugated) in milk (11% TRR, 0.08 mg eq/kg), liver (8.2% TRR, 0.50 mg eq/kg), kidney (28% TRR, 0.45 mg eq/kg), muscle (1.6% TRR,  $< 0.01$  mg eq/kg) and fat (0.9% TRR, 0.04 mg eq/kg); and M08

(free and conjugated) in milk (4.8% TRR, 0.04 mg eq/kg), liver (1.5% TRR, 0.09 mg eq/kg), kidney (2.4% TRR, 0.04 mg eq/kg) and muscle (0.9% TRR, < 0.01 mg eq/kg).

In laying hens, the metabolic fate of triflumuron was investigated using chlorophenyl-label triflumuron. Three hens received daily oral doses of 8.0 mg/kg bw (equivalent to 100 ppm in the feed (DM)) for five consecutive days. Animals were sacrificed 3 hours after the last treatment.

The TRR in edible tissues was the highest in fat (27 mg eq/kg), followed by skin (14 mg eq/kg), liver (7.3 mg eq/kg), kidney (3.1 mg eq/kg) and muscle (0.80 mg eq/kg). In eggs, the TRR consistently increased from 24 to 96 hours after application (0.61–0.98 mg eq/kg) and no plateau was reached. Only eggs collected 96 hours after the last application were used for extraction.

Extractability with the solvents used was > 78% TRR; methanol for liver and kidney, acetone and dichloromethane for muscle and eggs, and hexane and acetonitrile for fat and skin.

Parent triflumuron was a major component of the residue and was found at 86% TRR (0.57 mg eq/kg) in eggs, 91% TRR (0.73 mg eq/kg) in muscle, 97% TRR (26 mg eq/kg) in fat, 97% TRR (13 mg eq/kg) in skin, 59% TRR (1.8 mg eq/kg) in kidney and 86% TRR (6.2 mg eq/kg) in liver. The following metabolites, free and conjugated, were identified: M01 in eggs (7.6% TRR, 0.05 mg eq/kg), muscle (6.3% TRR, 0.05 mg eq/kg), fat (0.3% TRR, 0.08 mg eq/kg), skin (0.5% TRR, 0.07 mg eq/kg), kidney (4.4% TRR, 0.14 mg eq/kg) and liver (8.9% TRR, 0.65 mg eq/kg); and M02 (free and conjugated) in muscle (0.3% TRR, < 0.01 mg eq/kg), fat (< 0.1% TRR, < 0.03 mg eq/kg), skin (0.1% TRR, 0.1 mg eq/kg), kidney (26% TRR, 0.81 mg eq/kg) and liver (0.3% TRR, 0.02 mg eq/kg) (absent in eggs).

Five other hens received a single oral dose of the chlorophenyl-label at 2.5 mg/kg bw (equivalent to 33 ppm in the feed (DM)). Eggs were collected within 96 hours after dosing and the TRR in eggs (96 hours after application) was 0.075 mg eq/kg with 92% TRR extracted with acetone and then dichloromethane. Parent triflumuron was found at 85% TRR (0.064 mg eq/kg) and the only identified metabolite was M01 (3.3% TRR, 0.002 mg eq/kg).

### **Summary**

Parent triflumuron is the major component of the residue. Major metabolites were M03 and M04 in kidney of goats and M02 in kidney of hens. The Meeting concluded that the metabolic profiles were qualitatively similar between goats and hens.

### **Methods of analysis**

The Meeting received methods of analysis for supervised field trials and animal feeding studies.

Method 00722/M002 was for analysis of triflumuron, M07 and M08 in sunflower seeds, soya beans and its processed commodities and aspirated grain fractions. In general, triflumuron, M07 and M08 were extracted with acetonitrile or acetonitrile/hexane (3:2, v/v) and filtered. Determination was by LC-MS/MS using external matrix-matched standards. The method was validated for triflumuron in sunflower seeds, soya beans and processed commodities of soya beans (soya bean oil, cold pressed; soya bean oil, solvent extracted; soya bean flour; soya bean hulls; soya bean meal; and soya bean milk) (LOQ=0.01 mg/kg), and aspirated grain fractions (LOQ=0.1 mg/kg) with mean recovery ranges of 83–108%. The method was also validated for M07 and M08 in soya beans and soya bean products with a LOQ of 0.005 mg/kg (equivalent to 0.01 mg/kg triflumuron) with mean recovery ranges of 82–105%.

Method 73295 was for analysis of triflumuron residues in animal commodities. Residues of triflumuron were extracted with acetone (milk) or dichloromethane/methanol (9:1, v/v; muscle, liver, kidney or fat), filtered, and cleaned up. Determination was by HPLC-UV (240 nm). The LOQs for triflumuron in milk, certain tissues (muscle, liver and kidney) and fat were 0.01 mg/kg, 0.05 mg/kg and 0.1 mg/kg, respectively. The mean recoveries (76–96%) were within the acceptable range. The Meeting confirmed that the method is suitable for analysis of triflumuron in milk, muscle, liver, kidney and fat.

Method 00757 was for analysis of triflumuron residues in animal commodities. Residues of triflumuron are extracted with acetonitrile/n-hexane (3:2 v/v) and filtered. Determination is by LC-

MS/MS using external matrix-matched standards. The method was validated for determination of triflumuron in animal commodities with LOQs of 0.005 mg/kg in fat, kidney, liver, meat and milk and the mean recoveries (84–101%) were within the acceptable range. The Meeting confirmed that the method is suitable for milk, muscle, liver, kidney and fat.

### ***Stability of residues in stored analytical samples***

A stability study on triflumuron residues in fortified sunflower seed (high oil content crop) was available. The Meeting concluded that triflumuron in high oil content commodities stored at  $\leq -18$  °C was stable for at least 23 months.

Based on a stability study on M07 stored at  $\leq -20$  °C in fortified soya bean seed, the Meeting concluded that M07 in soya bean seed was stable for up to 3.3 months.

M08 stored at  $\leq -20$  °C in fortified soya bean seed was stable for at least 12 months.

In animal commodities, a stability study on triflumuron residues in fortified liver, muscle and milk stored at  $\leq -18$  °C was available. No significant degradation was observed for at least 3.4 months in liver and muscle and up to 3.0 months for milk. The Meeting concluded that triflumuron residues in animal commodities stored at  $\leq -18$  °C are stable for at least 3.0 months.

### ***Definition of the residue***

#### ***Plant commodities***

In the plant metabolism studies on apple, tomato, soya bean and potato, the predominant residue in solvent extracts was parent triflumuron (> 98% TRR in apple and tomato fruits; 16% TRR in soya bean seeds and 42–49% TRR in potatoes). Triflumuron was found in all primary crop commodities tested. The Meeting noted that suitable analytical methods exist to measure triflumuron in plant commodities. The Meeting considered that parent triflumuron was suitable marker for enforcement.

In deciding which compounds should be included in the residue definition for dietary risk assessment, the Meeting noted that no metabolites exceeded 10% TRR or 0.01 mg eq/kg in the metabolism studies on apples and tomatoes. In the metabolism study on soya bean, M02 and M07 exceeded 10% TRR and 0.01 mg eq/kg after acid hydrolysis of the unextracted residue. In the plant metabolism study on potatoes, M02 exceeded 10% TRR and 0.01 mg/kg after acid hydrolysis of the unextracted residue.

For M02, similar toxicity to parent triflumuron was assumed and the ADI for triflumuron (0–0.008 mg/kg bw) should apply to M02. The Meeting noted that the level of M02 in the soya bean metabolism study (DAT 77, free: 0.001 mg eq/kg, released by HCl hydrolysis: 0.063 mg eq/kg) was significant (total: 0.064 mg eq/kg), but that M02 (free and conjugated) was not analysed in the supervised trials. Considering the residue of the parent compound was 0.030 mg eq/kg in the same plant metabolism study at the same DAT, it was likely that the residue of M02 would be higher than that of the parent compound and it was necessary to estimate the residue level of M02 for dietary risk assessment. The Meeting concluded that the concentration of M02 in soya bean could be estimated to be 2.1 times (0.064 / 0.030) higher than parent triflumuron.

The Meeting established a separate ADI of 0–0.02 mg/kg bw and ARfD of 0.02 mg/kg bw to be applicable to M07 and M08 (expressed as M07). According to the plant metabolism study (DAT 60), free M07 was not found but the level of conjugated M07 (0.10 mg eq/kg) was higher than the parent compound (0.04 mg eq/kg). In the supervised field trials, free M07 was analysed, but conjugated M07 (released by HCl hydrolysis) was not. Considering the residue of the parent compound in the same plant metabolism study at the same DAT was 0.040 mg eq/kg, it was likely that the residue of M07 would be higher than that of the parent compound. Thus, it was necessary to estimate the residue level of conjugated M07 for dietary risk assessment. The Meeting concluded that the concentration of conjugated M07 in soya bean could be estimated to be 2.5 times (0.10 / 0.040) higher than parent.

In the plant metabolism study, triflumuron was released by HCl from the unextracted residue at a low concentration (0.004 mg eq/kg) where the application rate was 7.2 times higher than that of the maximum seasonal application rate in the Columbian GAP. The Meeting decided not to include conjugated triflumuron in the residue definition.

In the hydrolysis study simulating conditions of pasteurisation, baking/brewing/boiling, and sterilization, M07 and M08 were identified. In the processing study on soya bean (hulls, meal, flour, soya milk, solvent extracted oil and cold pressed oil), M07 and M08 were <LOQ (0.005 mg/kg). The Meeting concluded that further consideration of M07 and M08 in processed commodities was not necessary.

### *Animal commodities*

In the animal metabolism studies on lactating goat and laying hen, the predominant residue was parent triflumuron. Triflumuron is found in all animal commodities tested. The Meeting noted that suitable analytical methods exist to measure triflumuron in animal commodities. The Meeting considered parent triflumuron to be a suitable marker compound for enforcement.

In the animal metabolism study, the triflumuron residues were much higher in fat than in muscle (6–27 times higher in lactating goat and 27–85 times higher in laying hen). While no information was available on the partition of residues in milk or eggs, the Meeting considered triflumuron to be fat-soluble.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting noted that among the animal commodities tested, the residues that exceeded 10% TRR and 0.01 mg eq/kg were: in lactating goat, M03 and M04 (free and conjugated) in kidneys, and in laying hens, M02 in kidneys.

For M02, significant levels were only found in kidneys of hens and not found in lactating goats. The Meeting decided that it was not necessary to include M02 in the residue definition for animal commodities.

For M03, similar toxicity to parent triflumuron was assumed. M03 was found only in milk and kidney from lactating goat in the metabolism study. The estimated levels of M03 in animal commodities based on the calculated animal dietary burden were very low (0.012 mg/kg in kidney and 0.001 mg/kg in milk). The Meeting decided not to include M03 in the residue definition for dietary risk assessment.

No toxicity data were available for M04. Based on its structure, the Meeting concluded that it was appropriate to apply the TTC approach for a potentially genotoxic compound. The Meeting estimated that long-term dietary exposure to M04 from animal commodities (0.0041 µg/kg bw per day) was higher than the threshold of toxicological concern for potential genotoxic compounds (0.0025 µg/kg bw per day).

### *TTC consideration of M01*

Metabolite M01 was found in soya bean (seed and forage) in the metabolism study, tissues and milk from lactating goats, eggs and kidney from hens in the animal metabolism studies and kale, beet (tops and roots) and wheat (forage, heads and straw) in the confined rotational crop study. As no toxicity information was available for M01, based on its structure, the Meeting concluded that it was appropriate to apply the TTC approach for a potentially genotoxic compound.

The Meeting noted that the estimated long-term dietary exposure to M01 from soya bean, rotational crops (leafy vegetables, root and tuber vegetables and cereal grains) and animal commodities were higher (0.046 µg/kg bw per day) than the threshold of toxicological concern for potential genotoxic compounds (0.0025 µg/kg bw per day).

### *Conclusion*

The Meeting decided that the residue definition for compliance with the MRL for plant and animal commodities was triflumuron. The residue is fat-soluble.

The Meeting was unable to conclude on residue definitions for dietary risk assessment for plant and animal commodities.

### ***Results of supervised residue trials on crops***

#### ***Soya beans***

The critical GAP for triflururon on soya bean in Colombia is two applications at 0.077 kg ai/ha with a minimum interval between sprays of 15 days and a PHI of 21 days. In trials matching the Colombian GAP, residues of triflururon in soya beans were (n = 9): < 0.01 (3), 0.011, 0.014\_(2), 0.048, 0.051 and 0.055 mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg.

As the residue definitions for dietary risk assessment were not established, the Meeting could not estimate an STMR for soya bean or complete a dietary risk assessment. .

### ***Fates of residues during processing***

#### ***High temperature hydrolysis***

Triflururon was shown to be hydrolytically stable for the simulated conditions of pasteurisation (> 97% of AR, 90 °C, pH 4, 20 min). Under simulated baking/brewing/boiling conditions (100 °C, pH 5, 60 min), 89% of the AR remained as triflururon and M07 was formed (3.4% AR). Under the simulated sterilization condition (120 °C, pH 6, 20 min), 51% of triflururon remained and compounds derived from hydrolysis, M07 (17% of AR) and M08 (16% of AR), were formed. Further characterization was not conducted.

#### ***Processing***

The Meeting received information on the fate of triflururon residues during the processing of soya beans. The Meeting estimated processing factors for parent triflururon of 3.4 for soya bean hulls and 0.1 for soya bean meal, flour, soya milk, solvent extracted oil (RBD) and cold pressed oil (RBD).

### ***Residues in animal commodities***

#### ***Farm animal feeding studies***

The Meeting received a dairy cow feeding study. Triflururon in gelatine capsules was administered orally once daily to two groups of dairy cows (three animals in each group) for 29 days at levels equivalent to 5.9 ppm or 12 ppm in the feed (DM; 0.3 or 0.6 mg/kg bw). The residue levels of triflururon in milk, liver, kidney, muscle and fat were < 0.01, < 0.05, < 0.05, < 0.05 and < 0.1 mg/kg, respectively, at both dose levels.

#### ***Farm animal dietary burden***

The OECD diets include soya bean, hulls, meal, soya bean hay and fodder. In the supervised trials for soya bean, only seed was analysed. The levels of triflururon in soya bean hay and forage were estimated using plant metabolism study.

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 2018 OECD Feed diets listed in Appendix XIV Electronic attachments to the 2016 edition of the FAO manual<sup>19</sup>, are presented in Annex 6 and summarized below.

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<sup>19</sup> <http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

Table 2 Animal dietary burden for triflumuron

	Animal dietary burden of triflumuron, ppm of dry matter diet							
	US-Canada		EU		Australia		Japan	
	Max	Mean	max	mean	max	mean	max	mean
Beef cattle	0.009	0.009	0.008	0.008	13 <sup>a</sup>	13 <sup>c</sup>	0.012	0.012
Dairy cattle	3.1	3.1	0.009	0.09	6.1 <sup>b</sup>	6.1 <sup>d</sup>	0.011	0.011
Poultry – broiler	0.007	0.007	0.013	0.013	0.008	0.008	0.005	0.005
Poultry – layer	0.007	0.007	1.5 <sup>e g</sup>	1.5 <sup>f h</sup>	0.008	0.008	0.005	0.005

<sup>a</sup> Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian tissues

<sup>b</sup> Highest maximum dairy cattle dietary burden suitable for MRL estimates for mammalian milk

<sup>c</sup> Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian tissues.

<sup>d</sup> Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

<sup>e</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry tissues.

<sup>f</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry tissues.

<sup>g</sup> Highest maximum poultry dietary burden suitable for MRL estimates for poultry eggs.

<sup>h</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry eggs.

### **Animal commodity maximum residue levels**

#### **Cattle**

The Meeting noted that no residues were detected in milk at 2× the dietary burden for dairy cattle or in tissues at the approximate dietary burden for beef cattle. The Meeting estimated maximum residue levels of 0.01(\*) mg/kg for milks, 0.05(\*) mg/kg for mammalian offal, 0.1(\*) (fat) for meat, mammalian and 0.1(\*) mg/kg for mammalian fat.

Table 3 Maximum residue levels of triflumuron in poultry commodities

	Feed Level (ppm) for eggs residues	Triflumuron (mg /kg) in eggs	Feed Level (ppm) for tissue residues	Triflumuron (mg /kg)			
				Muscle	Liver	Kidney	Fat
HR Determination (broiler or laying hen)							
Feeding Study	100	0.57	100	0.73	6.2	1.8	26
Dietary burden and estimate of highest residue	1.5	0.0085	1.5	0.011	0.093	0.027	0.39

The Meeting noted that no feeding study for laying hen was available. The Meeting considered the metabolism study where hens were administered triflumuron for 5 days at rates 67× the estimated dietary burdens. In the absence of a poultry feeding study no maximum residue levels were estimated for poultry.

### **RECOMMENDATIONS**

Definition of the residue for compliance with the MRL for animal and plant commodities: triflumuron

Definition of the residue for dietary risk assessment for animal and plant commodities: a conclusion could not be reached.

**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 definitions for dietary risk assessment.



## 5.29 Valifenalate (318)

### TOXICOLOGY

Valifenalate is the ISO-approved common name for methyl-*N*-(isopropoxycarbonyl)-*L*-valyl-(3*RS*)-3-(4-chlorophenyl)- $\beta$ -alaninate (IUPAC), CAS number 283159-90-0.

Valifenalate is a racemic mixture of L-(R)- and L-(S)-valifenalate. It is an antiperonosporic fungicide used to control mildew in many crops including grapes, potatoes and tomatoes. Its pesticidal mode of action is as a cellulose synthase inhibitor.

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

All critical studies contained statements of compliance with GLP and were conducted in accordance with current test guidelines, unless otherwise stated. A literature search did not identify any toxicological information additional to that submitted for the current assessment.

#### **Biochemical aspects**

The toxicokinetics and metabolism of  $^{14}\text{C}$ -radiolabelled valifenalate have been investigated in the rat, following oral dosing. Following a single oral dose of valifenalate, concentrations of radioactivity in whole blood increased rapidly to reach  $C_{\text{max}}$  at 1–2 hours post-dose. The maximum concentration following a single high dose of 1000 mg/kg bw was markedly lower than 10 times that seen following a low dose of 100 mg/kg bw, indicating saturation of absorption. Radioactivity was rapidly excreted, mainly in the faeces, with a lower proportion in urine. The majority of the radioactivity in tissues was found in the GI tract. The liver and kidneys also contained concentrations higher than those in the blood. Residual radioactivity declined rapidly with time and was below the limit of quantification at 72 hours post-dose.

Repeated administration of the low dose (100 mg/kg bw per day) given for 14 days with non-radiolabelled valifenalate followed by a single radiolabelled dose, did not result in any increase in tissue residues. Bioaccumulation is not predicted based on such rapid excretion. A sex difference in the excretion of radioactivity was apparent: excretion in the faeces was higher in male (83%) than in female rats (58%), with a lower proportion eliminated in the urine in males (9%) compared to females (34%). The majority of the administered radioactivity was excreted within 48 hours of dosing. In bile-cannulated rats, the majority of the administered dose was excreted in bile (65% and 49% of the dose in male and female rats, respectively). Based on these results, approximately 80% of the administered dose was absorbed. Valifenalate or its metabolites were not eliminated via expired air.

Valifenalate was found to be extensively metabolized in rats; six metabolites were identified. At the low dose level of 100 mg/kg bw only a small proportion of the administered radioactivity was eliminated as unchanged valifenalate (5–8% in faeces; not detected in urine). In high-dose groups (1000 mg/kg bw), more unchanged valifenalate was excreted compared to the low-dose groups, with females showing more extensive metabolism at this high dose compared to males (unchanged valifenalate excreted was 40% in males and 10% in females). The metabolites were the products of primary metabolism, mainly:

- *O*-demethylation - forming R2, identified as RS- $\beta$ -alanine; *N*-[(1-methylethoxy)carbonyl]-*L*-valyl-3-(4-chlorophenyl; valifenalate acid), (found up to 36% in urine);
- hydroxylation at both carbons 2 and 3 of the chlorophenyl moieties of the parent molecule - forming R3, (only found in faeces up to 5%) and R4 (found in urine up to 0.8%);
- side-chain cleavage - forming R5, (found up to 3.6% in urine).

The diastereoisomeric ratio (S,R:S,S) of the unchanged parent compound and of R2 did not alter notably as measured in rat urine and faeces

### **Toxicological data**

The acute oral LD<sub>50</sub> of valifenalate was > 5000 mg/kg bw and the dermal LD<sub>50</sub> was > 2000 mg/kg bw. The inhalation LC<sub>50</sub> of valifenalate was > 3.118 mg/L. Valifenalate was not irritating to skin or eyes in rabbits and was not considered to be a skin sensitizer in the guinea pig maximization test.

In repeated-dose toxicity studies on mice (28-day and 90-day), rats (28-day and 90-day) and dogs (28-day, 90-day and one-year), the main effects were reduced body weight gain, increased liver weight and hepatocellular hypertrophy, along with changes in clinical chemistry parameters.

In a 90-day toxicity study in mice, valifenalate was administered at dietary concentrations of 0, 110, 900 and 7000 ppm (equal to 0, 15.3, 134 and 995 mg/kg bw per day for males, 0, 16.7, 148 and 1144 mg/kg per day for females). The NOAEL was 110 ppm (equal to 15.3 mg/kg bw per day), based on decreased body weight gain and liver histopathology (vacuolation in males due to fat accumulation) at 900 ppm (equal to 134 mg/kg bw per day).

In a 90-day toxicity study in rats valifenalate was administered in the diet at varying concentrations to obtain dietary doses of 0, 7, 150 or 1000 mg/kg bw per day (10 rats/sex per dose). The NOAEL for this study was 150 mg/kg bw per day based on the macroscopic change of distended caecum at 1000 mg/kg bw per day.

In a 28-day study in dogs valifenalate was administered in gelatin capsules at doses of 0, 250, 500 or 1000 mg/kg bw per day (three dogs/sex per dose). The main target organ was the liver. The NOAEL was 250 mg/kg bw per day based on increased liver weight and liver histopathology (hepatocellular hypertrophy), and clinical chemistry changes at 500 mg/kg bw per day.

In a 13-week study in dogs valifenalate was administered in gelatin capsules at dose levels of 0, 50, 250 and 750 mg/kg bw per day (four dogs/sex per dose). Similarly to the 28-day dog study, the liver was a target organ, however, effects on the thyroid were also observed after 90 days (follicular cell hypertrophy). The NOAEL was 50 mg/kg bw per day based on changes in clinical chemistry (increased alkaline phosphatase), liver (hepatocellular hypertrophy) and thyroid (follicular cell hypertrophy) at 250 mg/kg bw per day.

In a one-year dog study valifenalate was administered in gelatin capsules at dose levels of 0, 1, 7, 50 or 250 mg/kg bw per day (four dogs/sex per dose). The NOAEL was 50 mg/kg bw per day based on changes in clinical chemistry, liver effects (increased weight and hepatocellular hypertrophy) and thyroid alterations (follicular cell hypertrophy) at 250 mg/kg bw per day.

In a 78-week dietary toxicity and carcinogenicity study, mice received valifenalate at dietary levels of 0, 150, 850 or 5000 ppm (equal to 0, 16.8, 97.2 and 657 mg/kg bw per day for males, 0, 21.6, 124 and 657 mg/kg bw per day for females). The NOAEL for carcinogenicity was 150 ppm (equal to 16.8 mg/kg bw per day) with a LOAEL of 850 ppm (equal to 97.2 mg/kg bw per day) based on liver adenomas exceeding the historical control range at the mid and high dose, and at the high dose also an increase in liver carcinoma outside the historical control range was seen in males. The NOAEL for chronic toxicity was 150 ppm (equal to 16.8 mg/kg bw per day) based on increased liver weight accompanied by histopathological changes in the liver (hepatocellular hypertrophy, centrilobular hepatocellular vacuolation) at 850 ppm (equal to 97.2 mg/kg bw per day).

In a two-year toxicity and carcinogenicity study, rats received valifenalate in the diet at varying concentrations to obtain dietary doses of 0, 15, 150 or 1000 mg/kg bw per day. No neoplastic lesions related to treatment were observed. The NOAEL for chronic toxicity was 150 mg/kg bw per day based on thyroid (follicular cell hypertrophy) and kidney (pelvic hyperplasia) changes at 1000 mg/kg bw per day.

The meeting concluded that valifenalate is carcinogenic in mice, but not in rats.

Valifenalate 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 valifenalate is unlikely to be genotoxic.

In view of the lack of genotoxicity, the finding of malignant liver tumours in male mice only at the highest dose, which is expected to show a threshold, and the absence of carcinogenicity in rats, the Meeting concluded that valifenalate is unlikely to pose a carcinogenic risk to humans via the diet.

In a two-generation study rats were fed diets containing valifenalate at concentrations of 0, 1250, 4300 and 15 000 ppm (equal to 0, 81, 277 and 986 mg/kg bw per day in males, 0, 93, 319 and 1146 mg/kg bw per day in females). In the absence of adverse effects, the parental NOAEL was 15 000 ppm (equal to 986 mg/kg bw per day), the highest dose tested. The NOAEL for offspring toxicity was 1250 ppm (equal to 81 mg/kg bw per day) based on decreased F<sub>2</sub> pup body weight gain during lactation, at 4300 ppm (equal to 277 mg/kg bw per day). The reproductive NOAEL was set at 15 000 ppm (equal to 986 mg/kg bw per day), the highest dose tested.

In a developmental toxicity study in rats valifenalate was administered via oral gavage at dose levels of 0, 100, 300 or 1000 mg/kg bw per day from GD 6–19. No signs of maternal or developmental toxicity were observed in this study, therefore the maternal and embryo/fetal NOAELs were 1000 mg/kg bw per day, the highest dose tested.

In a rabbit developmental toxicity study valifenalate was administered by oral gavage from GD 6 to GD 28 at dose levels of 0, 100, 300 or 1000 mg/kg bw per day. No signs of maternal or developmental toxicity were observed in this study, therefore the maternal and embryo/fetal NOAELs were 1000 mg/kg bw per day, the highest dose tested.

The Meeting concluded that valifenalate is not teratogenic.

No evidence of neurotoxicity was reported in routine toxicological studies with valifenalate.

The Meeting concluded that valifenalate is unlikely to be neurotoxic.

No evidence of immunotoxicity was reported in routine toxicological studies with valifenalate.

The Meeting concluded that valifenalate is unlikely to be immunotoxic.

### ***Toxicological data on metabolites and/or degradates***

Metabolite IR5839 (valifenalate acid, R2), found in plants, rats and other animals, was not acutely toxic via oral exposure (LD<sub>50</sub> > 2000 mg/kg bw). Metabolite IR5839 did not induce gene mutations in an Ames test, nor did it induce mutations at the Tk<sup>+/-</sup> locus of mouse lymphoma L5178Y cells. Metabolite IR5839 induced structural chromosome aberrations in an in vitro assay, without any increase in polyploidy. In a follow-up in vivo micronucleus assay in mice, metabolite IR5839 did not induce micronuclei. IR5839 (R2) was one of the main metabolic products of valifenalate in rats (up to 36% in urine) and can be considered covered by studies conducted with the parent compound.

Metabolite PCBA (4-chlorobenzoic acid), found in soil, did not induce mutations at the Tk<sup>+/-</sup> locus of mouse lymphoma L5178Y cells. PCBA induced structural chromosome aberrations in an in vitro assay with human lymphocytes and a slight increase in polyploidy was observed. In a follow-up in vivo micronucleus assay in mice, PCBA did not induce micronuclei. It was concluded that TTC Cramer class III can be applied (value 1.5 µg/kg bw per day).

Valifenalate acid glucosyl ester is the glucosyl ester of the metabolite IR5839 (valifenalate acid, R2) and will therefore not be more toxic than R2. As R2 is covered by studies conducted with the parent compound, the Meeting concluded that this will also hold for this glucosyl ester of R2.

Metabolite β-4-chlorophenylalanine (coded R5) was found in the rat metabolism study, its level at most 3.6% of administered dose. No further data is available for this metabolite or on its conjugate β-4-chlorophenylalanine-*N*-glucoside. As no genotoxicity data has been submitted, the TTC approach could be used for both metabolites in which case TTC value is 0.0025 µg/kg bw per day.

The Meeting concluded that metabolites valifenalate acid (IR5839, R2) and valifenalate acid glucosyl ester are toxicologically relevant and of equal potency to the parent. The Meeting concluded

that a TTC approach could be used for metabolites PCBA (4-chlorobenzoic acid),  $\beta$ -4-chlorophenylalanine and its conjugate  $\beta$ -4-chlorophenylalanine-*N*-glucoside.

### Microbiological data

No information is available.

### Human data

No clinical cases or poisoning incidents have been recorded at pilot plant production level.

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

### Toxicological evaluation

An ADI of 0–0.2 mg/kg bw was established on the basis of the NOAEL of 16.8 mg/kg bw per day in the 78-week study in mice and supported by the NOAEL of 15.3 mg/kg bw per day set by the 90-day study in mice, and employing a safety factor of 100. This provides a margin of 600 with respect to the LOAEL for benign liver tumours found in mice.

The Meeting concluded that it was not necessary to establish an ARfD for valifenalate in view of its low acute oral toxicity, 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 valifenalate

Species	Study	Effect	NOAEL	LOAEL
Mouse	90-day study of toxicity <sup>a</sup>	Toxicity	110 ppm, equal to 15.3 mg/kg bw per day	900 ppm, equal to 134 mg/kg bw per day
	Two year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	150 ppm, equal to 16.8 mg/kg bw per day	850 ppm, equal to 97.2 mg/kg bw per day
		Carcinogenicity	150 ppm, equal to 16.8 mg/kg bw per day	850 ppm, equal to 97.2 mg/kg bw per day
Rat	90-day study of toxicity <sup>a</sup>	Toxicity	150 mg/kg bw per day	1000 mg/kg bw per day
	Two-year study of toxicity and carcinogenicity <sup>a</sup>	Toxicity	150 mg/kg bw per day	1000 mg/kg bw per day
		Carcinogenicity	1000 mg/kg bw per day <sup>b</sup>	-
	Two-generation study of reproductive toxicity <sup>a</sup>	Reproductive toxicity	15 000 ppm, equal to 986 mg/kg bw per day <sup>b</sup>	-
		Parental toxicity	15 000 ppm, equal to 986 mg/kg bw per day <sup>b</sup>	-
		Offspring toxicity	1250 ppm, equal to 81 mg/kg bw per day	4300 ppm, equal to 277 mg/kg bw per day
Developmental toxicity <sup>c</sup>	Maternal toxicity	1000 mg/kg bw per day <sup>b</sup>	-	
	Embryo and fetal toxicity	1000 mg/kg bw per day <sup>b</sup>	-	
Rabbit	Developmental toxicity study <sup>c</sup>	Maternal toxicity	1000 mg/kg bw per day <sup>b</sup>	-
		Embryo and fetal toxicity	1000 mg/kg bw per day <sup>b</sup>	-

Dog	90-day study of toxicity <sup>d</sup>	Toxicity	50 mg/kg bw per day	250 mg/kg bw per day
	One-year study of toxicity <sup>d</sup>	Toxicity	50 mg/kg bw per day	250 mg/kg bw per day

<sup>a</sup> Dietary administration.

<sup>b</sup> Highest dose tested.

<sup>c</sup> Gavage administration.

<sup>d</sup> Capsule administration.

*Acceptable daily intake (ADI), applies to valifenalate, valifenalate acid and valifenalate acid glucosyl ester, expressed as valifenalate*

0–0.2 mg/kg bw

*Acute reference dose (ARfD), applies to valifenalate, valifenalate acid and valifenalate acid glucosyl ester, expressed as valifenalate*

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 valifenalate**

#### ***Absorption, distribution, excretion and metabolism in mammals***

Rate and extent of oral absorption	Rapid absorption ( $T_{max}$ 1–2 hours) and approximately 80% absorbed at 100 mg/kg bw (based on urine, bile, cage wash and tissue/carcass)
Dermal absorption	No data
Distribution	Highest tissue levels found in GI tract, liver and kidney
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Rapid (ca 99% within 48 hours); in bile-cannulated rats predominantly in bile (65–49%), urine (13–31%) and faeces (17–16%)
Metabolism in animals	Extensively metabolized; main metabolite R2 (valifenalate acid); oxidation and cleavage reactions
Toxicologically significant compounds in animals and plants	Valifenalate, valifenalate acid and its glucosyl ester, PCBA (4-chlorobenzoic acid), $\beta$ -4-chlorophenylalanine and $\beta$ -4-chlorophenylalanine- <i>N</i> -glucoside

#### ***Acute toxicity***

Rat, LD <sub>50</sub> , oral	> 5000 mg/kg bw
Rat, LD <sub>50</sub> , dermal	> 2000 mg/kg bw
Rat, LC <sub>50</sub> , inhalation	> 3.118 mg/L
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea pig, dermal sensitization	Not sensitizing (maximization test)

#### ***Short-term studies of toxicity***

Target/critical effect	Decreased body weight gain (mice), liver weight and histopathology (mice, dog), caecum histopathology (rat), thyroid histopathology and clinical chemistry (dog)
Lowest relevant oral NOAEL	15.3 mg/kg bw per day (mouse)
Lowest relevant dermal NOAEL	1000 mg/kg bw per day (rat; highest dose tested)
Lowest relevant inhalation NOAEC	No data

Long-term studies of toxicity and carcinogenicity

Target/critical effect	Liver (mouse); Thyroid and kidneys (rat)
Lowest relevant NOAEL	16.8 mg/kg bw per day (mouse)
Carcinogenicity	Carcinogenic in mice, not carcinogenic in rats <sup>a</sup>
<b>Genotoxicity</b>	No evidence of genotoxicity <sup>a</sup>
<b>Reproductive toxicity</b>	
Target/critical effect	Decreased pup body weight gain
Lowest relevant parental NOAEL	986 mg/kg bw per day, highest dose tested
Lowest relevant offspring NOAEL	81 mg/kg bw per day
Lowest relevant reproductive NOAEL	986 mg/kg bw per day, highest dose tested
<b>Developmental toxicity</b>	
Target/critical effect	None
Lowest relevant maternal NOAEL	1000 mg/kg bw per day (rat, rabbit; highest dose tested)
Lowest relevant embryo/fetal NOAEL	1000 mg/kg bw per day (rat, rabbit; highest dose tested)
<b>Neurotoxicity</b>	
Acute neurotoxicity NOAEL	No specific data; unlikely to be neurotoxic
Subchronic neurotoxicity NOAEL	No specific data; unlikely to be neurotoxic
Developmental neurotoxicity NOAEL	No specific data; unlikely to be neurotoxic
<b>Immunotoxicity</b>	No specific data; unlikely to be immunotoxic <sup>a</sup>
Studies on toxicologically relevant metabolites	
<b>Acute toxicity</b>	
<b>IR5839 (valifenalate acid, R2), rat, oral</b>	LD <sub>50</sub> > 2000 mg/kg bw (rat)
<b>Genotoxicity</b>	
<b>IR5839 (valifenalate acid, R2)</b>	Ames: negative In vitro mammalian cell gene mutation: negative In vitro chromosome aberration: positive In vivo micronucleus: negative
<b>PCBA (4-chlorobenzoic acid)</b>	In vitro mammalian cell gene mutation: negative In vitro chromosome aberration: positive In vivo micronucleus: negative
<b>Human data</b>	No clinical cases or poisoning incidents have been recorded.

<sup>a</sup> Unlikely to pose a carcinogenic risk to humans via exposure from the diet.

### Summary

	Value	Study	Safety factor
ADI	0–0.2 mg/kg bw <sup>a</sup>	78-week mouse study, supported by the 90-day mouse study	100
ARfD	Unnecessary		

<sup>a</sup> applies to valifenalate, valifenalate acid and valifenalate acid glucosyl ester, expressed as valifenalate

## RESIDUE AND ANALYTICAL ASPECTS

Valifenalate (methyl (3*RS*)-3-(4-chlorophenyl)-*N*-[*N*-(isopropoxycarbonyl)-*L*-valyl]- $\beta$ -alaninate) is a fungicide belonging to the chemical group of valinamide carbamates. It interferes with cell wall synthesis affecting all the growth stages of the pathogens controlled, both outside (on the spores), or inside the plant (on the mycelium), affecting the metabolism of the fungal cell wall.

Valifenalate was scheduled at the Fiftieth Session of the CCPR as a new compound for evaluation by the 2019 JMPR.

The Meeting received information from the manufacturer on identity, physical and chemical properties, metabolism studies on plants and lactating goats, environmental fate, analytical methods and stability in stored analytical samples, use patterns, supervised residue trials and processing studies.

Valifenalate technical is an equimolar mixture of diastereomers (*S,R*) and (*S,S*).

Table 1 Summary information on valifenalate and its degradation products

Code names, chemical names and structures of valifenalate and its degradation products			
Code Name/ Number	Chemical Name	Chemical Structure	Occurrence in
Valifenalate	methyl (3 <i>RS</i> )-3-(4-chlorophenyl)- <i>N</i> -[ <i>N</i> -(isopropoxycarbonyl)- <i>L</i> -valyl]- $\beta$ -alaninate		Grapes, tomato, lettuce, potato, goat, rotational crops, soil
Valifenalate-acid R2	3-(4-chlorophenyl)-3-[[ <i>N</i> -(isopropoxycarbonyl)- <i>L</i> -valyl]amino]propionic acid		Grapes, tomato, lettuce, potato, goat, rat, rotational crops, soil
$\beta$ -4-chlorophenylalanine- <i>N</i> -glucoside	3-amino-3-(4-chlorophenyl)propionic acid- <i>N</i> -glucoside		Grapes, tomato, lettuce, potato, rotational crops
Valifenalate-acid glucosyl ester	3-(4-chlorophenyl)-3-[[ <i>N</i> -(isopropoxycarbonyl)- <i>L</i> -valyl]amino]propionic glucosyl ester		Grapes, tomato, lettuce, potato, rotational crops
$\beta$ -4-chlorophenylalanine R5	3-amino-3-(4-chlorophenyl)propionic acid		Goat, rat
PCBA	4-chlorobenzoic acid		Soil

Based on the physical chemical properties, valifenalate is not very volatile, nor is it soluble in water and nonpolar solvents. Valifenalate is photochemically stable. Based on the Log  $K_{ow}$ , valifenalate has the potential to sequester to fatty matrices.

### **PLANT METABOLISM**

The Meeting received plant metabolism studies investigating the nature of the residues following foliar application of valifenalate to grapes, lettuce, tomatoes and potatoes.

#### **Grape - fruit**

Fourteen pots of grape vine plants (variety *Trebbiano*), maintained outdoor, were sprayed four times with [ $^{14}\text{C}$ -U-phenyl]-valifenalate at a low rate of 15 g ai/hL per application (equivalent to the critical GAP) and a higher rate of 75 g ai/hL per application with re-treatment intervals of 11-14 days. Grapes were harvested at maturity, 74 days following the last application.

The total radioactive residues (TRRs) in grapes following treatment at the lower rate were 0.19 mg eq/kg, where 0.08 mg eq/kg (42% TRR) was found in the surface wash and 0.11 mg eq/kg (58% TRR) was found in the washed grapes. At the higher application rate, TRRs in grapes (1.67 mg eq/kg) were higher as were those in the surface wash (1.18 mg eq/kg; 71% TRR) and washed grapes (0.53 mg eq/kg; 32% TRR). Only the surface washes and extracts from the low treatment study were analysed.

The total radioactivity extracted following water surface wash and sequential extractions with acetone:water and acetone released 95% TRR with 5% remaining unextracted. Valifenalate accounted for all the radioactivity in the surface wash (42% TRR; 0.08 mg eq/kg) and the majority of the radioactivity in the solvent extract (24% TRR; 0.05 mg eq/kg), representing a total of 66% TRR (0.13 mg eq/kg). The valifenalate-acid metabolite was observed in the extract at 13% TRR (0.02 mg eq/kg) with the minor valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside metabolites collectively representing approximately 10% TRR (0.016 mg eq/kg).

#### **Grape - leaves**

Vine plants (variety *Barbera*), maintained in a growth chamber under controlled environmental conditions, were sprayed once with [ $^{14}\text{C}$ -U-phenyl]-valifenalate at a rate of 15 g ai/hL. Leaves were collected 2 hours, 1, 3, 8, 14 and 30 days after treatment. At sampling times of 14, 23 and 30 days, the new leaves grown after treatment were separately analysed.

The TRRs, determined by summing the radioactivity in the washes with those of the washed leaves, remained relatively unchanged as the sampling time increased from 2 hours (56 mg eq/kg) to 30 days (51 mg eq/kg).

Greater than 88% TRR in the treated leaves was removed by surface washing with acetone. Extraction of the washed leaves with acetone:water and acetone released an additional 3–11% TRR resulting in less than 0.5% TRR unextracted at all sampling intervals. New leaves collected on sampling days 23 and 30 were extracted with the same solvents and 96–98% TRR was released with limited radioactivity remaining unextracted.

Valifenalate accounted for all the radioactivity in the surface washes at all sampling times, representing greater than 88% TRR, however, concentrations of the parent compound declined relatively slowly with increasing sampling time, from 53 mg eq/kg (2 hours following the foliar spray application) to 48 mg eq/kg (30 days post-treatment). Parent accounted for the majority of the compounds identified (> 38% radioactivity present) in the washed leaf extracts, yet concentrations of valifenalate declined at a faster rate, from 4.2 mg eq/kg to 0.75 mg eq/kg, as the duration following sampling increased. This decline was accompanied by an increase in concentration of the valifenalate-acid (0.06 mg eq/kg (1 day post-treatment) to 0.25 mg eq/kg at the end of the experiment) and the unknown metabolites (0.6 mg eq/kg (1 day post-treatment) to 1.0 mg eq/kg). In new leaves, valifenalate,



valifenalate-acid and unknown metabolites accounted for 20–27% TRR (0.03–0.06 mg eq/kg), 20% TRR (0.03–0.04 mg eq/kg) and 49–58% TRR (0.09–0.11 mg eq/kg), respectively.

#### *Tomato - leaves*

Fourteen pots of tomato plants (variety *Marmande*), maintained in growth chambers under controlled environmental conditions, were sprayed 30–40 days after sowing with a single foliar application of [<sup>14</sup>C-U-phenyl]-valifenalate at a concentration of 0.25 g ai/L, equivalent to 0.625 mg ai/plant.

TRRs in treated leaves decreased from 36 mg eq/kg, 2 hours after treatment, to 8.7 mg eq/kg, 28 days after treatment. The radioactivity in the acetone surface washes and washed leaves decreased from 31 mg eq/kg and 4.6 mg eq/kg, respectively, 2 hours following application, to 7.1 mg eq/kg and 1.4 mg eq/kg, respectively, 28 days following application, demonstrating a rapid penetration of the radioactivity into the leaves and a corresponding rapid dissipation of the radioactive residues in washed leaves. A 3-fold increase in unextracted residues was observed within the same time interval (0.04 mg eq/kg to 0.12 mg eq/kg). The parent compound, valifenalate, accounted for all the radioactivity in the surface washes (> 8.0% TRR), and was identified as the major residue in the acetone:water and acetone extracts of the washed leaves (11–18% TRR; 1.0–5.2 mg eq/kg), for a total of 93–100% TRR (0.13–55.4 mg eq/kg). Three minor metabolites, valifenalate-acid, valifenalate acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside were also identified in the leaf extracts, neither of which represented more than 1.5% TRR (0.22 mg eq/kg).

Analysis of new leaves, grown after the foliar spray application and sampled 21 and 28 days following treatment, showed that some of the radioactivity which penetrated the sprayed plants translocated to the new leaves. The total radioactivity in the new leaves was 0.81 mg eq/kg and 0.84 mg eq/kg at 21 and 28 days, respectively, of which up to 98% TRR was extracted with the same solvents as those used for treated leaves. Valifenalate and valifenalate-acid represented 29–45% TRR (0.23–0.38 mg eq/kg) and 20–28% TRR (0.16–0.22 mg eq/kg), respectively, accounting for the majority of the radioactivity in the solvent extracts. Valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside were also identified, representing 6–10% TRR (0.05–0.08 mg eq/kg).

#### *Lettuce*

Six lettuce plants (variety *Romana*), grown in one pot maintained outdoors, received three foliar spray applications of [<sup>14</sup>C-U-phenyl]-valifenalate formulated as a wettable powder, at a rate of 150 g ai/ha per application. The applications were performed at intervals of seven days. TRRs in mature lettuce plants harvested 7 days following the last application were 3.6 mg eq/kg.

Analysis of the water surface wash (32% TRR) and the combined acetone:water and acetone extracts (70% TRR) showed that the parent compound was the main component of these fractions, representing all the radioactivity in the surface wash and 64% TRR in the extracts, for a total of 96% TRR (3.55 mg eq/kg). Once valifenalate penetrated into the lettuce leaves, it was metabolized into the valifenalate-acid (1.8% TRR; 0.07 mg eq/kg), the valifenalate-acid glucosyl ester (1.1% TRR; 0.04 mg eq/kg) and the  $\beta$ -4-chlorophenylalanine-N-glucoside (2.6% TRR; 0.09 mg eq/kg).

#### *Potato - leaves*

Fourteen pots of potato plants (variety *Primura*), maintained outdoors, were sprayed with a single foliar application of [<sup>14</sup>C-U-phenyl]-valifenalate at a concentration of 0.25 g ai/L, equivalent to 0.625 mg ai/plant.

The radioactivity in the leaves dissipated from 10 mg eq/kg, 2 hours after treatment, to 5.6 mg eq/kg, 28 days following treatment. In a similar manner, TRRs in the acetone surface wash declined from 9.4 mg eq/kg to 4.5 mg eq/kg within the same sampling interval, with a corresponding increase in extracted (acetone:water and acetone) radioactivity, from 5% TRR (0.55 mg eq/kg) to 19% TRR (1.0 mg eq/kg).

Analysis of the leaf surface wash solutions demonstrated that the entire radioactivity on the leaf surface corresponded to the parent compound, valifenalate. Some of the parent compound that had

penetrated into the leaves appeared to undergo O-demethylation to the valifenalate-acid, which accounted for 0.06–0.87% TRR (0.006–0.05 mg eq/kg), followed by conjugation to valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside, both of which increased from 0.10 to 0.61% TRR (0.01 to 0.04 mg eq/kg), with the increase in sampling time.

### *Potato tubers*

Four pots of potato plants (variety *Primura*), maintained outdoors, received three applications of [ $^{14}\text{C}$ -U-phenyl]-valifenalate at 150 g ai/ha per application. The applications were performed at intervals of 7 days. The plants were harvested at maturity, 21 days following the last application.

The majority of the radioactive residue (98% TRR) in tubers was extracted with acetone:water and acetone, with unextracted residues accounting for  $\leq 10\%$  TRR. The TRRs in the leaves (58.3 mg eq/kg, radioactivity not further investigated) were significantly higher than those in tubers (0.013 mg eq/kg) demonstrating minimal translocation from the leaves to the tubers.

While chromatographic analysis of the potato tuber extracts revealed that the parent compound was not detected in tubers, four metabolites were identified, valifenalate-acid (15% TRR; 0.002 mg eq/kg), valifenalate-acid glucosyl ester (16% TRR; 0.002 mg eq/kg),  $\beta$ -4-chlorophenylalanine (32% TRR; 0.004 mg eq/kg) and  $\beta$ -4-chlorophenylalanine-N-glucoside (0.75% TRR; 0.0001 mg eq/kg).

In summary, the metabolism of valifenalate is adequately understood in grapes, tomato (leaves), lettuce and potato, representing fruit, a root and tuber vegetable and a leafy crop. In all crops, except potato tuber, the major component of the residue is valifenalate (66–99% TRR). Metabolites identified were the valifenalate-acid, valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside. In all metabolism studies, there was evidence of limited translocation of the radioactivity from the site of application.

The degradation of  $^{14}\text{C}$ -valifenalate proceeds predominantly via O-demethylation to the valifenalate-acid followed by conjugation to valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside. The major plant metabolite, valifenalate-acid, was identified as a major metabolite in rats.

Surface washes and extracts of all crops tested were further analysed by HPLC to determine the ratio of S,R and S,S diastereomers of valifenalate and the valifenalate-acid metabolite (grape leaves only). Valifenalate and the valifenalate-acid metabolite in both surface washes and extracts were made up of S,R and S,S diastereomers in similar ratios (approximately 50%). Therefore, no changes in the isomeric ratio were observed in any of the plant metabolism studies.

### **ANIMAL METABOLISM**

The Meeting received animal metabolism studies with valifenalate in goats and rats. A metabolism study in laying hen was not provided to the Meeting. Evaluation of the rat metabolism study was carried out by the WHO Core Assessment Group.

#### *Lactating Goat*

[ $^{14}\text{C}$ -U-phenyl]-valifenalate was orally administered to a lactating goat (*Saanan*, weighing 60 kg) by gelatine capsules, twice daily for 5 consecutive days. The average daily dose level was equivalent to 13 ppm in the feed (dry matter). The goat was sacrificed 23 hours after administration of the last dose.

The majority of the administered dose (AD) was excreta-related (83.1% AD). Limited radioactivity was eliminated in the milk (0.02% AD) and the tissue burden was low (0.13% AD). The remainder of the radioactivity was recovered in the GI tract, accounting for 15% AD. The overall recovered radioactivity accounted for 98% AD.

Radioactivity in milk remained low throughout the study duration with no plateau observed ( $\leq 0.003$  mg eq/kg). In the tissues, TRRs were highest in liver (0.11 mg eq/kg) followed by kidney (0.045 mg eq/kg), fat (omental and renal; 0.011 mg eq/kg) and muscle (hind and fore quarter;

0.003 mg eq/kg). Due to the low levels of radioactivity in muscle, no further analysis was undertaken to elucidate the nature of the residues.

Successive extractions of milk and tissues using various organic solvents released more than 83% TRR. The unextracted residues ranged from 4–8% TRR.

Valifenalate accounted for the majority of the radioactivity in milk (53% TRR). The minor metabolites, valifenalate-acid and  $\beta$ -4-chlorophenylalanine were also observed, however, neither accounted for more than 3% TRR (0.0001 mg eq/kg).

Valifenalate accounted for approximately 2% TRR (0.002 mg eq/kg) in both liver and kidney. The valifenalate-acid was the predominant metabolite detected in both tissues accounting for 51% TRR (0.023 mg eq/kg) in kidney and 61% TRR (0.066 mg eq/kg) in liver. The only other identified metabolite was  $\beta$ -4-chlorophenylalanine, representing 9% TRR (0.004 mg eq/kg) in kidney and 2% TRR (0.002 mg eq/kg) in liver.

In renal and omental fat, valifenalate accounted for the majority of the radioactivity (64% TRR; 0.002 mg/kg), and the valifenalate-acid was the only metabolite identified, representing 9–18% TRR ( $\leq$  0.002 mg eq/kg).

The Meeting concluded that, in the species investigated (goats and rats), the total administered radioactivity was predominantly eliminated in excreta. Qualitatively there are no major differences among the metabolic profiles with the exception that the metabolism in rats was more extensive than in goats. The routes and products of metabolism were similar across both animals, resulting from O-demethylation to form the valifenalate-acid metabolite followed by hydrolysis of the amide bond to form  $\beta$ -4-chlorophenylalanine.

### **ENVIRONMENTAL FATE IN SOIL**

The Meeting received information on hydrolysis, soil photolysis, aerobic degradation and the behaviour of [ $^{14}$ C]-valifenalate in confined rotational crops..

#### **Hydrolysis**

Valifenalate was hydrolytically stable at pH4. Its hydrolytic degradation increased with increasing pH. The DT<sub>50</sub> at pH 7 (25 °C) was estimated to be 91 days and at pH 9 (25 °C) was 4.2 days. The major hydrolytic degradation product identified was the valifenalate-acid which was demonstrated to be stable to hydrolysis at all tested pH.

#### **Photolysis - Soil**

Valifenalate is stable to photolysis.

#### **Aerobic degradation in soil**

The degradation of [ $^{14}$ C-U-phenyl]-valifenalate was investigated in various soil types (including sandy loam, loamy sand, loam, silty clay loam) under aerobic laboratory conditions (20 °C for up to 96 days).

Following first order kinetics or first-order multi-compartment (FOMC) kinetics, the resulting DT<sub>50</sub> values for valifenalate ranged from 0.04–0.36 days while those for its major degradation product, valifenalate-acid, ranged from 0.33–0.93 days.

The resulting DT<sub>50</sub> values for the soil metabolite PCBA ranged from 2–3 days.

The Meeting concluded that valifenalate, valifenalate-acid and PCBA are not persistent in soil.

#### **Confined rotational crop**

Bare sandy loam soil was treated with an aqueous solution of [ $^{14}$ C-U-phenyl]-valifenalate at a rate of 1440 g ai/ha, equivalent to almost 10-fold the highest annual rate. The treated soil was aged for 30, 120 and 365 days prior to sowing winter wheat, carrot and lettuce. Crops were harvested at maturity. Winter

wheat was also harvested at an intermediate growth stage (forage).

In carrot, TRRs were  $\leq 0.008$  mg eq/kg at all plant-back intervals (PBI), while TRRs in carrot leaves decreased from 0.056 mg eq/kg at the 30-day PBI to 0.018 mg eq/kg at the 365-day PBI. In lettuce, TRRs at the 30-day PBI were 0.017 mg eq/kg and remained at 0.09 mg eq/kg at PBIs of 120 and 365 days. In wheat forage, straw and grain, TRRs consistently declined with increasing PBI (forage: 0.018 mg eq/kg (30-day PBI) to 0.008 mg eq/kg (120-day PBI) to  $< 0.006$  mg eq/kg (365-day PBI); straw: 0.098 mg eq/kg (30-day PBI) to 0.051 mg eq/kg (120-day PBI) to 0.030 mg eq/kg (365-day PBI); grain: 0.030 mg eq/kg (30-day PBI) to 0.013 mg eq/kg (120-day PBI) to 0.005 mg eq/kg (365-day PBI)).

The radioactivity released following acetone:water extraction ranged from 33 to 73% TRR. The unextracted residue ranged between 29 and 67% of TRR ( $< 0.01$  to 0.05 mg eq/kg) for all crops at all PBIs. A high proportion of this radioactivity was incorporated into the cellulose (5–38% TRR;  $< 0.01$  to 0.03 mg eq/kg) and lignin fractions (1–22% of TRR;  $\leq 0.01$  mg eq/kg).

Valifenalate appeared to be taken up from the soil into the crops where it was metabolized into three compounds, valifenalate-acid, valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside. The main residue found in all crops was the unchanged parent, valifenalate. The amount of valifenalate detected in raw commodities destined for human consumption was very low (lettuce: 19% of TRR, 0.003 mg eq/kg; wheat grain: 19% of TRR; 0.006 mg eq/kg) while that in feed commodities (carrot leaves, wheat forage and wheat straw) was  $\leq 4$  8% TRR ( $\leq 0.03$  mg eq/kg). Valifenalate-acid was not observed in wheat forage at any PBI, however, it was present in almost all other tested matrices, accounting for 6–11% TRR (0.001–0.006 mg eq/kg) in carrot leaves, 5% TRR (0.0009 mg eq/kg) in lettuce (30-day PBI), 17% TRR (0.002 mg eq/kg) in wheat straw (365-day PBI) and  $< 1$ % TRR (0.002 mg eq/kg) in wheat grain (30-day PBI). Both valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine-N-glucoside were present but at concentrations lower than those of the acid metabolite.

The Meeting concluded that, considering the residues of valifenalate and its associated metabolites in follow crops were low following application to bare soil at 10-fold the highest annual rate, no significant residues of the parent compound or the metabolites are anticipated following treatment at the maximum annual rate.

## **METHODS OF ANALYSIS**

The Meeting received descriptions and validation data for an analytical method capable of quantifying residues of valifenalate and valifenalate-acid in diverse plant matrices. Sequential extractions were carried out with acetonitrile: 0.02 M triethylamine or dichloromethane. After clean-up the final extracts were quantified for residues of valifenalate and/or valifenalate-acid using liquid chromatography with tandem mass spectrometric detection (LC-MS/MS). The LOQ was reported to be 0.01 mg/kg for each analyte for all plant matrices. Recoveries of valifenalate and valifenalate-acid were typically within the acceptable range of 70–120% with relative standard deviations below 20%.

The Meeting also received descriptions and validation data for several analytical methods for analysis of residues of valifenalate and the valifenalate-acid metabolite in milk, eggs and livestock matrices. Extraction solvents used were acetonitrile: 0.02 M triethylamine, hexane pre-saturated with acetonitrile in combination with acetonitrile pre-saturated with hexane, hexane:acetone and acetonitrile. Clean-up of the extracts was performed using liquid partitioning. For all methods, residues of valifenalate and valifenalate-acid were quantified using LC-MS/MS. The LOQs achieved for all animal commodities were 0.01 mg/kg for each analyte. Recoveries of valifenalate and the valifenalate-acid were typically within the acceptable range of 70–120% with relative standard deviations below 20%.

Many of the methods, capable of analysing valifenalate and/or valifenalate-acid in plant and animal matrices, were successfully validated by independent laboratories, demonstrating good reproducibility. Some of the methods were also subjected to radiovalidation, where 73–109% of the valifenalate residues were recovered from samples collected from the metabolism studies, demonstrating the efficiency of the data collection analytical methods to extract incurred residues of valifenalate.

**STABILITY OF PESTICIDE RESIDUES IN STORED ANALYTICAL SAMPLES**

The stability of valifenalate and valifenalate-acid was investigated in lettuce, tomatoes, onions, potatoes, grapes and wine. Samples were fortified with each analyte at various concentrations, stored frozen at -20 °C and taken for analysis at intervals up to 24 months.

Residues of valifenalate and valifenalate-acid were determined to be stable at -20 °C for at least 24 months in high water content commodities (lettuce, tomatoes and onions), grapes (high acid), potatoes (high starch) and wine.

Studies on storage stability of valifenalate in milk and animal tissues were not provided to the Meeting.

**DEFINITION OF THE RESIDUE**

The nature of the valifenalate residues was investigated in grapes (leaves and fruit), lettuce, tomatoes (leaves) and potatoes (leaves and tubers) following foliar treatment.

As valifenalate was, in most cases, the major analyte in all tested plant matrices (66–99% TRR; 0.13–5.5 mg eq/kg) and suitable analytical methods are available to analyse the parent compound, the Meeting considered that valifenalate was a suitable marker for enforcement of MRLs for plants.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the valifenalate-acid and its conjugate valifenalate-acid glucosyl ester and  $\beta$ -4-chlorophenylalanine and its conjugate  $\beta$ -4-chlorophenylalanine-N-glucoside.

In the metabolism studies, the ratios of the combined levels of valifenalate-acid (free and conjugated) to the parent compound were up to 0.23. In a few of the supervised residue trials conducted on grapes, where residues of free valifenalate-acid were reported, the ratios of valifenalate-acid to the parent ranged from 0.085–0.83. The median of all ratios was 0.25.

In the metabolism studies where  $\beta$ -4-chlorophenylalanine and/or its conjugate  $\beta$ -4-chlorophenylalanine-N-glucoside were measured, the ratios of these metabolites to the parent compound ranged from 0.0018–0.026 (median = 0.0046).

The toxicological properties of these metabolites were considered. Valifenalate-acid is not likely to be more potent than the parent compound, given its toxicity profile as well as its detection in rats at significant levels. While the valifenalate-acid-glucosyl-ester was not observed in the rat, considering it is a conjugate of the valifenalate-acid, the metabolite valifenalate-acid glucosyl ester was also considered to be covered by the parent compound.

$\beta$ -4-chlorophenylalanine-N-glucoside was not detected in the rat metabolism study. This metabolite is the glucoside conjugate of  $\beta$ -4-chlorophenylalanine which was observed as a minor metabolite (< 10%) in the rat metabolism study but no conclusion on its toxicological relevance could be drawn. Therefore, the Meeting noted that the TTC for potential genotoxicity (0.0025  $\mu$ g/kg bw per day) should be applied for  $\beta$ -4-chlorophenylalanine (free and conjugated). The estimated maximum long-term dietary exposure to  $\beta$ -4-chlorophenylalanine (free and conjugated) is 0.001  $\mu$ g/kg bw per day and below the TTC. It is therefore unlikely to present a public health concern based on the uses considered by the current Meeting.

Noting the above, the Meeting decided the residue definition for dietary risk assessment for plant commodities should be valifenalate and the valifenalate-acid (free and conjugated), expressed as valifenalate equivalents.

As residues of valifenalate-acid (free and conjugated) were not measured in field trials approximating GAP, an adjustment factor of 1.25 was derived from the metabolism studies and a select number of grape residue trials. This factor will be used to convert residues of valifenalate to total residues of valifenalate and the valifenalate-acid (free and conjugated). The Meeting considered the factor would only be applied to supervised trial median residues (STMRS) to estimate the relevant values required for dietary risk assessment.

The nature of the valifenalate residues was investigated in lactating goat. Following oral administration of the test substance to a lactating goat (13 ppm feed), valifenalate was the predominant analyte in milk and fat (renal and omental) accounting for 53–63% TRR (0.002–0.007 mg eq/kg). In kidney and liver, the parent accounted for < 3% TRR (< 0.003 mg eq/kg), with valifenalate-acid representing the majority of the radioactivity in these tissues (51–61% TRR; 0.02–0.07 mg eq/kg). Due to the low levels of radioactivity in muscle (0.01% AD; 0.003 mg eq/kg), no further analysis was undertaken to elucidate the nature of the residues.

No farm animal feeding studies were provided to the Meeting.

As the livestock dietary burden is anticipated to be zero, based on the uses considered by the current Meeting, residues of valifenalate and valifenalate-acid in animal matrices are not anticipated. Based on the available information, the Meeting decided that the parent was a suitable marker for all animal matrices. Suitable methods are available for valifenalate in animal commodities.

Noting the above, the Meeting concluded that for enforcement of MRLs for livestock matrices, the residue definition should be valifenalate.

In deciding which compounds should be included in the residue definition for risk assessment, the Meeting considered the likely occurrence of the metabolites valifenalate-acid and  $\beta$ -4-chlorophenylalanine.

Valifenalate-acid may contribute significantly to the consumer exposure as it is present in liver and kidney at levels 25–30 fold higher than that of the parent compound in the goat metabolism study. In these same tissues,  $\beta$ -4-chlorophenylalanine was present at levels 4-fold higher than that of the parent.

The valifenalate-acid was detected as a major metabolite in the rat metabolism study and not likely to be more potent than the parent. Therefore, the valifenalate-acid is considered to be toxicologically covered by the parent compound.

$\beta$ -4-chlorophenylalanine was observed as a minor metabolite (< 10%) in the rat metabolism study but no conclusion on its toxicological relevance could be drawn. Therefore, similar to plant commodities, the Meeting noted that the TTC for potential genotoxicity (0.0025  $\mu$ g/kg bw per day) should be applied for  $\beta$ -4-chlorophenylalanine. The long-term dietary exposure to  $\beta$ -4-chlorophenylalanine residues in animal matrices is not likely to contribute to the estimated exposure for plants above, considering the current livestock dietary burden of 0.

Noting the above, the Meeting concluded that the residue definition for dietary risk assessment for animal commodities should be valifenalate and valifenalate-acid, expressed as valifenalate.

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

Definition of the residue for risk assessment for plant commodities: *valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), free and conjugated, expressed as valifenalate.*

Definition of the residue for risk assessment for animal commodities: *valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), expressed as valifenalate.*

There is insufficient data to characterize whether the sum of residues in the residue definition (sum of valifenalate and valifenalate-acid) is fat-soluble. The nature of the residues in muscle was not investigated. The log  $K_{ow}$  for valifenalate is 3.11 and the log  $K_{ow}$  value of valifenalate acid is expected to be lower, suggesting the residue does not preferentially partition into fatty matrices.

On the weight of evidence, the Meeting decided the residue is not *fat-soluble*.

## **Results of supervised residue trials in crops**

### **Grapes**

The critical GAP for grapes is from the Ukraine; 4 × 120 g ai/ha, 10-day RTI and 30-day PHI.

As there were no supervised residue trials conducted in accordance with the Ukrainian GAP, the GAP from Italy was considered; 3 × 120 g ai/ha, 10–14 day RTI and 28-day PHI for wine grape and 70-day PHI for table grape.

In trials from Europe, matching the GAP from Italy, residues of valifenalate in grapes in ranked order were (n = 16): < 0.010, 0.013, 0.014, 0.019, 0.040, 0.045, 0.051, 0.058, 0.067, 0.073, 0.086, 0.087, 0.095, 0.11, 0.12 and 0.13 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.3 and 0.079 (1.25 × 0.0625) mg/kg, respectively, for grapes.

### **Onion, Bulb**

The critical GAP for bulb onions/shallots is from Bulgaria; 3 × 150 g ai/ha, 7-day RTI and 3-day PHI.

In trials from Europe matching the critical GAP, valifenalate residues in bulb onions in ranked order were (n = 12): < 0.01 (4), 0.014, 0.018, 0.042, 0.079, 0.087, 0.18 (2) and 0.26 mg/kg

The Meeting estimated a maximum residue level and STMR of 0.5 and 0.0375 (1.25 × 0.030) mg/kg, respectively, for onion, bulb.

The critical GAP from Bulgaria also includes shallots. The Meeting decided the data could be used to extrapolate the maximum residue level and the STMR values for onion to shallot.

### **Tomatoes**

The critical GAP for field tomato/eggplant is from France; 3 × 150 g ai/ha, minimum 7-day RTI and 3-day PHI.

In trials from Europe matching the critical GAP, valifenalate residues in field tomatoes in ranked order were (n = 9): < 0.01 (2), 0.014, 0.021, 0.039, 0.051, 0.055, 0.088 and 0.27 mg/kg.

The Meeting estimated a maximum residue level and STMR of 0.4 and 0.049 (1.25 × 0.039) mg/kg, respectively, for tomatoes.

The critical GAP from France for field tomato also covers eggplants. The Meeting decided the data could be used to extrapolate the maximum residue level and the STMR values of tomato to eggplants.

## **FATE OF RESIDUES DURING PROCESSING**

### **Processing**

The Meeting did not receive information on the nature of residues under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation. However, the Meeting received information on the fate of valifenalate and valifenalate-acid residues during the processing of grapes and information on the fate of valifenalate residues during the processing of tomatoes. For estimation of maximum residue levels, processing factors calculated for valifenalate for the processed commodities of grapes and tomatoes are shown in the table below.

For dietary risk assessment, processing factors, best estimates, STMR-Ps and HR-Ps (canned tomatoes only) were calculated for valifenalate and valifenalate-acid. In the case of the tomato processed commodities, residues of valifenalate-acid were not reported in the study, therefore, the ratio of 1.25 was applied to each of the individual valifenalate residues, to calculate the total residues of

valifenalate and valifenalate acid (free and conjugated), from which the processing factors were then derived.

Table 2 Derivation of maximum residue levels for processed commodities

Commodity	Calculated Processing Factors	Best Estimate	Maximum Residue Level, mg/kg
Grapes (maximum residue level = 0.3 mg/kg)			
Must	0.93, 0.86	0.90 (mean)	-
Wet pomace (wine making)	3.6, 2.2	2.9 (mean)	-
Bottled wine	0.56, 0.46, 0.70	0.56 (median)	-
Wet pomace (juice)	2.7, 1.5	2.1 (mean)	-
Juice, pasteurized	0.45, 0.50	0.48 (mean)	-
Tomatoes (maximum residue level = 0.4 mg/kg)			
Juice	0.32	0.32 (n = 1)	-
Ketchup	0.27	0.27 (n = 1)	-
Canned, peeled	< 0.1	0.1 (n = 1)	-
Puree (13% dry matter)	0.51	0.51 (n = 1)	-
Paste (33% dry matter)	0.83	0.83 (n = 1)	-

Table 3 Derivation of STMR-Ps for processed commodities

Commodity	Calculated Processing Factors <sup>a</sup>	Best Estimate	RAC STMR (mg/kg)	STMR-P <sup>b</sup> (mg/kg)
Grapes				
Must	0.94, 1.1	1.0 (mean)	0.079	0.079
Wet pomace (wine making)	3.4, 2.8	3.1 (mean)		0.24
Bottled wine	0.52, 0.65, 0.76	0.65 (median)		0.051
Wet pomace (juice)	2.5, 1.9	2.2 (mean)		0.16
Juice, pasteurized	0.54, 0.54	0.54 (mean)		0.043
Tomatoes				
Juice	0.32	0.32 (n = 1)	0.049	0.016
Ketchup	0.28	0.28 (n = 1)		0.014
Canned, peeled	< 0.1	< 0.1 (n = 1)		0.005
Puree (13% dry matter)	0.51	0.51 (n = 1)		0.025
Paste (33% dry matter)	0.82	0.82 (n = 1)		0.040

<sup>a</sup> PF based on total residues of valifenalate and valifenalate-acid (free and conjugated), determined by multiplying all valifenalate residues in all processed commodities by 1.25, expressed as parent equivalents.

<sup>b</sup> STMR-P is used for the dietary exposure estimates and are based on the residue definition for dietary risk assessment: valifenalate and valifenalate-acid (free and conjugated), expressed as parent equivalents

## RESIDUES IN ANIMAL COMMODITIES

### Farm animal feeding studies

The Meeting did not receive farm animal feeding studies.



### ***Estimated dietary burdens of farm animals***

For the uses considered by the current Meeting, grape pomace and tomato pomace are only potential feed items in Australia where they can be fed to beef or dairy cattle. However, valifenalate is not registered for use in Australia and neither of these feed items is traded. Therefore, the Meeting concluded that the dietary burdens for beef and dairy cattle are 0. Based on the uses considered by the current Meeting, there are no poultry feed items.

Thus, the Meeting estimated maximum residue levels of 0.01(\*) mg/kg for milks, meat (from mammals other than marine mammals), mammalian fats (except milk fats), edible offal (mammalian), eggs and poultry edible offal, fat and meat and STMRs of 0 mg/kg for milks, meat (from mammals other than marine mammals), mammalian fats (except milk fats), edible offal (mammalian), eggs and poultry edible offal, fat and meat.

## **RECOMMENDATIONS**

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

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

Definition of the residue for risk assessment for plant commodities: *valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), free and conjugated, expressed as valifenalate.*

Definition of the residue for risk assessment for animal commodities: *valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), expressed as valifenalate.*

The residue is not fat-soluble.

## **DIETARY RISK ASSESSMENT**

### ***Long-term dietary exposure***

The ADI for valifenalate is 0–0.2 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for valifenalate 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 2019 JMPR Report. The IEDIs were 0% of the maximum ADI.

The Meeting concluded that long-term dietary exposure to residues of valifenalate from uses considered by the JMPR is unlikely to present a public health concern.

### ***Acute dietary exposure***

The Meeting determined that establishment of an acute reference dose is unnecessary for valifenalate. The Meeting therefore concluded that acute dietary exposure to residues of valifenalate, resulting from uses that have been considered by the JMPR, is unlikely to present a public health concern.



## 6 Future Work

The items listed below are tentatively scheduled to be considered by the Meeting in 2020. The compounds listed include those recommended as priorities by the CCPR at its Fiftieth and earlier Sessions and compounds scheduled for re-evaluation within the CCPR periodic review programme.

Updated calls for data are available at least ten months before each JMPR meeting from the web pages of the Joint Secretariat<sup>20</sup>.

### NEW COMPOUNDS

TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
Flutianil	Flutianil
Mefentrifluconazole	Mefentrifluconazole
Pyrasulfutole	Pyrasulfutole
Pyraziflumid	Pyraziflumid
	Pyridate (315)
Tetraniliprole	Tetraniliprole
Spiropidion (reserve)	Spiropidion (reserve)
Ethalfuralin (reserve)	Ethalfuralin (reserve)
Inpyrfluxam (reserve)	Inpyrfluxam (reserve)
Isoflucypram (reserve)	Isoflucypram (reserve)

PERIODIC RE-EVALUATIONS	
TOXICOLOGY	RESIDUE
Diazinon (22)	Diazinon (22)
Fipronil (202)	Fipronil (202)
Prochloraz (142)	Prochloraz (142)
Methidathion (51)	Methidathion (51)
Terbufos (167) (reserve)	Terbufos (167) (reserve)
Carbaryl (008) (reserve)	Carbaryl (008) (reserve)
Quintozene (64) (reserve)	Quintozene (64)
Ethoxyquin (35)	Ethoxyquin (35)

<sup>20</sup> <http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/>

NEW USES AND OTHER EVALUATIONS	
TOXICOLOGY EVALUATIONS	RESIDUE EVALUATIONS
<b>Follow up evaluations</b>	
Dimethoate (027)	
Carbosulfan (145)/Carbofuran (096)	
	Bixafen (262)
	Chlorothalonil (81)
	Difenoconazole (224)
	Fenbuconazole (197)
	Flutriafol (248)
Fenpyroximate (193)	Fenpyroximate (193)
	Imidacloprid (206)
	Isoprothiolane (299)
	Isoxaflutole (268)
	Profenofos (171)
	Prothioconazole (232)
	Quinclorac (287)
	Spiromesifen (294)
	Thiamethoxam (245)
	Trinexapac-ethyl (271)
	Tebuconazole (189)
	Trifloxystrobin (213)
	Cypermethrin (118) (Reserve)
	Fenpicoxamid (305) (Reserve)
	Pydiflumetofen (309) (Reserve)
	Sulfoxaflor (252) (Reserve)
	S-Methoprene (147) (Reserve)

## Annex 1: Acceptable daily intakes, short-term dietary intakes, acute reference doses, recommended maximum residue levels and supervised trials median residue values recorded by the 2019 JMPR Meeting.

The following abbreviations are used in Annex 1.

* (following name of pesticide)	New compound
** (following name of pesticide)	Compound reviewed within CCPR periodic review programme
* (following a recommended maximum residue level)	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.
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 previous recommendations)	The previous recommendation is withdrawn, or withdrawal of the recommended Maximum residue level or existing Codex or draft MRL is recommended.

Table 1 Acceptable daily intakes (ADIs), acute reference doses (ARfDs), acute and long-term dietary exposures, recommended maximum residue levels, supervised trials median residue values (STMRs) and other values recorded by the 2019 JMPR meeting.

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<b>Afidopyropen (312)*</b>  ADI: 0–0.08 mg/kg bw ARfD: 0.2 mg/kg bw (for women of child- bearing age) ARfD: 0.3 mg/kg bw (for general population)	AM 0660	Almond hulls	0.6 (dw)		Median: 0.064 (ar)	
	DF 0226	Apple, dried (peeled)	0.02		0.013	0.019
	VB 0041	Cabbages, Head	0.5		0.02	0.10
	FS 0013	Cherries, Subgroup of	0.03		0.02	0.031
	FC 0001	Citrus Fruit, Group of	0.15		0.0535 <sup>a</sup>	0.086 <sup>a</sup>
	OR 0004	Citrus oil <sup>b</sup>	0.7		0.22	
	AB 0001	Citrus pulp, dry <sup>b</sup>	0.4		0.13	
	HH 3209	Coriander, leaves	5		2.5	4.8
	AB 1204	Cotton gin trash	1.5		Median: 0.65	Highest: 1.0
	SO 0691	Cotton seed	0.08		0.02	
	VC 0424	Cucumber	0.7		0.17	0.60
	HH 0730	Dill, leaves	5		2.5	4.8
	MO 0096	Edible offal (mammalian)	0.2		liver: 0.22 kidney: 0.13	liver: 0.34 kidney: 0.13
	PE 0112	Eggs	0.01(*)		0.022	0.098
	VO 2046	Eggplants, Subgroup of	0.15		0.030	0.12
	VB 0042	Flowerhead Brassicas, Subgroup of	0.4		0.135	0.34
	VC 2040	Fruiting vegetables, Cucurbits – Melon, Pumpkins and Winter squashes, Subgroup of	0.05		0.027 <sup>a</sup>	0.048 <sup>a</sup>
HS 0784	Ginger, rhizome (fresh)	0.01(*)		0	0	
VL 2050	Leafy greens, Subgroup of	2		0.88	2.6	

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VL 0054	Leaves of Brassicaceae, Subgroup of	5		2.5	4.8
	MF 0100	Mammalian fats (except milk fats)	0.01(*)		0.13	0.13
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)		muscle: 0.18 fat: 0.13	muscle: 0.26 fat: 0.13
	ML 0106	Milks	0.001(*)		0.020	
	HH 0740	Parsley, leaves	5		2.5	4.8
	FS 2001	Peaches, Subgroup of	0.015		0.02	0.022
	VO 0051	Peppers, Subgroup of, excluding okra, martynia and roselle	0.1		0.036	0.11
	HS 0444	Peppers, chili dried	1		0.36	1.1
	FP 0009	Pome fruit, Group of, excluding persimmon	0.03		0.021	0.029
	FS 0014	Plums, Subgroup of	0.01(*)		0.02	0.02
	PO 0111	Poultry, edible offal of	0.01(*)		0.024 (Liver)	0.11 (Liver)
	PF 0111	Poultry, fats	0.01(*)		0.022	0.098
	PM 0110	Poultry, meat	0.01(*)		0.022	0.098
	VD 0541	Soya bean (dry)	0.01(*)		0.02	
	VS 2080	Stem and Petioles, Subgroup of	3		0.54	2.2
	VC 0431	Summer squash	0.07		0.039	0.050
	VO 2045	Tomatoes, Subgroup of	0.15		0.030	0.12
	VO 0448	Tomatoes, dried	0.7		0.17	0.70
	TN 0085	Tree nuts, Group of	0.01(*)		0.02	0.02
	VR 0071	Tuberous and corm vegetables, Subgroup of	0.01(*)		0	0
	HS 0794	Turmeric, root (fresh)	0.01(*)		0	0
	JF 0226	Apples, juice (pasteurized)			0.013	
	FP 0226	Apples, canned			0.013	
	FP 0226	Apples, sauce/puree			0.013	
	OR 0691	Cotton seed (refined oil)			0.0013	
	JF 0004	Citrus juice (raw) <sup>b</sup>			0.012	
		Citrus peel (fresh) <sup>b</sup>			0.096	0.15
	FC 0004	Marmalade <sup>b</sup>			0.012	
	VO 0448	Tomatoes, canned			0.016	0.065
	JF 0448	Tomatoes, juice (raw)			0.0026	
	VO 0448	Tomatoes, paste (concentrates sauce/puree)			0.016	
	VO 0448	Tomatoes, sauce/puree (single strength)			0.0072	

<sup>a</sup> Based on whole fruit, since no data were submitted on flesh only.

<sup>b</sup> Based on processing studies on oranges.

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

Definition of the residue for dietary risk assessment for plant commodities: *Sum of afidopyropen + dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl rac-cyclopropanecarboxylate (M007), expressed as afidopyropen.*

Definition of the residue for compliance with the MRL for animal commodities: *Afidopyropen*.

Definition of the residue for dietary risk assessment for animal commodities, excluding liver: *Afidopyropen + (3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a, 12b-trimethyl--9-(pyridin-3-yl)-1, 3,4,4a,5,6,6a,12, 12a,12b-decahydro-2H,11H-benzo- [f] pyrano[4,3-b]chromen-11-one (M001) + Cyclopropane carboxylic acid (CPCA/M061) and (2R)-3-carboxy-2- [(cyclopropylcarbonyl)oxy]- N, N, N-trimethylpropan-1- aminium chloride (CPCA-carnitine conjugate/M060), expressed as afidopyropen.*

Definition of the residue for dietary risk assessment for animal commodities, liver: *Afidopyropen + (3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a, 12b-trimethyl--9-(pyridin-3-yl)-1, 3,4,4a,5,6,6a,12, 12a,12b-*

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<p><i>decahydro-2H,11H-benzo-[f]pyrano[4,3-b]chromen-11-one (M001) + Cyclopropane carboxylic acid (CPCA/M061) and (2R)-3-carboxy-2-[(cyclopropylcarbonyl)oxy]-N,N,N-trimethylpropan-1-aminium chloride (CPCA-carnitine conjugate/M060) + [(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-3-(cyclopropylcarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-9-(1-oxidopyridin-3-yl)-11-oxo-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropane-carboxylate (M017), expressed as afidopyropen.</i></p> <p>The residue is not fat-soluble</p>						
<p><b>Benzovindiflupyr(261)</b> ADI: 0–0.05 mg/kg bw ARfD: 0.1 mg/kg bw</p>						
	VA 2031	Bulb onion, Subgroup of	0.02	-	0.01	0.015
	GS 0659	Sugar cane	0.4	0.04	0.069	0.25
	DM 0659	Sugar cane, molasses	-	-	0.006	-
		Sugar cane refined sugar	-	-	0.003	-
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>Benzovindiflupyr.</i></p> <p>The residue is fat-soluble.</p>						
<p><b>Bifenthrin (178)</b> ADI: 0–0.01 mg/kg bw ARfD: 0.01 mg/kg bw</p>						
	FB 0275	Strawberry <sup>c</sup>	3 <sup>c</sup>	3	0.46	2.3
	AS 0081	Straw and fodder (dry) of cereal grains	1 (dw)	-	Median: 0.26 (ar)	Highest: 0.45 (ar)
<p><sup>c</sup> On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of bifenthrin for the consumption of strawberries may present a public health concern.</p> <p>Definition of the residue for compliance with the MRL for plant and animal commodities and dietary risk assessment for plant commodities: <i>Bifenthrin (sum of isomers).</i></p> <p>The residue is fat-soluble.</p>						
<p><b>Buprofezin (173)</b> ADI: 0–0.009 mg/kg bw ARfD: 0.5 mg/kg bw</p>						
	AB 0001	Citrus pulp, dry	5	2	Median: 0.97	Highest: 1.9
	OR 0001	Citrus oil, edible	6		1.2	
	OC 0305	Olive oil, crude	20		3.9	
<p><b>Aniline</b> ADI: 0–0.02 mg/kg bw ARfD: 0.02 mg/kg bw</p>						
	TN 0085	Group of tree nuts	0.05(*)		0.05	0.05
	AM 0660	Almond hulls	3	2	Median: 0.22	
	TN 0660	Almond	W	0.05(*)	--	
	MF 0100	Mammalian fats except milk fats	0.01(*)		0	0
	PE 0112	Eggs	0.01(*)		0	0
	PO 0111	Poultry, edible offal of	0.01(*)		0	0
	PF 0111	Poultry fats	0.01(*)		0	0
	PM 0110	Poultry meat	0.01(*)		0	0
		Citrus flesh			0.039	0.078
		Citrus peel			0.67	1.3
	JF 0001	Citrus juice			0.12	
		Orange marmalade			0.25	
	DF 0226	Apples, dried			0.17	0.59
		Apple canned			0.015	
		Apple puree			0.019	
		Apple jelly			0.015	
	JF 0226	Apple juice			0.16	
	AB 1230	Apple pomace wet			Median: 0.56	
	DF 0269	Dried grapes			0.27	1.2
	JF 0269	Grape juice			0.073	
		Grape wine			0.2	
		Olive canned (pickled, fermented)			0.76	1.2

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>Buprofezin.</i> The residue is not fat-soluble.						
<b>Clethodim (187) **</b> ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	AL 1020	Alfalfa fodder	W	10		
	AL 0061	Beans fodder	W	10		
	VD 0071	Beans (dry)	W	2		
	VP 0061	Beans, except broad bean and soya bean	W	0.5(*)		
	SO 0691	Cotton seed	W	0.5		
	OC 0691	Cotton seed oil, crude	W	0.5(*)		
	OR 0691	Cotton seed oil, edible	W	0.5(*)		
	MO 0105	Edible offal (Mammalian)	W	0.2(*)		
	PE 0112	Eggs	W	0.05(*)		
	VD 0561	Field pea (dry)	W	2		
	AM 1051	Fodder beet	W	0.1(*)		
	VA 0381	Garlic	W	0.5		
	MM 0095	Meat (from mammals other than marine mammals)	W	0.2(*)		
	ML 0106	Milks	W	0.05(*)		
	VA 0385	Onion, Bulb	W	0.5		
	SO 0697	Peanut	W	5		
	VR 0589	Potato	W	0.5		
	PM 0110	Poultry meat	W	0.2(*)		
	PO 0111	Poultry, Edible offal of	W	0.2(*)		
	SO 0495	Rape seed	W	0.5		
	OC 0495	Rape seed oil, Crude	W	0.5(*)		
	OR 0495	Rape seed oil, Edible	W	0.5(*)		
	VD 0541	Soya bean (dry)	W	10		
	OC 0541	Soya bean oil, crude	W	1		
OR 0541	Soya bean oil, refined	W	0.5(*)			
VR 0596	Sugar beet	W	0.1			
SO 0702	Sunflower seed	W	0.5			
OC 0702	Sunflower seed oil, crude	W	0.1(*)			
VO 0448	Tomato	W	1			
Definition of the residue for compliance with the MRL for plant commodities: <i>Sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME) and dimethyl 3-[2-(ethylsulfonyl)propyl]-3-hydroxy-pentanedioate (DME-OH), expressed as clethodim.</i>						
Definition of the residue for compliance with the MRL for animal commodities: <i>Sum of clethodim and its metabolites convertible to dimethyl 3-[2-(ethylsulfonyl)propyl]-pentanedioate (DME), expressed as clethodim.</i>						
Definition of the residue for dietary risk assessment for plant and animal commodities: <i>A conclusion could not be reached.</i> The residue is fat-soluble.						
<b>Cyclaniliprole (207)</b> ADI: 0–0.04 mg/kg bw ARfD: Unnecessary	TN 0660	Almonds	0.03		0.019	
	AM 0660	Almond hulls	6		Median: 1.7	
	FB 2006	Bush berries, Subgroup of	1.5		0.275	
	FB 0267	Elderberries	1.5		0.275	
	FB 2254	Guelder rose	1.5		0.275	
	FB 2005	Cane berries, Subgroup of	0.8		0.27	
	FS 0013	Cherries, Subgroup of	0.7	0.9	0.14	
	VB 0041	Cabbages, head	0.7		0.0325	
	VO 2700	Cherry Tomato	W	0.1		
	FC 0001	Citrus fruit, Group of	0.4	-	0.087	
	OR 0001	Citrus oil, edible	50		10.1	



Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	VC 2039	Cucumbers and summer squashes, Subgroup of	0.05	0.06	0.021	
	DV 0448	Tomato, dried	0.35	0.4	0.11	
	MO 0105	Edible offal (mammalian)	0.2	0.01(*)	kidney 0.052 liver 0.061	
	VO 2046	Subgroup of Eggplants	0.15	0.1	0.0525	
	PE 0112	Eggs	0.01(*)		0	
	VB 0042	Flowerhead Brassicas, Subgroup of	0.8	1	0.28	
	FB 0269	Grapes	0.6	0.8	0.12	
	VB 2036	Head Brassicas, Subgroup of	W	0.7		
	VL 2050	Leafy greens, Subgroup of	7		2.4	
	VL 0054	Leaves of Brassicaceae, Subgroup of	10	15	3.5	
	MM 0095	Meat (from mammals other than marine mammals)	0.25 (fat)	0.01(*) (fat)	muscle 0.016 fat 0.064	
	FB 2009	Low growing berries, Subgroup of (except cranberries)	0.4		0.12	
	VC 2040	Melons, pumpkins and winter squashes, Subgroup of	0.1	0.15	0.041	
	MF 0100	Mammalian fats (except milk fats)	0.25	0.01(*)	0.064	
	ML 0106	Milks	0.01	0.01(*)	0.004	
	FM 0183	Milk fats	0.2	0.01(*)	0.108	
	VO 0051	Peppers, Subgroup of (except Martynia, Okra and Roselle)	0.15	0.2	0.0525	
	HS 0444	Peppers, Chili, dried	1.5	2	0.525	
	FS 2001	Peaches (including Apricots and Nectarines), Subgroup of	0.3	0.3	0.053	
	FP 0009	Pome fruits	W	0.3		
	FP 0009	Pome fruits, Group of (excluding Japanese persimmons)	0.2	-	0.057	
	FS 0014	Plums, Subgroup of	0.15	0.2	0.052	
	PO 0111	Poultry, edible offal	0.01(*)	0		
	PF 0111	Poultry, fats	0.01(*)	0		
	PM 0110	Poultry, meat	0.01(*)	0		
	DT 1114	Tea, green, black (black, fermented and dried)	50		12.5	
	VO 2045	Tomatoes, Subgroup of	0.08		0.033	
	VR 2071	Tuberous and corm vegetables, Subgroup of	0.01(*)		0	
	DF 0014	Prunes	0.6	0.8	0.19	
	VO 0448	Tomato	W	0.1		
		Citrus juice			0.01	
	JF 0226	Apple, juice			0.019	
		Grape, must			0.08	
	JF 0269	Grape, juice			0.04	
		Grape, wine			0.04	
		Potato crisps			0	
		Potato flakes/granules			0	
		Tea infusion			1.8	
		Tomato, canned			0.005	
	VW 0448	Tomato, paste			0.04	
	JF 0448	Tomato, juice			0.03	

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<p>Definition of the residue for compliance with the MRL for plant and animal commodities: <i>Cyclaniliprole</i>.</p> <p>Definition of the residue for estimation of dietary risk assessment for plant commodities: <i>Cyclaniliprole</i> + 3-bromo-2-((2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b]-[1,4]oxazin-4-ylidene)amino)-5-chloro-N-(1-cyclopropylethyl)benzamide (NK-1375), expressed as cyclaniliprole equivalents. The molecular weight conversion factor to express NK-1375 in cyclaniliprole equivalents = 1.064.</p> <p>Definition of the residue for estimation of dietary risk assessment for animal commodities: <i>Cyclaniliprole</i>.</p> <p>The residue is fat-soluble.</p>						
<b>Cypermethrin (118)</b> ADI: 0–0.02 mg/kg bw ARfD: 0.04 mg/kg bw	VR 0604	Ginseng	0.03(*)		0.03	0.03
	DV 0604	Ginseng, dried including red ginseng	0.15		0.06	0.10
	DM 0604	Ginseng, extracts	0.06(*)		0.06	0.06
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant and animal commodities: <i>Cypermethrin</i> (sum of isomers).</p> <p>The residue is fat-soluble.</p>						
<b>Dimethoate (027)**</b> ADI: 0–0.001 mg/kg bw ARfD: 0.02 mg/kg bw	VS 0620	Artichoke, globe	W	0.05		
	VS 0621	Asparagus	W	0.05(*)		
	GC 0640	Barley	W	2		
	VB 0402	Brussels sprouts	W	0.2		
	VB 0403	Cabbage, Savoy	W	0.05(*)		
	MO 0812	Cattle, Edible offal of	W	0.05(*)		
	VB 0404	Cauliflower	W	0.2		
	VS 0624	Celery	W	0.5		
	FS 0013	Cherries	W	2		
	FC 0001	Citrus fruits	W	5		
	PE 0112	Eggs	W	0.05(*)		
	VL 0482	Lettuce, Head	W	0.3		
	MF 0100	Mammalian fats (except milk fats)	W	0.05(*)		
	FI 0345	Mango	W	1 (Po)		
	MM 0096	Meat of cattle, goats, horses, pigs and sheep	W	0.05(*)		
	ML 0107	Milk of cattle, goats and sheep	W	0.05(*)		
	FP 0230	Pear	W	1		
	VP 0063	Peas (pods and succulent=immature seeds)	W	1		
	HS 0444	Peppers Chili, dried	W	3		
	VO 0445	Peppers, sweet (including pimento or pimiento)	W	0.5		
	VR 0589	Potato	W	0.05		
	PF 0111	Poultry fats	W	0.05(*)		
	PM 0110	Poultry meat	W	0.05(*)		
	PO 0111	Poultry, edible offal of	W	0.05(*)		
	MO 0822	Sheep, edible offal of	W	0.05(*)		
	HS 0191	Spices, fruits and berries	W	0.5		
	HS 0193	Spices, roots and rhizomes	W	0.1(*)		
HS 0190	Spices, seeds	W	5			
VR 0596	Sugar beet	W	0.05			
FT 0305	Table olives	W	0.5			
VL 0506	Turnip greens	W	1			
VR 0506	Turnip, Garden	W	0.1			

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	GC 0654	Wheat	W	0.05		
	AS 0654	Wheat straw and fodder, dry	W	1		
<p>The residue definition for compliance with the MRL in plant and animal commodities is: <i>Dimethoate and omethoate (measured and reported separately).</i></p> <p>Definition of the residue for dietary risk assessment for plant and animal commodities: <i>The Meeting was unable to recommend a definition for dietary risk assessment.</i></p> <p>The residue is not fat-soluble.</p>						
<b>Fluazifop-p-butyl (283)<sup>d</sup></b> ADI: 0–0.004 mg/kg bw ARfD: 0.4 mg/kg bw	FB 2005	Cane berries, Subgroup of	0.08	0.01(*)	0.021	0.074
	FB 0021	Currants, black, red, white	W	0.01(*)		
	FB 0268	Gooseberry	W	0.01(*)		
	FB 2006	Bush berries, Subgroup of	0.3	-	0.021	0.26
	FB 0267	Elderberries	0.3		0.021	0.26
	FB 2254	Guelder rose	0.3		0.021	0.26
	FB 0275	Strawberry	3	0.3	0.685	1.5
<p><sup>d</sup> Based on the decision of CCPR 2017 (REP17/PR) to withdraw the draft MRLs for sweet potato and yam, long-term dietary exposure is unlikely to present a public health concern.</p> <p>Definition of the residue for compliance with the MRL for plant commodities: <i>Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.</i></p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>The sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL), 5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid.</i></p> <p>Definition of the residue for compliance with MRLs and for dietary risk assessment for animal commodities: <i>Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid.</i></p> <p>The residue is fat-soluble.</p>						
<b>Fluensulfone (265)</b> ADI: 0–0.01 mg/kg bw ARfD: 0.3 mg/kg bw	FC 0001	Citrus fruit, Group of	0.2		0.01	0.063
	FP 0009	Pome fruit, Group of (except Persimmon, Japanese)	0.2		0	0
	FS 0012	Stone fruit, Group of	0.09		0	0
	FB 2008	Small fruit vine climbing, Subgroup of	0.7		0	0
	GS 0659	Sugar cane	0.06		0.01	0.01
	TN 0085	Tree nuts, Group of	0.025(*)		0.01	0.01
	SB 0716	Coffee bean	0.05		0	
	GC 2086	Wheat, similar grains, and pseudocereals without husks, Subgroup of	0.08		0.01	
	GC 2087	Barley, similar grains, and pseudocereals with husks, Subgroup of	0.08		0.01	
	GC 2091	Maize cereals, Subgroup of	0.15		0.01	
	GC 2090	Sweet corns, Subgroup of	0.15		0.01	0.01 (corn- on-the-cob, baby corn)
	GC 2088	Rice cereals, Subgroup of	0.04		0.01	
	GC 2089	Sorghum grain and millet, Subgroup of	0.04		0.01	
	AS 0162	Hay or fodder (dry) of grasses except maize fodder and rice straw and	15 (dw)		0.01 (ar) [median]	0.02 (ar) [highest]

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		fodder, dry				
	AS 0645	Maize fodder	0.6 (dw)		0.01 (ar) [median]	0.01 (ar) [highest]
	AS 0649	Rice straw and fodder, dry	0.06 (dw)		0.01 (ar) [median]	0.01 (ar) [highest]
	AS 0081	Straw or fodder (dry) of cereal grains (except maize fodder and rice straw and fodder, dry)	6 (dw)		0.01(ar) [median]	0.01 (ar) [highest]
	AM 0660	Almond hulls	7 (dw)		0.01 (ar) [median]	
	AB 0001	Citrus pulp, dry	1.5		0.01 [median]	
	OR 0001	Citrus oil, edible	1.5		0.34	
	JF 0226	Apple juice	0.4		0	
	DF 0226	Apples, dried	1		0	0
	DF 0014	Prunes	0.3		0	0
	DF 5259	Dried grapes	2		0	0
	DM 0659	Sugar cane molasses	0.5		0	0
<p>Definition of the residue for compliance with the MRL for plant commodities: <i>Sum of fluensulfone and 3,4,4-trifluorobut-3-ene-1-sulfonic acid (BSA), expressed as fluensulfone equivalents.</i></p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>Fluensulfone.</i></p> <p>Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: <i>Fluensulfone.</i></p> <p>The residue is fat-soluble.</p>						
<b>Fluxapyroxad (256)</b> ADI: 0–0.02 mg/kg bw ARfD: 0.3 mg/kg bw	FC 0001	Citrus fruit, Group of	W	1	--	--
	FC 0002	Lemons and Limes (including Citron), Subgroup of	1	--	0.38	0.46
	FC 0003	Mandarins, Subgroup of	1	--	0.38	0.46
	FC 0004	Oranges, Sweet, Sour (including Orange-like hybrids), Subgroup of	1.5	--	0.395	0.59
	FC 0005	Pummelo and Grapefruits (including Shaddock-like hybrids, among other Grapefruit), Subgroup of	0.6	--	0.15	0.27
	OR 0001	Citrus oil, edible	90	60	23	--
	AB 0001	Citrus pulp, dry	8	--	1.9	--
		Lemon/lime/mandarin juice (raw)	--	--	0.015	--
	JF 0004	Orange juice (raw)	--	--	0.016	--
	JF 0203	Grapefruit juice (raw)	--	--	0.006	--
		Grapefruit oil	--	--	8.9	--
		Lemon/lime peel (fresh)	--	--	0.72	0.87
		Orange peel (fresh)	--	--	0.72	1.1
		Citrus wet pomace	--	--	0.47	0.71
		Marmalade	--	--	0.026	--
<p>Definition of the residue for compliance with the MRL for plant and animal commodities: <i>Fluxapyroxad.</i></p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>Sum of fluxapyroxad and 3-(difluoromethyl)-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)-1-(β-D-glucopyranosyl)-N-(3',4',5'-trifluorobiphenyl-2-yl)-1H-pyrazole-4-carboxamide (M700F048) and expressed as parent equivalents.</i></p> <p>Definition of the residue for dietary risk assessment for animal commodities: <i>Sum of fluxapyroxad and 3-(difluoromethyl)-</i></p>						

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg	
			New	Previous			
<p><i>N</i>-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1<i>H</i>-pyrazole-4-carboxamide (M700F008) expressed as parent equivalents.</p> <p>The residue is fat-soluble.</p>							
<b>Isfetamid (290)</b> ADI: 0-0.05 mg/kg bw ARfD: 3 mg/kg bw	FB 2006	Bush berries, Subgroup of	4	5	0.31	3	
	VD 2065	Dry beans (except soya beans), Subgroup of	0.09	0.05	0.01		
	VD 2066	Dry peas, Subgroup of	0.09	0.05	0.01		
<p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: <i>Isfetamid</i>.</p> <p>Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: <i>Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido)propanoyl]phenoxy]propanoic acid (PPA), expressed as isofetamid.</i></p> <p>The residue is fat-soluble.</p>							
<b>Kresoxim-methyl (199)</b> ADI: 0-0.3 mg/kg bw ARfD: Unnecessary	FP 0009	Pome fruit	W	0.2			
	FP 0009	Pome fruit (except Persimmon, Japanese)	0.15		0.11		
		Apple sauce			0.032		
	JF 0226	Apple juice			0.022		
	DF 0226	Apples, dried			0.043		
<p>Definition of the residue for compliance with the MRL for plant commodities: <i>Kresoxim-methyl</i>.</p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>Sum of kresoxim-methyl and metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1) and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) including their conjugates expressed as kresoxim-methyl.</i></p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: <i>Sum of metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) expressed as kresoxim-methyl.</i></p> <p>The residue is not fat-soluble.</p>							
<b>Mandestrobin (307)*</b> ADI: 0-0.2 mg/kg bw ARfD: 3 mg/kg bw (for women of child-bearing age)	FB 0269	Grapes	5	-	1.4	3.7	
	DF 0269	Grapes, dried (=Currents, Raisins and Sultanas)	10		2.8	7.4	
	MF 0100	Mammalian fats (except milk fats)	0.01(*)	-	0	0	
	ML 0106	Milks	0.01(*)	-	0	-	
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)	-	0 (muscle) 0 (fat)	0 (muscle) 0 (fat)	
	MO 0105	Edible offal (mammalian)	0.01(*)	-	0 (liver) 0 (kidney)	0 (liver) 0 (kidney)	
	PE 0112	Eggs	0.01(*)	-	0	0	
	PF 0111	Poultry fats	0.01(*)	-	0	0	
	PM 0110	Poultry meat	0.01(*)	-	0 (muscle) 0 (fat)	0 (muscle) 0 (fat)	
	PO 0111	Poultry, edible offal of	0.01(*)	-	0	0	
	FB 0275	Strawberry	3.0	-	0.87	2.2	
	SO 0495	Rape seed	0.2	-	0.02	-	
	OR 0495	Rape seed oil	-	-	0.0012		
	<p>Definition of the residue for compliance with MRL in plant and animal commodities and for dietary risk assessment in plant</p>						

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMTR or STMTR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
commodities: <i>Mandestrobin</i> .						
Definition of the residue for acute dietary risk assessment in animal commodities: <i>The sum of parent, (2RS)-2-[2-(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide (4-OH-mandestrobin) + (2RS)-2-(2-hydroxymethylphenyl)-2-methoxy-N-methylacetamide (De-XY-mandestrobin) + 2RS)-2-[2-(2-hydroxymethyl-5-methylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide (2-CH<sub>2</sub>-OH-mandestrobin) + 2-({2-[(1RS)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (2-COOH-mandestrobin), + 3-({2-[(1RS)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (5-COOH-mandestrobin) and their conjugates, expressed as parent compound.</i>						
Definition of the residue for long-term dietary risk assessment in animal commodities: <i>The sum of parent, (2RS)-2-[2-(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide (4-OH-mandestrobin), and its conjugates, expressed as parent compound.</i>						
The residue is fat-soluble.						
<b>Metconazole (313)*</b> ADI: 0–0.04 mg/kg bw ARfD: 0.04 mg/kg bw  <b>Triazole alanine and Triazole acetic</b> ADI: 0–1 mg/kg bw ARfD: Unnecessary <b>1,2,4-triazole</b> ADI: 0–0.2 mg/kg bw ARfD: 0.3 mg/kg bw	FI 0327	Banana	0.1(*)		0.1	0.1
	FB 0020	Blueberries	0.5		0.14	0.33
	VP 0061	Beans with pods (Phaseolus spp.) immature pods and succulent seeds)	0.05(*)		0	0
	SO 0691	Cotton seed	0.3		0.0345	
	MO 0105	Edible offal (mammalian)	0.04(*)		0.037	0.037
	PE 0112	Eggs	0.04(*)		0	0
	VA 0381	Garlic	0.05(*)		0.05	0.05
	TN 0085	Tree nuts, Group of	0.04(*)		0	0
	GC 0645	Maize	0.015		0.01	
	MF 0100	Mammalian fats (except milk fats)	0.04(*)		0	0
	MM 0095	Meat (from mammals other than marine mammals)	0.04(*)		0	0
	ML 0106	Milks	0.04(*)		0	
	VA 0385	Onion, bulb	0.05(*)		0.05	0.05
	SO 0697	Peanut	0.04(*)		0.04	
	PO 0111	Poultry, Edible offal of	0.04(*)		0.019	0.020
	PF 0111	Poultry fats	0.04(*)		0	0
	PM 0110	Poultry meat	0.04(*)		0	0
	SO 0495	Rape seed	0.15		0.02	
	FS 0013	Cherries, Subgroup of	0.3		0.07	0.16
	VD 2065	Subgroup of dry beans except soya beans	0.04(*)		0.04	
	VD 2066	Dry peas, Subgroup of	0.15		0.0425	
	FS 2001	Peaches, Subgroup of	0.2		0.045	0.09
	FS 0014	Plums, Subgroup of	0.1		0.040	0.05
	SO 2091	Sunflower seeds, Subgroup of	1.5		0.089	
	VR 2071	Tuberous and corm vegetables, Subgroup of	0.04(*)		0	0
	VR 0596	Sugar beet	0.07		0.02	
	VD 0541	Soya bean (dry)	0.04		0.01	
	GS 0659	Sugar cane	0.06		0.0205	0.036
	GC 0447	Sweet corn (Corn-on-the- cob)	0.015		0.01	0.01
	DF 0014	Prunes, dried	0.5		0.092	0.115
	OR 0495	Rape seed oil, Edible	0.5		0.032	
OR 0697	Peanut oil, Edible	0.06		0.056		
OR 0691	Cotton seed oil, Edible	-		0.004		

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	OR 0541	Soya bean oil, refined	-		0.005	
	AL 3354	Soya bean hay	8 (dw)		Median: 1.7 (ar)	Highest: 3.1 (ar)
	AS 0640	Barley straw and fodder, dry	25 (dw)		Median: 5.9 (ar) (hay), 2.3 (ar) (straw)	Highest: 13 (ar) (hay), 8.8 (ar) (straw)
	AS 0647	Oat straw and fodder, dry	25 (dw)		Median: 5.9 (ar) (hay), 2.3 (ar) (straw)	Highest: 13 (ar) (hay), 8.8 (ar) (straw)
	AS 0650	Rye straw and fodder, dry	25 (dw)		Median: 5.9 (ar) (hay), 2.3 (ar) (straw)	Highest: 13 (ar) (hay), 8.8 (ar) (straw)
	AS 0653	Triticale straw and fodder, dry	25 (dw)		Median: 5.9 (ar) (hay), 2.3 (ar) (straw)	Highest: 13 (ar) (hay), 8.8 (ar) (straw)
	AS 0654	Wheat straw and fodder, dry	25 (dw)		Median: 5.9 (ar) (hay), 2.3 (ar) (straw)	Highest: 13 (ar) (hay), 8.8 (ar) (straw)
	AB 1204	Cotton gin trash	10 (dw)		Median: 2.65 (ar)	Highest: 4.1 (ar)
	AS 0645	Maize fodder (dry)	7 (dw)		Median: 1.85 (ar)	Highest: 3.2 (ar)
		Sugar, sugar beet			0.012	
		Sugar cane, refined sugar			0.002	
<p>Definition of the residue for compliance with MRL for plant and animal commodities: <i>Metconazole (sum of cis and trans isomer)</i>.</p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>Metconazole (sum of cis and trans isomer)</i>.</p> <p>Definition of the residue for compliance with MRL and dietary risk assessment for animal commodities: <i>Sum of metconazole (cis and trans-isomer) and metabolites (1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol (M1; free and conjugated) and (1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid (M12; free and conjugated), expressed as metconazole.</i></p> <p>The residue is not fat-soluble.</p>						
<b>Omethoate (055)</b>	HS 0191	Spices, fruits and berries	W	0.01		
	HS 0193	Spices, roots and rhizomes	W	0.05		
<p>These MRLs applied to residues that may have resulted from the use of dimethoate.</p>						
<b>Penthiopyrad (253)</b> ADI: 0-0.1 mg/kg bw ARfD: 1 mg/kg bw	FB 2005	Cane berries, Subgroup of	10		3.7	4.8
	FB 2006	Bush berries, Subgroup of	7		1.7	4.0
	FB 0267	Elderberries	7		1.7	4.0
	FB 2254	Guelder rose	7		1.7	4.0
<p>Definition of the residue for compliance with MRL for plant commodities: <i>Penthiopyrad</i>.</p> <p>Definition of the residue for compliance with MRL for animal commodities and for dietary risk assessment for plant and animal commodities: <i>Sum of penthiopyrad and 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide (PAM), expressed as penthiopyrad.</i></p> <p>The residue is not fat-soluble.</p>						
<b>Picoxystrobin (258)</b> ADI: 0-0.09 mg/kg bw ARfD: 0.09 mg/kg bw	GC 0651	Sorghum Grain	0.02		0.01	
	SO 0691	Cottonseed	2		0.205	
	SB 0716	Coffee bean	0.04		0.01	
	DT 1114	Tea, Green, Black (black, fermented and dried)	15		1.2	
	MO 0105	Edible offal (Mammalian)	0.02	0.02	Liver: 0.006	Liver: 0.01

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
					Kidney: 0	Kidney: 0
	MF 0100	Mammalian fats (except milk fats)	0.02	0.02	0.008	0.015
	MM 0095	Meat (from mammals other than marine mammals)	0.02 (fat)	0.02 (fat)	Muscle: 0 Fat: 0.008	Muscle: 0 Fat: 0.015
	ML 0106	Milks	0.01(*)	0.01(*)	0	
	AL 1020	Alfalfa fodder	10 (dw)		Median: 1.3 (dw)	Highest: 7.4 (dw)
	AS 0651	Sorghum straw and fodder, dry	1 (dw)		Median: 0.042 (dw)	Highest: 0.053 (dw)
<p>Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: <i>Picoxystrobin</i>.</p> <p>Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: <i>Picoxystrobin</i>.</p> <p>The residue is fat-soluble.</p>						
<b>Propiconazole (160)</b> ADI: 0–0.07 mg/kg bw ARfD: 0.3 mg/kg bw	FS 2001	Peaches, Subgroup of	4 (Po)	0.7 (Po)	1.7	2.5
<p>Definition of the residue for compliance with the MRL for plant and animal commodities: <i>Propiconazole</i>.</p> <p>Definition of the residue for dietary risk assessment for plant and animal commodities: <i>Propiconazole plus all metabolites convertible to 2,4-dichloro-benzoic acid, expressed as propiconazole</i>.</p> <p>The residue is fat-soluble.</p>						
<b>Pydiflumetofen (309)</b> ADI: 0–0.1 mg/kg bw ARfD: 0.3 mg/kg bw	GC 2087	Barley, similar grains, and pseudocereals with husks, Subgroup of	3		0.23	
	AS 0640	Barley straw and fodder, dry	50 (dw)		Median: 9.2 (dw)	Highest: 40 (dw)
	VB 0040	Brassica vegetables (except Brassica leafy vegetables), Group of	0.1		0.02	0.09
	SO 0691	Cottonseed	0.3		0.08	
	VD 2065	Dry beans, Subgroup of	0.4		0.028	
	VD 2066	Dry peas, Subgroup of	0.4		0.028	
	MO 0105	Edible offal (Mammalian)	0.1		Liver: 0.044 Kidney: 0.051	Liver: 0.43 Kidney: 0.29
	PE 0112	Eggs	0.02		0.02	0.03
	VC 0045	Fruiting vegetables, Cucurbits, Group of	0.4		0.12	0.27
	VO 0050	Fruiting vegetables, other than Cucurbits, Group of (except Martynia, Okra and Roselle)	0.5		0.11	0.42
	VL 2050	Leafy greens, Subgroup of <sup>e</sup>	40 <sup>e</sup>		12.5	17
	VL 0054	Leaves of Brassicaceae, Subgroup of	0.1		0.02	0.09
	VL 2052	Leaves of root and tuber vegetables, Subgroup of (except leaves of tuber vegetables)	0.07		0.02	0.05
	AL 0157	Legume animal feeds	30 (dw)		Median: 9.2 (dw)	Highest: 15 (dw)
	VP 0060	Legume vegetables, Group of	0.02		0.02	0.02
	GC 2091	Maize cereals, Subgroup of	0.04		0.03	
	CF 1255	Maize flour	0.07		0.048	



Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
	AS 0645	Maize fodder	18 (dw)		3.1 (ar)	13 (ar)
	OR 0645	Maize oil, edible	0.08		0.057	
	VO 2709	Martynia	0.02		0.02	0.02
	MF 0100	Mammalian fats (except milk fats)	0.1		0.015	0.069
	MM 0095	Meat (from mammals other than marine mammals)	0.1 (fat)		Muscle: 0.02 Fat: 0.015	Muscle: 0.02 Fat: 0.069
	ML 0106	Milks	0.01(*)		0.02	
	AS 0646	Millet fodder, dry	0.3 (dw)		Median: 0.08 (ar)	Highest:0.28 (ar)
	AS 0647	Oat straw and fodder, dry	50 (dw)		Median: 9.2 (dw)	Highest: 40 (dw)
	VO 0442	Okra	0.02		0.02	0.02
	SO 0697	Peanut	0.05		0.03	
	OR 0697	Peanut oil, edible	0.15		0.072	
	HS 0444	Peppers, Chili, dried	5		1.1	4.2
	DV 0589	Potato, dried	0.5		0.13	0.36
	PO 0111	Poultry, Edible offal of	0.01(*)		0.02	0.02
	PF 0111	Poultry fats	0.01(*)		0.02	0.02
	PM 0110	Poultry meat	0.01(*)		0.02	0.02
	GC 2088	Rice cereals, Subgroup of	0.03		0.03	
	AS 0649	Rice straw and fodder, dry	0.3 (dw)		Median: 0.08 (ar)	Highest:0.28 (ar)
	VR 2070	Root vegetables, Subgroup of	0.1		0.02	0.07
	VO 0446	Roselle	0.02		0.02	0.02
	AS 0650	Rye straw and fodder, dry	50 (dw)		Median: 9.2 (dw)	Highest: 40 (dw)
	SO 2090	Small seed oilseeds, Subgroup of	0.9		0.0945	
	GC 2089	Sorghum Grain and Millet, Subgroup of	0.03		0.03	
	AS 0651	Sorghum straw and fodder, dry	0.3 (dw)		Median: 0.08 (ar)	Highest:0.28 (ar)
	VS 2080	Stems and petioles, Subgroup of	15		4.4	9.3
	SO 2091	Sunflower seeds, Subgroup of	0.3		0.08	
	GC 2090	Sweet Corns, Subgroup of	0.03		0.03	0.03
	DV 0448	Tomato, dried	7		1.2	4.4
	AS 0653	Triticale straw and fodder, dry	50 (dw)		Median: 9.2 (dw)	Highest: 40 (dw)
	VR 2071	Tuberous and corm vegetables, Subgroup of	0.1		0.03	0.084
	CM 0654	Wheat bran, processed	1		0.14	
	CF 1211	Wheat germ	0.6		0.091	
	GC 2086	Wheat, similar grains, and pseudocereals without husks, Subgroup of	0.4		0.063	
	AS 0654	Wheat straw and fodder, dry	50 (dw)		Median: 9.2 (dw)	Highest: 40 (dw)
		Barley bran			0.083	
		Barley flour			0.053	
		Maize bran			0.14	
		Maize germs			0.063	
		Maize grits			0.013	
	CF 0645	Maize meal			0.028	
		Maize starch			0.013	
		Miso			0.004	

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMTR or STMTR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		Oats bran			0.003	
		Oats flour			0.011	
		Pearled barley			0.01	
		Potato chips			0.014	
		Potato crisps			0.014	
		Potato flakes			0.014	
		Potato starch			0.014	
		Potato, baked (unpeeled)			0.014	0.038
		Potato, boiled (peeled)			0.014	0.038
		Rape seed refined oil			0.035	
		Rolled oats			0.003	
		Soya bean flour			0.002	
		Soya bean milk			0.002	
	OR 0541	Soya bean oil, refined			0.005	
		Soya sauce			0.002	
		Tofu			0.004	
	JF 0048	Tomato juice (pasteurised)			0.005	
	VW 0448	Tomato paste			0.075	
		Tomato puree			0.037	
		Tomato wet pomace			0.43	
		Tomato, canned			0.005	0.019
	CF 1211	Wheat flour			0.02	
		Wheat gluten			0.11	
		Wheat starch			0.002	
		Wheat, wholemeal bread			0.027	

<sup>e</sup>On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of pydiflumetofen for the consumption of Leafy greens may present a public health concern.

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

*Pydiflumetofen.*

Definition of the residue for compliance with the MRL for animal commodities: *Pydiflumetofen.*

Definition of the residue for dietary risk assessment for animal commodities, except mammalian liver and kidney: *Sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen.*

Definition of the residue for dietary risk assessment for mammalian liver and kidney: *Sum of pydiflumetofen, 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, and 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl)ethyl]pyrazole-4-carboxamide (SYN547897) and its conjugates, expressed as pydiflumetofen.*

The residue is fat-soluble.

<b>Pyflubumide (314)*</b> ADI: 0–0.007 mg/kg bw ARfD: 0.008 mg/kg bw	FP 0226	Apple <sup>f</sup>	1 <sup>f</sup>		0.41	0.55
	DT 1114	Tea, Green, Black (black, fermented and dried) <sup>f</sup>	80 <sup>f</sup>		13	
	JF 0226	Apple juice			0.001	
		Apple sauce			0.008	
	DF 0226	Apples, dried			0.02	0.028
		Tea infusion			0.004	

<sup>f</sup>On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of pyflubumide for the consumption of apple and tea may present a public health concern.

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

Definition of the residue for estimation of dietary risk assessment for plant commodities: *Sum of pyflubumide and 3'-isobutyl-1,3,5-trimethyl-4'-[2,2,2-trifluoro-1-methoxy-1-(trifluoromethyl)ethyl]pyrazole-4-carboxanilide, expressed as pyflubumide.*

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<b>Pyraclostrobin (210)</b> ADI: 0–0.03 mg/kg bw ARfD: 0.7 mg/kg bw	VR 2070	Root vegetables, Subgroup of	W	0.5		
	VR 2070	Root vegetables, Subgroup of (includes all commodities in the subgroup except sugar beet)	0.5	-	0.12	0.3
	VL 0502	Spinach	0.6	1.5	0.071	0.31
Definition of the residue for compliance with MRL and for dietary risk assessment for plant and animal commodities: <i>Pyraclostrobin</i> . The residue is fat-soluble.						
<b>Pyridate (315)*</b> ADI: 0–0.2 mg/kg bw ARfD: 2 mg/kg bw						
<b>Pyrifluquinazon (316)*</b> ADI: 0–0.005 mg/kg bw ARfD: 1 mg/kg bw						
Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: <i>Sum of pyrifluquinazon and 1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-01) expressed as pyrifluquinazon</i> . Definition of the residue for compliance with the MRL for animal commodities: Tissues: <i>Sum of 1,2,3,4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-01) and 1,2,3,4-tetrahydro-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2,4-dione (IV-203) and their conjugates (expressed as pyrifluquinazon)</i> . Milk: <i>1,2,3,4-tetrahydro-3-[3-(1-oxy-pyridylmethylene)amino]-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazolin-2-one (IV-04) (expressed as pyrifluquinazon)</i> . Definition of the residue for dietary risk assessment for animal commodities: <i>a conclusion could not be reached</i> . The residue is not fat-soluble.						
<b>Pyriofenone (310)</b> ADI: 0–0.09 mg/kg bw ARfD: Unnecessary	MF 0100	Mammalian fats (except milk fats)	0.01(*)	-	0	
	ML 0106	Milks	0.01(*)	-	0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)	-	0 (muscle) 0 (fat)	
	MO 0105	Edible offal (mammalian)	0.01(*)	-	0	
	PE 0112	Eggs	0.01(*)	-	0	
	PF 0111	Poultry fats	0.01(*)	-	0	
	PM 0110	Poultry meat	0.01(*)	-	0 (muscle) 0 (fat)	
	PO 0111	Poultry, edible offal of	0.01(*)	-	0	
Definition of the residue for compliance with the MRL and dietary risk assessment for plant and animal commodities: <i>Pyriofenone</i> .						
<b>Pyriproxyfen (200)</b> ADI: 0–0.1 mg/kg bw ARfD: Unnecessary	FI 0345	Mango	0.02(*)		0.02	
Definition of the residue for compliance with the MRL and dietary risk assessment in plant and animal commodities: <i>Pyriproxyfen</i> . The residue is fat-soluble.						

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMTR or STMTR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
<b>Tolclofos-methyl (191)**</b> ADI: 0–0.07 mg/kg bw ARfD: Unnecessary	VL 0482	Lettuce, head	W	2		
	VL 0483	Lettuce, leaf	W	2		
	VL 2050	Leafy greens except spinach, purslane and chard	0.7		0.36	
	VR 0589	Potato	0.3	0.2	0.060	
	MO 0105	Edible offal (Mammalian)	0.01(*)		0.0055 (kidney) 0.0033 (liver)	
	PE 0112	Eggs	0.01(*)		0	
	MF 0100	Mammalian fats (except milk fats)	0.01(*)		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)		0	
	ML 0106	Milks	0.01(*)		0	
	PF 0111	Poultry fats	0.01(*)		0	
	PM 0110	Poultry meat	0.01(*)		0	
	PO 0111	Poultry, Edible offal of	0.01(*)		0	
VR 0494	Radish	W	0.1			
<p>Definition of the residue for compliance with the MRL for plant and animal commodities: <i>Tolclofos-methyl</i>.</p> <p>Definition of the residue for dietary risk assessment for plant commodities: <i>Sum of tolclofos-methyl, 2,6-dichloro-4-methylphenol (ph-CH<sub>3</sub>, incl. conjugates), O,O-dimethyl O-2,6-dichloro-4-(hydroxymethyl) phenylphosphorothioate (TM-CH<sub>2</sub>OH, incl. conjugates), O-methyl O-hydrogen O-2,6-dichloro-4-(hydroxymethyl) phenylphosphorothioate (DM-TM-CH<sub>2</sub>OH) and O-methyl O-hydrogen O-(2,6-dichloro-4-methylphenyl) phosphorothioate (DM-TM), expressed as tolclofos-methyl.</i></p> <p>Definition of the residue for dietary risk assessment for animal commodities: <i>Sum of tolclofos-methyl and 3,5-dichloro-4-hydroxybenzoic acid (ph-COOH), expressed as tolclofos-methyl.</i></p> <p>The residue is fat-soluble.</p>						
<b>Tolfenpyrad (269)</b> ADI: 0–0.006 mg/kg bw ARfD: 0.01 mg/kg bw	FC 0002	Lemons and Limes, Subgroup of	0.9		0.085	0.18
	FC 0003	Mandarins, Subgroup of	0.9		0.085	0.18
	FC 0004	Oranges, Sweet, Sour, Subgroup of	0.6		0.061	0.13
	FC 0005	Pummelo and Grapefruits, Subgroup of	0.6		0.042	0.099
	VA 2031	Bulb Onions, Subgroup of	0.09		0.0125	0.057
	VO 2045	Tomatoes, Subgroup of <sup>g</sup>	0.7 <sup>g</sup>		0.13	0.5
	VO 0051	Peppers, Subgroup of (except okra, martynia, and roselle)	0.5		0.11	0.32
	VO 2046	Eggplants, Subgroup of <sup>g</sup>	0.7 <sup>g</sup>		0.13	0.5
	AB 0001	Citrus pulp, dry	6		Median: 1.7	--
	OR 0001	Citrus oil, edible	80		22	--
	HS 0444	Peppers chili, dried	5		1.1	3.2
	ML 0106	Milks	0.01(*)		0.0038	
	MF 0100	Mammalian fats except milk fats	0.01(*)		0.0022	0.0022
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)		0.0043	0.0043
	MO 0105	Edible offal (mammalian)	0.4		0.29	0.38
	PE 0112	Eggs	0.01(*)		0	0
	PO 0111	Poultry, edible offal of	0.01(*)		0	0
	PF 0111	Poultry fats	0.01(*)		0	0
	PM 0110	Poultry meat	0.01(*)		0	0
			Lemon + Mandarin Juice			0.058

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMTR or STMTR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
		Lemon + Mandarin peel			1.3	2.7
		Lemon + Mandarin Marmalade/Jam			0.032	0.068
		Orange Peel (fresh)			0.91	2.0
	JF 0004	Orange Juice			0.042	--
		Orange Marmalade/Jam			0.023	0.050
		Grapefruit Peel (fresh)			0.62	1.5
	JF 0203	Grapefruit Juice			0.029	--
		Tomato Puree			0.044	--
		Tomato Paste			0.14	--
<p>§ On the basis of the information provided to the JMPR it was concluded that the estimated acute dietary exposure to residues of tolfenpyrad for the consumption of these commodities may present a public health concern.</p> <p>Definition of the residue for compliance with the MRL and for dietary risk assessment for plant commodities: <i>Tolfenpyrad</i>.</p> <p>Definition of the residue for compliance with the MRL and for dietary risk assessment for animal commodities: <i>Sum of tolfenpyrad, and free and conjugated PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylamino]phenoxy]benzoic acid and OH-PT-CA (4-[4-[[4-chloro-3(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonylamino]phenoxy] benzoic acid) (released with alkaline hydrolysis) expressed as tolfenpyrad.</i></p> <p>The residue is not fat-soluble.</p>						
<p><b>Triflumuron (317)*</b> ADI: 0–0.008 mg/kg bw ARfD: Unnecessary</p> <p><b>4-trifluoromethoxyaniline (metabolite M07)</b> ADI: 0-0.02 mg/kg bw ARfD: 0.02 mg/kg bw</p>						
<p>Definition of the residue for compliance with the MRL for animal and plant commodities: <i>Triflumuron</i>.</p> <p>Definition of the residue for dietary risk assessment for animal and plant commodities: <i>A conclusion could not be reached.</i></p> <p>The residue is fat-soluble.</p>						
<p><b>Valifenalate (318)*</b> ADI: 0–0.2 mg/kg bw ARfD: Unnecessary</p>						
	VO 0440	Eggplants	0.4		0.049	
	FB 0269	Grapes	0.3		0.079	
	VA 0385	Onion, bulb	0.5		0.0375	
	VA 0388	Shallot	0.5		0.0375	
	VO 0448	Tomato	0.4		0.049	
	MO 0105	Edible offal (mammalian)	0.01(*)		0	
	PE 0112	Eggs	0.01(*)		0	
	ML 0106	Milks	0.01(*)		0	
	MM 0095	Meat (from mammals other than marine mammals)	0.01(*)		0	
	MF 0100	Mammalian fats (except milk fats)	0.01(*)		0	
	PO 0111	Poultry edible offal	0.01(*)		0	
	PF 0111	Poultry fat	0.01(*)		0	
	PM 0110	Poultry meat	0.01(*)		0	
	-	Grape, must	-	-	0.079	-
	JF 0269	Grape, juice	-	-	0.043	-
	-	Grape, wine	-	-	0.051	-
	-	Tomato, canned	-	-	0.005	-
	VW 0448	Tomato, paste	-	-	0.040	-
	JF 0448	Tomato, juice	-	-	0.016	-

Pesticide (Codex reference number)	CCN	Commodity	Recommended maximum residue level (mg/kg)		STMR or STMR-P mg/kg	HR or HR-P mg/kg
			New	Previous		
Definition of the residue for compliance with the MRL for plant and animal commodities: <i>Valifenalate</i> Definition of the residue for dietary risk assessment for plant commodities: <i>Valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), free and conjugated, expressed as valifenalate.</i> Definition of the residue for dietary risk assessment for animal commodities: <i>Valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), expressed as valifenalate.</i> The residue is not fat-soluble.						
<b>Recommended MRLs, STMRs and HR values for Spices</b>						
Active substance	CCN	Commodity name	Recommended maximum residue level, mg/kg		STMR or STMR- P, mg/kg	
			New	Previous		
Acetamiprid (246) ADI: 0–0.07 mg/kg bw ARfD: 0.1 mg/kg bw	HS 0775 HS 0190	Cardamom, pods and seeds Spices, seeds, Subgroup of	W 2	0.1 -	Median: 0.57 <sup>h</sup>	
Carbendazim ((072) ADI: 0–0.03 mg/kg bw ARfD: 0.1 mg/kg bw (for women of child- bearing age) 0.5 mg/kg bw (for the general population)	HS 0190	Spices, seeds, Subgroup of	5		Median: 0.525 <sup>h</sup>	
<sup>h</sup> based on monitoring data						

## 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)
Accephate (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), 2019 (R)
Acetochlor (280)	2015 (T, R), 2019 (T, R)
Acibenzolar- <i>S</i> -methyl (288)	2016 (T, R)
Acrylonitrile	1965 (T, R)
Afidopyropen (312)	2019 (T, R)
Aldicarb (117)	1979 (T, R), 1982 (T,R), 1985 (R), 1988 (R), 1990 (R), 1991 (corr. to 1990 evaluation), 1992 (T), 1993 (R), 1994 (R), 1996 (R), 2001 (R), 2002 (R), 2006 (R)
Aldrin (001)	1965 (T), 1966 (T, R), 1967 (R), 1974 (R), 1975 (R), 1977 (T), 1990 (R), 1992 (R)
Allethrin	1965 (T, R)
Ametoctradin (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)
Azocyclotin (129)	1979 (R), 1981 (T), 1982 (R), 1983 (R), 1985 (R), 1989 (T,R), 1991 (R), 1994 (T), 2005 (T,R)
Azoxystrobin (229)	2008 (T,R), 2011 (R), 2012 (R), 2013 (R), 2017 (R), 2019 (R)
Benalaxyl (155)	1986 (R), 1987 (T), 1988 (R), 1992 (R), 1993 (R), 2005 (T), 2009 (R)
Bendiocarb (137)	1982 (T,R), 1984 (T,R), 1989 (R), 1990 (R)
Benomyl (069)	1973 (T,R), 1975 (T,R), 1978 (T,R), 1983 (T,R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (R)
Bentazone (172)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1995 (R), 1998 (T,R), 1999 (corr. to 1998 report), 2004 (T), 2012 (T), 2013 (R), 2016 (T), 2018 (R)
Benzovindiflupyr (261)	2013 (T), 2014 (R), 2016 (R), 2019 (R)
BHC (technical-grade)	1965 (T), 1968 (T,R), 1973 (T,R) (see also Lindane)
Bicyclopyrone (295)	2017 (T, R)
Bifenazate (219)	2006 (T,R), 2008 (R), 2010 (R)
Bifenthrin (178)	1992 (T,R), 1995 (R), 1996 (R), 1997 (R), 2009 (T), 2010 (R), 2015 (R), 2019 (R)
Binapacryl (003)	1969 (T,R), 1974 (R), 1982 (T), 1984 (R), 1985 (T,R)
Bioresmethrin (093)	1975 (R), 1976 (T,R), 1991 (T,R)
Biphenyl	See Diphenyl
Bitertanol (144)	1983 (T), 1984 (R), 1986 (R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1998 (T), 1999 (R), 2002 (R)
Bixafen (262)	2013 (T,R), 2016 (R)
Boscalid (221)	2006 (T,R), 2008 (R), 2010 (R), 2019 (T, R)
Bromide ion (047)	1968 (R), 1969 (T, R), 1971 (R), 1979 (R), 1981 (R), 1983 (R), 1988 (T, R), 1989 (R), 1992 (R)
Bromomethane (052)	1965 (T, R), 1966 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R), 1992 (R)
Bromophos (004)	1972 (T,R), 1975 (R), 1977 (T,R), 1982 (R), 1984 (R), 1985 (R)
Bromophos-ethyl (005)	1972 (T,R), 1975 (T,R), 1977 (R)
Bromopropylate (070)	1973 (T,R), 1993 (T,R)
Butocarboxim (139)	1983 (R), 1984 (T), 1985 (T), 1986 (R)
Buprofezin (173)	1991 (T,R), 1995 (R), 1996 (corr. to 1995 report.), 1999 (R), 2008 (T,R), 2009 (R), 2012 (R), 2014 (R), 2016 (R), 2019 (T, R)



<i>sec</i> -Butylamine (089)	1975 (T,R), 1977 (R), 1978 (T,R), 1979 (R), 1980 (R), 1981 (T), 1984 (T,R: withdrawal of temporary ADI, but no evaluation)
Cadusafos (174)	1991 (T,R), 1992 (R), 1992 (R), 2009 (R), 2010 (R)
Campheclor (071)	1968 (T,R), 1973 (T,R)
Captafol (006)	1969 (T,R), 1973 (T,R), 1974 (R), 1976 (R), 1977 (T,R), 1982 (T), 1985 (T,R), 1986 (corr. to 1985 report), 1990 (R), 1999 (ARfD)
Captan (007)	1965 (T), 1969 (T,R), 1973 (T), 1974 (R), 1977 (T,R), 1978 (T,R), 1980 (R), 1982 (T), 1984 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1994 (R), 1995 (T), 1997 (R), 2000 (R), 2004 (T), 2007 (T), 2017 (R)
Carbaryl (008)	1965 (T), 1966 (T,R), 1967 (T,R), 1968 (R), 1969 (T,R), 1970 (R), 1973 (T,R), 1975 (R), 1976 (R), 1977 (R), 1979 (R), 1984 (R), 1996 (T), 2001 (T), 2002 (R), 2007 (R)
Carbendazim (072)	1973 (T,R), 1976 (R), 1977 (T), 1978 (R), 1983 (T,R), 1985 (T,R), 1987 (R), 1988 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2003 (R), 2005 (T), 2012 (R), 2019 (R)
Carbofuran (096)	1976 (T,R), 1979 (T,R), 1980 (T), 1982 (T), 1991 (R), 1993 (R), 1996 (T), 1997 (R), 1999 (corr. to 1997 report), 2002 (T,R), 2003 (R) (See also carbosulfan), 2004 (R), 2008 (T), 2009 (R)
Carbon disulfide (009)	1965 (T,R), 1967 (R), 1968 (R), 1971 (R), 1985 (R)
Carbon tetrachloride (010)	1965 (T,R), 1967 (R), 1968 (T,R), 1971 (R), 1979 (R), 1985 (R)
Carbophenothion (011)	1972 (T,R), 1976 (T,R), 1977 (T,R), 1979 (T,R), 1980 (T,R), 1983 (R)
Carbosulfan (145)	1984 (T,R), 1986 (T), 1991 (R), 1992 (corr. to 1991 report), 1993 (R), 1997 (R), 1999 (R), 2002 (R), 2003 (T,R), 2004 (R, corr. to 2003 report)
Cartap (097)	1976 (T,R), 1978 (T,R), 1995 (T,R)
Chinomethionat (080)	1968 (T,R) (as oxythioquinox), 1974 (T,R), 1977 (T,R), 1981 (T,R), 1983 (R), 1984 (T,R), 1987 (T)
Chlorantraniliprole (230)	2008 (T,R), 2010 (R), 2013 (R), 2014 (R), 2016 (R), 2019 (R)
Chlorbenseide	1965 (T)
Chlordane (012)	1965 (T), 1967 (T,R), 1969 (R), 1970 (T,R), 1972 (R), 1974 (R), 1977 (T,R), 1982 (T), 1984 (T,R), 1986 (T)
Chlordimeform (013)	1971 (T,R), 1975 (T,R), 1977 (T), 1978 (T,R), 1979 (T), 1980 (T), 1985 (T), 1986 (R), 1987 (T)

Chlorfenapyr (254)	2013 (T), 2018 (T,R)
Chlorfenson	1965 (T)
Chlorfenvinphos (014)	1971 (T,R), 1984 (R), 1994 (T), 1996 (R)
Chlormequat (015)	1970 (T,R), 1972 (T,R), 1976 (R), 1985 (R), 1994 (T,R), 1997 (T), 1999 (ARfD), 2000 (R), 2017 (T, 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)
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)
Clothianidin (238)	2010 (T,R), 2011 (R), 2014 (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)
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)
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)

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)
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)
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), 2019 (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)
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)
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)
Diflubenzuron (130)	1981 (T,R), 1983 (R), 1984 (T,R), 1985 (T,R), 1988 (R), 2001 (T), 2002 (R), 2011 (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)
Dimethomorph (225)	2007 (T,R), 2014 (R), 2016 (R)
Dimethrin	1965 (T)
Dinocap (087)	1969 (T,R), 1974 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (R), 2000 (T), 2001 (R)
Dinotefuran (255)	2012 (T,R)
Dioxathion (028)	1968 (T,R), 1972 (R)
Diphenyl (029)	1966 (T,R), 1967 (T)
Diphenylamine (030)	1969 (T,R), 1976 (T,R), 1979 (R), 1982 (T), 1984 (T,R), 1998 (T), 2001 (R), 2003 (R), 2008 (R)
Diquat (031)	1970 (T,R), 1972 (T,R), 1976 (R), 1977 (T,R), 1978 (R), 1994 (R), 2013 (T,R), 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- <i>ortho</i> -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)
Enamectin benzoate (247)	2011 (T,R), 2014 (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)
Ethion (034)	1968 (T,R), 1969 (R), 1970 (R), 1972 (T,R), 1975 (R), 1982 (T), 1983 (R), 1985 (T), 1986 (T), 1989 (T), 1990 (T), 1994 (R)
Ethiprole (304)	2018 (T, R)
Ethoprophos (149)	1983 (T), 1984 (R), 1987 (T), 1999 (T), 2004 (R)
Ethoxyquin (035)	1969 (T,R), 1998 (T), 1999 (R), 2005 (T), 2008 (R)
Ethylene dibromide	See 1,2-Dibromoethane
Ethylene dichloride	See 1,2-Dichloroethane
Ethylene oxide	1965 (T,R), 1968 (T,R), 1971 (R)
Ethylenethiourea (ETU) (108)	1974 (R), 1977 (T,R), 1986 (T,R), 1987 (R), 1988 (T,R), 1990 (R), 1993 (T,R)
Etofenprox (184)	1993 (T,R), 2011 (T,R)
Etoxazole (241)	2010 (T,R), 2011 (R)
Etrimfos (123)	1980 (T,R), 1982 (T,R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R)
Famoxadone (208)	2003 (T,R)
Fenamidone (264)	2013 (T), 2014 (T,R)
Fenamiphos (085)	1974 (T,R), 1977 (R), 1978 (R), 1980 (R), 1985 (T), 1987 (T), 1997 (T), 1999 (R), 2002 (T), 2006 (R)
Fenarimol (192)	1995 (T,R,E), 1996 (R and corr. to 1995 report)
Fenzaquin (297)	2017 (T, R), 2019 (R)
Fenbuconazole (197)	1997 (T,R), 2009 (R), 2012 (T), 2013 (R)
Fenbutatin oxide (109)	1977 (T,R), 1979 (R), 1992 (T), 1993 (R)
Fenchlorfos (036)	1968 (T,R), 1972 (R), 1983 (R)
Fenhexamid (215)	2005 (T,R)
Fenitrothion (037)	1969 (T,R), 1974 (T,R), 1976 (R), 1977 (T,R), 1979 (R), 1982 (T), 1983 (R), 1984 (T,R), 1986 (T,R),

	1987 (R and corr. to 1986 R evaluation), 1988 (T), 1989 (R), 2000 (T), 2003 (R), 2004 (R, corr. to 2003 report), 2007 (T,R)
Fenpicoxamid (305)	2018 (T,R)
Fenpropathrin (185)	1993 (T,R), 2006 (R), 2012 (T), 2014 (R)
Fenpropimorph (188)	1994 (T), 1995 (R), 1999 (R), 2001 (T), 2004 (T), 2016 (T), 2017 (T, R)
Fenpyrazamine (298)	2017 (R, T)
Fenpyroximate (193)	1995 (T,R), 1996 (corr. to 1995 report), 1999 (R), 2004 (T), 2007 (T), 2010 (R), 2013 (R), 2017 (T, R), 2018 (R)
Fensulfothion (038)	1972 (T,R), 1982 (T), 1983 (R)
Fenthion (039)	1971 (T,R), 1975 (T,R), 1977 (R), 1978 (T,R), 1979 (T), 1980 (T), 1983 (R), 1989 (R), 1995 (T,R,E), 1996 (corr. to 1995 report), 1997 (T), 2000 (R)
Fentin compounds (040)	1965 (T), 1970 (T,R), 1972 (R), 1986 (R), 1991 (T,R), 1993 (R), 1994 (R)
Fenvalerate (119)	1979 (T,R), 1981 (T,R), 1982 (T), 1984 (T,R), 1985 (R), 1986 (T,R), 1987 (R and corr. to 1986 report), 1988 (R), 1990 (R), 1991 (corr. to 1990 R evaluation), 2012 (T,R)
Ferbam	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1996 (T,R)
Fipronil (202)	1997 (T), 2000 (T), 2001 (R), 2016 (R)
Fipronil-desulfinyl	1997 (T)
Fonicamid (282)	2015 (T,R), 2016 (R), 2017 (R), 2019 (R)
Fluazifop-P-butyl	2016 (T,R), 2019 (R)
Flubendiamide (242)	2010 (T,R)
Flucythrinate (152)	1985 (T,R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1993 (R)
Fludioxonil (211)	2004 (T,R), 2006 (R), 2010 (R), 2012 (R), 2013 (R), 2018 (R)
Fluensulfone (265)	2013 (T), 2014 (T,R), 2016 (T,R), 2017 (R), 2019 (R)
Flufenoxuron (275)	2014 (T,R)
Flumethrin (195)	1996 (T,R)
Fluazinam (306)	2018 (T,R)
Fluopicolide (235)	2009 (T,R), 2014 (R)
Fluopyram (243)	2010 (T,R), 2012 (R), 2014 (R), 2015 (R), 2017 (R)
Flupyradifurone (285)	2015 (T), 2016 (R), 2017 (R), 2019 (R)
Flusilazole (165)	1989 (T,R), 1990 (R), 1991 (R), 1993 (R), 1995 (T), 2007 (T,R)

Flutolanil (205)	2002 (T,R), 2013 (R)
Flutriafol (248)	2011 (T,R), 2015 (R)
Fluxapyroxad (256)	2012 (T,R), 2015 (R), 2018 (T,R), 2019 (R)
Folpet (041)	1969 (T,R), 1973 (T), 1974 (R), 1982 (T), 1984 (T,R), 1986 (T), 1987 (R), 1990 (T,R), 1991 (corr. to 1990 R evaluation), 1993 (T,R), 1994 (R), 1995 (T), 1997 (R), 1998 (R), 1999 (R), 2002 (T), 2004 (T), 2007 (T)
Formothion (042)	1969 (T,R), 1972 (R), 1973 (T,R), 1978 (R), 1998 (R)
Fosetyl Aluminium (302)	2017 (T, R), 2019 (R)
Glufosinate-ammonium (175)	1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1994 (R), 1998 (R), 1999 (T,R), 2012 (T,R), 2014 (R)
Glyphosate (158)	1986 (T,R), 1987 (R and corr. to 1986 report), 1988 (R), 1994 (R), 1997 (T,R), 2004 (T), 2005 (R), 2011 (T,R), 2013 (R), 2016 (T), 2019 (R)
Guazatine (114)	1978 (T,R), 1980 (R), 1997 (T,R)
Haloxyfop (194)	1995 (T,R), 1996 (R and corr. to 1995 report), 2001 (R), 2006 (T), 2009 (R)
Heptachlor (043)	1965 (T), 1966 (T,R), 1967 (R), 1968 (R), 1969 (R), 1970 (T,R), 1974 (R), 1975 (R), 1977 (R), 1987 (R), 1991 (T,R), 1992 (corr. to 1991 report, Annex I), 1993 (R), 1994 (R)
Hexachlorobenzene (044)	1969 (T,R), 1973 (T,R), 1974 (T,R), 1978 (T), 1985 (R)
Hexaconazole (170)	1990 (T,R), 1991 (R and corr. to 1990 R evaluation), 1993 (R)
Hexythiazox (176)	1991 (T,R), 1994 (R), 1998 (R), 2008 (T), 2009 (R)
Hydrogen cyanide (045)	1965 (T,R)
Hydrogen phosphide (046)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1971 (R)
Imazalil (110)	1977 (T,R), 1980 (T,R), 1984 (T,R), 1985 (T,R), 1986 (T), 1988 (R), 1989 (R), 1991 (T), 1994 (R), 2000 (T), 2001 (T), 2005 (T), 2018 (T,R)
Imazamox (276)	2014 (T,R), 2017 (R)
Imazapic (266)	2013 (T,R), 2015 (R)
Imazapyr (267)	2013 (T,R), 2015 (R), 2017 (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)
Iprodione (111)	1977 (T,R), 1980 (R), 1992 (T), 1994 (R), 1995 (T), 2001 (R)
Isofenphos (131)	1981 (T,R), 1982 (T,R), 1984 (R), 1985 (R), 1986 (T,R), 1988 (R), 1992 (R)

Isofetamid (290)	2016 (T,R), 2018 (R), 2019 (R)
Isoprothiolane (299)	2017 (T, R)
Isopyrazam (249)	2011 (T,R), 2017 (R)
Isoxaflutole (268)	2013 (T,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)
Maleic hydrazide (102)	1976 (T,R), 1977 (T,R), 1980 (T), 1984 (T,R), 1996 (T), 1998 (R)
Mancozeb (050)	1967 (T,R), 1970 (T,R), 1974 (R), 1977 (R), 1980 (T,R), 1993 (T,R)
Mandestrobin (307)	2018 (T), 2019 (R),
Mandipropamid (231)	2008 (T,R), 2013 (R), 2018 (R)
Maneb	See Dithiocarbamates, 1965 (T), 1967 (T,R), 1987 (T), 1993 (T,R)
MCPA (257)	2012 (T,R)
Mecarbam (124)	1980 (T,R), 1983 (T,R), 1985 (T,R), 1986 (T,R), 1987 (R)
Meptyldinocap (244)	2010 (T, R)
Mesotrione (277)	2014 (T, R), 2019 (T, R)
Metaflumizone (236)	2009 (T, R), 2019 (T, R)
Metalaxyl (138)	1982 (T, R), 1984 (R), 1985 (R), 1986 (R), 1987 (R), 1989 (R), 1990 (R), 1992 (R), 1995 (R)
Metalaxyl –M (212)	2002 (T), 2004 (R)
Metconazole (313)	2019 (T, R)
Methacrifos (125)	1980 (T,R), 1982 (T), 1986 (T), 1988 (T), 1990 (T,R), 1992 (R)
Methamidophos (100)	1976 (T,R), 1979 (R), 1981 (R), 1982 (T,R), 1984 (R), 1985 (T), 1989 (R), 1990 (T,R), 1994 (R), 1996 (R), 1997 (R), 2002 (T), 2003 (R), 2004 (R, corr. to 2003 report)



Methidathion (051)	1972 (T,R), 1975 (T,R), 1979 (R), 1992 (T,R), 1994 (R), 1997 (T)
Methiocarb (132)	1981 (T,R), 1983 (T,R), 1984 (T), 1985 (T), 1986 (R), 1987 (T,R), 1988 (R), 1998 (T), 1999 (R), 2005 (R)
Methomyl (094)	1975 (R), 1976 (R), 1977 (R), 1978 (R), 1986 (T,R), 1987 (R), 1988 (R), 1989 (T,R), 1990 (R), 1991 (R), 2001 (T,R), 2004 (R), 2008 (R)
Methoprene (147)	1984 (T,R), 1986 (R), 1987 (T and corr. to 1986 report), 1988 (R), 1989 (R), 2001 (T), 2005 (R), 2016 (R), 2019 (R)
Methoxychlor	1965 (T), 1977 (T)
Methoxyfenozide (209)	2003 (T,R), 2004 (corr. to 2003 report), 2006 (R), 2009 (R), 2012 (R)
Methyl bromide (052)	See Bromomethane
Metrafenone (278)	2014 (T,R), 2016 (R)
Metiram (186)	1993 (T), 1995 (R)
Mevinphos (053)	1965 (T), 1972 (T,R), 1996 (T), 1997 (E,R), 2000 (R)
MGK 264	1967 (T,R)
Monocrotophos (054)	1972 (T,R), 1975 (T,R), 1991 (T,R), 1993 (T), 1994 (R)
Myclobutanil (181)	1992 (T,R), 1997 (R), 1998 (R), (2001 (R)), 2014 (T,R)
Nabam	See Dithiocarbamates, 1965 (T), 1976 (T,R)
Natamycin (300)	2017 (T, R)
Nitrofen (140)	1983 (T,R)
Norflurazon (308)	2018 (T,R)
Novaluron (217)	2005 (T,R), 2010 (R)
Omethoate (055)	1971 (T,R), 1975 (T,R), 1978 (T,R), 1979 (T), 1981 (T,R), 1984 (R), 1985 (T), 1986 (R), 1987 (R), 1988 (R), 1990 (R), 1998 (R)
Organomercury compounds	1965 (T), 1966 (T,R), 1967 (T,R)
Oxamyl (126)	1980 (T,R), 1983 (R), 1984 (T), 1985 (T,R), 1986 (R), 2002 (T,R), 2017 (T, R)
Oxathiapiprolin (291)	2016 (T,R), 2018 (R)
Oxydemeton-methyl (166)	1965 (T, as demeton-S-methyl sulfoxide), 1967 (T), 1968 (R), 1973 (T,R), 1982 (T), 1984 (T,R), 1989 (T,R), 1992 (R), 1998 (R), 1999 (corr. to 1992 report), 2002 (T), 2004 (R)
Oxythioquinox	See Chinomethionat
Paclobutrazol (161)	1988 (T,R), 1989 (R)

Paraquat (057)	1970 (T,R), 1972 (T,R), 1976 (T,R), 1978 (R), 1981 (R), 1982 (T), 1985 (T), 1986 (T), 2003 (T), 2004 (R), 2009 (R)
Parathion (058)	1965 (T), 1967 (T,R), 1969 (R), 1970 (R), 1984 (R), 1991 (R), 1995 (T,R), 1997 (R), 2000 (R)
Parathion-methyl (059)	1965 (T), 1968 (T, R), 1972 (R), 1975 (T,R), 1978 (T,R), 1979 (T), 1980 (T), 1982 (T), 1984 (T,R), 1991 (R), 1992 (R), 1994 (R), 1995 (T), 2000 (R), 2003 (R)
Penconazole (182)	1992 (T, R), 1995 (R), 2015 (T), 2016 (R)
Pendimethalin (292)	2016 (T, R), 2019 (R)
Penthiopyrad (253)	2011 (T), 2012 (R), 2013 (R), 2019 (R)
Permethrin (120)	1979 (T, R), 1980 (R), 1981 (T,R), 1982 (R), 1983 (R), 1984 (R), 1985 (R), 1986 (T,R), 1987 (T), 1988 (R), 1989 (R), 1991 (R), 1992 (corr. to 1991 report), 1999 (T)
2-Phenylphenol (056)	1969 (T,R), 1975 (R), 1983 (T), 1985 (T,R), 1989 (T), 1990 (T,R), 1999 (T,R), 2002 (R)
Phenothrin (127)	1979 (R), 1980 (T,R), 1982 (T), 1984 (T), 1987 (R), 1988 (T,R)
Phenthoate (128)	1980 (T,R), 1981 (R), 1984 (T)
Phorate (112)	1977 (T,R), 1982 (T), 1983 (T), 1984 (R), 1985 (T), 1990 (R), 1991 (R), 1992 (R), 1993 (T), 1994 (T), 1996 (T), 2004 (T), 2005 (R), 2012 (R), 2014 (R)
Phosalone (060)	1972 (T,R), 1975 (R), 1976 (R), 1993 (T), 1994 (R), 1997 (T), 1999 (R), 2001 (T)
Phosmet (103)	1976 (R), 1977 (corr. to 1976 R evaluation), 1978 (T,R), 1979 (T,R), 1981 (R), 1984 (R), 1985 (R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1994 (T), 1997 (R), 1998 (T), 2002 (R), 2003 (R), 2007 (R)
Phosphine	See Hydrogen phosphide
Phosphamidon (061)	1965 (T), 1966 (T), 1968 (T,R), 1969 (R), 1972 (R), 1974 (R), 1982 (T), 1985 (T), 1986 (T)
Phosphonic acid (301)	2017 (T, R)
Phoxim (141)	1982 (T), 1983 (R), 1984 (T,R), 1986 (R), 1987 (R), 1988 (R)
Picoxystrobin (258)	2012 (T,R), 2013 (R), 2016 (R), 2017 (R), 2019 (R)
Pinoxaden (293)	2016 (T,R)
Piperonyl butoxide (062)	1965 (T,R), 1966 (T,R), 1967 (R), 1969 (R), 1972 (T,R), 1992 (T,R), 1995 (T), 2001 (R), 2002 (R)
Pirimicarb (101)	1976 (T,R), 1978 (T,R), 1979 (R), 1981 (T,R), 1982 (T), 1985 (R), 2004 (T), 2006 (R)

Pirimiphos-methyl (086)	1974 (T,R), 1976 (T,R), 1977 (R), 1979 (R), 1983 (R), 1985 (R), 1992 (T), 1994 (R), 2003 (R), 2004 (R, corr. to 2003 report), 2006 (T)
Prochloraz (142)	1983 (T,R), 1985 (R), 1987 (R), 1988 (R), 1989 (R), 1990 (R), 1991 (corr. to 1990 report, Annex I, and R evaluation), 1992 (R), 2001 (T), 2004 (R), 2009 (R)
Procymidone(136)	1981 (R), 1982 (T), 1989 (T,R), 1990 (R), 1991 (corr. to 1990 Annex I), 1993 (R), 1998 (R), 2007 (T)
Profenofos (171)	1990 (T,R), 1992 (R), 1994 (R), 1995 (R), 2007 (T), 2008 (R), 2011 (R), 2018 (R)
Propamocarb (148)	1984 (T,R), 1986 (T,R), 1987 (R), 2005 (T), 2006 (R), 2014 (R), 2018 (R)
Propargite (113)	1977 (T,R), 1978 (R), 1979 (R), 1980 (T,R), 1982 (T,R), 1999 (T), 2002 (R), 2006 (R)
Propham (183)	1965 (T), 1992 (T,R)
Propiconazole (160)	1987 (T, R), 1991 (R), 1994 (R), 2004 (T), 2006 (R), 2007 (R), 2013 (R), 2014 (R), 2015 (R), 2017 (R), 2018 (R), 2019 (R)
Propineb	1977 (T, R), 1980 (T), 1983 (T), 1984 (R), 1985 (T, R), 1993 (T, R), 2004 (R)
Propoxur (075)	1973 (T, R), 1977 (R), 1981 (R), 1983 (R), 1989 (T), 1991 (R), 1996 (R)
Propylene oxide (250)	2011 (T, R), 2017 (T, R)
Propylenethiourea (PTU, 150)	1993 (T, R), 1994 (R), 1999 (T)
Prothioconazole (232)	2008 (T, R), 2009 (R), 2014 (R), 2017 (R)
Pydiflumetofen (309)	2018 (T, R), 2019 (R)
Pyflubumide (314)	2019 (T, R)
Pymetrozine (279)	2014 (T, R)
Pyraclostrobin (210)	2003 (T), 2004 (R), 2006 (R), 2011 (R), 2012 (R), 2014 (R), 2018 (T, R), 2019 (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)
Pyridate (315)	2019 (T)
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)
Quinoxifen (223)	2006 (T, R)

Quintozene (064)	1969 (T, R), 1973 (T,R), 1974 (R), 1975 (T,R), 1976 (Annex I, corr. to 1975 R evaluation), 1977 (T,R), 1995 (T,R), 1998 (R)
Saflufenacil (251)	2011 (T, R), 2016 (R), 2017 (R)
Sedaxane (259)	2012 (T, R), 2014 (R)
Spices	2004 (R), 2005 (R), 2007 (R), 2010 (R), 2015 (R)
Spinetoram (233)	2008 (T, R), 2012 (R), 2017 (R)
Spinosad (203)	2001 (T, R), 2004 (R), 2008 (R), 2011 (R)
Spirodiclofen (237)	2009 (T, R)
Spiromesifen (294)	2016 (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)
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)
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)
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)
Thiamethoxam (245)	2010 (T, R), 2011 (R), 2012 (R), 2014 (R)
Thiodicarb (154)	1985 (T, R), 1986 (T), 1987 (R), 1988 (R), 2000 (T), 2001 (R)
Thiometon (076)	1969 (T, R), 1973 (T,R), 1976 (R), 1979 (T,R), 1988 (R)
Thiophanate-methyl (077)	1973 (T, R), 1975 (T, R), 1977 (T), 1978 (R), 1988 (R), 2002 (R), 1990 (R), 1994 (R), 1995 (T,E), 1998 (T,R), 2006 (T), 2017 (T)
Thiram (105)	See Dithiocarbamates, 1965 (T), 1967 (T, R), 1970 (T,R), 1974 (T), 1977 (T), 1983 (R), 1984 (R), 1985 (T,R), 1987 (T), 1988 (R), 1989 (R), 1992 (T), 1996 (R)
Tioxazafen (211)	2018 (T, R)

Tolclofos-methyl (191)	1994 (T, R), 1996 (corr. to Annex II of 1995 report), 2019 (T, R)
Tolfenpyrad (269)	2013 (T), 2016 (R), 2019 (R)
Tolyfluanid (162)	1988 (T, R), 1990 (R), 1991 (corr. to 1990 report), 2002 (T, R), 2003 (R)
Toxaphene	See Camphechlor
Triadimefon (133)	1979 (R), 1981 (T, R), 1983 (T,R), 1984 (R), 1985 (T,R), 1986 (R), 1987 (R and corr. to 1986 R evaluation), 1988 (R), 1989 (R), 1992 (R), 1995 (R), 2004 (T), 2007 (R)
Triadimenol (168)	1989 (T, R), 1992 (R), 1995 (R), 2004 (T), 2007 (R), 2014 (R)
Triazolylalanine	1989 (T, R)
Triazophos (143)	1982 (T), 1983 (R), 1984 (corr. to 1983 report, Annex I), 1986 (T, R), 1990 (R), 1991 (T and corr. to 1990 R evaluation), 1992 (R), 1993 (T, R), 2002 (T), 2007 (R), 2010 (R), 2013 (R)
Trichlorfon (066)	1971 (T,R), 1975 (T,R), 1978 (T,R), 1987 (R)
Trichloronat	1971 (T,R)
Trichloroethylene	1968 (R)
Tricyclohexyltin hydroxide	See Cyhexatin
Trifloxystrobin (213)	2004 (T, R), 2012 (R), 2015 (R), 2017 (R)
Triflumezopyrim (303)	2017 (T, R)
Triflumizole (270)	2013 (T, R)
Triflumuron (317)	2019 (T, R)
Triforine (116)	1977 (T), 1978 (T, R), 1997 (T), 2004 (R), 2014 (T,R)
Trinexapac-ethyl (271)	2013 (T,R)
Triphenyltin compounds	See Fentin compounds
Valifenelate (318)	2019 (T, R)
Vamidothion (078)	1973 (T, R), 1982 (T), 1985 (T, R), 1987 (R), 1988 (T), 1990 (R), 1992 (R)
Vinclozolin (159)	1986 (T, R), 1987 (R and corr. to 1986 report and R evaluation), 1988 (T, R), 1989 (R), 1990 (R), 1992 (R), 1995 (T)
Zineb (105)	See Dithiocarbamates, 1965 (T), 1967 (T, R), 1993 (T)
Ziram (105)	See Dithiocarbamates, 1965 (T), 1967 (T, R), 1996 (T,R)
Zoxamide (227)	2007 (T, R), 2009 (R)



### Annex 3: International estimated daily intakes of pesticide residues

ACETAMIPRID (246)				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 µg/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						
HS 0771	Anise, seed	RAC	0.57	0.16	0.09	0.01	0.01	0.01	0.01	0.01	0.37	0.21	0.08	0.05	0.09	0.05					
HS 0774	Caraway, seed	RAC	0.57	0.16	0.09	0.01	0.01	0.01	0.01	0.37	0.21	0.08	0.05	0.09	0.05						
HS 0779	Coriander, seed	RAC	0.57	0.08	0.05	0.01	0.01	0.01	0.01	0.19	0.11	0.04	0.02	0.05	0.03						
HS 0780	Cumin, seed	RAC	0.57	0.08	0.05	0.01	0.01	0.01	0.01	0.19	0.11	0.04	0.02	0.05	0.03						
HS 0789	Nutmeg	RAC	0.57	0.03	0.02	0.01	0.01	0.01	0.01	0.70	0.40	0.03	0.02	0.01	0.01						
Total intake (µg/person)=				0.3			0.0			0.0			1.0			0.2			0.2		
Bodyweight per region (kg bw) =				60			60			60			60			60			60		
ADI (µg/person)=				4200			4200			4200			4200			4200			4200		
%ADI=				0.0%			0.0%			0.0%			0.0%			0.0%			0.0%		
Rounded %ADI=				0%			0%			0%			0%			0%			0%		

ACETAMIPRID (246)				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 µg/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						
HS 0771	Anise, seed	RAC	0.57	NC	-	0.07	0.04	0.08	0.05	0.05	0.03	0.12	0.07	0.02	0.01						
HS 0774	Caraway, seed	RAC	0.57	NC	-	0.07	0.04	NC	-	0.05	0.03	0.12	0.07	0.02	0.01						
HS 0779	Coriander, seed	RAC	0.57	0.11	0.06	0.04	0.02	NC	-	0.02	0.01	0.06	0.03	0.01	0.01						
HS 0780	Cumin, seed	RAC	0.57	0.11	0.06	0.04	0.02	NC	-	0.02	0.01	0.06	0.03	0.01	0.01						
HS 0789	Nutmeg	RAC	0.57	0.03	0.02	0.04	0.02	0.02	0.01	0.01	0.01	0.13	0.07	0.05	0.03						
Total intake (µg/person)=				0.1			0.1			0.1			0.1			0.3			0.1		
Bodyweight per region (kg bw) =				60			60			55			60			60			60		
ADI (µg/person)=				4200			4200			3850			4200			4200			4200		
%ADI=				0.0%			0.0%			0.0%			0.0%			0.0%			0.0%		
Rounded %ADI=				0%			0%			0%			0%			0%			0%		

ACETAMIPRID (246)				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		Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
HS 0771	Anise, seed	RAC	0.57	0.01	0.01	0.50	0.29	NC	-	0.01	0.01	0.02	0.01
HS 0774	Caraway, seed	RAC	0.57	0.01	0.01	0.50	0.29	0.22	0.13	0.01	0.01	0.02	0.01
HS 0779	Coriander, seed	RAC	0.57	0.01	0.01	0.25	0.14	NC	-	0.01	0.01	0.01	0.01
HS 0780	Cumin, seed	RAC	0.57	0.01	0.01	0.25	0.14	NC	-	0.01	0.01	0.01	0.01
HS 0789	Nutmeg	RAC	0.57	0.01	0.01	0.02	0.01	0.01	0.01	0.01	0.01	NC	-
Total intake (µg/person)=				0.0		0.9		0.1		0.0		0.0	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg/person)=				4200		4200		4200		4200		4200	
% ADI=				0.0%		0.0%		0.0%		0.0%		0.0%	
Rounded % ADI=				0%		0%		0%		0%		0%	



**AFIDOPYROPEN (312)**

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 µg/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	0.0535	32.25	1.73	11.67	0.62	16.70	0.89	76.01	4.07	33.90	1.81	92.97	4.97
JF 0001	Group of Citrus fruit, juice	PP	0.012	1.30	0.02	2.37	0.03	0.22	0.00	13.88	0.17	0.75	0.01	2.63	0.03
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.021	19.35	0.41	34.06	0.72	17.87	0.38	25.74	0.54	7.69	0.16	56.85	1.19
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.013	0.32	0.00	3.07	0.04	0.07	0.00	5.00	0.07	0.29	0.00	5.57	0.07
FS 0013	Subgroup of Cherries, raw	RAC	0.02	0.92	0.02	9.15	0.18	0.01	0.00	0.61	0.01	0.06	0.00	6.64	0.13
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
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.02	8.01	0.16	5.87	0.12	0.18	0.00	8.19	0.16	1.64	0.03	22.46	0.45
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.135	2.54	0.34	0.49	0.07	0.01	0.00	3.57	0.48	7.79	1.05	3.12	0.42
VB 0041	Cabbages, head, raw	RAC	0.02	2.73	0.05	27.92	0.56	0.55	0.01	4.47	0.09	4.27	0.09	10.25	0.21
VC 0424	Cucumber, raw	RAC	0.17	8.01	1.36	30.66	5.21	1.45	0.25	19.84	3.37	0.27	0.05	34.92	5.94
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.039	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 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.027	42.62	1.15	46.85	1.26	4.21	0.11	67.02	1.81	12.84	0.35	110.47	2.98
VO 0448	Tomato, raw	RAC	0.03	41.73	1.25	75.65	2.27	10.66	0.32	82.87	2.49	24.75	0.74	200.93	6.03
-	Tomato, canned (& peeled)	PP	0.016	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.02	0.11	0.00	1.50	0.02
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.016	2.34	0.04	1.33	0.02	1.57	0.03	4.24	0.07	0.34	0.01	2.83	0.05
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0026	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 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.036	8.48	0.31	13.74	0.49	10.13	0.36	11.29	0.41	9.52	0.34	26.36	0.95
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.03	5.58	0.17	4.31	0.13	0.89	0.03	9.31	0.28	13.64	0.41	20.12	0.60
VL 2050	Subgroup of Leafy greens	RAC	0.88	3.93	3.46	5.28	4.65	3.07	2.70	14.53	12.79	8.25	7.26	12.75	11.22
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.5	2.63	6.58	9.27	23.18	1.86	4.65	5.82	14.55	19.53	48.83	4.90	12.25
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.02	72.79	1.46	59.05	1.18	20.55	0.41	74.20	1.48	61.12	1.22	73.24	1.46
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	63.11	0.00	316.33	0.00	651.91	0.00	72.06	0.00	84.88	0.00	132.70	0.00
VS 2080	Subgroup of stems and petioles	RAC	0.54	3.11	1.68	5.52	2.98	3.42	1.85	8.29	4.48	0.02	0.01	4.00	2.16
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.02	4.06	0.08	3.27	0.07	7.01	0.14	13.93	0.28	14.01	0.28	9.36	0.19
OR 0691	Cotton seed oil, edible	PP	0.0013	3.22	0.00	1.54	0.00	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.00
HH 0756	Coriander leaves (cilantro), raw	RAC	2.5	0.13	0.33	0.23	0.58	0.14	0.35	0.35	0.88	NC	-	0.17	0.43
HH 0730	Dill leaves, raw	RAC	2.5	0.16	0.40	0.29	0.73	0.18	0.45	0.44	1.10	NC	-	0.21	0.53
HH 0740	Parsley leaves, raw (incl dried)	RAC	2.5	0.60	1.50	1.07	2.68	0.66	1.65	1.60	4.00	NC	-	0.77	1.93
HS 0784	Ginger, rhizome, raw incl dried	RAC	0	0.25	0.00	0.01	0.00	0.16	0.00	1.16	0.00	0.59	0.00	0.01	0.00

AFIDOPYROPEN (312)				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 µg/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												
HS 0794	Turmeric, root, raw (incl dried)	RAC	0	0.04	0.00	0.01	0.00	0.01	0.00	0.17	0.00	0.17	0.00	0.09	0.00												
HS 0444	Peppers, chili, dried	PP	0.36	0.42	0.15	0.53	0.19	0.84	0.30	0.50	0.18	0.95	0.34	0.37	0.13												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.18	24.96	4.49	57.95	10.43	16.70	3.01	38.38	6.91	26.46	4.76	29.00	5.22												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.13	6.24	0.81	14.49	1.88	4.18	0.54	9.60	1.25	6.62	0.86	7.25	0.94												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.13	3.29	0.43	6.14	0.80	0.82	0.11	1.57	0.20	2.23	0.29	1.07	0.14												
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)	RAC	0.022	14.63	0.32	29.76	0.65	8.04	0.18	129.68	2.85	25.04	0.55	35.66	0.78												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.022	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	0.024	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.13	0.24	0.01	0.10	0.00												
PE 0112	Eggs, raw, (incl dried)	RAC	0.022	7.84	0.17	23.08	0.51	2.88	0.06	14.89	0.33	9.81	0.22	14.83	0.33												
Total intake (µg/person)=				35.8				74.3				20.0				71.5				74.6				66.7			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				4800				4800				4800				4800				4800							
%ADI=				0.7%				1.5%				0.4%				1.5%				1.6%				1.4%			
Rounded %ADI=				1%				2%				0%				1%				2%				1%			

AFIDOPYROPEN (312)				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 µg/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	0.0535	38.66	2.07	54.93	2.94	26.36	1.41	51.46	2.75	51.06	2.73	466.36	24.95
JF 0001	Group of Citrus fruit, juice	PP	0.012	36.84	0.44	3.75	0.05	0.30	0.00	21.62	0.26	21.82	0.26	46.67	0.56
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.021	51.09	1.07	65.40	1.37	42.71	0.90	45.29	0.95	62.51	1.31	7.74	0.16
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.013	14.88	0.19	11.98	0.16	0.15	0.00	9.98	0.13	30.32	0.39	3.47	0.05
FS 0013	Subgroup of Cherries, raw	RAC	0.02	1.40	0.03	4.21	0.08	0.04	0.00	2.93	0.06	1.50	0.03	NC	-
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
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.02	13.03	0.26	16.29	0.33	8.29	0.17	12.95	0.26	5.35	0.11	0.04	0.00
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.135	9.50	1.28	6.77	0.91	NC	-	3.21	0.43	9.36	1.26	0.75	0.10
VB 0041	Cabbages, head, raw	RAC	0.02	8.97	0.18	27.12	0.54	1.44	0.03	24.96	0.50	4.55	0.09	11.23	0.22

**AFIDOPYROPEN (312)**

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 µg/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
VC 0424	Cucumber, raw	RAC	0.17	6.72	1.14	11.03	1.88	32.10	5.46	15.10	2.57	4.05	0.69	9.57	1.63
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.039	NC	-	NC	-	5.48	0.21	NC	-	NC	-	1.03	0.04
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.027	20.68	0.56	25.00	0.68	85.72	2.31	34.31	0.93	11.54	0.31	23.32	0.63
VO 0448	Tomato, raw	RAC	0.03	32.13	0.96	51.27	1.54	34.92	1.05	73.37	2.20	15.15	0.45	8.88	0.27
-	Tomato, canned (& peeled)	PP	0.016	7.57	0.12	2.66	0.04	0.30	0.00	0.97	0.02	7.31	0.12	0.41	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.016	4.96	0.08	3.20	0.05	0.15	0.00	1.61	0.03	6.88	0.11	0.52	0.01
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0026	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 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.036	6.39	0.23	15.53	0.56	19.09	0.69	10.36	0.37	8.29	0.30	4.53	0.16
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.03	1.01	0.03	1.69	0.05	21.37	0.64	3.00	0.09	1.40	0.04	NC	-
VL 2050	Subgroup of Leafy greens	RAC	0.88	18.38	16.17	18.73	16.48	82.36	72.48	25.32	22.28	17.60	15.49	7.37	6.49
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.5	0.10	0.25	NC	-	26.78	66.95	5.00	12.50	0.58	1.45	5.68	14.20
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.02	106.33	2.13	117.78	2.36	42.12	0.84	195.70	3.91	222.52	4.45	80.47	1.61
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	226.09	0.00	234.58	0.00	161.10	0.00	185.04	0.00	234.85	0.00	100.25	0.00
VS 2080	Subgroup of stems and petioles	RAC	0.54	9.31	5.03	8.57	4.63	NC	-	3.88	2.10	24.46	13.21	5.89	3.18
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.02	8.52	0.17	8.94	0.18	15.09	0.30	9.60	0.19	14.57	0.29	26.26	0.53
OR 0691	Cotton seed oil, edible	PP	0.0013	1.68	0.00	0.66	0.00	1.13	0.00	1.18	0.00	0.89	0.00	0.37	0.00
HH 0756	Coriander leaves (cilantro), raw	RAC	2.5	NC	-	NC	-	5.66	14.15	NC	-	NC	-	0.25	0.63
HH 0730	Dill leaves, raw	RAC	2.5	0.48	1.20	0.01	0.03	NC	-	1.17	2.93	NC	-	0.31	0.78
HH 0740	Parsley leaves, raw (incl dried)	RAC	2.5	1.43	3.58	2.14	5.35	NC	-	2.54	6.35	0.78	1.95	1.14	2.85
HS 0784	Ginger, rhizome, raw incl dried	RAC	0	0.27	0.00	0.07	0.00	0.54	0.00	0.69	0.00	0.58	0.00	0.56	0.00
HS 0794	Turmeric, root, raw (incl dried)	RAC	0	NC	-	NC	-	NC	-	NC	-	0.08	0.00	0.02	0.00
HS 0444	Peppers, chili, dried	PP	0.36	0.11	0.04	0.21	0.08	0.36	0.13	0.21	0.08	0.25	0.09	0.15	0.05
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.18	112.02	20.16	120.71	21.73	63.46	11.42	88.99	16.02	96.24	17.32	41.02	7.38
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.13	28.01	3.64	30.18	3.92	15.86	2.06	22.25	2.89	24.06	3.13	10.25	1.33
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.13	6.44	0.84	15.51	2.02	3.79	0.49	8.29	1.08	18.44	2.40	8.00	1.04

AFIDOPYROPEN (312)				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 µg/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
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)	RAC	0.022	73.76	1.62	53.86	1.18	23.98	0.53	87.12	1.92	53.38	1.17	84.45	1.86
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.022	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	0.024	0.33	0.01	0.72	0.02	0.27	0.01	0.35	0.01	0.80	0.02	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.022	25.84	0.57	29.53	0.65	28.05	0.62	33.19	0.73	36.44	0.80	8.89	0.20
Total intake (µg/person)=				75.3				77.7				185.3			
Bodyweight per region (kg bw) =				60				60				55			
ADI (µg/person)=				4800				4800				4400			
%ADI=				1.6%				1.6%				4.2%			
Rounded %ADI=				2%				2%				4%			

AFIDOPYROPEN (312)				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: µg/person					
				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 kumquat commodities)	RAC	0.0535	20.93	1.12	2.35	0.13	30.71	1.64	0.15	0.01	4.45	0.24
JF 0001	Group of Citrus fruit, juice	PP	0.012	0.11	0.00	0.29	0.00	13.55	0.16	0.14	0.00	0.33	0.00
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.021	68.85	1.45	10.93	0.23	70.82	1.49	189.78	3.99	19.56	0.41
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.013	0.03	0.00	0.10	0.00	7.19	0.09	0.03	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.02	0.01	0.00	0.01	0.00	5.96	0.12	0.01	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	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.02	0.02	0.00	0.01	0.00	10.76	0.22	0.01	0.00	NC	-
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.135	0.02	0.00	0.02	0.00	4.86	0.66	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.02	3.82	0.08	2.99	0.06	49.16	0.98	0.01	0.00	NC	-
VC 0424	Cucumber, raw	RAC	0.17	0.68	0.12	1.81	0.31	10.40	1.77	0.01	0.00	0.04	0.01
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.039	0.09	0.00	1.01	0.04	NC	-	1.91	0.07	NC	-
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.027	5.04	0.14	6.54	0.18	38.26	1.03	11.70	0.32	NC	-
VO 0448	Tomato, raw	RAC	0.03	12.99	0.39	4.79	0.14	58.40	1.75	0.92	0.03	0.09	0.00
-	Tomato, canned (& peeled)	PP	0.016	0.07	0.00	0.08	0.00	2.42	0.04	0.07	0.00	NC	-

**AFIDOPYROPEN (312)**

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: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.016	0.58	0.01	0.22	0.00	2.21	0.04	0.24	0.00	3.10	0.05
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.0026	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.036	8.97	0.32	14.13	0.51	25.14	0.91	0.91	0.03	NC	-
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.03	1.31	0.04	8.26	0.25	3.95	0.12	0.01	0.00	NC	-
VL 2050	Subgroup of Leafy greens	RAC	0.88	4.99	4.39	3.29	2.90	7.53	6.63	3.05	2.68	6.09	5.36
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	2.5	3.58	8.95	2.64	6.60	NC	-	1.83	4.58	3.65	9.13
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.02	15.80	0.32	14.29	0.29	104.36	2.09	17.11	0.34	35.20	0.70
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	250.41	0.00	208.74	0.00	213.64	0.00	602.70	0.00	388.95	0.00
VS 2080	Subgroup of stems and petioles	RAC	0.54	5.33	2.88	3.85	2.08	5.80	3.13	3.60	1.94	7.20	3.89
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0.02	4.39	0.09	135.53	2.71	6.11	0.12	0.72	0.01	317.74	6.35
OR 0691	Cotton seed oil, edible	PP	0.0013	1.28	0.00	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00
HH 0756	Coriander leaves (cilantro), raw	RAC	2.5	0.22	0.55	0.16	0.40	NC	-	0.15	0.38	0.30	0.75
HH 0730	Dill leaves, raw	RAC	2.5	0.28	0.70	0.20	0.50	0.65	1.63	0.19	0.48	0.38	0.95
HH 0740	Parsley leaves, raw (incl dried)	RAC	2.5	1.03	2.58	0.74	1.85	1.87	4.68	0.70	1.75	1.39	3.48
HS 0784	Ginger, rhizome, raw incl dried	RAC	0	0.75	0.00	0.68	0.00	0.06	0.00	0.02	0.00	0.01	0.00
HS 0794	Turmeric, root, raw (incl dried)	RAC	0	0.02	0.00	0.12	0.00	0.17	0.00	0.01	0.00	0.10	0.00
HS 0444	Peppers, chili, dried	PP	0.36	0.58	0.21	1.27	0.46	1.21	0.44	0.12	0.04	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.18	23.34	4.20	40.71	7.33	97.15	17.49	18.06	3.25	57.71	10.39
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.13	5.84	0.76	10.18	1.32	24.29	3.16	4.52	0.59	14.43	1.88
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.13	1.05	0.14	1.14	0.15	18.69	2.43	0.94	0.12	3.12	0.41
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)	RAC	0.022	3.92	0.09	12.03	0.26	57.07	1.26	5.03	0.11	55.56	1.22
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.022	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.024	0.10	0.00	0.70	0.02	0.97	0.02	0.10	0.00	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.022	3.84	0.08	4.41	0.10	27.25	0.60	1.13	0.02	7.39	0.16

Total intake (µg/person)=	32.8	30.6	65.9	22.7	47.8
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	4800	4800	4800	4800	4800
% ADI=	0.7%	0.6%	1.4%	0.5%	1.0%
Rounded %ADI=	1%	1%	1%	0%	1%

**BENZOVINDIFLUPYR (261)**

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 µg/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
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.058	19.35	1.12	34.06	1.98	17.87	1.04	25.74	1.49	7.69	0.45	56.85	3.30
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.003	0.32	0.00	3.07	0.01	0.07	0.00	5.00	0.02	0.29	0.00	5.57	0.02
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.29	12.68	3.68	9.12	2.64	0.03	0.01	16.88	4.90	3.70	1.07	54.42	15.78
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.7	0.51	0.36	0.51	0.36	0.01	0.01	1.27	0.89	0.12	0.08	2.07	1.45
JF 0269	Grape juice (from wine grapes)	PP	0.022	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	0.38	0.33	0.13	0.13	0.05	0.01	0.00	0.02	0.01	0.01	0.00	0.02	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.023	0.67	0.02	12.53	0.29	2.01	0.05	1.21	0.03	3.53	0.08	4.01	0.09
VA 2031	Subgroup of bulb onions	RAC	0.01	31.65	0.32	43.28	0.43	3.68	0.04	38.48	0.38	20.46	0.20	47.29	0.47
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.023	53.14	1.22	86.21	1.98	6.28	0.14	92.76	2.13	15.64	0.36	155.30	3.57
VO 0448	Tomato, raw	RAC	0.089	41.73	3.71	75.65	6.73	10.66	0.95	82.87	7.38	24.75	2.20	200.93	17.88
-	Tomato, canned (& peeled)	PP	0.003	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	0.037	2.34	0.09	1.33	0.05	1.57	0.06	4.24	0.16	0.34	0.01	2.83	0.10
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.008	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 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.089	10.45	0.93	13.74	1.22	13.81	1.23	14.53	1.29	15.25	1.36	27.93	2.49
VO 2046	Subgroup of eggplants	RAC	0.089	5.58	0.50	4.31	0.38	0.89	0.08	9.31	0.83	13.64	1.21	20.12	1.79
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 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.58	0.01	0.05	0.00	0.37	0.00	0.03	0.00	1.65	0.02	0.30	0.00
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0055	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0066	12.99	0.09	10.43	0.07	3.63	0.02	13.10	0.09	10.70	0.07	13.10	0.09
-	Soya sauce	PP	0.004	0.01	0.00	0.02	0.00	0.01	0.00	0.34	0.00	0.03	0.00	0.01	0.00
-	Soya flour	PP	0.004	0.05	0.00	0.86	0.00	0.02	0.00	1.02	0.00	0.01	0.00	0.15	0.00
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.011	1.62	0.02	3.22	0.04	0.92	0.01	1.50	0.02	2.90	0.03	0.17	0.00
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
GC 0650	Rye, raw (incl flour)	RAC	0.023	0.13	0.00	19.38	0.45	0.10	0.00	0.12	0.00	0.03	0.00	2.15	0.05
GC 0653	Triticale, raw (incl flour)	RAC	0.023	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.01	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.023	0.01	0.00	1.12	0.03	NC	-	0.03	0.00	0.56	0.01	NC	-

**BENZOVINDIFLUPYR (261)**

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 µg/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
CF 1210	Wheat, germ	PP	0.017	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.00	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.012	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	0.008	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	0.008	301.24	2.41	268.64	2.15	30.21	0.24	222.51	1.78	134.73	1.08	343.12	2.74
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
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.175	3.55	0.62	19.31	3.38	4.98	0.87	3.02	0.53	7.85	1.37	3.98	0.70
-	Barley, pot&pearled	PP	0.083	7.12	0.59	7.34	0.61	0.02	0.00	0.03	0.00	0.67	0.06	0.20	0.02
-	Barley, flour (white flour and wholemeal flour)	PP	0.072	2.93	0.21	0.30	0.02	0.02	0.00	0.01	0.00	0.48	0.03	0.01	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.175	0.05	0.01	7.05	1.23	0.10	0.02	1.71	0.30	0.96	0.17	0.04	0.01
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
GS 0659	Sugar cane, raw	RAC	0.069	38.16	2.63	NC	-	12.58	0.87	0.34	0.02	17.79	1.23	42.78	2.95
-	Sugar cane, molasses	PP	0.006	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.003	61.52	0.18	86.27	0.26	18.80	0.06	80.02	0.24	66.39	0.20	56.32	0.17
SO 0495	Rape seed, raw	RAC	0.023	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	0.023	0.35	0.01	0.44	0.01	0.19	0.00	0.97	0.02	3.28	0.08	0.77	0.02
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	0.46	0.00	1.21	0.01	6.64	0.07	2.52	0.03	1.25	0.01	1.83	0.02
OR 0697	Peanut oil, edible	PP	0.016	0.36	0.01	0.01	0.00	2.57	0.04	0.07	0.00	2.29	0.04	0.36	0.01
-	Peanut butter	PP	0.006	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 (i.e. green coffee)	RAC	0.015	0.96	0.01	0.16	0.00	0.91	0.01	0.27	0.00	1.37	0.02	0.46	0.01
SM 0716	Coffee bean, roasted	PP	0.006	0.19	0.00	0.91	0.01	0.16	0.00	2.50	0.02	0.39	0.00	0.40	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.008	0.07	0.00	0.94	0.01	0.07	0.00	0.70	0.01	0.07	0.00	0.29	0.00
-	Coffee bean, substitutes, containing coffee	PP	0.015	0.01	0.00	0.01	0.00	0.16	0.00	0.17	0.00	0.02	0.00	0.03	0.00
HS 0444	Peppers, chili, dried	PP	0.89	0.42	0.37	0.53	0.47	0.84	0.75	0.50	0.45	0.95	0.85	0.37	0.33
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 80% as muscle	RAC	0.01	24.96	0.25	57.95	0.58	16.70	0.17	38.38	0.38	26.46	0.26	29.00	0.29
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	6.24	0.06	14.49	0.14	4.18	0.04	9.60	0.10	6.62	0.07	7.25	0.07

**BENZOVINDIFLUPYR (261)**

## 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 µg/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												
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	0.014	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	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 (µg/person)=				23.8				34.4				8.0				24.8				15.2				56.6			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				3000				3000				3000				3000				3000							
%ADI=				0.8%				1.1%				0.3%				0.8%				0.5%				1.9%			
Rounded %ADI=				1%				1%				0%				1%				1%				2%			

**BENZOVINDIFLUPYR (261)**

## 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 µg/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
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.058	51.09	2.96	65.40	3.79	42.71	2.48	45.29	2.63	62.51	3.63	7.74	0.45
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.003	14.88	0.04	11.98	0.04	0.15	0.00	9.98	0.03	30.32	0.09	3.47	0.01
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.29	6.33	1.84	11.22	3.25	5.21	1.51	9.38	2.72	4.55	1.32	0.78	0.23
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.7	3.09	2.16	1.51	1.06	0.03	0.02	1.38	0.97	4.26	2.98	0.42	0.29
JF 0269	Grape juice (from wine grapes)	PP	0.022	0.56	0.01	1.96	0.04	0.02	0.00	2.24	0.05	2.27	0.05	0.34	0.01
-	Graps must (from wine-grapes)	PP	0.38	0.16	0.06	0.09	0.03	0.01	0.00	0.12	0.05	0.11	0.04	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.023	88.93	2.05	62.41	1.44	1.84	0.04	25.07	0.58	61.17	1.41	5.84	0.13
VA 2031	Subgroup of bulb onions	RAC	0.01	20.67	0.21	31.32	0.31	37.52	0.38	35.08	0.35	11.77	0.12	13.74	0.14
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.023	27.81	0.64	41.93	0.96	123.30	2.84	49.47	1.14	15.95	0.37	35.99	0.83
VO 0448	Tomato, raw	RAC	0.089	32.13	2.86	51.27	4.56	34.92	3.11	73.37	6.53	15.15	1.35	8.88	0.79
-	Tomato, canned (& peeled)	PP	0.003	7.57	0.02	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.02	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.037	4.96	0.18	3.20	0.12	0.15	0.01	1.61	0.06	6.88	0.25	0.52	0.02
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.008	0.80	0.01	0.07	0.00	0.05	0.00	0.61	0.00	0.40	0.00	0.08	0.00



**BENZOVINDIFLUPYR (261)**

**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 µg/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
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.089	6.39	0.57	15.53	1.38	19.13	1.70	10.53	0.94	8.29	0.74	5.25	0.47
VO 2046	Subgroup of eggplants	RAC	0.089	1.01	0.09	1.69	0.15	21.37	1.90	3.00	0.27	1.40	0.12	NC	-
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 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	0.02	0.00	0.33	0.00	6.64	0.07	3.94	0.04	NC	-	5.78	0.06
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	1.87	0.01	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0055	NC	-	NC	-	0.68	0.00	0.87	0.00	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0066	19.06	0.13	21.06	0.14	5.94	0.04	33.78	0.22	40.05	0.26	13.39	0.09
-	Soya sauce	PP	0.004	0.45	0.00	0.29	0.00	2.93	0.01	4.35	0.02	0.09	0.00	0.70	0.00
-	Soya flour	PP	0.004	0.22	0.00	0.27	0.00	0.29	0.00	0.17	0.00	NC	-	NC	-
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.011	3.80	0.04	1.25	0.01	0.90	0.01	2.33	0.03	2.70	0.03	3.83	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
GC 0650	Rye, raw (incl flour)	RAC	0.023	3.21	0.07	35.38	0.81	0.21	0.00	6.50	0.15	1.49	0.03	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.023	0.01	0.00	0.17	0.00	0.29	0.01	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	0.023	NC	-	NC	-	0.02	0.00	0.83	0.02	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.017	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	0.012	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	0.008	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	0.008	198.08	1.58	193.03	1.54	106.24	0.85	185.09	1.48	168.67	1.35	131.59	1.05
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
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.175	35.17	6.15	49.45	8.65	8.86	1.55	34.31	6.00	44.87	7.85	15.82	2.77
-	Barley, pot&pearled	PP	0.083	0.57	0.05	2.56	0.21	0.33	0.03	0.56	0.05	0.36	0.03	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.072	0.08	0.01	0.03	0.00	0.01	0.00	0.05	0.00	0.68	0.05	0.05	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.175	7.50	1.31	6.26	1.10	0.15	0.03	4.87	0.85	3.16	0.55	2.98	0.52
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
GS 0659	Sugar cane, raw	RAC	0.069	NC	-	NC	-	4.27	0.29	0.01	0.00	NC	-	3.24	0.22
-	Sugar cane, molasses	PP	0.006	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.003	92.24	0.28	95.72	0.29	24.12	0.07	77.39	0.23	117.73	0.35	100.67	0.30
SO 0495	Rape seed, raw	RAC	0.023	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-



**BENZOVINDIFLUPYR (261)**

## International Estimated Daily Intake (IEDI)

ADI = 0 - 0.05 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.058	68.85	3.99	10.93	0.63	70.82	4.11	189.78	11.01	19.56	1.13
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.003	0.03	0.00	0.10	0.00	7.19	0.02	0.03	0.00	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.29	0.14	0.04	0.36	0.10	15.22	4.41	0.01	0.00	0.09	0.03
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.7	0.01	0.01	0.13	0.09	1.06	0.74	0.01	0.01	0.03	0.02
JF 0269	Grape juice (from wine grapes)	PP	0.022	0.01	0.00	0.01	0.00	0.41	0.01	0.01	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.38	0.01	0.00	0.01	0.00	0.11	0.04	0.01	0.00	0.19	0.07
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.023	0.31	0.01	0.23	0.01	60.43	1.39	0.52	0.01	31.91	0.73
VA 2031	Subgroup of bulb onions	RAC	0.01	9.83	0.10	22.30	0.22	34.69	0.35	9.65	0.10	2.39	0.02
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.023	5.96	0.14	9.74	0.22	51.82	1.19	13.61	0.31	0.05	0.00
VO 0448	Tomato, raw	RAC	0.089	12.99	1.16	4.79	0.43	58.40	5.20	0.92	0.08	0.09	0.01
-	Tomato, canned (& peeled)	PP	0.003	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	0.037	0.58	0.02	0.22	0.01	2.21	0.08	0.24	0.01	3.10	0.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.008	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), incl okra	RAC	0.089	15.20	1.35	14.23	1.27	25.14	2.24	0.91	0.08	NC	-
VO 2046	Subgroup of eggplants	RAC	0.089	1.31	0.12	8.26	0.74	3.95	0.35	0.01	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 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.01	2.76	0.03	0.07	0.00	0.33	0.00	3.16	0.03	NC	-
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.0055	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.0066	2.32	0.02	2.54	0.02	18.70	0.12	2.51	0.02	6.29	0.04
-	Soya sauce	PP	0.004	0.01	0.00	0.13	0.00	0.17	0.00	0.01	0.00	0.56	0.00
-	Soya flour	PP	0.004	0.11	0.00	0.08	0.00	0.07	0.00	0.01	0.00	0.03	0.00
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.011	1.53	0.02	2.52	0.03	3.52	0.04	3.56	0.04	0.74	0.01
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
GC 0650	Rye, raw (incl flour)	RAC	0.023	0.03	0.00	0.01	0.00	13.95	0.32	0.01	0.00	0.88	0.02
GC 0653	Triticale, raw (incl flour)	RAC	0.023	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	0.023	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.02
CF 1210	Wheat, germ	PP	0.017	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-

**BENZOVINDIFLUPYR (261)**

## 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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
CP 1212	Wheat, wholemeal bread	PP	0.012	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	0.008	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	0.008	44.78	0.36	86.96	0.70	214.05	1.71	20.31	0.16	103.60	0.83
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
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.175	3.15	0.55	2.31	0.40	43.92	7.69	3.72	0.65	16.26	2.85
-	Barley, pot&pearled	PP	0.083	5.46	0.45	0.01	0.00	1.44	0.12	0.01	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.072	0.02	0.00	NC	-	0.32	0.02	0.01	0.00	NC	-
GC 0647	Oats, raw (incl rolled)	RAC	0.175	0.37	0.06	0.07	0.01	2.79	0.49	0.10	0.02	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
GS 0659	Sugar cane, raw	RAC	0.069	5.62	0.39	50.91	3.51	NC	-	11.04	0.76	0.10	0.01
-	Sugar cane, molasses	PP	0.006	NC	-	NC	-	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.003	28.13	0.08	55.38	0.17	78.09	0.23	18.04	0.05	45.60	0.14
SO 0495	Rape seed, raw	RAC	0.023	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.023	0.07	0.00	0.03	0.00	4.62	0.11	0.03	0.00	NC	-
SO 0697	Peanuts, nutmeat, raw (incl roasted, excl oil, excl butter)	RAC	0.01	7.14	0.07	0.42	0.00	1.83	0.02	6.22	0.06	0.53	0.01
OR 0697	Peanut oil, edible	PP	0.016	5.02	0.08	0.05	0.00	0.17	0.00	0.29	0.00	NC	-
-	Peanut butter	PP	0.006	0.01	0.00	0.03	0.00	0.05	0.00	NC	-	NC	-
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.015	0.83	0.01	0.69	0.01	1.09	0.02	2.91	0.04	0.82	0.01
SM 0716	Coffee bean, roasted	PP	0.006	0.02	0.00	0.41	0.00	7.50	0.05	0.01	0.00	0.06	0.00
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.008	0.03	0.00	0.05	0.00	0.60	0.00	0.01	0.00	5.53	0.04
-	Coffee bean, substitutes, containing coffee	PP	0.015	0.01	0.00	0.03	0.00	0.13	0.00	0.01	0.00	NC	-
HS 0444	Peppers, chili, dried	PP	0.89	0.58	0.52	1.27	1.13	1.21	1.08	0.12	0.11	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.01	23.34	0.23	40.71	0.41	97.15	0.97	18.06	0.18	57.71	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.01	5.84	0.06	10.18	0.10	24.29	0.24	4.52	0.05	14.43	0.14
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	0.014	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	108.75	0.00	70.31	0.00	436.11	0.00	61.55	0.00	79.09	0.00

**BENZOVINDIFLUPYR (261)**

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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
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 (µg/person)=	12.3	11.0	44.2	16.0	9.9
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (µg/person)=	3000	3000	3000	3000	3000
%ADI=	0.4%	0.4%	1.5%	0.5%	0.3%
Rounded %ADI=	0%	0%	1%	1%	0%

**BIFENTHRIN (178)**

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 µg/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, incl kumquat commodities)	RAC	0.05	34.91	1.75	16.51	0.83	17.23	0.86	104.48	5.22
FB 0264	Blackberries, raw	RAC	0.29	0.35	0.10	0.11	0.03	0.01	0.00	0.02	0.01	0.01	0.00	1.23	0.36
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	0.29	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00
FB 0272	Raspberries, red, black, raw	RAC	0.29	0.07	0.02	0.93	0.27	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00
FB 0020	Blueberries, raw	RAC	0.67	0.01	0.01	0.03	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine )	RAC	0.06	16.25	0.98	28.96	1.74	2.87	0.17	24.22	1.45	9.33	0.56	68.64	4.12
FB 0275	Strawberry, raw	RAC	0.46	0.70	0.32	2.01	0.92	0.04	0.02	1.36	0.63	0.37	0.17	2.53	1.16
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	5.23	0.05	6.94	0.07	99.45	0.99	32.47	0.32	48.30	0.48	24.70	0.25
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	10.48	0.10	0.01	0.00	7.24	0.07	6.87	0.07	19.98	0.20	6.25	0.06
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
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.115	6.43	0.74	40.26	4.63	0.80	0.09	9.94	1.14	12.07	1.39	17.73	2.04
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.06	42.41	2.54	76.50	4.59	10.69	0.64	85.07	5.10	24.98	1.50	203.44	12.21
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	2.34	0.09	1.33	0.05	1.57	0.06	4.24	0.17	0.34	0.01	2.83	0.11
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.07	1.97	0.14	NC	-	3.68	0.26	3.24	0.23	5.72	0.40	1.57	0.11
VO 0444	Peppers, chili, raw	RAC	0.14	3.99	0.56	7.30	1.02	2.93	0.41	5.62	0.79	NC	-	17.44	2.44
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	0.05	5.58	0.28	4.31	0.22	0.89	0.04	9.31	0.47	13.64	0.68	20.12	1.01
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.16	0.03	0.03	0.31	0.36	0.01	0.01	0.05	0.06	0.47	0.55	0.11	0.13
VL 0494	Radish leaves, raw	RAC	1.75	0.26	0.46	0.45	0.79	0.28	0.49	0.68	1.19	NC	-	0.33	0.58
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0	1.97	0.00	0.51	0.00	0.02	0.00	0.79	0.00	3.68	0.00	3.80	0.00
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
OR 0541	Soya oil, refined	PP	0.05	12.99	0.65	10.43	0.52	3.63	0.18	13.10	0.66	10.70	0.54	13.10	0.66
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.05	87.83	4.39	374.04	18.70	668.92	33.45	121.64	6.08	94.20	4.71	247.11	12.36
VS 0624	Celery	RAC	0.7	2.14	1.50	3.79	2.65	2.35	1.65	5.69	3.98	0.02	0.01	2.75	1.93
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.25	381.15	95.29	341.55	85.39	38.35	9.59	281.89	70.47	172.83	43.21	434.07	108.52
GC 0654	Wheat, raw (incl meslin)	RAC	0.25	0.01	0.00	1.12	0.28	NC	-	0.01	0.00	0.56	0.14	NC	-
-	Wheat, bulgur	PP	0.25	NC	-	NC	-	NC	-	0.03	0.01	NC	-	NC	-

**BIFENTHRIN (178)**

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 µg/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
CF 1210	Wheat, germ	PP	0.45	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.06	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.19	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.03	0.01	0.01	0.00
CP 1211	Wheat, white bread	PP	0.061	0.25	0.02	0.63	0.04	0.12	0.01	0.43	0.03	1.39	0.08	0.22	0.01
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.25	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.078	301.24	23.50	268.64	20.95	30.21	2.36	222.51	17.36	134.73	10.51	343.12	26.76
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
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 0495	Rape seed, raw	RAC	0.05	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.04	0.01	0.00
OR 0495	Rape seed oil, edible	PP	0.08	0.35	0.03	0.44	0.04	0.19	0.02	0.97	0.08	3.28	0.26	0.77	0.06
OR 0691	Cotton seed oil, edible	PP	0.005	3.22	0.02	1.54	0.01	1.01	0.01	0.74	0.00	1.12	0.01	2.93	0.01
DH 1100	Hops, dry	RAC	1.9	0.01	0.02	0.04	0.08	0.01	0.02	0.01	0.02	NC	-	0.01	0.02
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	5.2	2.28	11.86	1.98	10.30	0.46	2.39	2.43	12.64	1.29	6.71	3.04	15.81
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	0.59	6.24	3.68	14.49	8.55	4.18	2.46	9.60	5.66	6.62	3.90	7.25	4.28
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.59	3.29	1.94	6.14	3.62	0.82	0.48	1.57	0.93	2.23	1.32	1.07	0.63
MO 0105	Edible offal (mammalian), raw	RAC	0.07	4.79	0.34	9.68	0.68	2.97	0.21	5.49	0.38	3.84	0.27	5.03	0.35
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.053	289.65	15.35	485.88	25.75	26.92	1.43	239.03	12.67	199.91	10.60	180.53	9.57
Total intake (µg/person)=								173.7	201.4	62.8	156.5	98.6	219.1		
Bodyweight per region (kg bw) =								60	60	60	60	60	60		
ADI (µg/person)=								600	600	600	600	600	600		
%ADI=								28.9%	33.6%	10.5%	26.1%	16.4%	36.5%		
Rounded %ADI=								30%	30%	10%	30%	20%	40%		

<b>BIFENTHRIN (178)</b>				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 µg/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	0.05	114.42	5.72	62.91	3.15	26.97	1.35	96.72	4.84	96.22	4.81	563.19	28.16
FB 0264	Blackberries, raw	RAC	0.29	0.09	0.03	0.52	0.15	0.14	0.04	0.24	0.07	NC	-	0.01	0.00
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	0.29	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	0.01	0.00
FB 0272	Raspberries, red, black, raw	RAC	0.29	0.47	0.14	0.91	0.26	0.01	0.00	0.99	0.29	1.14	0.33	NC	-
FB 0020	Blueberries, raw	RAC	0.67	0.04	0.03	0.23	0.15	0.01	0.01	0.83	0.56	0.33	0.22	NC	-
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine )	RAC	0.06	142.23	8.53	105.77	6.35	7.87	0.47	52.44	3.15	109.22	6.55	10.96	0.66
FB 0275	Strawberry, raw	RAC	0.46	4.49	2.07	5.66	2.60	0.02	0.01	6.63	3.05	5.75	2.65	0.05	0.02
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	25.76	0.26	23.65	0.24	23.83	0.24	24.37	0.24	19.43	0.19	101.55	1.02
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	1.80	0.02	0.63	0.01	10.05	0.10	1.07	0.01	3.52	0.04	16.44	0.16
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
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.115	20.71	2.38	39.81	4.58	25.06	2.88	37.93	4.36	18.12	2.08	16.74	1.93
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.06	44.88	2.69	55.49	3.33	35.44	2.13	75.65	4.54	27.00	1.62	9.61	0.58
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	4.96	0.20	3.20	0.13	0.15	0.01	1.61	0.06	6.88	0.28	0.52	0.02
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.07	NC	-	NC	-	0.04	0.00	0.17	0.01	NC	-	0.72	0.05
VO 0444	Peppers, chili, raw	RAC	0.14	5.57	0.78	14.00	1.96	8.25	1.16	5.77	0.81	6.44	0.90	2.53	0.35
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	0.05	1.01	0.05	1.69	0.08	21.37	1.07	3.00	0.15	1.40	0.07	NC	-
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.16	NC	-	NC	-	NC	-	NC	-	NC	-	0.13	0.15
VL 0494	Radish leaves, raw	RAC	1.75	NC	-	NC	-	NC	-	3.78	6.62	NC	-	0.48	0.84
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0	10.72	0.00	1.99	0.00	2.72	0.00	4.26	0.00	4.23	0.00	NC	-
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
OR 0541	Soya oil, refined	PP	0.05	19.06	0.95	21.06	1.05	5.94	0.30	33.78	1.69	40.05	2.00	13.39	0.67
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.05	290.31	14.52	300.35	15.02	214.25	10.71	242.72	12.14	348.67	17.43	137.52	6.88
VS 0624	Celery	RAC	0.7	7.68	5.38	2.85	2.00	NC	-	3.34	2.34	16.83	11.78	4.04	2.83
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.25	253.07	63.27	244.73	61.18	134.44	33.61	235.10	58.78	216.39	54.10	167.40	41.85



**BIFENTHRIN (178)**

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 µg/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												
GC 0654	Wheat, raw (incl meslin)	RAC	0.25	NC	-	NC	-	NC	-	0.01	0.00	NC	-	NC	-												
-	Wheat, bulgur	PP	0.25	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-												
CF 1210	Wheat, germ	PP	0.45	0.97	0.44	0.10	0.05	0.03	0.01	0.01	0.00	NC	-	0.04	0.02												
CP 1212	Wheat, wholemeal bread	PP	0.19	0.03	0.01	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.01	0.02	0.00												
CP 1211	Wheat, white bread	PP	0.061	1.30	0.08	0.46	0.03	0.06	0.00	0.22	0.01	2.44	0.15	0.77	0.05												
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.25	NC	-	NC	-	NC	-	4.36	1.09	NC	-	NC	-												
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.078	198.08	15.45	193.03	15.06	106.24	8.29	185.09	14.44	168.67	13.16	131.59	10.26												
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												
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 0495	Rape seed, raw	RAC	0.05	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-												
OR 0495	Rape seed oil, edible	PP	0.08	12.52	1.00	7.63	0.61	3.00	0.24	6.01	0.48	NC	-	NC	-												
OR 0691	Cotton seed oil, edible	PP	0.005	1.68	0.01	0.66	0.00	1.13	0.01	1.18	0.01	0.89	0.00	0.37	0.00												
DH 1100	Hops, dry	RAC	1.9	NC	-	NC	-	0.02	0.04	0.02	0.04	NC	-	NC	-												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	5.2	2.91	15.13	1.73	9.00	1.14	5.93	1.85	9.62	2.29	11.91	0.74	3.85												
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	0.59	28.01	16.52	30.18	17.81	15.86	9.36	22.25	13.13	24.06	14.20	10.25	6.05												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.59	6.44	3.80	15.51	9.15	3.79	2.24	8.29	4.89	18.44	10.88	8.00	4.72												
MO 0105	Edible offal (mammalian), raw	RAC	0.07	15.17	1.06	5.19	0.36	6.30	0.44	6.78	0.47	3.32	0.23	3.17	0.22												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.053	388.92	20.61	335.88	17.80	49.15	2.60	331.25	17.56	468.56	24.83	245.45	13.01												
Total intake (µg/person)=				195.1				187.4				92.4				183.0				199.5				134.3			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (µg/person)=				600				600				550				600				600				600			
%ADI=				32.5%				31.2%				16.8%				30.5%				33.3%				22.4%			
Rounded %ADI=				30%				30%				20%				30%				30%				20%			

<b>BIFENTHRIN (178)</b>				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				Intake = daily intake: µg/person					
				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	0.05	21.16	1.06	2.94	0.15	58.52	2.93	0.44	0.02	5.13	0.26
FB 0264	Blackberries, raw	RAC	0.29	0.01	0.00	7.29	2.11	0.25	0.07	0.01	0.00	NC	-
FB 0266	Dewberries, incl boysen- & loganberry, raw	RAC	0.29	0.01	0.00	0.01	0.00	NC	-	0.01	0.00	NC	-
FB 0272	Raspberries, red, black, raw	RAC	0.29	0.01	0.00	0.01	0.00	2.04	0.59	0.01	0.00	NC	-
FB 0020	Blueberries, raw	RAC	0.67	NC	-	NC	-	0.20	0.13	NC	-	NC	-
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine )	RAC	0.06	0.60	0.04	1.26	0.08	103.25	6.20	0.74	0.04	44.23	2.65
FB 0275	Strawberry, raw	RAC	0.46	0.01	0.00	0.01	0.00	3.35	1.54	0.01	0.00	0.01	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.01	44.80	0.45	118.17	1.18	25.25	0.25	454.49	4.54	310.23	3.10
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	12.25	0.12	6.83	0.07	0.76	0.01	0.01	0.00	20.12	0.20
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
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.115	5.46	0.63	4.28	0.49	58.72	6.75	0.02	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.06	13.17	0.79	4.92	0.30	62.69	3.76	1.04	0.06	0.11	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	0.58	0.02	0.22	0.01	2.21	0.09	0.24	0.01	3.10	0.12
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.07	6.23	0.44	0.10	0.01	NC	-	NC	-	NC	-
VO 0444	Peppers, chili, raw	RAC	0.14	3.47	0.49	3.56	0.50	16.30	2.28	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	0.05	1.31	0.07	8.26	0.41	3.95	0.20	0.01	0.00	NC	-
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	1.16	0.04	0.05	0.03	0.03	NC	-	0.01	0.01	NC	-
VL 0494	Radish leaves, raw	RAC	1.75	0.44	0.77	0.32	0.56	NC	-	0.30	0.53	0.59	1.03
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0	0.21	0.00	0.02	0.00	5.51	0.00	0.02	0.00	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
OR 0541	Soya oil, refined	PP	0.05	2.32	0.12	2.54	0.13	18.70	0.94	2.51	0.13	6.29	0.31
VR 0075	Group of Root and tuber vegetables, raw (incl processed)	RAC	0.05	282.25	14.11	232.11	11.61	281.91	14.10	620.21	31.01	459.96	23.00
VS 0624	Celery	RAC	0.7	3.66	2.56	2.65	1.86	4.84	3.39	2.47	1.73	4.94	3.46
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl germ, incl wholemeal bread, incl white flour products, incl white bread)	RAC	0.25	57.20	14.30	110.47	27.62	272.62	68.16	25.82	6.46	132.04	33.01
GC 0654	Wheat, raw (incl meslin)	RAC	0.25	NC	-	NC	-	NC	-	NC	-	0.97	0.24
-	Wheat, bulgur	PP	0.25	0.01	0.00	NC	-	NC	-	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.45	0.04	0.02	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.19	0.01	0.00	0.01	0.00	0.03	0.01	0.01	0.00	0.01	0.00

**BIFENTHRIN (178)**

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				Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
CP 1211	Wheat, white bread	PP	0.061	0.43	0.03	0.41	0.03	1.56	0.10	0.11	0.01	0.07	0.00	
-	Wheat, Fermented Beverages (Korean jakju and takju)	PP	0.25	NC	-	NC	-	NC	-	NC	-	NC	-	
CF 1211	Wheat, white flour (incl white flour products: starch, gluten, macaroni, pastry)	PP	0.078	44.78	3.49	86.96	6.78	214.05	16.70	20.31	1.58	103.60	8.08	
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	
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 0495	Rape seed, raw	RAC	0.05	NC	-	0.01	0.00	NC	-	NC	-	NC	-	
OR 0495	Rape seed oil, edible	PP	0.08	0.07	0.01	0.03	0.00	4.62	0.37	0.03	0.00	NC	-	
OR 0691	Cotton seed oil, edible	PP	0.005	1.28	0.01	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00	
DH 1100	Hops, dry	RAC	1.9	NC	-	NC	-	0.04	0.08	NC	-	NC	-	
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	5.2	0.53	2.76	5.25	27.30	0.86	4.47	0.56	2.91	0.88	4.58	
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	0.59	5.84	3.44	10.18	6.01	24.29	14.33	4.52	2.66	14.43	8.51	
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.59	1.05	0.62	1.14	0.67	18.69	11.03	0.94	0.55	3.12	1.84	
MO 0105	Edible offal (mammalian), raw	RAC	0.07	4.64	0.32	1.97	0.14	10.01	0.70	3.27	0.23	3.98	0.28	
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.053	108.75	5.76	70.31	3.73	436.11	23.11	61.55	3.26	79.09	4.19	
Total intake (µg/person)=								57.5	104.4	196.2	61.0	117.3		
Bodyweight per region (kg bw) =								60	60	60	60	60		
ADI (µg/person)=								600	600	600	600	600		
%ADI=								9.6%	17.4%	32.7%	10.2%	19.5%		
Rounded %ADI=								10%	20%	30%	10%	20%		

**BUPROFEZIN (173)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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 (excl kumquat commodities)	RAC	0.04	2.42	0.10	2.15	0.09	0.43	0.02	10.74	0.43	6.59	0.26	14.06	0.56
-	Lemon, juice (single strength, incl. concentrated)	PP	0.12	0.01	0.00	0.01	0.00	0.11	0.01	0.09	0.01	0.18	0.02	0.17	0.02
FC 0003	Subgroup of Mandarins, raw	RAC	0.04	6.18	0.25	3.66	0.15	0.25	0.01	6.82	0.27	3.49	0.14	19.38	0.78
-	Subgroup of Mandarins, juice	PP	0.12	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.04	20.66	0.83	5.23	0.21	11.90	0.48	37.90	1.52	21.16	0.85	56.46	2.26
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.12	1.27	0.15	2.20	0.26	0.09	0.01	11.81	1.42	0.46	0.06	1.69	0.20
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.04	0.64	0.03	0.35	0.01	0.93	0.04	6.10	0.24	1.01	0.04	1.36	0.05
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.12	0.01	0.00	0.16	0.02	0.02	0.00	1.97	0.24	0.12	0.01	0.77	0.09
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.28	13.49	3.78	26.63	7.46	15.05	4.21	16.28	4.56	6.47	1.81	47.88	13.41
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.16	0.32	0.05	3.07	0.49	0.07	0.01	5.00	0.80	0.29	0.05	5.57	0.89
FP 0230	Pear, raw	RAC	1.09	2.16	2.35	6.24	6.80	0.05	0.05	4.07	4.44	1.16	1.26	5.34	5.82
FS 0013	Subgroup of Cherries, raw	RAC	0.73	0.92	0.67	9.15	6.68	0.01	0.01	0.61	0.45	0.06	0.04	6.64	4.85
FS 0014	Subgroup of Plums, raw	RAC	0.155	2.40	0.37	8.60	1.33	0.06	0.01	2.52	0.39	0.58	0.09	4.16	0.64
DF 0014	Plums, dried (prunes)	PP	0.465	0.09	0.04	0.06	0.03	0.01	0.00	0.18	0.08	0.04	0.02	0.06	0.03
-	Peaches and nectarines, raw	RAC	1.355	2.87	3.89	2.21	2.99	0.15	0.20	5.94	8.05	1.47	1.99	15.66	21.22
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.17	13.02	2.21	9.25	1.57	0.03	0.01	16.91	2.87	3.70	0.63	54.44	9.25
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.27	0.51	0.14	0.51	0.14	0.01	0.00	1.27	0.34	0.12	0.03	2.07	0.56
JF 0269	Grape juice (from wine grapes)	PP	0.073	0.14	0.01	0.29	0.02	0.05	0.00	0.30	0.02	0.24	0.02	0.05	0.00
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.2	0.67	0.13	12.53	2.51	2.01	0.40	1.21	0.24	3.53	0.71	4.01	0.80
FB 0275	Strawberry, raw	RAC	0.44	0.70	0.31	2.01	0.88	0.04	0.02	1.36	0.60	0.37	0.16	2.53	1.11
FT 0305	Table olives, raw (incl preserved)	RAC	1.125	0.70	0.79	0.32	0.36	0.01	0.01	1.53	1.72	0.17	0.19	1.85	2.08
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	0.01	5.23	0.05	6.94	0.07	99.45	0.99	32.47	0.32	48.30	0.48	24.70	0.25
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	10.48	0.10	0.01	0.00	7.24	0.07	6.87	0.07	19.98	0.20	6.25	0.06
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.195	53.14	10.36	86.21	16.81	6.28	1.22	92.76	18.09	15.64	3.05	155.30	30.28
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.24	42.04	10.09	76.13	18.27	10.69	2.57	84.59	20.30	24.92	5.98	203.27	48.78
-	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

**BUPROFEZIN (173)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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												
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.053	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 0444	Peppers, chili, raw	RAC	0.33	3.99	1.32	7.30	2.41	2.93	0.97	5.62	1.85	NC	-	17.44	5.76												
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.33	4.49	1.48	6.44	2.13	7.21	2.38	5.68	1.87	9.52	3.14	8.92	2.94												
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	72.79	0.73	59.05	0.59	20.55	0.21	74.20	0.74	61.12	0.61	73.24	0.73												
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												
-	Olive oil (virgin and residue oil)	PP	3.9	2.17	8.46	0.13	0.51	0.05	0.20	1.32	5.15	0.10	0.39	2.76	10.76												
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.08	0.96	0.08	0.16	0.01	0.91	0.07	0.27	0.02	1.37	0.11	0.46	0.04												
SM 0716	Coffee bean, roasted	PP	0.0256	0.19	0.00	0.91	0.02	0.16	0.00	2.50	0.06	0.39	0.01	0.40	0.01												
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.016	0.07	0.00	0.94	0.02	0.07	0.00	0.70	0.01	0.07	0.00	0.29	0.00												
HH 0722	Basil leaves, raw (incl dried)	RAC	0.45	0.14	0.06	0.26	0.12	0.16	0.07	0.38	0.17	NC	-	0.19	0.09												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	9	2.28	20.52	1.98	17.82	0.46	4.14	2.43	21.87	1.29	11.61	3.04	27.36												
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	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)	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 (µg/person)=				70.1				91.2				19.1				100.9				34.8				192.8			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				540				540				540				540				540							
%ADI=				13.0%				16.9%				3.5%				18.7%				6.4%				35.7%			
Rounded %ADI=				10%				20%				4%				20%				6%				40%			

**BUPROFEZIN (173)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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 (excl kumquat commodities)	RAC	0.04	3.78	0.15	8.84	0.35	0.92	0.04	6.71	0.27	4.09	0.16	4.57	0.18
-	Lemon, juice (single strength, incl. concentrated)	PP	0.12	0.60	0.07	0.36	0.04	0.01	0.00	1.49	0.18	0.43	0.05	0.24	0.03
FC 0003	Subgroup of Mandarins, raw	RAC	0.04	12.34	0.49	14.99	0.60	16.08	0.64	10.76	0.43	9.94	0.40	NC	-
-	Subgroup of Mandarins, juice	PP	0.12	0.04	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.04	15.68	0.63	24.00	0.96	6.80	0.27	29.09	1.16	15.39	0.62	160.47	6.42
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.12	33.31	4.00	1.78	0.21	0.28	0.03	18.97	2.28	14.01	1.68	13.36	1.60
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.04	2.19	0.09	1.24	0.05	0.60	0.02	3.44	0.14	4.60	0.18	299.96	12.00
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.12	2.89	0.35	1.61	0.19	0.02	0.00	1.15	0.14	7.39	0.89	33.07	3.97
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.28	41.14	11.52	56.49	15.82	26.64	7.46	31.58	8.84	51.94	14.54	3.05	0.85
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.16	14.88	2.38	11.98	1.92	0.15	0.02	9.98	1.60	30.32	4.85	3.47	0.56
FP 0230	Pear, raw	RAC	1.09	8.79	9.58	8.44	9.20	12.37	13.48	9.60	10.46	10.27	11.19	0.23	0.25
FS 0013	Subgroup of Cherries, raw	RAC	0.73	1.40	1.02	4.21	3.07	0.04	0.03	2.93	2.14	1.50	1.10	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.155	3.75	0.58	3.33	0.52	5.94	0.92	2.64	0.41	2.50	0.39	0.06	0.01
DF 0014	Plums, dried (prunes)	PP	0.465	0.61	0.28	0.35	0.16	0.05	0.02	0.35	0.16	0.49	0.23	0.13	0.06
-	Peaches and nectarines, raw	RAC	1.355	8.76	11.87	12.98	17.59	8.23	11.15	10.09	13.67	3.64	4.93	0.04	0.05
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.17	6.48	1.10	11.31	1.92	5.21	0.89	9.50	1.62	4.66	0.79	0.78	0.13
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.27	3.09	0.83	1.51	0.41	0.03	0.01	1.38	0.37	4.26	1.15	0.42	0.11
JF 0269	Grape juice (from wine grapes)	PP	0.073	0.56	0.04	1.96	0.14	0.02	0.00	2.24	0.16	2.27	0.17	0.34	0.02
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.2	88.93	17.79	62.41	12.48	1.84	0.37	25.07	5.01	61.17	12.23	5.84	1.17
FB 0275	Strawberry, raw	RAC	0.44	4.49	1.98	5.66	2.49	0.02	0.01	6.63	2.92	5.75	2.53	0.05	0.02
FT 0305	Table olives, raw (incl preserved)	RAC	1.125	2.00	2.25	2.48	2.79	0.01	0.01	1.21	1.36	1.64	1.85	0.27	0.30
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	0.01	25.76	0.26	23.65	0.24	23.83	0.24	24.37	0.24	19.43	0.19	101.55	1.02
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	1.80	0.02	0.63	0.01	10.05	0.10	1.07	0.01	3.52	0.04	16.44	0.16
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.195	27.81	5.42	41.93	8.18	123.30	24.04	49.47	9.65	15.95	3.11	35.99	7.02
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.24	43.88	10.53	55.41	13.30	35.38	8.49	74.88	17.97	26.50	6.36	9.51	2.28
-	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	0.053	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 0444	Peppers, chili, raw	RAC	0.33	5.57	1.84	14.00	4.62	8.25	2.72	5.77	1.90	6.44	2.13	2.53	0.83

**BUPROFEZIN (173)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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												
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.33	0.82	0.27	1.53	0.50	10.85	3.58	4.59	1.51	1.84	0.61	2.00	0.66												
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	106.33	1.06	117.78	1.18	42.12	0.42	195.70	1.96	222.52	2.23	80.47	0.80												
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												
-	Olive oil (virgin and residue oil)	PP	3.9	3.40	13.26	9.49	37.01	0.02	0.08	4.28	16.69	2.74	10.69	0.48	1.87												
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.08	0.60	0.05	NC	-	0.62	0.05	1.71	0.14	NC	-	3.51	0.28												
SM 0716	Coffee bean, roasted	PP	0.0256	7.02	0.18	9.75	0.25	0.02	0.00	5.09	0.13	13.38	0.34	0.77	0.02												
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.016	0.75	0.01	0.30	0.00	0.04	0.00	0.67	0.01	2.43	0.04	1.43	0.02												
HH 0722	Basil leaves, raw (incl dried)	RAC	0.45	0.52	0.23	0.05	0.02	3.23	1.45	0.18	0.08	0.12	0.05	0.27	0.12												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	9	2.91	26.19	1.73	15.57	1.14	10.26	1.85	16.65	2.29	20.61	0.74	6.66												
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	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)	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 (µg/person)=				127.9				153.0				87.6				121.2				108.6				50.9			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (µg/person)=				540				540				495				540				540				540			
%ADI=				23.7%				28.3%				17.7%				22.4%				20.1%				9.4%			
Rounded %ADI=				20%				30%				20%				20%				20%				9%			

## BUPROFEZIN (173)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/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 (excl kumquat commodities)	RAC	0.04	0.61	0.02	0.73	0.03	4.01	0.16	0.01	0.00	NC	-
-	Lemon, juice (single strength, incl. concentrated)	PP	0.12	0.01	0.00	0.01	0.00	0.16	0.02	0.01	0.00	NC	-
FC 0003	Subgroup of Mandarins, raw	RAC	0.04	0.16	0.01	0.27	0.01	9.06	0.36	0.01	0.00	0.02	0.00
-	Subgroup of Mandarins, juice	PP	0.12	0.01	0.00	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.04	1.18	0.05	1.11	0.04	14.28	0.57	0.05	0.00	1.08	0.04
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.12	0.08	0.01	0.26	0.03	12.61	1.51	0.14	0.02	0.33	0.04
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.04	0.63	0.03	0.01	0.00	1.58	0.06	0.01	0.00	NC	-
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.12	0.03	0.00	0.02	0.00	0.78	0.09	0.01	0.00	NC	-
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.28	66.67	18.67	2.06	0.58	55.83	15.63	188.29	52.72	1.38	0.39
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.16	0.03	0.00	0.10	0.02	7.19	1.15	0.03	0.00	NC	-
FP 0230	Pear, raw	RAC	1.09	0.07	0.08	0.14	0.15	9.45	10.30	0.01	0.01	0.14	0.15
FS 0013	Subgroup of Cherries, raw	RAC	0.73	0.01	0.01	0.01	0.01	5.96	4.35	0.01	0.01	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.155	0.07	0.01	0.01	0.00	15.56	2.41	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.465	0.01	0.00	0.01	0.00	0.37	0.17	0.01	0.00	NC	-
-	Peaches and nectarines, raw	RAC	1.355	0.02	0.03	0.01	0.01	7.47	10.12	0.01	0.01	NC	-
FB 0269	Grapes, raw (incl must, excl dried, excl juice, excl wine)	RAC	0.17	0.14	0.02	0.36	0.06	15.33	2.61	0.01	0.00	0.28	0.05
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.27	0.01	0.00	0.13	0.04	1.06	0.29	0.01	0.00	0.03	0.01
JF 0269	Grape juice (from wine grapes)	PP	0.073	0.01	0.00	0.01	0.00	0.41	0.03	0.01	0.00	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.2	0.31	0.06	0.23	0.05	60.43	12.09	0.52	0.10	31.91	6.38
FB 0275	Strawberry, raw	RAC	0.44	0.01	0.00	0.01	0.00	3.35	1.47	0.01	0.00	0.01	0.00
FT 0305	Table olives, raw (incl preserved)	RAC	1.125	0.01	0.01	0.01	0.01	1.75	1.97	0.01	0.01	0.24	0.27
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	0.01	44.80	0.45	118.17	1.18	25.25	0.25	454.49	4.54	310.23	3.10
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.01	12.25	0.12	6.83	0.07	0.76	0.01	0.01	0.00	20.12	0.20
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.195	5.96	1.16	9.74	1.90	51.82	10.10	13.61	2.65	0.05	0.01
VO 0448	Tomato, raw (incl canned, excl juice, excl paste)	RAC	0.24	13.10	3.14	4.90	1.18	62.16	14.92	1.04	0.25	0.09	0.02
-	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	0.053	0.05	0.00	0.01	0.00	0.42	0.02	0.01	0.00	0.02	0.00
VO 0444	Peppers, chili, raw	RAC	0.33	3.47	1.15	3.56	1.17	16.30	5.38	0.01	0.00	NC	-



**BUPROFEZIN (173)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.009 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
VO 0445	Peppers, sweet, raw (incl dried)	RAC	0.33	5.49	1.81	10.57	3.49	8.84	2.92	0.91	0.30	NC	-		
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	15.80	0.16	14.29	0.14	104.36	1.04	17.11	0.17	35.20	0.35		
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		
-	Olive oil (virgin and residue oil)	PP	3.9	0.03	0.12	0.02	0.08	2.14	8.35	0.01	0.04	0.10	0.39		
SB 0716	Coffee bean, raw (i.e. green coffee)	RAC	0.08	0.83	0.07	0.69	0.06	1.09	0.09	2.91	0.23	0.82	0.07		
SM 0716	Coffee bean, roasted	PP	0.0256	0.02	0.00	0.41	0.01	7.50	0.19	0.01	0.00	0.06	0.00		
-	Coffee bean, instant coffee (incl essences and concentrates)	PP	0.016	0.03	0.00	0.05	0.00	0.60	0.01	0.01	0.00	5.53	0.09		
HH 0722	Basil leaves, raw (incl dried)	RAC	0.45	0.25	0.11	0.18	0.08	0.13	0.06	0.17	0.08	0.33	0.15		
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	9	0.53	4.77	5.25	47.25	0.86	7.74	0.56	5.04	0.88	7.92		
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	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)	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 (µg/person)=				32.4				64.5				117.3			
Bodyweight per region (kg bw) =				60				60				60			
ADI (µg/person)=				540				540				540			
%ADI=				6.0%				11.9%				21.7%			
Rounded %ADI=				6%				10%				20%			



**CARBENDAZIM 0(72)**

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				Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
HS 0771	Anise, seed	RAC	0.525	0.01	0.01	0.50	0.26	NC	-	0.01	0.01	0.02	0.01	
HS 0774	Caraway, seed	RAC	0.525	0.01	0.01	0.50	0.26	0.22	0.12	0.01	0.01	0.02	0.01	
HS 0779	Coriander, seed	RAC	0.525	0.01	0.01	0.25	0.13	NC	-	0.01	0.01	0.01	0.01	
HS 0780	Cumin, seed	RAC	0.525	0.01	0.01	0.25	0.13	NC	-	0.01	0.01	0.01	0.01	
HS 0789	Nutmeg	RAC	0.525	0.01	0.01	0.02	0.01	0.01	0.01	0.01	0.01	NC	-	
Total intake (µg/person)=					0.0		0.8		0.1		0.0		0.0	
Bodyweight per region (kg bw) =					60		60		60		60		60	
ADI (µg/person)=					1800		1800		1800		1800		1800	
%ADI=					0.0%		0.0%		0.0%		0.0%		0.0%	
Rounded %ADI=					0%		0%		0%		0%		0%	

## CYCLANILIPROLE (296)

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 µg/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	0.087	32.25	2.81	11.67	1.02	16.70	1.45	76.01	6.61	33.90	2.95	92.97	8.09
JF 0001	Group of Citrus fruit, juice	PP	0.01	1.30	0.01	2.37	0.02	0.22	0.00	13.88	0.14	0.75	0.01	2.63	0.03
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.057	19.35	1.10	34.06	1.94	17.87	1.02	25.74	1.47	7.69	0.44	56.85	3.24
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.019	0.32	0.01	3.07	0.06	0.07	0.00	5.00	0.10	0.29	0.01	5.57	0.11
FS 0013	Subgroup of Cherries, raw	RAC	0.14	0.92	0.13	9.15	1.28	0.01	0.00	0.61	0.09	0.06	0.01	6.64	0.93
FS 0014	Subgroup of Plums, raw	RAC	0.052	2.40	0.12	8.60	0.45	0.06	0.00	2.52	0.13	0.58	0.03	4.16	0.22
DF 0014	Plums, dried (prunes)	PP	0.19	0.09	0.02	0.06	0.01	0.01	0.00	0.18	0.03	0.04	0.01	0.06	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.053	8.01	0.42	5.87	0.31	0.18	0.01	8.19	0.43	1.64	0.09	22.46	1.19
FB 2005	Subgroup of Caneberries, raw	RAC	0.27	0.42	0.11	1.05	0.28	0.01	0.00	0.02	0.01	0.02	0.01	1.24	0.33
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.275	0.53	0.15	1.31	0.36	0.40	0.11	1.66	0.46	0.01	0.00	0.99	0.27
JF 0269	Grape juice (from wine grapes)	PP	0.04	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	0.08	0.33	0.03	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	0.04	0.67	0.03	12.53	0.50	2.01	0.08	1.21	0.05	3.53	0.14	4.01	0.16
FB 1235	Table grapes, raw (incl dried grapes)	RAC	0.12	14.82	1.78	11.26	1.35	0.05	0.01	22.16	2.66	4.19	0.50	63.05	7.57
FB 0275	Strawberry, raw	RAC	0.12	0.70	0.08	2.01	0.24	0.04	0.00	1.36	0.16	0.37	0.04	2.53	0.30
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.28	2.54	0.71	0.49	0.14	0.01	0.00	3.57	1.00	7.79	2.18	3.12	0.87
VB 0041	Cabbages, head, raw	RAC	0.0325	2.73	0.09	27.92	0.91	0.55	0.02	4.47	0.15	4.27	0.14	10.25	0.33
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.021	10.52	0.22	39.36	0.83	2.07	0.04	25.74	0.54	2.80	0.06	44.83	0.94
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.041	42.62	1.75	46.85	1.92	4.21	0.17	67.02	2.75	12.84	0.53	110.47	4.53
VO 0448	Tomato, raw	RAC	0.033	41.73	1.38	75.65	2.50	10.66	0.35	82.87	2.73	24.75	0.82	200.93	6.63
-	Tomato, canned (& peeled)	PP	0.005	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.01	0.11	0.00	1.50	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	2.34	0.09	1.33	0.05	1.57	0.06	4.24	0.17	0.34	0.01	2.83	0.11
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.03	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 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.0525	8.48	0.45	13.74	0.72	10.13	0.53	11.29	0.59	9.52	0.50	26.36	1.38
VO 2046	Subgroup of eggplants	RAC	0.0525	5.58	0.29	4.31	0.23	0.89	0.05	9.31	0.49	13.64	0.72	20.12	1.06
VL 2050	Subgroup of Leafy greens	RAC	2.4	3.93	9.43	5.28	12.67	3.07	7.37	14.53	34.87	8.25	19.80	12.75	30.60
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.5	2.63	9.21	9.27	32.45	1.86	6.51	5.82	20.37	19.53	68.36	4.90	17.15
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	63.11	0.00	316.33	0.00	651.91	0.00	72.06	0.00	84.88	0.00	132.70	0.00
TN 0660	Almonds, nutmeat	RAC	0.019	1.38	0.03	0.08	0.00	0.01	0.00	1.00	0.02	0.06	0.00	0.81	0.02

**CYCLANILIPROLE (296)**

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 µg/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												
HS 0444	Peppers, chili, dried	PP	0.525	0.42	0.22	0.53	0.28	0.84	0.44	0.50	0.26	0.95	0.50	0.37	0.19												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	12.5	2.28	28.50	1.98	24.75	0.46	5.75	2.43	30.38	1.29	16.13	3.04	38.00												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.016	24.96	0.40	57.95	0.93	16.70	0.27	38.38	0.61	26.46	0.42	29.00	0.46												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.064	6.24	0.40	14.49	0.93	4.18	0.27	9.60	0.61	6.62	0.42	7.25	0.46												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.064	3.29	0.21	6.14	0.39	0.82	0.05	1.57	0.10	2.23	0.14	1.07	0.07												
MO 0105	Edible offal (mammalian), raw	RAC	0.061	4.79	0.29	9.68	0.59	2.97	0.18	5.49	0.33	3.84	0.23	5.03	0.31												
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	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 (µg/person)=				61.6				90.1				24.9				109.3				116.0				126.3			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				2400				2400				2400				2400				2400							
%ADI=				2.6%				3.8%				1.0%				4.6%				4.8%				5.3%			
Rounded %ADI=				3%				4%				1%				5%				5%							

**CYCLANILIPROLE (296)**

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 µg/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	0.087	38.66	3.36	54.93	4.78	26.36	2.29	51.46	4.48	51.06	4.44	466.36	40.57
JF 0001	Group of Citrus fruit, juice	PP	0.01	36.84	0.37	3.75	0.04	0.30	0.00	21.62	0.22	21.82	0.22	46.67	0.47
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.057	51.09	2.91	65.40	3.73	42.71	2.43	45.29	2.58	62.51	3.56	7.74	0.44
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.019	14.88	0.28	11.98	0.23	0.15	0.00	9.98	0.19	30.32	0.58	3.47	0.07
FS 0013	Subgroup of Cherries, raw	RAC	0.14	1.40	0.20	4.21	0.59	0.04	0.01	2.93	0.41	1.50	0.21	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.052	3.75	0.20	3.33	0.17	5.94	0.31	2.64	0.14	2.50	0.13	0.06	0.00
DF 0014	Plums, dried (prunes)	PP	0.19	0.61	0.12	0.35	0.07	0.05	0.01	0.35	0.07	0.49	0.09	0.13	0.02

CYCLANILIPROLE (296)				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 µg/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
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.053	13.03	0.69	16.29	0.86	8.29	0.44	12.95	0.69	5.35	0.28	0.04	0.00
FB 2005	Subgroup of Caneberries, raw	RAC	0.27	0.56	0.15	1.43	0.39	0.14	0.04	1.23	0.33	1.14	0.31	0.01	0.00
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.275	1.31	0.36	5.50	1.51	0.01	0.00	2.57	0.71	0.82	0.23	2.15	0.59
JF 0269	Grape juice (from wine grapes)	PP	0.04	0.56	0.02	1.96	0.08	0.02	0.00	2.24	0.09	2.27	0.09	0.34	0.01
-	Graps must (from wine-grapes)	PP	0.08	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	0.04	88.93	3.56	62.41	2.50	1.84	0.07	25.07	1.00	61.17	2.45	5.84	0.23
FB 1235	Table grapes, raw (incl dried grapes)	RAC	0.12	19.22	2.31	17.53	2.10	5.32	0.64	15.12	1.81	22.29	2.67	2.51	0.30
FB 0275	Strawberry, raw	RAC	0.12	4.49	0.54	5.66	0.68	0.02	0.00	6.63	0.80	5.75	0.69	0.05	0.01
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.28	9.50	2.66	6.77	1.90	NC	-	3.21	0.90	9.36	2.62	0.75	0.21
VB 0041	Cabbages, head, raw	RAC	0.0325	8.97	0.29	27.12	0.88	1.44	0.05	24.96	0.81	4.55	0.15	11.23	0.36
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.021	7.14	0.15	16.92	0.36	37.58	0.79	15.16	0.32	4.42	0.09	12.67	0.27
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.041	20.68	0.85	25.00	1.03	85.72	3.51	34.31	1.41	11.54	0.47	23.32	0.96
VO 0448	Tomato, raw	RAC	0.033	32.13	1.06	51.27	1.69	34.92	1.15	73.37	2.42	15.15	0.50	8.88	0.29
-	Tomato, canned (& peeled)	PP	0.005	7.57	0.04	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.04	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	4.96	0.20	3.20	0.13	0.15	0.01	1.61	0.06	6.88	0.28	0.52	0.02
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.03	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 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.0525	6.39	0.34	15.53	0.82	19.09	1.00	10.36	0.54	8.29	0.44	4.53	0.24
VO 2046	Subgroup of eggplants	RAC	0.0525	1.01	0.05	1.69	0.09	21.37	1.12	3.00	0.16	1.40	0.07	NC	-
VL 2050	Subgroup of Leafy greens	RAC	2.4	18.38	44.11	18.73	44.95	82.36	197.66	25.32	60.77	17.60	42.24	7.37	17.69
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.5	0.10	0.35	NC	-	26.78	93.73	5.00	17.50	0.58	2.03	5.68	19.88
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	226.09	0.00	234.58	0.00	161.10	0.00	185.04	0.00	234.85	0.00	100.25	0.00
TN 0660	Almonds, nutmeat	RAC	0.019	0.81	0.02	2.21	0.04	0.03	0.00	1.02	0.02	1.47	0.03	NC	-
HS 0444	Peppers, chili, dried	PP	0.525	0.11	0.06	0.21	0.11	0.36	0.19	0.21	0.11	0.25	0.13	0.15	0.08
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	12.5	2.91	36.38	1.73	21.63	1.14	14.25	1.85	23.13	2.29	28.63	0.74	9.25
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.016	112.02	1.79	120.71	1.93	63.46	1.02	88.99	1.42	96.24	1.54	41.02	0.66
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.064	28.01	1.79	30.18	1.93	15.86	1.02	22.25	1.42	24.06	1.54	10.25	0.66
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.064	6.44	0.41	15.51	0.99	3.79	0.24	8.29	0.53	18.44	1.18	8.00	0.51

**CYCLANILIPROLE (296)**

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 µg/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												
MO 0105	Edible offal (mammalian), raw	RAC	0.061	15.17	0.93	5.19	0.32	6.30	0.38	6.78	0.41	3.32	0.20	3.17	0.19												
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	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 (µg/person)=				108.1				97.9				322.6				126.8				100.0				95.0			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (µg/person)=				2400				2400				2200				2400				2400				2400			
%ADI=				4.5%				4.1%				14.7%				5.3%				4.2%				4.0%			
Rounded %ADI=				5%				4%				10%				5%				4%				4%			

## CYCLANILIPROLE (296)

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				Intake = daily intake: µg/person					
				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 kumquat commodities)	RAC	0.087	20.93	1.82	2.35	0.20	30.71	2.67	0.15	0.01	4.45	0.39
JF 0001	Group of Citrus fruit, juice	PP	0.01	0.11	0.00	0.29	0.00	13.55	0.14	0.14	0.00	0.33	0.00
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.057	68.85	3.92	10.93	0.62	70.82	4.04	189.78	10.82	19.56	1.11
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.019	0.03	0.00	0.10	0.00	7.19	0.14	0.03	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.14	0.01	0.00	0.01	0.00	5.96	0.83	0.01	0.00	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.052	0.07	0.00	0.01	0.00	15.56	0.81	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	0.19	0.01	0.00	0.01	0.00	0.37	0.07	0.01	0.00	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.053	0.02	0.00	0.01	0.00	10.76	0.57	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.27	0.01	0.00	7.30	1.97	2.29	0.62	0.01	0.00	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.275	0.82	0.23	4.05	1.11	5.94	1.63	0.43	0.12	2.66	0.73
JF 0269	Grape juice (from wine grapes)	PP	0.04	0.01	0.00	0.01	0.00	0.41	0.02	0.01	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.08	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	0.04	0.31	0.01	0.23	0.01	60.43	2.42	0.52	0.02	31.91	1.28
FB 1235	Table grapes, raw (incl dried grapes)	RAC	0.12	0.16	0.02	0.92	0.11	19.62	2.35	0.02	0.00	0.21	0.03
FB 0275	Strawberry, raw	RAC	0.12	0.01	0.00	0.01	0.00	3.35	0.40	0.01	0.00	0.01	0.00
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.28	0.02	0.01	0.02	0.01	4.86	1.36	0.01	0.00	NC	-
VB 0041	Cabbages, head, raw	RAC	0.0325	3.82	0.12	2.99	0.10	49.16	1.60	0.01	0.00	NC	-
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.021	0.92	0.02	3.20	0.07	13.55	0.28	1.91	0.04	0.05	0.00
VC 2040	Subgroup of Melons, Pumpkins and Winter squashes	RAC	0.041	5.04	0.21	6.54	0.27	38.26	1.57	11.70	0.48	NC	-
VO 0448	Tomato, raw	RAC	0.033	12.99	0.43	4.79	0.16	58.40	1.93	0.92	0.03	0.09	0.00
-	Tomato, canned (& peeled)	PP	0.005	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	0.04	0.58	0.02	0.22	0.01	2.21	0.09	0.24	0.01	3.10	0.12
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.03	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilepeppers), excl okra	RAC	0.0525	8.97	0.47	14.13	0.74	25.14	1.32	0.91	0.05	NC	-
VO 2046	Subgroup of eggplants	RAC	0.0525	1.31	0.07	8.26	0.43	3.95	0.21	0.01	0.00	NC	-
VL 2050	Subgroup of Leafy greens	RAC	2.4	4.99	11.98	3.29	7.90	7.53	18.07	3.05	7.32	6.09	14.62
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	3.5	3.58	12.53	2.64	9.24	NC	-	1.83	6.41	3.65	12.78
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	250.41	0.00	208.74	0.00	213.64	0.00	602.70	0.00	388.95	0.00
TN 0660	Almonds, nutmeat	RAC	0.019	0.01	0.00	0.01	0.00	0.61	0.01	0.01	0.00	NC	-
HS 0444	Peppers, chili, dried	PP	0.525	0.58	0.30	1.27	0.67	1.21	0.64	0.12	0.06	NC	-



## CYCLANILIPROLE (296)

## 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				Intake = daily intake: µg/person															
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake										
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	12.5	0.53	6.63	5.25	65.63	0.86	10.75	0.56	7.00	0.88	11.00										
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.016	23.34	0.37	40.71	0.65	97.15	1.55	18.06	0.29	57.71	0.92										
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.064	5.84	0.37	10.18	0.65	24.29	1.55	4.52	0.29	14.43	0.92										
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.064	1.05	0.07	1.14	0.07	18.69	1.20	0.94	0.06	3.12	0.20										
MO 0105	Edible offal (mammalian), raw	RAC	0.061	4.64	0.28	1.97	0.12	10.01	0.61	3.27	0.20	3.98	0.24										
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	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 (µg/person)=				40.3				91.0				61.2				33.5				44.7			
Bodyweight per region (kg bw) =				60				60				60				60				60			
ADI (µg/person)=				2400				2400				2400				2400				2400			
%ADI=				1.7%				3.8%				2.6%				1.4%				1.9%			
Rounded %ADI=				2%				4%				3%				1%				2%			

FLUAZIFOP-P-BUTYL (283) sweet potato and yam excluded				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.004 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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	0.011	32.25	0.35	11.67	0.13	16.70	0.18	76.01	0.84	33.90	0.37	92.97	1.02
JF 0001	Group of Citrus fruit, juice	PP	0.0077	1.30	0.01	2.37	0.02	0.22	0.00	13.88	0.11	0.75	0.01	2.63	0.02
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.011	19.79	0.22	38.25	0.42	17.96	0.20	32.56	0.36	8.08	0.09	64.45	0.71
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.011	11.60	0.13	23.79	0.26	0.25	0.00	11.84	0.13	2.41	0.03	33.44	0.37
FB 2005	Subgroup of Caneberries, raw	RAC	0.021	0.42	0.01	1.05	0.02	0.01	0.00	0.02	0.00	0.02	0.00	1.24	0.03
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.021	0.53	0.01	1.31	0.03	0.40	0.01	1.66	0.03	0.01	0.00	0.99	0.02
FB 0267	Elderberries, raw (incl processed)	RAC	0.021	0.44	0.01	0.27	0.01	0.34	0.01	1.41	0.03	NC	-	0.87	0.02
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine )	RAC	0.011	16.25	0.18	28.96	0.32	2.87	0.03	24.22	0.27	9.33	0.10	68.64	0.76
FB 0275	Strawberry, raw	RAC	0.685	0.70	0.48	2.01	1.38	0.04	0.03	1.36	0.93	0.37	0.25	2.53	1.73
FT 0305	Table olives, raw (incl preserved)	RAC	0.011	0.70	0.01	0.32	0.00	0.01	0.00	1.53	0.02	0.17	0.00	1.85	0.02
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.011	5.23	0.06	6.94	0.08	99.45	1.09	32.47	0.36	48.30	0.53	24.70	0.27
VA 0381	Garlic, raw	RAC	0.12	2.29	0.27	5.78	0.69	0.11	0.01	3.69	0.44	1.65	0.20	3.91	0.47
-	Onions, dry, raw	RAC	0.12	29.36	3.52	37.50	4.50	3.56	0.43	34.78	4.17	18.81	2.26	43.38	5.21
VB 0041	Cabbages, head, raw	RAC	0.2	2.73	0.55	27.92	5.58	0.55	0.11	4.47	0.89	4.27	0.85	10.25	2.05
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.053	51.75	2.74	81.80	4.34	16.99	0.90	102.02	5.41	26.32	1.39	214.77	11.38
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.053	5.58	0.30	4.31	0.23	0.89	0.05	9.31	0.49	13.64	0.72	20.12	1.07
VL 0483	Lettuce, leaf, raw	RAC	0.013	0.53	0.01	0.36	0.00	0.16	0.00	6.21	0.08	1.90	0.02	6.05	0.08
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.32	0.68	0.22	NC	-	NC	-	0.39	0.12	0.22	0.07	0.49	0.16
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.42	1.97	0.83	0.51	0.21	0.02	0.01	0.79	0.33	3.68	1.55	3.80	1.60
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	2.4	2.39	5.74	1.61	3.86	10.47	25.13	1.84	4.42	12.90	30.96	7.44	17.86
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	2.9	0.58	1.68	0.05	0.15	0.37	1.07	0.03	0.09	1.65	4.79	0.30	0.87
-	Soya paste (i.e. miso)	PP	2.9	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	2.9	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	2.4	12.99	31.18	10.43	25.03	3.63	8.71	13.10	31.44	10.70	25.68	13.10	31.44
-	Soya sauce	PP	2.9	0.01	0.03	0.02	0.06	0.01	0.03	0.34	0.99	0.03	0.09	0.01	0.03
-	Soya flour	PP	0.9	0.05	0.05	0.86	0.77	0.02	0.02	1.02	0.92	0.01	0.01	0.15	0.14
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.4	1.62	0.65	3.22	1.29	0.92	0.37	1.50	0.60	2.90	1.16	0.17	0.07
VR 0577	Carrots, raw	RAC	0.18	9.51	1.71	30.78	5.54	0.37	0.07	8.75	1.58	2.80	0.50	6.10	1.10
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 0596	Sugar beet, raw	RAC	0.19	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-

**FLUAZIFOP-P-BUTYL (283) sweet potato and yam excluded**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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												
-	Sugar beet, sugar	PP	0.068	0.02	0.00	NC	-	0.01	0.00	0.09	0.01	0.07	0.00	12.63	0.86												
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	1.3	1.58	2.05	2.80	3.64	1.74	2.26	4.21	5.47	NC	-	2.03	2.64												
VR 0506	Turnip, garden, raw	RAC	1.3	2.50	3.25	4.44	5.77	2.75	3.58	6.67	8.67	0.14	0.18	3.22	4.19												
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.1	59.74	5.97	316.14	31.61	9.78	0.98	60.26	6.03	54.12	5.41	119.82	11.98												
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.011	99.68	1.10	86.27	0.95	31.38	0.35	80.36	0.88	84.18	0.93	99.10	1.09												
TN 0660	Almonds, nutmeat	RAC	0.011	1.38	0.02	0.08	0.00	0.01	0.00	1.00	0.01	0.06	0.00	0.81	0.01												
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.011	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	0.011	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.00	0.09	0.00	0.13	0.00												
TN 0678	Walnut, nutmeat	RAC	0.011	0.23	0.00	1.49	0.02	0.01	0.00	0.33	0.00	0.07	0.00	2.06	0.02												
SO 0702	Sunflower seed, raw	RAC	0.3	0.09	0.03	0.33	0.10	0.09	0.03	0.24	0.07	0.02	0.01	0.01	0.00												
OR 0702	Sunflower seed oil, edible	PP	0.009	2.97	0.03	14.42	0.13	0.43	0.00	3.46	0.03	2.20	0.02	5.53	0.05												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.053	20.53	1.09	9.80	0.52	6.42	0.34	4.73	0.25	7.14	0.38	18.68	0.99												
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.011	12.61	0.14	1.35	0.01	0.27	0.00	8.04	0.09	0.58	0.01	21.80	0.24												
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.011	1.36	0.01	3.59	0.04	1.44	0.02	5.18	0.06	2.02	0.02	1.70	0.02												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.018	24.96	0.45	57.95	1.04	16.70	0.30	38.38	0.69	26.46	0.48	29.00	0.52												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.048	6.24	0.30	14.49	0.70	4.18	0.20	9.60	0.46	6.62	0.32	7.25	0.35												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.048	3.29	0.16	6.14	0.29	0.82	0.04	1.57	0.08	2.23	0.11	1.07	0.05												
MO 0105	Edible offal (mammalian), raw	RAC	0.088	4.79	0.42	9.68	0.85	2.97	0.26	5.49	0.48	3.84	0.34	5.03	0.44												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.1	289.65	28.97	485.88	48.59	26.92	2.69	239.03	23.90	199.91	19.99	180.53	18.05												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.016	14.63	0.23	29.76	0.48	8.04	0.13	129.68	2.07	25.04	0.40	35.66	0.57												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.016	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	0.054	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.29	0.24	0.01	0.10	0.01												
PE 0112	Eggs, raw, (incl dried)	RAC	0.014	7.84	0.11	23.08	0.32	2.88	0.04	14.89	0.21	9.81	0.14	14.83	0.21												
Total intake (µg/person)=				95.5				150.4				49.9				105.3				100.4				121.0			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				240				240				240				240				240							
%ADI=				39.8%				62.6%				20.8%				43.9%				41.8%				50.4%			
Rounded %ADI=				40%				60%				20%				40%				40%				50%			

## FLUAZIFOP-P-BUTYL (283) sweet potato and yam excluded

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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	0.011	38.66	0.43	54.93	0.60	26.36	0.29	51.46	0.57	51.06	0.56	466.36	5.13
JF 0001	Group of Citrus fruit, juice	PP	0.0077	36.84	0.28	3.75	0.03	0.30	0.00	21.62	0.17	21.82	0.17	46.67	0.36
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.011	71.38	0.79	81.73	0.90	42.91	0.47	58.89	0.65	103.85	1.14	12.48	0.14
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.011	19.98	0.22	24.87	0.27	14.41	0.16	19.54	0.21	10.78	0.12	0.50	0.01
FB 2005	Subgroup of Caneberries, raw	RAC	0.021	0.56	0.01	1.43	0.03	0.14	0.00	1.23	0.03	1.14	0.02	0.01	0.00
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.021	1.31	0.03	5.50	0.12	0.01	0.00	2.57	0.05	0.82	0.02	2.15	0.05
FB 0267	Elderberries, raw (incl processed)	RAC	0.021	8.20	0.17	0.14	0.00	NC	-	NC	-	NC	-	1.87	0.04
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine )	RAC	0.011	142.23	1.56	105.77	1.16	7.87	0.09	52.44	0.58	109.22	1.20	10.96	0.12
FB 0275	Strawberry, raw	RAC	0.685	4.49	3.08	5.66	3.88	0.02	0.01	6.63	4.54	5.75	3.94	0.05	0.03
FT 0305	Table olives, raw (incl preserved)	RAC	0.011	2.00	0.02	2.48	0.03	0.01	0.00	1.21	0.01	1.64	0.02	0.27	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.011	25.76	0.28	23.65	0.26	23.83	0.26	24.37	0.27	19.43	0.21	101.55	1.12
VA 0381	Garlic, raw	RAC	0.12	0.98	0.12	1.49	0.18	12.88	1.55	3.74	0.45	2.05	0.25	1.14	0.14
-	Onions, dry, raw	RAC	0.12	19.69	2.36	29.83	3.58	24.64	2.96	31.35	3.76	9.72	1.17	12.59	1.51
VB 0041	Cabbages, head, raw	RAC	0.2	8.97	1.79	27.12	5.42	1.44	0.29	24.96	4.99	4.55	0.91	11.23	2.25
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.053	64.74	3.43	68.31	3.62	36.05	1.91	82.09	4.35	54.50	2.89	11.69	0.62
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.053	1.01	0.05	1.69	0.09	21.37	1.13	3.00	0.16	1.40	0.07	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.013	14.50	0.19	11.76	0.15	13.14	0.17	19.50	0.25	4.81	0.06	2.23	0.03
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.32	5.07	1.62	0.83	0.27	0.17	0.05	3.70	1.18	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.42	10.72	4.50	1.99	0.84	2.72	1.14	4.26	1.79	4.23	1.78	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	2.4	1.51	3.62	1.50	3.60	1.90	4.56	5.11	12.26	1.36	3.26	23.43	56.23
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	2.9	0.02	0.06	0.33	0.96	6.64	19.26	3.94	11.43	NC	-	5.78	16.76
-	Soya paste (i.e. miso)	PP	2.9	NC	-	NC	-	NC	-	1.87	5.42	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	2.9	NC	-	NC	-	0.68	1.97	0.87	2.52	NC	-	NC	-
OR 0541	Soya oil, refined	PP	2.4	19.06	45.74	21.06	50.54	5.94	14.26	33.78	81.07	40.05	96.12	13.39	32.14
-	Soya sauce	PP	2.9	0.45	1.31	0.29	0.84	2.93	8.50	4.35	12.62	0.09	0.26	0.70	2.03
-	Soya flour	PP	0.9	0.22	0.20	0.27	0.24	0.29	0.26	0.17	0.15	NC	-	NC	-
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.4	3.80	1.52	1.25	0.50	0.90	0.36	2.33	0.93	2.70	1.08	3.83	1.53
VR 0577	Carrots, raw	RAC	0.18	26.26	4.73	27.13	4.88	10.07	1.81	16.49	2.97	44.69	8.04	8.75	1.58
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 0596	Sugar beet, raw	RAC	0.19	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Sugar beet, sugar	PP	0.068	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-

**FLUAZIFOP-P-BUTYL (283) sweet potato and yam excluded**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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 0497	Swede, raw (i.e. Rutabaga)	RAC	1.3	10.01	13.01	1.66	2.16	NC	-	NC	-	3.06	3.98	2.99	3.89												
VR 0506	Turnip, garden, raw	RAC	1.3	5.78	7.51	15.35	19.96	NC	-	6.54	8.50	1.95	2.54	4.73	6.15												
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.1	225.03	22.50	234.24	23.42	71.48	7.15	177.55	17.76	234.55	23.46	37.71	3.77												
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.011	92.24	1.01	95.72	1.05	28.47	0.31	77.39	0.85	117.73	1.30	103.90	1.14												
TN 0660	Almonds, nutmeat	RAC	0.011	0.81	0.01	2.21	0.02	0.03	0.00	1.02	0.01	1.47	0.02	NC	-												
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.011	NC	-	0.40	0.00	NC	-	NC	-	NC	-	0.07	0.00												
TN 0672	Pecan, nutmeat	RAC	0.011	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00												
TN 0678	Walnut, nutmeat	RAC	0.011	0.34	0.00	0.84	0.01	0.28	0.00	0.39	0.00	0.45	0.00	NC	-												
SO 0702	Sunflower seed, raw	RAC	0.3	0.01	0.00	1.32	0.40	0.03	0.01	1.17	0.35	NC	-	0.02	0.01												
OR 0702	Sunflower seed oil, edible	PP	0.009	9.50	0.09	11.37	0.10	0.49	0.00	5.15	0.05	2.63	0.02	2.80	0.03												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.053	10.71	0.57	4.23	0.22	7.19	0.38	7.54	0.40	5.66	0.30	2.38	0.13												
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.011	17.78	0.20	48.67	0.54	0.10	0.00	22.50	0.25	14.09	0.15	2.46	0.03												
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.011	10.90	0.12	12.44	0.14	0.77	0.01	9.48	0.10	22.07	0.24	8.15	0.09												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.018	112.02	2.02	120.71	2.17	63.46	1.14	88.99	1.60	96.24	1.73	41.02	0.74												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.048	28.01	1.34	30.18	1.45	15.86	0.76	22.25	1.07	24.06	1.15	10.25	0.49												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.048	6.44	0.31	15.51	0.74	3.79	0.18	8.29	0.40	18.44	0.89	8.00	0.38												
MO 0105	Edible offal (mammalian), raw	RAC	0.088	15.17	1.33	5.19	0.46	6.30	0.55	6.78	0.60	3.32	0.29	3.17	0.28												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.1	388.92	38.89	335.88	33.59	49.15	4.92	331.25	33.13	468.56	46.86	245.45	24.55												
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.016	73.76	1.18	53.86	0.86	23.98	0.38	87.12	1.39	53.38	0.85	84.45	1.35												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.016	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	0.054	0.33	0.02	0.72	0.04	0.27	0.01	0.35	0.02	0.80	0.04	NC	-												
PE 0112	Eggs, raw, (incl dried)	RAC	0.014	25.84	0.36	29.53	0.41	28.05	0.39	33.19	0.46	36.44	0.51	8.89	0.12												
Total intake (µg/person)=				169.0				171.0				77.7				220.3				209.7				165.3			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (µg/person)=				240				240				220				240				240							
%ADI=				70.4%				71.2%				35.3%				91.8%				87.4%				68.9%			
Rounded %ADI=				70%				70%				40%				90%				90%				70%			

## FLUAZIFOP-P-BUTYL (283) sweet potato and yam excluded

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person					
				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 kumquat commodities)	RAC	0.011	20.93	0.23	2.35	0.03	30.71	0.34	0.15	0.00	4.45	0.05
JF 0001	Group of Citrus fruit, juice	PP	0.0077	0.11	0.00	0.29	0.00	13.55	0.10	0.14	0.00	0.33	0.00
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.011	68.89	0.76	11.06	0.12	80.62	0.89	189.82	2.09	19.56	0.22
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.011	0.09	0.00	0.03	0.00	33.36	0.37	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.021	0.01	0.00	7.30	0.15	2.29	0.05	0.01	0.00	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.021	0.82	0.02	4.05	0.09	5.94	0.12	0.43	0.01	2.66	0.06
FB 0267	Elderberries, raw (incl processed)	RAC	0.021	0.71	0.01	3.52	0.07	NC	-	0.38	0.01	2.32	0.05
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.011	0.60	0.01	1.26	0.01	103.25	1.14	0.74	0.01	44.23	0.49
FB 0275	Strawberry, raw	RAC	0.685	0.01	0.01	0.01	0.01	3.35	2.29	0.01	0.01	0.01	0.01
FT 0305	Table olives, raw (incl preserved)	RAC	0.011	0.01	0.00	0.01	0.00	1.75	0.02	0.01	0.00	0.24	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.011	44.80	0.49	118.17	1.30	25.25	0.28	454.49	5.00	310.23	3.41
VA 0381	Garlic, raw	RAC	0.12	0.82	0.10	2.06	0.25	3.79	0.45	0.03	0.00	0.29	0.03
-	Onions, dry, raw	RAC	0.12	9.01	1.08	20.24	2.43	30.90	3.71	9.61	1.15	2.11	0.25
VB 0041	Cabbages, head, raw	RAC	0.2	3.82	0.76	2.99	0.60	49.16	9.83	0.01	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.053	15.50	0.82	5.78	0.31	71.52	3.79	2.00	0.11	12.50	0.66
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.053	1.31	0.07	8.26	0.44	3.95	0.21	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.013	0.29	0.00	0.03	0.00	6.71	0.09	0.01	0.00	NC	-
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.32	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.42	0.21	0.09	0.02	0.01	5.51	2.31	0.02	0.01	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	2.4	7.11	17.06	2.33	5.59	3.76	9.02	44.70	107.28	3.27	7.85
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	2.9	2.76	8.00	0.07	0.20	0.33	0.96	3.16	9.16	NC	-
-	Soya paste (i.e. miso)	PP	2.9	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	2.9	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	2.4	2.32	5.57	2.54	6.10	18.70	44.88	2.51	6.02	6.29	15.10
-	Soya sauce	PP	2.9	0.01	0.03	0.13	0.38	0.17	0.49	0.01	0.03	0.56	1.62
-	Soya flour	PP	0.9	0.11	0.10	0.08	0.07	0.07	0.06	0.01	0.01	0.03	0.03
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.4	1.53	0.61	2.52	1.01	3.52	1.41	3.56	1.42	0.74	0.30
VR 0577	Carrots, raw	RAC	0.18	2.07	0.37	3.00	0.54	25.29	4.55	0.05	0.01	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 0596	Sugar beet, raw	RAC	0.19	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.068	0.56	0.04	0.24	0.02	NC	-	NC	-	5.13	0.35

**FLUAZIFOP-P-BUTYL (283) sweet potato and yam excluded**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person									
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake				
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	1.3	2.71	3.52	1.96	2.55	7.80	10.14	1.83	2.38	3.66	4.76				
VR 0506	Turnip, garden, raw	RAC	1.3	4.29	5.58	3.10	4.03	6.41	8.33	2.90	3.77	5.79	7.53				
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.1	23.96	2.40	13.56	1.36	213.41	21.34	104.35	10.44	8.56	0.86				
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.011	33.75	0.37	106.29	1.17	78.09	0.86	29.09	0.32	45.70	0.50				
TN 0660	Almonds, nutmeat	RAC	0.011	0.01	0.00	0.01	0.00	0.61	0.01	0.01	0.00	NC	-				
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.011	0.04	0.00	0.05	0.00	NC	-	0.01	0.00	0.01	0.00				
TN 0672	Pecan, nutmeat	RAC	0.011	0.15	0.00	0.22	0.00	0.31	0.00	0.01	0.00	0.01	0.00				
TN 0678	Walnut, nutmeat	RAC	0.011	0.01	0.00	0.01	0.00	0.81	0.01	0.01	0.00	NC	-				
SO 0702	Sunflower seed, raw	RAC	0.3	0.02	0.01	0.01	0.00	0.03	0.01	2.23	0.67	NC	-				
OR 0702	Sunflower seed oil, edible	PP	0.009	0.37	0.00	0.09	0.00	12.98	0.12	4.01	0.04	0.20	0.00				
SO 0691	Cotton seed, raw (incl oil)	RAC	0.053	8.14	0.43	0.32	0.02	2.84	0.15	2.69	0.14	0.97	0.05				
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.011	0.18	0.00	0.11	0.00	11.00	0.12	0.06	0.00	0.49	0.01				
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.011	0.95	0.01	1.32	0.01	11.64	0.13	2.96	0.03	14.73	0.16				
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.018	23.34	0.42	40.71	0.73	97.15	1.75	18.06	0.33	57.71	1.04				
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.048	5.84	0.28	10.18	0.49	24.29	1.17	4.52	0.22	14.43	0.69				
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.048	1.05	0.05	1.14	0.05	18.69	0.90	0.94	0.05	3.12	0.15				
MO 0105	Edible offal (mammalian), raw	RAC	0.088	4.64	0.41	1.97	0.17	10.01	0.88	3.27	0.29	3.98	0.35				
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.1	108.75	10.88	70.31	7.03	436.11	43.61	61.55	6.16	79.09	7.91				
PM 0110	Poultry meat, raw (incl prepared)	RAC	0.016	3.92	0.06	12.03	0.19	57.07	0.91	5.03	0.08	55.56	0.89				
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.016	NC	-	NC	-	0.32	0.01	NC	-	NC	-				
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.054	0.10	0.01	0.70	0.04	0.97	0.05	0.10	0.01	NC	-				
PE 0112	Eggs, raw, (incl dried)	RAC	0.014	3.84	0.05	4.41	0.06	27.25	0.38	1.13	0.02	7.39	0.10				
Total intake (µg/person)=								61.1		37.9		179.2		157.5		55.9	
Bodyweight per region (kg bw) =								60		60		60		60		60	
ADI (µg/person)=								240		240		240		240		240	
%ADI=								25.4%		15.8%		74.6%		65.6%		23.3%	
Rounded %ADI=								30%		20%		70%		70%		20%	

FLUAZIFOP-P-BUTYL (283) sweet potato and yam included				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.004 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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	0.011	32.25	0.35	11.67	0.13	16.70	0.18	76.01	0.84	33.90	0.37	92.97	1.02
JF 0001	Group of Citrus fruit, juice	PP	0.0077	1.30	0.01	2.37	0.02	0.22	0.00	13.88	0.11	0.75	0.01	2.63	0.02
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.011	19.79	0.22	38.25	0.42	17.96	0.20	32.56	0.36	8.08	0.09	64.45	0.71
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.011	11.60	0.13	23.79	0.26	0.25	0.00	11.84	0.13	2.41	0.03	33.44	0.37
FB 2005	Subgroup of Caneberries, raw	RAC	0.021	0.42	0.01	1.05	0.02	0.01	0.00	0.02	0.00	0.02	0.00	1.24	0.03
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.021	0.53	0.01	1.31	0.03	0.40	0.01	1.66	0.03	0.01	0.00	0.99	0.02
FB 0267	Elderberries, raw (incl processed)	RAC	0.021	0.44	0.01	0.27	0.01	0.34	0.01	1.41	0.03	NC	-	0.87	0.02
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine )	RAC	0.011	16.25	0.18	28.96	0.32	2.87	0.03	24.22	0.27	9.33	0.10	68.64	0.76
FB 0275	Strawberry, raw	RAC	0.685	0.70	0.48	2.01	1.38	0.04	0.03	1.36	0.93	0.37	0.25	2.53	1.73
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.011	5.23	0.06	6.94	0.08	99.45	1.09	32.47	0.36	48.30	0.53	24.70	0.27
VA 2031	Subgroup of bulb onions	RAC	0.12	31.65	3.80	43.28	5.19	3.68	0.44	38.48	4.62	20.46	2.46	47.29	5.67
VB 0041	Cabbages, head, raw	RAC	0.2	2.73	0.55	27.92	5.58	0.55	0.11	4.47	0.89	4.27	0.85	10.25	2.05
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.053	51.75	2.74	81.80	4.34	16.99	0.90	102.02	5.41	26.32	1.39	214.77	11.38
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.053	5.58	0.30	4.31	0.23	0.89	0.05	9.31	0.49	13.64	0.72	20.12	1.07
VL 0483	Lettuce, leaf, raw	RAC	0.013	0.53	0.01	0.36	0.00	0.16	0.00	6.21	0.08	1.90	0.02	6.05	0.08
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.32	0.68	0.22	NC	-	NC	-	0.39	0.12	0.22	0.07	0.49	0.16
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.42	1.97	0.83	0.51	0.21	0.02	0.01	0.79	0.33	3.68	1.55	3.80	1.60
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	2.4	2.39	5.74	1.61	3.86	10.47	25.13	1.84	4.42	12.90	30.96	7.44	17.86
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	2.9	0.58	1.68	0.05	0.15	0.37	1.07	0.03	0.09	1.65	4.79	0.30	0.87
OR 0541	Soya oil, refined	PP	2.4	12.99	31.18	10.43	25.03	3.63	8.71	13.10	31.44	10.70	25.68	13.10	31.44
-	Soya flour	PP	3.2	0.05	0.16	0.86	2.75	0.02	0.06	1.02	3.26	0.01	0.03	0.15	0.48
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.4	1.62	0.65	3.22	1.29	0.92	0.37	1.50	0.60	2.90	1.16	0.17	0.07
VR 0577	Carrots, raw	RAC	0.18	9.51	1.71	30.78	5.54	0.37	0.07	8.75	1.58	2.80	0.50	6.10	1.10
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 0596	Sugar beet, raw	RAC	0.19	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar beet, sugar	PP	0.068	0.02	0.00	NC	-	0.01	0.00	0.09	0.01	0.07	0.00	12.63	0.86
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	1.3	1.58	2.05	2.80	3.64	1.74	2.26	4.21	5.47	NC	-	2.03	2.64
VR 0506	Turnip, garden, raw	RAC	1.3	2.50	3.25	4.44	5.77	2.75	3.58	6.67	8.67	0.14	0.18	3.22	4.19
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.1	59.74	5.97	316.14	31.61	9.78	0.98	60.26	6.03	54.12	5.41	119.82	11.98
VR 0508	Sweet potato, raw (incl dried)	RAC	1	0.18	0.18	0.18	0.18	42.16	42.16	1.61	1.61	3.06	3.06	6.67	6.67



**FLUAZIFOP-P-BUTYL (283) sweet potato and yam included**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMTR mg/kg	Diets as g/person/day				Intake as µg/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												
VR 0600	Yams, raw (incl dried)	RAC	1	0.02	0.02	NC	-	90.40	90.40	6.45	6.45	0.74	0.74	0.65	0.65												
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.011	99.68	1.10	86.27	0.95	31.38	0.35	80.36	0.88	84.18	0.93	99.10	1.09												
TN 0660	Almonds, nutmeat	RAC	0.011	1.38	0.02	0.08	0.00	0.01	0.00	1.00	0.01	0.06	0.00	0.81	0.01												
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.011	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	0.011	0.05	0.00	0.05	0.00	0.02	0.00	0.14	0.00	0.09	0.00	0.13	0.00												
TN 0678	Walnut, nutmeat	RAC	0.011	0.23	0.00	1.49	0.02	0.01	0.00	0.33	0.00	0.07	0.00	2.06	0.02												
OR 0699	Safflower seed oil, edible	PP	0.009	0.01	0.00	0.08	0.00	NC	-	0.01	0.00	0.12	0.00	0.01	0.00												
SO 0702	Sunflower seed, raw	RAC	0.3	0.09	0.03	0.33	0.10	0.09	0.03	0.24	0.07	0.02	0.01	0.01	0.00												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.053	20.53	1.09	9.80	0.52	6.42	0.34	4.73	0.25	7.14	0.38	18.68	0.99												
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.011	12.61	0.14	1.35	0.01	0.27	0.00	8.04	0.09	0.58	0.01	21.80	0.24												
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.011	1.36	0.01	3.59	0.04	1.44	0.02	5.18	0.06	2.02	0.02	1.70	0.02												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.024	6.24	0.15	14.49	0.35	4.18	0.10	9.60	0.23	6.62	0.16	7.25	0.17												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.048	3.29	0.16	6.14	0.29	0.82	0.04	1.57	0.08	2.23	0.11	1.07	0.05												
MO 0105	Edible offal (mammalian), raw	RAC	0.088	4.79	0.42	9.68	0.85	2.97	0.26	5.49	0.48	3.84	0.34	5.03	0.44												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.1	289.65	28.97	485.88	48.59	26.92	2.69	239.03	23.90	199.91	19.99	180.53	18.05												
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.016	1.46	0.02	2.98	0.05	0.80	0.01	12.97	0.21	2.50	0.04	3.57	0.06												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.016	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	0.054	0.12	0.01	0.12	0.01	0.11	0.01	5.37	0.29	0.24	0.01	0.10	0.01												
PE 0112	Eggs, raw, (incl dried)	RAC	0.014	7.84	0.11	23.08	0.32	2.88	0.04	14.89	0.21	9.81	0.14	14.83	0.21												
Total intake (µg/person)=				94.9				150.5				182.0				111.9				103.1				127.4			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				240				240				240				240				240							
%ADI=				39.5%				62.7%				75.8%				46.6%				43.0%				53.1%			
Rounded %ADI=				40%				60%				80%				50%				40%				50%			

FLUAZIFOP-P-BUTYL (283) sweet potato and yam included				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.004 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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	0.011	38.66	0.43	54.93	0.60	26.36	0.29	51.46	0.57	51.06	0.56	466.36	5.13
JF 0001	Group of Citrus fruit, juice	PP	0.0077	36.84	0.28	3.75	0.03	0.30	0.00	21.62	0.17	21.82	0.17	46.67	0.36
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.011	71.38	0.79	81.73	0.90	42.91	0.47	58.89	0.65	103.85	1.14	12.48	0.14
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.011	19.98	0.22	24.87	0.27	14.41	0.16	19.54	0.21	10.78	0.12	0.50	0.01
FB 2005	Subgroup of Caneberries, raw	RAC	0.021	0.56	0.01	1.43	0.03	0.14	0.00	1.23	0.03	1.14	0.02	0.01	0.00
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.021	1.31	0.03	5.50	0.12	0.01	0.00	2.57	0.05	0.82	0.02	2.15	0.05
FB 0267	Elderberries, raw (incl processed)	RAC	0.021	8.20	0.17	0.14	0.00	NC	-	NC	-	NC	-	1.87	0.04
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine )	RAC	0.011	142.23	1.56	105.77	1.16	7.87	0.09	52.44	0.58	109.22	1.20	10.96	0.12
FB 0275	Strawberry, raw	RAC	0.685	4.49	3.08	5.66	3.88	0.02	0.01	6.63	4.54	5.75	3.94	0.05	0.03
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.011	25.76	0.28	23.65	0.26	23.83	0.26	24.37	0.27	19.43	0.21	101.55	1.12
VA 2031	Subgroup of bulb onions	RAC	0.12	20.67	2.48	31.32	3.76	37.52	4.50	35.08	4.21	11.77	1.41	13.74	1.65
VB 0041	Cabbages, head, raw	RAC	0.2	8.97	1.79	27.12	5.42	1.44	0.29	24.96	4.99	4.55	0.91	11.23	2.25
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.053	64.74	3.43	68.31	3.62	36.05	1.91	82.09	4.35	54.50	2.89	11.69	0.62
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.053	1.01	0.05	1.69	0.09	21.37	1.13	3.00	0.16	1.40	0.07	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.013	14.50	0.19	11.76	0.15	13.14	0.17	19.50	0.25	4.81	0.06	2.23	0.03
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.32	5.07	1.62	0.83	0.27	0.17	0.05	3.70	1.18	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.42	10.72	4.50	1.99	0.84	2.72	1.14	4.26	1.79	4.23	1.78	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	2.4	1.51	3.62	1.50	3.60	1.90	4.56	5.11	12.26	1.36	3.26	23.43	56.23
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	2.9	0.02	0.06	0.33	0.96	6.64	19.26	3.94	11.43	NC	-	5.78	16.76
OR 0541	Soya oil, refined	PP	2.4	19.06	45.74	21.06	50.54	5.94	14.26	33.78	81.07	40.05	96.12	13.39	32.14
-	Soya flour	PP	3.2	0.22	0.70	0.27	0.86	0.29	0.93	0.17	0.54	NC	-	NC	-
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.4	3.80	1.52	1.25	0.50	0.90	0.36	2.33	0.93	2.70	1.08	3.83	1.53
VR 0577	Carrots, raw	RAC	0.18	26.26	4.73	27.13	4.88	10.07	1.81	16.49	2.97	44.69	8.04	8.75	1.58
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 0596	Sugar beet, raw	RAC	0.19	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Sugar beet, sugar	PP	0.068	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	1.3	10.01	13.01	1.66	2.16	NC	-	NC	-	3.06	3.98	2.99	3.89
VR 0506	Turnip, garden, raw	RAC	1.3	5.78	7.51	15.35	19.96	NC	-	6.54	8.50	1.95	2.54	4.73	6.15
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.1	225.03	22.50	234.24	23.42	71.48	7.15	177.55	17.76	234.55	23.46	37.71	3.77
VR 0508	Sweet potato, raw (incl dried)	RAC	1	0.93	0.93	0.32	0.32	64.65	64.65	5.37	5.37	0.30	0.30	3.13	3.13

**FLUAZIFOP-P-BUTYL (283) sweet potato and yam included**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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 0600	Yams, raw (incl dried)	RAC	1	NC	-	NC	-	0.03	0.03	0.71	0.71	NC	-	17.57	17.57
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.011	92.24	1.01	95.72	1.05	28.47	0.31	77.39	0.85	117.73	1.30	103.90	1.14
TN 0660	Almonds, nutmeat	RAC	0.011	0.81	0.01	2.21	0.02	0.03	0.00	1.02	0.01	1.47	0.02	NC	-
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.011	NC	-	0.40	0.00	NC	-	NC	-	NC	-	0.07	0.00
TN 0672	Pecan, nutmeat	RAC	0.011	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00
TN 0678	Walnut, nutmeat	RAC	0.011	0.34	0.00	0.84	0.01	0.28	0.00	0.39	0.00	0.45	0.00	NC	-
OR 0699	Safflower seed oil, edible	PP	0.009	0.01	0.00	0.01	0.00	0.01	0.00	0.06	0.00	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.3	0.01	0.00	1.32	0.40	0.03	0.01	1.17	0.35	NC	-	0.02	0.01
SO 0691	Cotton seed, raw (incl oil)	RAC	0.053	10.71	0.57	4.23	0.22	7.19	0.38	7.54	0.40	5.66	0.30	2.38	0.13
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.011	17.78	0.20	48.67	0.54	0.10	0.00	22.50	0.25	14.09	0.15	2.46	0.03
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.011	10.90	0.12	12.44	0.14	0.77	0.01	9.48	0.10	22.07	0.24	8.15	0.09
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.024	28.01	0.67	30.18	0.72	15.86	0.38	22.25	0.53	24.06	0.58	10.25	0.25
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.048	6.44	0.31	15.51	0.74	3.79	0.18	8.29	0.40	18.44	0.89	8.00	0.38
MO 0105	Edible offal (mammalian), raw	RAC	0.088	15.17	1.33	5.19	0.46	6.30	0.55	6.78	0.60	3.32	0.29	3.17	0.28
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.1	388.92	38.89	335.88	33.59	49.15	4.92	331.25	33.13	468.56	46.86	245.45	24.55
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.016	7.38	0.12	5.39	0.09	2.40	0.04	8.71	0.14	5.34	0.09	8.45	0.14
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.016	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	0.054	0.33	0.02	0.72	0.04	0.27	0.01	0.35	0.02	0.80	0.04	NC	-
PE 0112	Eggs, raw, (incl dried)	RAC	0.014	25.84	0.36	29.53	0.41	28.05	0.39	33.19	0.46	36.44	0.51	8.89	0.12

Total intake (µg/person)=	165.2	167.3	130.7	202.8	206.6	181.8
Bodyweight per region (kg bw) =	60	60	55	60	60	60
ADI (µg/person)=	240	240	220	240	240	240
%ADI=	68.9%	69.7%	59.4%	84.5%	86.1%	75.7%
Rounded %ADI=	70%	70%	60%	80%	90%	80%

FLUAZIFOP-P-BUTYL (283) sweet potato and yam included				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.004 mg/kg bw					
Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person					
				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 kumquat commodities)	RAC	0.011	20.93	0.23	2.35	0.03	30.71	0.34	0.15	0.00	4.45	0.05
JF 0001	Group of Citrus fruit, juice	PP	0.0077	0.11	0.00	0.29	0.00	13.55	0.10	0.14	0.00	0.33	0.00
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.011	68.89	0.76	11.06	0.12	80.62	0.89	189.82	2.09	19.56	0.22
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	0.011	0.09	0.00	0.03	0.00	33.36	0.37	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	0.021	0.01	0.00	7.30	0.15	2.29	0.05	0.01	0.00	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	0.021	0.82	0.02	4.05	0.09	5.94	0.12	0.43	0.01	2.66	0.06
FB 0267	Elderberries, raw (incl processed)	RAC	0.021	0.71	0.01	3.52	0.07	NC	-	0.38	0.01	2.32	0.05
FB 0269	Grapes, raw (incl must, incl dried, incl juice, incl wine)	RAC	0.011	0.60	0.01	1.26	0.01	103.25	1.14	0.74	0.01	44.23	0.49
FB 0275	Strawberry, raw	RAC	0.685	0.01	0.01	0.01	0.01	3.35	2.29	0.01	0.01	0.01	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.011	44.80	0.49	118.17	1.30	25.25	0.28	454.49	5.00	310.23	3.41
VA 2031	Subgroup of bulb onions	RAC	0.12	9.83	1.18	22.30	2.68	34.69	4.16	9.65	1.16	2.39	0.29
VB 0041	Cabbages, head, raw	RAC	0.2	3.82	0.76	2.99	0.60	49.16	9.83	0.01	0.00	NC	-
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.053	15.50	0.82	5.78	0.31	71.52	3.79	2.00	0.11	12.50	0.66
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.053	1.31	0.07	8.26	0.44	3.95	0.21	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.013	0.29	0.00	0.03	0.00	6.71	0.09	0.01	0.00	NC	-
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.32	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.42	0.21	0.09	0.02	0.01	5.51	2.31	0.02	0.01	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	2.4	7.11	17.06	2.33	5.59	3.76	9.02	44.70	107.28	3.27	7.85
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	2.9	2.76	8.00	0.07	0.20	0.33	0.96	3.16	9.16	NC	-
OR 0541	Soya oil, refined	PP	2.4	2.32	5.57	2.54	6.10	18.70	44.88	2.51	6.02	6.29	15.10
-	Soya flour	PP	3.2	0.11	0.35	0.08	0.26	0.07	0.22	0.01	0.03	0.03	0.10
VD 0072	Peas (dry) (Pisum spp), raw	RAC	0.4	1.53	0.61	2.52	1.01	3.52	1.41	3.56	1.42	0.74	0.30
VR 0577	Carrots, raw	RAC	0.18	2.07	0.37	3.00	0.54	25.29	4.55	0.05	0.01	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 0596	Sugar beet, raw	RAC	0.19	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Sugar beet, sugar	PP	0.068	0.56	0.04	0.24	0.02	NC	-	NC	-	5.13	0.35
VR 0497	Swede, raw (i.e. Rutabaga)	RAC	1.3	2.71	3.52	1.96	2.55	7.80	10.14	1.83	2.38	3.66	4.76
VR 0506	Turnip, garden, raw	RAC	1.3	4.29	5.58	3.10	4.03	6.41	8.33	2.90	3.77	5.79	7.53

**FLUAZIFOP-P-BUTYL (283) sweet potato and yam included**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.004 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.1	23.96	2.40	13.56	1.36	213.41	21.34	104.35	10.44	8.56	0.86		
VR 0508	Sweet potato, raw (incl dried)	RAC	1	28.83	28.83	61.55	61.55	0.15	0.15	221.94	221.94	NC	-		
VR 0600	Yams, raw (incl dried)	RAC	1	70.93	70.93	30.62	30.62	0.07	0.07	5.65	5.65	30.85	30.85		
GS 0659	Sugar cane, raw (incl sugar, incl molasses)	RAC	0.011	33.75	0.37	106.29	1.17	78.09	0.86	29.09	0.32	45.70	0.50		
TN 0660	Almonds, nutmeat	RAC	0.011	0.01	0.00	0.01	0.00	0.61	0.01	0.01	0.00	NC	-		
TN 0669	Macadamia nuts, nutmeat (i.e. Queensland nuts)	RAC	0.011	0.04	0.00	0.05	0.00	NC	-	0.01	0.00	0.01	0.00		
TN 0672	Pecan, nutmeat	RAC	0.011	0.15	0.00	0.22	0.00	0.31	0.00	0.01	0.00	0.01	0.00		
TN 0678	Walnut, nutmeat	RAC	0.011	0.01	0.00	0.01	0.00	0.81	0.01	0.01	0.00	NC	-		
OR 0699	Safflower seed oil, edible	PP	0.009	0.01	0.00	NC	-	NC	-	NC	-	NC	-		
SO 0702	Sunflower seed, raw	RAC	0.3	0.02	0.01	0.01	0.00	0.03	0.01	2.23	0.67	NC	-		
SO 0691	Cotton seed, raw (incl oil)	RAC	0.053	8.14	0.43	0.32	0.02	2.84	0.15	2.69	0.14	0.97	0.05		
SO 0305	Olives for oil production, raw (incl oil)	RAC	0.011	0.18	0.00	0.11	0.00	11.00	0.12	0.06	0.00	0.49	0.01		
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.011	0.95	0.01	1.32	0.01	11.64	0.13	2.96	0.03	14.73	0.16		
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.024	5.84	0.14	10.18	0.24	24.29	0.58	4.52	0.11	14.43	0.35		
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.048	1.05	0.05	1.14	0.05	18.69	0.90	0.94	0.05	3.12	0.15		
MO 0105	Edible offal (mammalian), raw	RAC	0.088	4.64	0.41	1.97	0.17	10.01	0.88	3.27	0.29	3.98	0.35		
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.1	108.75	10.88	70.31	7.03	436.11	43.61	61.55	6.16	79.09	7.91		
PM 0110	Poultry meat, raw (incl prepared) - 10% as fat	RAC	0.016	0.39	0.01	1.20	0.02	5.71	0.09	0.50	0.01	5.56	0.09		
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.016	NC	-	NC	-	0.32	0.01	NC	-	NC	-		
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.054	0.10	0.01	0.70	0.04	0.97	0.05	0.10	0.01	NC	-		
PE 0112	Eggs, raw, (incl dried)	RAC	0.014	3.84	0.05	4.41	0.06	27.25	0.38	1.13	0.02	7.39	0.10		
Total intake (µg/person)=				160.4				128.7				175.8			
Bodyweight per region (kg bw) =				60				60				60			
ADI (µg/person)=				240				240				240			
%ADI=				66.8%				53.6%				73.2%			
Rounded %ADI=				70%				50%				70%			
				384.5				384.5				384.5			
				60				60				60			
				240				240				240			
				160.2%				160.2%				160.2%			
				30%				30%				30%			

## FLUXAPYROXAD (256)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets as g/person/day				Intake as µg/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 kumquat commodities)	RAC	0.38	4.78	1.82	2.42	0.92	3.61	1.37	25.18	9.57	8.25	3.14	15.77	5.99
-	Lemon, juice (single strength, incl. concentrated)	PP	0.015	0.01	0.00	0.01	0.00	0.11	0.00	0.09	0.00	0.18	0.00	0.17	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.38	6.18	2.35	3.66	1.39	0.25	0.10	6.82	2.59	3.49	1.33	19.38	7.36
-	Subgroup of Mandarins, juice	PP	0.015	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.395	20.66	8.16	5.23	2.07	11.90	4.70	37.90	14.97	21.16	8.36	56.46	22.30
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.016	1.27	0.02	2.20	0.04	0.09	0.00	11.81	0.19	0.46	0.01	1.69	0.03
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.15	0.64	0.10	0.35	0.05	0.93	0.14	6.10	0.92	1.01	0.15	1.36	0.20
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.006	0.01	0.00	0.16	0.00	0.02	0.00	1.97	0.01	0.12	0.00	0.77	0.00
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.3	19.35	5.81	34.06	10.22	17.87	5.36	25.74	7.72	7.69	2.31	56.85	17.06
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.05	0.32	0.02	3.07	0.15	0.07	0.00	5.00	0.25	0.29	0.01	5.57	0.28
FS 0013	Subgroup of Cherries, raw	RAC	0.755	0.92	0.69	9.15	6.91	0.01	0.01	0.61	0.46	0.06	0.05	6.64	5.01
FS 0014	Subgroup of Plums, raw	RAC	0.44	2.40	1.06	8.60	3.78	0.06	0.03	2.52	1.11	0.58	0.26	4.16	1.83
DF 0014	Plums, dried (prunes)	PP	1.2	0.09	0.11	0.06	0.07	0.01	0.01	0.18	0.22	0.04	0.05	0.06	0.07
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.465	8.01	3.72	5.87	2.73	0.18	0.08	8.19	3.81	1.64	0.76	22.46	10.44
FB 2005	Subgroup of Caneberries, raw	RAC	1.3	0.42	0.55	1.05	1.37	0.01	0.01	0.02	0.03	0.02	0.03	1.24	1.61
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.3	0.53	0.69	1.31	1.70	0.40	0.52	1.66	2.16	0.01	0.01	0.99	1.29
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	1.3	0.62	0.81	0.33	0.43	0.34	0.44	1.42	1.85	0.01	0.01	1.51	1.96
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.47	12.68	5.96	9.12	4.29	0.03	0.01	16.88	7.93	3.70	1.74	54.42	25.58
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2	0.51	1.02	0.51	1.02	0.01	0.02	1.27	2.54	0.12	0.24	2.07	4.14
JF 0269	Grape juice (from wine grapes)	PP	0.16	0.14	0.02	0.29	0.05	0.05	0.01	0.30	0.05	0.24	0.04	0.05	0.01
-	Graps must (from wine-grapes)	PP	0.11	0.33	0.04	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	0.11	0.67	0.07	12.53	1.38	2.01	0.22	1.21	0.13	3.53	0.39	4.01	0.44
FB 2009	Subgroup of Low growing berries, raw	RAC	1.3	0.71	0.92	2.02	2.63	0.04	0.05	1.39	1.81	0.37	0.48	2.53	3.29
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.055	5.23	0.29	6.94	0.38	99.45	5.47	32.47	1.79	48.30	2.66	24.70	1.36
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.145	10.48	1.52	0.01	0.00	7.24	1.05	6.87	1.00	19.98	2.90	6.25	0.91
FI 0350	Papaya, raw	RAC	0.054	0.35	0.02	0.01	0.00	3.05	0.16	0.80	0.04	7.28	0.39	1.00	0.05

**FLUXAPYROXAD (256)**

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 µg/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
VA 0381	Garlic, raw	RAC	0.23	2.29	0.53	5.78	1.33	0.11	0.03	3.69	0.85	1.65	0.38	3.91	0.90
-	Onions, dry, raw	RAC	0.23	29.36	6.75	37.50	8.63	3.56	0.82	34.78	8.00	18.81	4.33	43.38	9.98
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.22	2.54	0.56	0.49	0.11	0.01	0.00	3.57	0.79	7.79	1.71	3.12	0.69
VB 0402	Brussels sprouts, raw	RAC	0.22	0.63	0.14	6.41	1.41	0.13	0.03	1.03	0.23	NC	-	2.35	0.52
VB 0041	Cabbages, head, raw	RAC	0.04	2.73	0.11	27.92	1.12	0.55	0.02	4.47	0.18	4.27	0.17	10.25	0.41
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.22	0.45	0.10	4.56	1.00	0.09	0.02	0.73	0.16	NC	-	1.67	0.37
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.0525	53.14	2.79	86.21	4.53	6.28	0.33	92.76	4.87	15.64	0.82	155.30	8.15
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	0.013	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	0.051	2.34	0.12	1.33	0.07	1.57	0.08	4.24	0.22	0.34	0.02	2.83	0.14
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.013	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 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.07	8.48	0.59	13.74	0.96	10.13	0.71	11.29	0.79	9.52	0.67	26.36	1.85
VO 2046	Subgroup of eggplants	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
VL 0483	Lettuce, leaf, raw	RAC	0.51	0.53	0.27	0.36	0.18	0.16	0.08	6.21	3.17	1.90	0.97	6.05	3.09
VL 0502	Spinach, raw	RAC	6.8	0.74	5.03	0.22	1.50	0.02	0.14	0.91	6.19	0.04	0.27	2.92	19.86
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.7	2.63	4.47	9.27	15.76	1.86	3.16	5.82	9.89	19.53	33.20	4.90	8.33
VL 0494	Radish leaves, raw	RAC	1.2	0.26	0.31	0.45	0.54	0.28	0.34	0.68	0.82	NC	-	0.33	0.40
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.65	0.68	0.44	NC	-	NC	-	0.39	0.25	0.22	0.14	0.49	0.32
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.03	1.56	0.05	0.60	0.02	0.49	0.01	1.18	0.04	0.90	0.03	7.79	0.23
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	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	0.04	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 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	72.79	0.73	59.05	0.59	20.55	0.21	74.20	0.74	61.12	0.61	73.24	0.73
OR 0541	Soya oil, refined	PP	0.005	12.99	0.06	10.43	0.05	3.63	0.02	13.10	0.07	10.70	0.05	13.10	0.07
-	Soya sauce	PP	0.005	0.01	0.00	0.02	0.00	0.01	0.00	0.34	0.00	0.03	0.00	0.01	0.00
-	Soya flour	PP	0.005	0.05	0.00	0.86	0.00	0.02	0.00	1.02	0.01	0.01	0.00	0.15	0.00
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
VR 0577	Carrots, raw	RAC	0.06	9.51	0.57	30.78	1.85	0.37	0.02	8.75	0.53	2.80	0.17	6.10	0.37
VR 0588	Parsnip, raw	RAC	0.06	0.59	0.04	1.05	0.06	0.65	0.04	1.58	0.09	NC	-	0.76	0.05
VR 0494	Radish roots, raw	RAC	0.05	2.31	0.12	4.09	0.20	2.53	0.13	6.15	0.31	5.88	0.29	2.97	0.15
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.04	0.13	0.01	NC	-	0.08	0.00	0.66	0.03	0.47	0.02	88.94	3.56

FLUXAPYROXAD (256)				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 µg/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
VR 0573	Arrowroot, raw	RAC	0.01	1.53	0.02	0.01	0.00	0.93	0.01	1.33	0.01	0.47	0.00	0.02	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.08	0.00	0.01	0.00	482.56	4.83	0.99	0.01	25.75	0.26	3.29	0.03
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	1.57	0.02	0.01	0.00	0.96	0.01	1.36	0.01	0.48	0.00	0.02	0.00
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.18	0.00	0.18	0.00	42.16	0.42	1.61	0.02	3.06	0.03	6.67	0.07
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	0.26	0.00	1.27	0.01
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	0.01	0.00	NC	-	25.12	0.25	0.04	0.00	0.01	0.00	0.97	0.01
VR 0600	Yams, raw (incl dried)	RAC	0.01	0.02	0.00	NC	-	90.40	0.90	6.45	0.06	0.74	0.01	0.65	0.01
VS 0624	Celery	RAC	1.6	2.14	3.42	3.79	6.06	2.35	3.76	5.69	9.10	0.02	0.03	2.75	4.40
GC 0650	Rye, raw (incl flour)	RAC	0.085	0.13	0.01	19.38	1.65	0.10	0.01	0.12	0.01	0.03	0.00	2.15	0.18
GC 0653	Triticale, raw (incl flour)	RAC	0.085	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.03	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.014	0.01	0.00	1.12	0.02	NC	-	0.03	0.00	0.56	0.01	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	0.054	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	0.014	301.24	4.22	268.64	3.76	30.21	0.42	222.51	3.12	134.73	1.89	343.12	4.80
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.535	19.91	10.65	31.16	16.67	5.04	2.70	3.10	1.66	9.77	5.23	4.31	2.31
-	Barley, pot&pearled	PP	0.086	7.12	0.61	7.34	0.63	0.02	0.00	0.03	0.00	0.67	0.06	0.20	0.02
-	Barley, flour (white flour and wholemeal flour)	PP	0.08	2.93	0.23	0.30	0.02	0.02	0.00	0.01	0.00	0.48	0.04	0.01	0.00
-	Barley beer	PP	0.011	4.87	0.05	93.78	1.03	24.28	0.27	12.76	0.14	39.28	0.43	18.15	0.20
-	Barley Malt	PP	0.0054	0.09	0.00	1.04	0.01	0.18	0.00	0.33	0.00	0.04	0.00	0.10	0.00
-	Barley Malt Extract	PP	0.0054	0.01	0.00	0.05	0.00	0.05	0.00	0.07	0.00	0.08	0.00	0.01	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.535	0.05	0.03	7.05	3.77	0.10	0.05	1.71	0.91	0.96	0.51	0.04	0.02
CM 0649 (GC 0649)	Rice, husked, dry (incl beverages, incl starch, excl polished, excl flour, excl oil)	REP	0.55	1.17	0.64	1.30	0.72	31.05	17.08	4.79	2.63	0.25	0.14	2.16	1.19
CM 1205	Rice polished, dry	PP	0.066	34.21	2.26	10.39	0.69	41.72	2.75	82.38	5.44	150.24	9.92	70.47	4.65
-	Rice flour	PP	0.08	0.05	0.00	0.22	0.02	0.01	0.00	0.50	0.04	0.22	0.02	0.02	0.00
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.11	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.2	4.34	0.87	0.01	0.00	16.25	3.25	15.82	3.16	10.97	2.19	2.92	0.58



**FLUXAPYROXAD (256)**

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 µg/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 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl oil, incl beer, incl germ, excl starch, excl flour)	RAC	0.01	1.80	0.02	1.08	0.01	1.85	0.02	5.89	0.06	2.85	0.03	15.24	0.15
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.009	22.72	0.20	35.61	0.32	87.27	0.79	34.92	0.31	46.71	0.42	49.12	0.44
-	Maize starch	PP	0.001	0.08	0.00	NC	-	0.01	0.00	2.29	0.00	0.08	0.00	0.11	0.00
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 0090	Subgroup of Mustard seeds, raw (incl flour, excl oil)	RAC	0.09	0.02	0.00	0.03	0.00	0.01	0.00	0.16	0.01	0.02	0.00	0.04	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.09	0.02	0.00	NC	-	NC	-	0.01	0.00	0.13	0.01	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0.09	0.93	0.08	1.16	0.10	0.49	0.04	2.53	0.23	9.32	0.84	2.02	0.18
SO 0699	Safflower seed, raw (incl oil)	RAC	0.09	0.03	0.00	0.20	0.02	0.01	0.00	0.01	0.00	0.29	0.03	0.01	0.00
SO 0702	Sunflower seed, raw	RAC	0.055	0.09	0.00	0.33	0.02	0.09	0.00	0.24	0.01	0.02	0.00	0.01	0.00
OR 0702	Sunflower seed oil, edible	PP	0.004	2.97	0.01	14.42	0.06	0.43	0.00	3.46	0.01	2.20	0.01	5.53	0.02
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	20.53	1.64	9.80	0.78	6.42	0.51	4.73	0.38	7.14	0.57	18.68	1.49
-	Castor bean, raw (incl oil)	RAC	0.09	NC	-	0.07	0.01	NC	-	NC	-	NC	-	0.01	0.00
SO 0696	Palm kernels, raw (incl oil)	RAC	0.09	5.81	0.52	3.77	0.34	20.07	1.81	24.53	2.21	5.94	0.53	8.99	0.81
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, excl butter)	RAC	0.01	1.30	0.01	1.23	0.01	12.62	0.13	2.68	0.03	6.58	0.07	2.67	0.03
-	Peanut butter	PP	0.028	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.01	0.01	0.00	0.01	0.00
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.09	NC	-	NC	-	0.34	0.03	NC	-	NC	-	NC	-
-	Oilseeds, NES, raw (including flour, incl myrtle wax, incl Japan wax): beech nut, Aleurites moluccana; Carapa guineensis; Croton tiglium; Bassia latifolia; Guizotia abyssinia; Licania rigida; Perilla frutescens; Jatropha curcas; Shorea robusta; Pongamia glabra; Astrocaryum spp., as well as tea seeds, grape seed and tomato seeds for oil extraction	RAC	0.09	0.51	0.05	0.23	0.02	0.66	0.06	0.68	0.06	0.58	0.05	0.15	0.01
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.042	1.36	0.06	3.59	0.15	1.44	0.06	5.18	0.22	2.02	0.08	1.70	0.07
HS 0444	Peppers, chili, dried	PP	0.7	0.42	0.29	0.53	0.37	0.84	0.59	0.50	0.35	0.95	0.67	0.37	0.26
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.02	24.96	0.50	57.95	1.16	16.70	0.33	38.38	0.77	26.46	0.53	29.00	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.047	6.24	0.29	14.49	0.68	4.18	0.20	9.60	0.45	6.62	0.31	7.25	0.34

**FLUXAPYROXAD (256)**

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 µg/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												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.047	3.29	0.15	6.14	0.29	0.82	0.04	1.57	0.07	2.23	0.10	1.07	0.05												
MO 0105	Edible offal (mammalian), raw	RAC	0.081	4.79	0.39	9.68	0.78	2.97	0.24	5.49	0.44	3.84	0.31	5.03	0.41												
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) - 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	0.021	1.46	0.03	2.98	0.06	0.80	0.02	12.97	0.27	2.50	0.05	3.57	0.07												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.021	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	0.021	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.11	0.24	0.01	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 (µg/person)=				92.2				130.2				69.2				142.2				100.0				212.7			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				1200				1200				1200				1200				1200							
%ADI=				7.7%				10.9%				5.8%				11.8%				8.3%				17.7%			
Rounded %ADI=				8%				10%				6%				10%				8%				20%			

**FLUXAPYROXAD (256)**

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 µg/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 kumquat commodities)	RAC	0.38	8.45	3.21	14.69	5.58	2.88	1.09	8.16	3.10	21.14	8.03	5.93	2.25
-	Lemon, juice (single strength, incl. concentrated)	PP	0.015	0.60	0.01	0.36	0.01	0.01	0.00	1.49	0.02	0.43	0.01	0.24	0.00
FC 0003	Subgroup of Mandarins, raw	RAC	0.38	12.34	4.69	14.99	5.70	16.08	6.11	10.76	4.09	9.94	3.78	NC	-
-	Subgroup of Mandarins, juice	PP	0.015	0.04	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.395	15.68	6.19	24.00	9.48	6.80	2.69	29.09	11.49	15.39	6.08	160.47	63.39
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.016	33.31	0.53	1.78	0.03	0.28	0.00	18.97	0.30	14.01	0.22	13.36	0.21
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.15	2.19	0.33	1.24	0.19	0.60	0.09	3.44	0.52	4.60	0.69	299.96	44.99
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.006	2.89	0.02	1.61	0.01	0.02	0.00	1.15	0.01	7.39	0.04	33.07	0.20
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.3	51.09	15.33	65.40	19.62	42.71	12.81	45.29	13.59	62.51	18.75	7.74	2.32
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.05	14.88	0.74	11.98	0.60	0.15	0.01	9.98	0.50	30.32	1.52	3.47	0.17
FS 0013	Subgroup of Cherries, raw	RAC	0.755	1.40	1.06	4.21	3.18	0.04	0.03	2.93	2.21	1.50	1.13	NC	-

**FLUXAPYROXAD (256)**

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 µg/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
FS 0014	Subgroup of Plums, raw	RAC	0.44	3.75	1.65	3.33	1.47	5.94	2.61	2.64	1.16	2.50	1.10	0.06	0.03
DF 0014	Plums, dried (prunes)	PP	1.2	0.61	0.73	0.35	0.42	0.05	0.06	0.35	0.42	0.49	0.59	0.13	0.16
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.465	13.03	6.06	16.29	7.57	8.29	3.85	12.95	6.02	5.35	2.49	0.04	0.02
FB 2005	Subgroup of Caneberries, raw	RAC	1.3	0.56	0.73	1.43	1.86	0.14	0.18	1.23	1.60	1.14	1.48	0.01	0.01
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.3	1.31	1.70	5.50	7.15	0.01	0.01	2.57	3.34	0.82	1.07	2.15	2.80
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	1.3	8.26	10.74	0.14	0.18	0.07	0.09	0.13	0.17	0.19	0.25	1.87	2.43
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.47	6.33	2.98	11.22	5.27	5.21	2.45	9.38	4.41	4.55	2.14	0.78	0.37
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2	3.09	6.18	1.51	3.02	0.03	0.06	1.38	2.76	4.26	8.52	0.42	0.84
JF 0269	Grape juice (from wine grapes)	PP	0.16	0.56	0.09	1.96	0.31	0.02	0.00	2.24	0.36	2.27	0.36	0.34	0.05
-	Graps must (from wine-grapes)	PP	0.11	0.16	0.02	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	0.11	88.93	9.78	62.41	6.87	1.84	0.20	25.07	2.76	61.17	6.73	5.84	0.64
FB 2009	Subgroup of Low growing berries, raw	RAC	1.3	4.55	5.92	5.66	7.36	0.02	0.03	7.85	10.21	5.86	7.62	0.05	0.07
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.055	25.76	1.42	23.65	1.30	23.83	1.31	24.37	1.34	19.43	1.07	101.55	5.59
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.145	1.80	0.26	0.63	0.09	10.05	1.46	1.07	0.16	3.52	0.51	16.44	2.38
FI 0350	Papaya, raw	RAC	0.054	0.31	0.02	0.18	0.01	1.50	0.08	0.51	0.03	0.54	0.03	1.08	0.06
VA 0381	Garlic, raw	RAC	0.23	0.98	0.23	1.49	0.34	12.88	2.96	3.74	0.86	2.05	0.47	1.14	0.26
-	Onions, dry, raw	RAC	0.23	19.69	4.53	29.83	6.86	24.64	5.67	31.35	7.21	9.72	2.24	12.59	2.90
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.22	9.50	2.09	6.77	1.49	NC	-	3.21	0.71	9.36	2.06	0.75	0.17
VB 0402	Brussels sprouts, raw	RAC	0.22	2.24	0.49	2.67	0.59	6.23	1.37	0.32	0.07	4.19	0.92	2.58	0.57
VB 0041	Cabbages, head, raw	RAC	0.04	8.97	0.36	27.12	1.08	1.44	0.06	24.96	1.00	4.55	0.18	11.23	0.45
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.22	NC	-	NC	-	17.39	3.83	9.44	2.08	NC	-	1.83	0.40
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.0525	27.81	1.46	41.93	2.20	123.30	6.47	49.47	2.60	15.95	0.84	35.99	1.89
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	0.013	7.57	0.10	2.66	0.03	0.30	0.00	0.97	0.01	7.31	0.10	0.41	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.051	4.96	0.25	3.20	0.16	0.15	0.01	1.61	0.08	6.88	0.35	0.52	0.03
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.013	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 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.07	6.39	0.45	15.53	1.09	19.09	1.34	10.36	0.73	8.29	0.58	4.53	0.32
VO 2046	Subgroup of eggplants	RAC	0.07	1.01	0.07	1.69	0.12	21.37	1.50	3.00	0.21	1.40	0.10	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.51	14.50	7.40	11.76	6.00	13.14	6.70	19.50	9.95	4.81	2.45	2.23	1.14

FLUXAPYROXAD (256)				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 µg/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
VL 0502	Spinach, raw	RAC	6.8	2.20	14.96	1.76	11.97	13.38	90.98	2.94	19.99	5.53	37.60	0.02	0.14
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.7	0.10	0.17	NC	-	26.78	45.53	5.00	8.50	0.58	0.99	5.68	9.66
VL 0494	Radish leaves, raw	RAC	1.2	NC	-	NC	-	NC	-	3.78	4.54	NC	-	0.48	0.58
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.65	5.07	3.30	0.83	0.54	0.17	0.11	3.70	2.41	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.03	2.21	0.07	5.25	0.16	4.17	0.13	1.61	0.05	16.95	0.51	0.17	0.01
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	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	0.04	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 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	106.33	1.06	117.78	1.18	42.12	0.42	195.70	1.96	222.52	2.23	80.47	0.80
OR 0541	Soya oil, refined	PP	0.005	19.06	0.10	21.06	0.11	5.94	0.03	33.78	0.17	40.05	0.20	13.39	0.07
-	Soya sauce	PP	0.005	0.45	0.00	0.29	0.00	2.93	0.01	4.35	0.02	0.09	0.00	0.70	0.00
-	Soya flour	PP	0.005	0.22	0.00	0.27	0.00	0.29	0.00	0.17	0.00	NC	-	NC	-
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
VR 0577	Carrots, raw	RAC	0.06	26.26	1.58	27.13	1.63	10.07	0.60	16.49	0.99	44.69	2.68	8.75	0.53
VR 0588	Parsnip, raw	RAC	0.06	4.42	0.27	0.06	0.00	NC	-	NC	-	NC	-	1.12	0.07
VR 0494	Radish roots, raw	RAC	0.05	3.83	0.19	11.99	0.60	NC	-	5.26	0.26	2.19	0.11	4.37	0.22
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.04	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
VR 0573	Arrowroot, raw	RAC	0.01	0.02	0.00	0.01	0.00	2.05	0.02	0.21	0.00	NC	-	0.76	0.01
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	0.01	0.00	NC	-	20.96	0.21	0.14	0.00	NC	-	9.62	0.10
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	0.11	0.00	0.01	0.00	NC	-	0.22	0.00	NC	-	0.78	0.01
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	0.93	0.01	0.32	0.00	64.65	0.65	5.37	0.05	0.30	0.00	3.13	0.03
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	NC	-	10.74	0.11
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	NC	-	NC	-	1.93	0.02	0.84	0.01	NC	-	19.94	0.20
VR 0600	Yams, raw (incl dried)	RAC	0.01	NC	-	NC	-	0.03	0.00	0.71	0.01	NC	-	17.57	0.18
VS 0624	Celery	RAC	1.6	7.68	12.29	2.85	4.56	NC	-	3.34	5.34	16.83	26.93	4.04	6.46
GC 0650	Rye, raw (incl flour)	RAC	0.085	3.21	0.27	35.38	3.01	0.21	0.02	6.50	0.55	1.49	0.13	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.085	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, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.014	NC	-	NC	-	0.02	0.00	0.83	0.01	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	0.054	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.05	0.00	0.02	0.00

**FLUXAPYROXAD (256)**

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 µg/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
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	0.014	198.08	2.77	193.03	2.70	106.24	1.49	185.09	2.59	168.67	2.36	131.59	1.84
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.535	36.18	19.36	53.45	28.60	9.39	5.02	35.25	18.86	46.68	24.97	15.92	8.52
-	Barley, pot&pearled	PP	0.086	0.57	0.05	2.56	0.22	0.33	0.03	0.56	0.05	0.36	0.03	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.08	0.08	0.01	0.03	0.00	0.01	0.00	0.05	0.00	0.68	0.05	0.05	0.00
-	Barley beer	PP	0.011	180.21	1.98	259.46	2.85	45.91	0.51	172.36	1.90	234.42	2.58	65.30	0.72
-	Barley Malt	PP	0.0054	0.19	0.00	NC	-	0.04	0.00	0.08	0.00	NC	-	2.14	0.01
-	Barley Malt Extract	PP	0.0054	0.37	0.00	0.08	0.00	0.03	0.00	0.05	0.00	0.18	0.00	0.29	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.535	7.50	4.01	6.26	3.35	0.15	0.08	4.87	2.61	3.16	1.69	2.98	1.59
CM 0649 (GC 0649)	Rice, husked, dry (incl beverages, incl starch, excl polished, excl flour, excl oil)	REP	0.55	2.43	1.34	1.62	0.89	0.43	0.24	1.59	0.87	NC	-	5.03	2.77
CM 1205	Rice polished, dry	PP	0.066	13.38	0.88	10.80	0.71	262.08	17.30	57.16	3.77	12.83	0.85	62.78	4.14
-	Rice flour	PP	0.08	0.98	0.08	0.38	0.03	0.72	0.06	0.05	0.00	0.23	0.02	0.07	0.01
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.11	NC	-	NC	-	0.03	0.00	2.77	0.30	NC	-	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.2	NC	-	NC	-	1.44	0.29	1.15	0.23	NC	-	7.12	1.42
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl oil, incl beer, incl germ, excl starch, excl flour)	RAC	0.01	0.99	0.01	10.40	0.10	1.55	0.02	13.27	0.13	2.19	0.02	0.41	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.009	14.27	0.13	12.86	0.12	19.71	0.18	12.55	0.11	4.21	0.04	52.30	0.47
-	Maize starch	PP	0.001	NC	-	NC	-	0.19	0.00	7.13	0.01	NC	-	NC	-
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 0090	Subgroup of Mustard seeds, raw (incl flour, excl oil)	RAC	0.09	0.27	0.02	0.44	0.04	0.08	0.01	0.56	0.05	1.03	0.09	0.40	0.04
SO 0693	Linseed, raw (incl oil)	RAC	0.09	NC	-	NC	-	0.02	0.00	0.01	0.00	NC	-	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0.09	32.68	2.94	19.91	1.79	7.83	0.70	15.69	1.41	NC	-	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.09	0.02	0.00	0.01	0.00	0.01	0.00	0.16	0.01	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.055	0.01	0.00	1.32	0.07	0.03	0.00	1.17	0.06	NC	-	0.02	0.00
OR 0702	Sunflower seed oil, edible	PP	0.004	9.50	0.04	11.37	0.05	0.49	0.00	5.15	0.02	2.63	0.01	2.80	0.01
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	10.71	0.86	4.23	0.34	7.19	0.58	7.54	0.60	5.66	0.45	2.38	0.19
-	Castor bean, raw (incl oil)	RAC	0.09	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-

FLUXAPYROXAD (256)				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 µg/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												
SO 0696	Palm kernels, raw (incl oil)	RAC	0.09	5.33	0.48	5.04	0.45	11.83	1.06	7.94	0.71	10.77	0.97	4.53	0.41												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, excl butter)	RAC	0.01	5.56	0.06	2.71	0.03	9.56	0.10	5.78	0.06	13.56	0.14	1.08	0.01												
-	Peanut butter	PP	0.028	0.07	0.00	0.04	0.00	0.01	0.00	0.03	0.00	0.15	0.00	0.75	0.02												
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.09	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-												
-	Oilseeds, NES, raw (including flour, incl myrtle wax, incl Japan wax): beech nut, Aleurites moluccana; Carapa guineensis; Croton tiglium; Bassia latifolia; Guizotia abyssinia; Licania rigida; Perilla frutescens; Jatropha curcas; Shorea robusta; Pongamia glabra; Astrocaryum spp., as well as tea seeds, grape seed and tomato seeds for oil extraction	RAC	0.09	0.05	0.00	0.01	0.00	0.17	0.02	0.22	0.02	NC	-	0.32	0.03												
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.042	10.90	0.46	12.44	0.52	0.77	0.03	9.48	0.40	22.07	0.93	8.15	0.34												
HS 0444	Peppers, chili, dried	PP	0.7	0.11	0.08	0.21	0.15	0.36	0.25	0.21	0.15	0.25	0.18	0.15	0.11												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.02	112.02	2.24	120.71	2.41	63.46	1.27	88.99	1.78	96.24	1.92	41.02	0.82												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.047	28.01	1.32	30.18	1.42	15.86	0.75	22.25	1.05	24.06	1.13	10.25	0.48												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.047	6.44	0.30	15.51	0.73	3.79	0.18	8.29	0.39	18.44	0.87	8.00	0.38												
MO 0105	Edible offal (mammalian), raw	RAC	0.081	15.17	1.23	5.19	0.42	6.30	0.51	6.78	0.55	3.32	0.27	3.17	0.26												
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) - 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	0.021	7.38	0.15	5.39	0.11	2.40	0.05	8.71	0.18	5.34	0.11	8.45	0.18												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.021	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	0.021	0.33	0.01	0.72	0.02	0.27	0.01	0.35	0.01	0.80	0.02	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 (µg/person)=				179.1				185.6				238.2				188.8				200.2				185.6			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (µg/person)=				1200				1200				1100				1200				1200				1200			
%ADI=				14.9%				15.5%				21.7%				15.7%				16.7%				15.5%			
Rounded %ADI=				10%				20%				20%				20%				20%				20%			

**FLUXAPYROXAD (256)**

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: µg/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 kumquat commodities)	RAC	0.38	18.96	7.20	0.97	0.37	5.79	2.20	0.09	0.03	3.35	1.27
-	Lemon, juice (single strength, incl. concentrated)	PP	0.015	0.01	0.00	0.01	0.00	0.16	0.00	0.01	0.00	NC	-
FC 0003	Subgroup of Mandarins, raw	RAC	0.38	0.16	0.06	0.27	0.10	9.06	3.44	0.01	0.00	0.02	0.01
-	Subgroup of Mandarins, juice	PP	0.015	0.01	0.00	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.395	1.18	0.47	1.11	0.44	14.28	5.64	0.05	0.02	1.08	0.43
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.016	0.08	0.00	0.26	0.00	12.61	0.20	0.14	0.00	0.33	0.01
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.15	0.63	0.09	0.01	0.00	1.58	0.24	0.01	0.00	NC	-
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.006	0.03	0.00	0.02	0.00	0.78	0.00	0.01	0.00	NC	-
FP 0009	Group of Pome fruits, raw (incl apple cider, excl apple juice)	RAC	0.3	68.85	20.66	10.93	3.28	70.82	21.25	189.78	56.93	19.56	5.87
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.05	0.03	0.00	0.10	0.01	7.19	0.36	0.03	0.00	NC	-
FS 0013	Subgroup of Cherries, raw	RAC	0.755	0.01	0.01	0.01	0.01	5.96	4.50	0.01	0.01	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.44	0.07	0.03	0.01	0.00	15.56	6.85	0.01	0.00	NC	-
DF 0014	Plums, dried (prunes)	PP	1.2	0.01	0.01	0.01	0.01	0.37	0.44	0.01	0.01	NC	-
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.465	0.02	0.01	0.01	0.00	10.76	5.00	0.01	0.00	NC	-
FB 2005	Subgroup of Caneberries, raw	RAC	1.3	0.01	0.01	7.30	9.49	2.29	2.98	0.01	0.01	NC	-
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.3	0.82	1.07	4.05	5.27	5.94	7.72	0.43	0.56	2.66	3.46
FB 2007	Subgroup of Large shrub/tree berries, raw (including processed)	RAC	1.3	0.71	0.92	7.32	9.52	NC	-	0.38	0.49	2.32	3.02
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.47	0.14	0.07	0.36	0.17	15.22	7.15	0.01	0.00	0.09	0.04
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2	0.01	0.02	0.13	0.26	1.06	2.12	0.01	0.02	0.03	0.06
JF 0269	Grape juice (from wine grapes)	PP	0.16	0.01	0.00	0.01	0.00	0.41	0.07	0.01	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.11	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	0.11	0.31	0.03	0.23	0.03	60.43	6.65	0.52	0.06	31.91	3.51
FB 2009	Subgroup of Low growing berries, raw	RAC	1.3	0.01	0.01	0.01	0.01	3.37	4.38	0.01	0.01	0.01	0.01
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.055	44.80	2.46	118.17	6.50	25.25	1.39	454.49	25.00	310.23	17.06
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.145	12.25	1.78	6.83	0.99	0.76	0.11	0.01	0.00	20.12	2.92
FI 0350	Papaya, raw	RAC	0.054	6.47	0.35	0.25	0.01	0.19	0.01	0.01	0.00	26.42	1.43
VA 0381	Garlic, raw	RAC	0.23	0.82	0.19	2.06	0.47	3.79	0.87	0.03	0.01	0.29	0.07
-	Onions, dry, raw	RAC	0.23	9.01	2.07	20.24	4.66	30.90	7.11	9.61	2.21	2.11	0.49
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	0.22	0.02	0.00	0.02	0.00	4.86	1.07	0.01	0.00	NC	-
VB 0402	Brussels sprouts, raw	RAC	0.22	0.88	0.19	0.69	0.15	2.89	0.64	0.01	0.00	NC	-

**FLUXAPYROXAD (256)**

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: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VB 0041	Cabbages, head, raw	RAC	0.04	3.82	0.15	2.99	0.12	49.16	1.97	0.01	0.00	NC	-
VB 0467	Chinese cabbage, type pe-tsai, raw	RAC	0.22	0.62	0.14	0.49	0.11	NC	-	0.01	0.00	NC	-
VC 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.0525	5.96	0.31	9.74	0.51	51.82	2.72	13.61	0.71	0.05	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	0.013	0.07	0.00	0.08	0.00	2.42	0.03	0.07	0.00	NC	-
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.051	0.58	0.03	0.22	0.01	2.21	0.11	0.24	0.01	3.10	0.16
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.013	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.07	8.97	0.63	14.13	0.99	25.14	1.76	0.91	0.06	NC	-
VO 2046	Subgroup of eggplants	RAC	0.07	1.31	0.09	8.26	0.58	3.95	0.28	0.01	0.00	NC	-
VL 0483	Lettuce, leaf, raw	RAC	0.51	0.29	0.15	0.03	0.02	6.71	3.42	0.01	0.01	NC	-
VL 0502	Spinach, raw	RAC	6.8	0.17	1.16	0.01	0.07	0.81	5.51	0.01	0.07	NC	-
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	1.7	3.58	6.09	2.64	4.49	NC	-	1.83	3.11	3.65	6.21
VL 0494	Radish leaves, raw	RAC	1.2	0.44	0.53	0.32	0.38	NC	-	0.30	0.36	0.59	0.71
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0.65	NC	-	NC	-	NC	-	NC	-	NC	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.03	0.30	0.01	3.13	0.09	4.11	0.12	0.01	0.00	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	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	0.04	7.11	0.28	2.33	0.09	3.76	0.15	44.70	1.79	3.27	0.13
VD 0541	Soya bean, dry, raw (incl paste, incl curd, incl oil, incl sauce)	RAC	0.01	15.80	0.16	14.29	0.14	104.36	1.04	17.11	0.17	35.20	0.35
OR 0541	Soya oil, refined	PP	0.005	2.32	0.01	2.54	0.01	18.70	0.09	2.51	0.01	6.29	0.03
-	Soya sauce	PP	0.005	0.01	0.00	0.13	0.00	0.17	0.00	0.01	0.00	0.56	0.00
-	Soya flour	PP	0.005	0.11	0.00	0.08	0.00	0.07	0.00	0.01	0.00	0.03	0.00
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
VR 0577	Carrots, raw	RAC	0.06	2.07	0.12	3.00	0.18	25.29	1.52	0.05	0.00	NC	-
VR 0588	Parsnip, raw	RAC	0.06	1.02	0.06	0.74	0.04	3.50	0.21	0.69	0.04	1.37	0.08
VR 0494	Radish roots, raw	RAC	0.05	3.96	0.20	2.86	0.14	3.30	0.17	2.67	0.13	5.34	0.27
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.04	3.93	0.16	1.68	0.07	NC	-	NC	-	36.12	1.44
VR 0573	Arrowroot, raw	RAC	0.01	13.83	0.14	18.24	0.18	0.01	0.00	0.05	0.00	19.60	0.20
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.01	91.92	0.92	34.12	0.34	NC	-	259.92	2.60	45.48	0.45
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.01	14.22	0.14	18.75	0.19	0.01	0.00	0.06	0.00	20.14	0.20
VR 0508	Sweet potato, raw (incl dried)	RAC	0.01	28.83	0.29	61.55	0.62	0.15	0.00	221.94	2.22	NC	-



**FLUXAPYROXAD (256)**

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: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.01	NC	-	NC	-	0.01	0.00	NC	-	NC	-
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.01	6.71	0.07	31.91	0.32	NC	-	10.73	0.11	264.31	2.64
VR 0600	Yams, raw (incl dried)	RAC	0.01	70.93	0.71	30.62	0.31	0.07	0.00	5.65	0.06	30.85	0.31
VS 0624	Celery	RAC	1.6	3.66	5.86	2.65	4.24	4.84	7.74	2.47	3.95	4.94	7.90
GC 0650	Rye, raw (incl flour)	RAC	0.085	0.03	0.00	0.01	0.00	13.95	1.19	0.01	0.00	0.88	0.07
GC 0653	Triticale, raw (incl flour)	RAC	0.085	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	0.014	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.01
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	0.054	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	0.014	44.78	0.63	86.96	1.22	214.05	3.00	20.31	0.28	103.60	1.45
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.535	11.58	6.20	2.33	1.25	46.71	24.99	3.72	1.99	16.26	8.70
-	Barley, pot&pearled	PP	0.086	5.46	0.47	0.01	0.00	1.44	0.12	0.01	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.08	0.02	0.00	NC	-	0.32	0.03	0.01	0.00	NC	-
-	Barley beer	PP	0.011	16.25	0.18	11.36	0.12	225.21	2.48	19.49	0.21	52.17	0.57
-	Barley Malt	PP	0.0054	0.01	0.00	0.11	0.00	0.67	0.00	0.01	0.00	4.61	0.02
-	Barley Malt Extract	PP	0.0054	0.02	0.00	0.01	0.00	0.03	0.00	0.01	0.00	0.06	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.535	0.37	0.20	0.07	0.04	2.79	1.49	0.10	0.05	NC	-
CM 0649 (GC 0649)	Rice, husked, dry (incl beverages, incl starch, excl polished, excl flour, excl oil)	REP	0.55	13.54	7.45	3.52	1.94	1.96	1.08	0.01	0.01	8.84	4.86
CM 1205	Rice polished, dry	PP	0.066	30.20	1.99	218.34	14.41	12.77	0.84	15.24	1.01	51.35	3.39
-	Rice flour	PP	0.08	0.03	0.00	0.13	0.01	0.16	0.01	0.01	0.00	NC	-
-	Rice, Fermented Beverages (rice wine, sake)	PP	0.11	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.2	89.16	17.83	2.02	0.40	NC	-	35.38	7.08	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl oil, incl beer, incl germ, excl starch, excl flour)	RAC	0.01	0.88	0.01	0.58	0.01	4.07	0.04	7.96	0.08	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.009	94.34	0.85	8.09	0.07	28.03	0.25	55.94	0.50	28.07	0.25
-	Maize starch	PP	0.001	0.02	0.00	0.01	0.00	NC	-	NC	-	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

**FLUXAPYROXAD (256)**

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: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
SO 0090	Subgroup of Mustard seeds, raw (incl flour, excl oil)	RAC	0.09	0.04	0.00	0.18	0.02	0.29	0.03	0.02	0.00	0.01	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.09	0.07	0.01	NC	-	0.03	0.00	NC	-	NC	-
SO 0495	Rape seed, raw (incl oil)	RAC	0.09	0.19	0.02	0.07	0.01	12.07	1.09	0.08	0.01	NC	-
SO 0699	Safflower seed, raw (incl oil)	RAC	0.09	0.05	0.00	NC	-	NC	-	NC	-	NC	-
SO 0702	Sunflower seed, raw	RAC	0.055	0.02	0.00	0.01	0.00	0.03	0.00	2.23	0.12	NC	-
OR 0702	Sunflower seed oil, edible	PP	0.004	0.37	0.00	0.09	0.00	12.98	0.05	4.01	0.02	0.20	0.00
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	8.14	0.65	0.32	0.03	2.84	0.23	2.69	0.22	0.97	0.08
-	Castor bean, raw (incl oil)	RAC	0.09	NC	-	NC	-	NC	-	NC	-	NC	-
SO 0696	Palm kernels, raw (incl oil)	RAC	0.09	60.84	5.48	12.77	1.15	5.41	0.49	0.57	0.05	53.45	4.81
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl oil, excl butter)	RAC	0.01	18.82	0.19	0.54	0.01	2.23	0.02	6.90	0.07	0.53	0.01
-	Peanut butter	PP	0.028	0.01	0.00	0.03	0.00	0.05	0.00	NC	-	NC	-
SO 0701	Shea nut (karite nuts), nutmeat, raw (incl butter)	RAC	0.09	0.95	0.09	NC	-	NC	-	NC	-	NC	-
-	Oilseeds, NES, raw (including flour, incl myrtle wax, incl Japan wax): beech nut, Aleurites moluccana; Carapa guineensis; Croton tiglium; Bassia latifolia; Guizotia abyssinia; Licania rigida; Perilla frutescens; Jatropha curcas; Shorea robusta; Pongamia glabra; Astrocaryum spp., as well as tea seeds, grape seed and tomato seeds for oil extraction	RAC	0.09	1.00	0.09	0.42	0.04	NC	-	2.47	0.22	2.43	0.22
SB 0716	Coffee bean raw (incl roasted, incl instant coffee, incl substitutes)	RAC	0.042	0.95	0.04	1.32	0.06	11.64	0.49	2.96	0.12	14.73	0.62
HS 0444	Peppers, chili, dried	PP	0.7	0.58	0.41	1.27	0.89	1.21	0.85	0.12	0.08	NC	-
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) -80% as muscle	RAC	0.02	23.34	0.47	40.71	0.81	97.15	1.94	18.06	0.36	57.71	1.15
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.047	5.84	0.27	10.18	0.48	24.29	1.14	4.52	0.21	14.43	0.68
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.047	1.05	0.05	1.14	0.05	18.69	0.88	0.94	0.04	3.12	0.15
MO 0105	Edible offal (mammalian), raw	RAC	0.081	4.64	0.38	1.97	0.16	10.01	0.81	3.27	0.26	3.98	0.32
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) - 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	0.021	0.39	0.01	1.20	0.03	5.71	0.12	0.50	0.01	5.56	0.12
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.021	NC	-	NC	-	0.32	0.01	NC	-	NC	-
PO 0111	Poultry edible offal, raw (incl prepared)	RAC	0.021	0.10	0.00	0.70	0.01	0.97	0.02	0.10	0.00	NC	-

**FLUXAPYROXAD (256)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.02 mg/kg bw

Codex Code	Commodity description	Expr as	STM <sup>R</sup> mg/kg	Diets: g/person/day				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
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 (µg/person)=				101.8		82.1		170.5		114.7		92.8	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg/person)=				1200		1200		1200		1200		1200	
%ADI=				8.5%		6.8%		14.2%		9.6%		7.7%	
Rounded %ADI=				8%		7%		10%		10%		8%	

FLUENSULFONE (265)				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 µg/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, incl kumquat commodities)	RAC	0.01	34.91	0.35	16.51	0.17	17.23	0.17	104.48	1.04	35.57	0.36	98.49	0.98
FB 2009	Subgroup of Low growing berries, raw	RAC	0.01	0.71	0.01	2.02	0.02	0.04	0.00	1.39	0.01	0.37	0.00	2.53	0.03
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.01	6.43	0.06	40.26	0.40	0.80	0.01	9.94	0.10	12.07	0.12	17.73	0.18
VC 0424	Cucumber, raw	RAC	0.01	8.01	0.08	30.66	0.31	1.45	0.01	19.84	0.20	0.27	0.00	34.92	0.35
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.01	0.78	0.01	2.06	0.02	0.30	0.00	1.61	0.02	2.25	0.02	2.36	0.02
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.01	8.90	0.09	8.64	0.09	0.80	0.01	17.90	0.18	2.80	0.03	29.17	0.29
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 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.01	67.79	0.68	99.85	1.00	31.70	0.32	125.86	1.26	55.22	0.55	262.82	2.63
VL 0053	Group of Leafy vegetables, raw	RAC	0.01	8.47	0.08	22.36	0.22	7.74	0.08	25.51	0.26	45.77	0.46	21.22	0.21
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
VR 0574	Beetroot, raw	RAC	0.12	3.42	0.41	6.06	0.73	3.75	0.45	9.11	1.09	NC	-	4.39	0.53
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	0.12	9.51	1.14	30.78	3.69	0.37	0.04	8.75	1.05	2.80	0.34	6.10	0.73
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 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	0.12	0.51	0.06	0.91	0.11	0.56	0.07	1.37	0.16	NC	-	0.66	0.08
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	0.12	0.59	0.07	1.05	0.13	0.65	0.08	1.58	0.19	NC	-	0.76	0.09
VR 0494	Radish roots, raw	RAC	0.12	2.31	0.28	4.09	0.49	2.53	0.30	6.15	0.74	5.88	0.71	2.97	0.36
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.12	1.90	0.23	3.36	0.40	2.08	0.25	5.06	0.61	NC	-	2.44	0.29
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	0.12	1.58	0.19	2.80	0.34	1.74	0.21	4.21	0.51	NC	-	2.03	0.24
VR 0506	Turnip, garden, raw	RAC	0.12	2.50	0.30	4.44	0.53	2.75	0.33	6.67	0.80	0.14	0.02	3.22	0.39
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.01	63.11	0.63	316.33	3.16	651.91	6.52	72.06	0.72	84.88	0.85	132.70	1.33
VS 0624	Celery	RAC	0.1085	2.14	0.23	3.79	0.41	2.35	0.25	5.69	0.62	0.02	0.00	2.75	0.30
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.01	381.29	3.81	360.94	3.61	38.45	0.38	282.01	2.82	173.32	1.73	436.22	4.36

**FLUENSULFONE (265)**

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 µg/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 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.01	19.96	0.20	38.62	0.39	5.13	0.05	4.81	0.05	10.80	0.11	4.44	0.04
GC 2088	Subgroup of rice cereals	REP	0.01	45.40	0.45	14.99	0.15	84.88	0.85	111.73	1.12	194.75	1.95	93.12	0.93
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.01	5.80	0.06	2.32	0.02	23.09	0.23	16.72	0.17	27.14	0.27	2.92	0.03
GC 2091	Subgroup of Maize Cereals	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
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	RAC	0.01	38.16	0.38	NC	-	12.58	0.13	0.34	0.00	17.79	0.18	42.78	0.43
-	Sugar cane, molasses	PP	0	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
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
HS 0444	Peppers, chili, dried	PP	0.1	0.42	0.04	0.53	0.05	0.84	0.08	0.50	0.05	0.95	0.10	0.37	0.04
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0005	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.10	0.00	0.10	0.00
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Total intake (µg/person)=	10.8	17.6	12.3	15.4	8.7	17.7
Bodyweight per region (kg bw) =	60	60	60	60	60	60
ADI (µg/person)=	600	600	600	600	600	600
%ADI=	1.8%	2.9%	2.1%	2.6%	1.4%	2.9%
Rounded %ADI=	2%	3%	2%	3%	1%	3%

**FLUENSULFONE (265)**

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 µg/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	0.01	114.42	1.14	62.91	0.63	26.97	0.27	96.72	0.97	96.22	0.96	563.19	5.63
FB 2009	Subgroup of Low growing berries, raw	RAC	0.01	4.55	0.05	5.66	0.06	0.02	0.00	7.85	0.08	5.86	0.06	0.05	0.00
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.01	20.71	0.21	39.81	0.40	25.06	0.25	37.93	0.38	18.12	0.18	16.74	0.17
VC 0424	Cucumber, raw	RAC	0.01	6.72	0.07	11.03	0.11	32.10	0.32	15.10	0.15	4.05	0.04	9.57	0.10
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini), raw	RAC	0.01	NC	-	NC	-	5.48	0.05	NC	-	NC	-	1.03	0.01
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.01	9.20	0.09	11.95	0.12	14.63	0.15	8.99	0.09	7.86	0.08	2.46	0.02
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

FLUENSULFONE (265)				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 µg/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
VO 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.01	72.14	0.72	85.53	0.86	76.55	0.77	95.63	0.96	64.19	0.64	16.94	0.17
VL 0053	Group of Leafy vegetables, raw	RAC	0.01	18.83	0.19	21.85	0.22	121.23	1.21	43.09	0.43	18.18	0.18	18.32	0.18
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
VR 0574	Beetroot, raw	RAC	0.12	9.91	1.19	6.34	0.76	NC	-	9.65	1.16	19.11	2.29	6.47	0.78
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	0.12	26.26	3.15	27.13	3.26	10.07	1.21	16.49	1.98	44.69	5.36	8.75	1.05
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 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	0.12	0.01	0.00	0.42	0.05	13.01	1.56	0.26	0.03	2.70	0.32	0.97	0.12
VR 0587	Parsley turnip-rooted, raw	RAC	0.01	NC	-	NC	-	NC	-	NC	-	NC	-	0.61	0.01
VR 0588	Parsnip, raw	RAC	0.12	4.42	0.53	0.06	0.01	NC	-	NC	-	NC	-	1.12	0.13
VR 0494	Radish roots, raw	RAC	0.12	3.83	0.46	11.99	1.44	NC	-	5.26	0.63	2.19	0.26	4.37	0.52
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.12	NC	-	NC	-	26.64	3.20	18.92	2.27	NC	-	3.59	0.43
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	0.12	10.01	1.20	1.66	0.20	NC	-	NC	-	3.06	0.37	2.99	0.36
VR 0506	Turnip, garden, raw	RAC	0.12	5.78	0.69	15.35	1.84	NC	-	6.54	0.78	1.95	0.23	4.73	0.57
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.01	226.09	2.26	234.58	2.35	161.10	1.61	185.04	1.85	234.85	2.35	100.25	1.00
VS 0624	Celery	RAC	0.1085	7.68	0.83	2.85	0.31	NC	-	3.34	0.36	16.83	1.83	4.04	0.44
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.01	256.28	2.56	280.29	2.80	134.94	1.35	241.61	2.42	217.88	2.18	167.40	1.67
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.01	43.68	0.44	60.49	0.60	9.72	0.10	40.47	0.40	49.83	0.50	18.90	0.19
GC 2088	Subgroup of rice cereals	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
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.01	0.03	0.00	0.16	0.00	3.19	0.03	1.85	0.02	NC	-	7.12	0.07
GC 2091	Subgroup of Maize Cereals	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
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	RAC	0.01	NC	-	NC	-	4.27	0.04	0.01	0.00	NC	-	3.24	0.03
-	Sugar cane, molasses	PP	0	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
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
HS 0444	Peppers, chili, dried	PP	0.1	0.11	0.01	0.21	0.02	0.36	0.04	0.21	0.02	0.25	0.03	0.15	0.02

**FLUENSULFONE (265)**

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 µg/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												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0005	0.10	0.00	0.10	0.00	NC	-	0.10	0.00	0.71	0.00	NC	-												
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-												
Total intake (µg/person)=				17.0				17.0				16.7				16.6				20.8				16.0			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (µg/person)=				600				600				550				600				600				600			
%ADI=				2.8%				2.8%				3.0%				2.8%				3.5%				2.7%			
Rounded %ADI=				3%				3%				3%				3%				3%				3%			

**FLUENSULFONE (265)**

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				Intake = daily intake: µg/person							
				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	0.01	21.16	0.21	2.94	0.03	58.52	0.59	0.44	0.00	5.13	0.05		
FB 2009	Subgroup of Low growing berries, raw	RAC	0.01	0.01	0.00	0.01	0.00	3.37	0.03	0.01	0.00	0.01	0.00		
VB 0040	Group of Brassica vegetables (excl Brassica leafy vegetables), raw	RAC	0.01	5.46	0.05	4.28	0.04	58.72	0.59	0.02	0.00	NC	-		
VC 0424	Cucumber, raw	RAC	0.01	0.68	0.01	1.81	0.02	10.40	0.10	0.01	0.00	0.04	0.00		
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.01	0.09	0.00	1.01	0.01	NC	-	1.91	0.02	NC	-		
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.01	0.19	0.00	0.10	0.00	4.98	0.05	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 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.01	32.01	0.32	28.27	0.28	100.61	1.01	2.91	0.03	12.50	0.13		
VL 0053	Group of Leafy vegetables, raw	RAC	0.01	12.42	0.12	8.75	0.09	7.53	0.08	7.07	0.07	14.11	0.14		
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	-		
VR 0574	Beetroot, raw	RAC	0.12	5.86	0.70	4.23	0.51	9.46	1.14	3.96	0.48	7.91	0.95		
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	0.12	2.07	0.25	3.00	0.36	25.29	3.03	0.05	0.01	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 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	0.12	0.88	0.11	0.63	0.08	0.54	0.06	0.59	0.07	1.19	0.14		
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		

FLUENSULFONE (265)				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				Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
VR 0588	Parsnip, raw	RAC	0.12	1.02	0.12	0.74	0.09	3.50	0.42	0.69	0.08	1.37	0.16	
VR 0494	Radish roots, raw	RAC	0.12	3.96	0.48	2.86	0.34	3.30	0.40	2.67	0.32	5.34	0.64	
VR 0591	Japanese radish, raw (i.e. Chinese radish, Daikon)	RAC	0.12	3.25	0.39	2.35	0.28	NC	-	2.20	0.26	4.39	0.53	
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	0.12	2.71	0.33	1.96	0.24	7.80	0.94	1.83	0.22	3.66	0.44	
VR 0506	Turnip, garden, raw	RAC	0.12	4.29	0.51	3.10	0.37	6.41	0.77	2.90	0.35	5.79	0.69	
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0.01	250.41	2.50	208.74	2.09	213.64	2.14	602.70	6.03	388.95	3.89	
VS 0624	Celery	RAC	0.1085	3.66	0.40	2.65	0.29	4.84	0.53	2.47	0.27	4.94	0.54	
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.01	57.23	0.57	110.47	1.10	286.57	2.87	25.82	0.26	132.92	1.33	
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.01	11.99	0.12	5.22	0.05	49.50	0.50	3.82	0.04	16.26	0.16	
GC 2088	Subgroup of rice cereals	REP	0.01	52.55	0.53	286.02	2.86	18.64	0.19	19.67	0.20	75.09	0.75	
GC 2089	Subgroup of Sorghum Grain and Millet	RAC	0.01	150.90	1.51	2.80	0.03	NC	-	68.93	0.69	NC	-	
GC 2091	Subgroup of Maize Cereals	RAC	0.01	116.66	1.17	10.52	0.11	38.46	0.38	76.60	0.77	34.44	0.34	
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	RAC	0.01	5.62	0.06	50.91	0.51	NC	-	11.04	0.11	0.10	0.00	
-	Sugar cane, molasses	PP	0	NC	-	NC	-	NC	-	NC	-	NC	-	
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	
HS 0444	Peppers, chili, dried	PP	0.1	0.58	0.06	1.27	0.13	1.21	0.12	0.12	0.01	NC	-	
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.0005	NC	-	NC	-	0.32	0.00	NC	-	NC	-	
Total intake (µg/person)=					11.0		11.8		17.4		10.5		14.9	
Bodyweight per region (kg bw) =					60		60		60		60		60	
ADI (µg/person)=					600		600		600		600		600	
%ADI=					1.8%		2.0%		2.9%		1.8%		2.5%	
Rounded %ADI=					2%		2%		3%		2%		2%	



## KRESOXIM-METHYL (199)

## 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 µg/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
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.11	13.49	1.48	26.63	2.93	15.05	1.66	16.28	1.79	6.47	0.71	47.88	5.27
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.022	0.32	0.01	3.07	0.07	0.07	0.00	5.00	0.11	0.29	0.01	5.57	0.12
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.11	0.59	0.06	0.36	0.04	0.46	0.05	1.88	0.21	NC	-	1.15	0.13
FP 0229	Medlar, raw (incl processed)	RAC	0.11	0.47	0.05	0.29	0.03	0.36	0.04	1.49	0.16	NC	-	0.92	0.10
FP 0230	Pear, raw	RAC	0.11	2.16	0.24	6.24	0.69	0.05	0.01	4.07	0.45	1.16	0.13	5.34	0.59
FP 0231	Quince, raw	RAC	0.11	0.73	0.08	0.54	0.06	0.01	0.00	0.07	0.01	0.06	0.01	1.31	0.14
-	Peaches and nectarines, raw	RAC	0.37	2.87	1.06	2.21	0.82	0.15	0.06	5.94	2.20	1.47	0.54	15.66	5.79
FB 0021	Currants, Black, Red, White, raw	RAC	0.21	0.02	0.00	0.74	0.16	0.01	0.00	0.03	0.01	0.01	0.00	0.01	0.00
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.365	12.68	4.63	9.12	3.33	0.03	0.01	16.88	6.16	3.70	1.35	54.42	19.86
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.58	0.51	0.30	0.51	0.30	0.01	0.01	1.27	0.74	0.12	0.07	2.07	1.20
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
-	Graps must (from wine-grapes)	PP	0.11	0.33	0.04	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	0.095	0.67	0.06	12.53	1.19	2.01	0.19	1.21	0.11	3.53	0.34	4.01	0.38
FT 0305	Table olives, raw (incl preserved)	RAC	0.1	0.70	0.07	0.32	0.03	0.01	0.00	1.53	0.15	0.17	0.02	1.85	0.19
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.024	10.48	0.25	0.01	0.00	7.24	0.17	6.87	0.16	19.98	0.48	6.25	0.15
VA 0381	Garlic, raw	RAC	0.02	2.29	0.05	5.78	0.12	0.11	0.00	3.69	0.07	1.65	0.03	3.91	0.08
VA 0384	Leek, raw	RAC	3.2	0.18	0.58	1.59	5.09	0.03	0.10	0.28	0.90	0.01	0.03	3.21	10.27
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 0445	Peppers, sweet, raw (incl dried)	RAC	0.045	4.49	0.20	6.44	0.29	7.21	0.32	5.68	0.26	9.52	0.43	8.92	0.40
VR 0596	Sugar beet, raw (incl sugar)	RAC	0	0.13	0.00	NC	-	0.08	0.00	0.66	0.00	0.47	0.00	88.94	0.00
VR 0506	Turnip, garden, raw	RAC	0	2.50	0.00	4.44	0.00	2.75	0.00	6.67	0.00	0.14	0.00	3.22	0.00
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.02	381.29	7.63	360.94	7.22	38.45	0.77	282.01	5.64	173.32	3.47	436.22	8.72
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.035	19.96	0.70	38.62	1.35	5.13	0.18	4.81	0.17	10.80	0.38	4.44	0.16
TN 0672	Pecan, nutmeat	RAC	0.1	0.05	0.01	0.05	0.01	0.02	0.00	0.14	0.01	0.09	0.01	0.13	0.01
SO 0305	Olives for oil production, raw	RAC	0.1	1.47	0.15	0.67	0.07	NC	-	1.26	0.13	0.04	0.00	7.63	0.76
-	Olive oil (virgin and residue oil)	PP	0.34	2.17	0.74	0.13	0.04	0.05	0.02	1.32	0.45	0.10	0.03	2.76	0.94
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

**KRESOXIM-METHYL (199)**

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 µg/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												
MO 0105	Edible offal (mammalian), raw	RAC	0.009	4.79	0.04	9.68	0.09	2.97	0.03	5.49	0.05	3.84	0.03	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 (µg/person)=				24.0				33.0				4.3				29.7				9.8				71.6			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				18000				18000				18000				18000				18000							
%ADI=				0.1%				0.2%				0.0%				0.2%				0.1%				0.4%			
Rounded %ADI=				0%				0%				0%				0%				0%							

**KRESOXIM-METHYL (199)**

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 µg/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
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.11	41.14	4.53	56.49	6.21	26.64	2.93	31.58	3.47	51.94	5.71	3.05	0.34
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.022	14.88	0.33	11.98	0.26	0.15	0.00	9.98	0.22	30.32	0.67	3.47	0.08
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.11	0.96	0.11	NC	-	NC	-	3.92	0.43	NC	-	2.49	0.27
FP 0229	Medlar, raw (incl processed)	RAC	0.11	NC	-	NC	-	NC	-	NC	-	NC	-	1.98	0.22
FP 0230	Pear, raw	RAC	0.11	8.79	0.97	8.44	0.93	12.37	1.36	9.60	1.06	10.27	1.13	0.23	0.03
FP 0231	Quince, raw	RAC	0.11	0.19	0.02	0.18	0.02	0.11	0.01	0.04	0.00	0.28	0.03	NC	-
-	Peaches and nectarines, raw	RAC	0.37	8.76	3.24	12.98	4.80	8.23	3.05	10.09	3.73	3.64	1.35	0.04	0.01
FB 0021	Currants, Black, Red, White, raw	RAC	0.21	0.48	0.10	4.23	0.89	NC	-	1.51	0.32	0.49	0.10	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.365	6.33	2.31	11.22	4.10	5.21	1.90	9.38	3.42	4.55	1.66	0.78	0.28
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.58	3.09	1.79	1.51	0.88	0.03	0.02	1.38	0.80	4.26	2.47	0.42	0.24
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
-	Graps must (from wine-grapes)	PP	0.11	0.16	0.02	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	0.095	88.93	8.45	62.41	5.93	1.84	0.17	25.07	2.38	61.17	5.81	5.84	0.55
FT 0305	Table olives, raw (incl preserved)	RAC	0.1	2.00	0.20	2.48	0.25	0.01	0.00	1.21	0.12	1.64	0.16	0.27	0.03
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.024	1.80	0.04	0.63	0.02	10.05	0.24	1.07	0.03	3.52	0.08	16.44	0.39

**KRESOXIM-METHYL (199)**

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 µg/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				
VA 0381	Garlic, raw	RAC	0.02	0.98	0.02	1.49	0.03	12.88	0.26	3.74	0.07	2.05	0.04	1.14	0.02				
VA 0384	Leek, raw	RAC	3.2	4.01	12.83	4.41	14.11	0.72	2.30	0.54	1.73	16.41	52.51	0.03	0.10				
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 0445	Peppers, sweet, raw (incl dried)	RAC	0.045	0.82	0.04	1.53	0.07	10.85	0.49	4.59	0.21	1.84	0.08	2.00	0.09				
VR 0596	Sugar beet, raw (incl sugar)	RAC	0	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-				
VR 0506	Turnip, garden, raw	RAC	0	5.78	0.00	15.35	0.00	NC	-	6.54	0.00	1.95	0.00	4.73	0.00				
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.02	256.28	5.13	280.29	5.61	134.94	2.70	241.61	4.83	217.88	4.36	167.40	3.35				
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.035	43.68	1.53	60.49	2.12	9.72	0.34	40.47	1.42	49.83	1.74	18.90	0.66				
TN 0672	Pecan, nutmeat	RAC	0.1	0.38	0.04	NC	-	NC	-	0.27	0.03	NC	-	0.26	0.03				
SO 0305	Olives for oil production, raw	RAC	0.1	0.35	0.04	0.01	0.00	0.01	0.00	0.57	0.06	0.06	0.01	NC	-				
-	Olive oil (virgin and residue oil)	PP	0.34	3.40	1.16	9.49	3.23	0.02	0.01	4.28	1.46	2.74	0.93	0.48	0.16				
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	0.009	15.17	0.14	5.19	0.05	6.30	0.06	6.78	0.06	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 (µg/person)=								46.0		54.3		28.8		31.5		81.0		10.7	
Bodyweight per region (kg bw) =								60		60		55		60		60		60	
ADI (µg/person)=								18000		18000		16500		18000		18000		18000	
%ADI=								0.3%		0.3%		0.2%		0.2%		0.4%		0.1%	
Rounded %ADI=								0%		0%		0%		0%		0%		0%	

KRESOXIM-METHYL (199)				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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.11	66.67	7.33	2.06	0.23	55.83	6.14	188.29	20.71	1.38	0.15
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.022	0.03	0.00	0.10	0.00	7.19	0.16	0.03	0.00	NC	-
FP 0228	Loquat, raw (incl processed) (i.e. Japanese medlar)	RAC	0.11	0.94	0.10	4.68	0.51	NC	-	0.50	0.06	3.08	0.34
FP 0229	Medlar, raw (incl processed)	RAC	0.11	0.75	0.08	3.73	0.41	4.87	0.54	0.40	0.04	2.45	0.27
FP 0230	Pear, raw	RAC	0.11	0.07	0.01	0.14	0.02	9.45	1.04	0.01	0.00	0.14	0.02
FP 0231	Quince, raw	RAC	0.11	NC	-	NC	-	0.65	0.07	NC	-	NC	-
-	Peaches and nectarines, raw	RAC	0.37	0.02	0.01	0.01	0.00	7.47	2.76	0.01	0.00	NC	-
FB 0021	Currants, Black, Red, White, raw	RAC	0.21	0.01	0.00	NC	-	0.74	0.16	NC	-	NC	-
FB 0269	Grapes, raw (i.e. table grapes)	RAC	0.365	0.14	0.05	0.36	0.13	15.22	5.56	0.01	0.00	0.09	0.03
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.58	0.01	0.01	0.13	0.08	1.06	0.61	0.01	0.01	0.03	0.02
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	-
-	Graps must (from wine-grapes)	PP	0.11	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	0.095	0.31	0.03	0.23	0.02	60.43	5.74	0.52	0.05	31.91	3.03
FT 0305	Table olives, raw (incl preserved)	RAC	0.1	0.01	0.00	0.01	0.00	1.75	0.18	0.01	0.00	0.24	0.02
FI 0345	Mango, raw (incl canned mango, incl mango juice)	RAC	0.024	12.25	0.29	6.83	0.16	0.76	0.02	0.01	0.00	20.12	0.48
VA 0381	Garlic, raw	RAC	0.02	0.82	0.02	2.06	0.04	3.79	0.08	0.03	0.00	0.29	0.01
VA 0384	Leek, raw	RAC	3.2	0.02	0.06	1.44	4.61	1.22	3.90	0.01	0.03	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 0445	Peppers, sweet, raw (incl dried)	RAC	0.045	5.49	0.25	10.57	0.48	8.84	0.40	0.91	0.04	NC	-
VR 0596	Sugar beet, raw (incl sugar)	RAC	0	3.93	0.00	1.68	0.00	NC	-	NC	-	36.12	0.00
VR 0506	Turnip, garden, raw	RAC	0	4.29	0.00	3.10	0.00	6.41	0.00	2.90	0.00	5.79	0.00
GC 2086	Subgroup of wheat, similar grains and pseudocereals without husks, raw (including processed)	RAC	0.02	57.23	1.14	110.47	2.21	286.57	5.73	25.82	0.52	132.92	2.66
GC 2087	Subgroup of barley, similar grains, and pseudocereals with husks, raw (including processed)	RAC	0.035	11.99	0.42	5.22	0.18	49.50	1.73	3.82	0.13	16.26	0.57
TN 0672	Pecan, nutmeat	RAC	0.1	0.15	0.02	0.22	0.02	0.31	0.03	0.01	0.00	0.01	0.00
SO 0305	Olives for oil production, raw	RAC	0.1	NC	-	NC	-	0.02	0.00	NC	-	NC	-
-	Olive oil (virgin and residue oil)	PP	0.34	0.03	0.01	0.02	0.01	2.14	0.73	0.01	0.00	0.10	0.03
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

**KRESOXIM-METHYL (199)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.3 mg/kg bw

Codex Code	Commodity description	Expr as	STMTR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
MO 0105	Edible offal (mammalian), raw	RAC	0.009	4.64	0.04	1.97	0.02	10.01	0.09	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 (µg/person)=					10.5		10.2		41.2		23.1		7.7
Bodyweight per region (kg bw) =					60		60		60		60		60
ADI (µg/person)=					18000		18000		18000		18000		18000
%ADI=					0.1%		0.1%		0.2%		0.1%		0.0%
Rounded %ADI=					0%		0%		0%		0%		0%



**MANDESTROBIN (307)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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 (i.e. table grapes)	RAC	1.4	6.33	8.86	11.22	15.71	5.21	7.29	9.38	13.13	4.55	6.37	0.78	1.09
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2.8	3.09	8.65	1.51	4.23	0.03	0.08	1.38	3.86	4.26	11.93	0.42	1.18
FB 1236	Wine grapes, raw (incl must, juice, wine)	RAC	1.4	129.34	181.08	99.46	139.24	7.76	10.86	46.71	65.39	91.48	128.07	9.23	12.92
FB 0275	Strawberry, raw	RAC	0.87	4.49	3.91	5.66	4.92	0.02	0.02	6.63	5.77	5.75	5.00	0.05	0.04
SO 0495	Rape seed, raw	RAC	0.02	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.0012	12.52	0.02	7.63	0.01	3.00	0.00	6.01	0.01	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	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)	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 (µg/person)=

202.5

164.1

18.3

88.2

151.4

15.2

Bodyweight per region (kg bw) =

60

60

55

60

60

60

ADI (µg/person)=

12000

12000

11000

12000

12000

12000

%ADI=

1.7%

1.4%

0.2%

0.7%

1.3%

0.1%

Rounded %ADI=

2%

1%

0%

1%

1%

0%

**MANDESTROBIN (307)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 mg/kg bw

Codex Code	Commodity description	Expr as	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/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 (i.e. table grapes)	RAC	1.4	0.14	0.20	0.36	0.50	15.22	21.31	0.01	0.01	0.09	0.13				
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	2.8	0.01	0.03	0.13	0.36	1.06	2.97	0.01	0.03	0.03	0.08				
FB 1236	Wine grapes, raw (incl must, juice, wine)	RAC	1.4	0.58	0.81	0.70	0.98	98.85	138.39	0.73	1.02	44.12	61.77				
FB 0275	Strawberry, raw	RAC	0.87	0.01	0.01	0.01	0.01	3.35	2.91	0.01	0.01	0.01	0.01				
SO 0495	Rape seed, raw	RAC	0.02	NC	-	0.01	0.00	NC	-	NC	-	NC	-				
OR 0495	Rape seed oil, edible	PP	0.0012	0.07	0.00	0.03	0.00	4.62	0.01	0.03	0.00	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	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)	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 (µg/person)=				1.0				1.9				165.6		1.1		62.0	
Bodyweight per region (kg bw) =				60				60				60		60		60	
ADI (µg/person)=				12000				12000				12000		12000		12000	
% ADI=				0.0%				0.0%				1.4%		0.0%		0.5%	
Rounded % ADI=				0%				0%				1%		0%		1%	



**METCONAZOLE (313)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMTR mg/kg	Diets as g/person/day				Intake as µg/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
FS 0013	Subgroup of Cherries, raw	RAC	0.07	0.92	0.06	9.15	0.64	0.01	0.00	0.61	0.04	0.06	0.00	6.64	0.46
FS 0014	Subgroup of Plums, raw	RAC	0.04	2.40	0.10	8.60	0.34	0.06	0.00	2.52	0.10	0.58	0.02	4.16	0.17
DF 0014	Plums, dried (prunes)	PP	0.092	0.09	0.01	0.06	0.01	0.01	0.00	0.18	0.02	0.04	0.00	0.06	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.045	8.01	0.36	5.87	0.26	0.18	0.01	8.19	0.37	1.64	0.07	22.46	1.01
FB 0020	Blueberries, raw	RAC	0.14	0.01	0.00	0.03	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.1	5.23	0.52	6.94	0.69	99.45	9.95	32.47	3.25	48.30	4.83	24.70	2.47
VA 0381	Garlic, raw	RAC	0.05	2.29	0.11	5.78	0.29	0.11	0.01	3.69	0.18	1.65	0.08	3.91	0.20
-	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
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0	0.68	0.00	NC	-	NC	-	0.39	0.00	0.22	0.00	0.49	0.00
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.04	78.20	3.13	60.68	2.43	35.89	1.44	80.34	3.21	75.90	3.04	87.62	3.50
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	0.005	12.99	0.06	10.43	0.05	3.63	0.02	13.10	0.07	10.70	0.05	13.10	0.07
VD 2066	Subgroup of dry peas, raw	RAC	0.0425	9.09	0.39	3.35	0.14	1.06	0.05	9.48	0.40	15.11	0.64	10.58	0.45
VR 0596	Sugar beet, raw	RAC	0.02	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar beet, sugar	PP	0.012	0.02	0.00	NC	-	0.01	0.00	0.09	0.00	0.07	0.00	12.63	0.15
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	63.11	0.00	316.33	0.00	651.91	0.00	72.06	0.00	84.88	0.00	132.70	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
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
GS 0659	Sugar cane, raw	RAC	0.0205	38.16	0.78	NC	-	12.58	0.26	0.34	0.01	17.79	0.36	42.78	0.88
-	Sugar cane, molasses	PP	0.027	NC	-	NC	-	NC	-	NC	-	0.01	0.00	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.002	61.52	0.12	86.27	0.17	18.80	0.04	80.02	0.16	66.39	0.13	56.32	0.11
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0	4.06	0.00	3.27	0.00	7.01	0.00	13.93	0.00	14.01	0.00	9.36	0.00
SO 0495	Rape seed, raw	RAC	0.02	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	0.032	0.35	0.01	0.44	0.01	0.19	0.01	0.97	0.03	3.28	0.10	0.77	0.02
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.089	7.43	0.66	36.06	3.21	1.15	0.10	8.77	0.78	5.74	0.51	13.63	1.21
OR 0691	Cotton seed oil, edible	PP	0.004	3.22	0.01	1.54	0.01	1.01	0.00	0.74	0.00	1.12	0.00	2.93	0.01
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.04	0.46	0.02	1.21	0.05	6.64	0.27	2.71	0.11	1.26	0.05	1.84	0.07
OR 0697	Peanut oil, edible	PP	0.056	0.36	0.02	0.01	0.00	2.57	0.14	0.07	0.00	2.29	0.13	0.36	0.02

**METCONAZOLE (313)**

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 µg/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	
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	0.037	4.79	0.18	9.68	0.36	2.97	0.11	5.49	0.20	3.84	0.14	5.03	0.19	
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	0.019	0.12	0.00	0.12	0.00	0.11	0.00	5.37	0.10	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 (µg/person)=					8.3		11.0		13.7		11.3		11.8		13.9	
Bodyweight per region (kg bw) =					60		60		60		60		60		60	
ADI (µg/person)=					2400		2400		2400		2400		2400		2400	
%ADI=					0.3%		0.5%		0.6%		0.5%		0.5%		0.6%	
Rounded %ADI=					0%		0%		1%		0%		0%		1%	

**METCONAZOLE (313)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.04 mg/kg bw

Codex Code	Commodity description	Expr as	STMTR mg/kg	Diets as g/person/day				Intake as µg/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
FS 0013	Subgroup of Cherries, raw	RAC	0.07	1.40	0.10	4.21	0.29	0.04	0.00	2.93	0.21	1.50	0.11	NC	-
FS 0014	Subgroup of Plums, raw	RAC	0.04	3.75	0.15	3.33	0.13	5.94	0.24	2.64	0.11	2.50	0.10	0.06	0.00
DF 0014	Plums, dried (prunes)	PP	0.092	0.61	0.06	0.35	0.03	0.05	0.00	0.35	0.03	0.49	0.05	0.13	0.01
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.045	13.03	0.59	16.29	0.73	8.29	0.37	12.95	0.58	5.35	0.24	0.04	0.00
FB 0020	Blueberries, raw	RAC	0.14	0.04	0.01	0.23	0.03	0.01	0.00	0.83	0.12	0.33	0.05	NC	-
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.1	25.76	2.58	23.65	2.37	23.83	2.38	24.37	2.44	19.43	1.94	101.55	10.16
VA 0381	Garlic, raw	RAC	0.05	0.98	0.05	1.49	0.07	12.88	0.64	3.74	0.19	2.05	0.10	1.14	0.06
-	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
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0	5.07	0.00	0.83	0.00	0.17	0.00	3.70	0.00	NC	-	NC	-
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.04	107.87	4.31	119.29	4.77	45.91	1.84	201.31	8.05	224.04	8.96	104.90	4.20
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	0.005	19.06	0.10	21.06	0.11	5.94	0.03	33.78	0.17	40.05	0.20	13.39	0.07
VD 2066	Subgroup of dry peas, raw	RAC	0.0425	5.01	0.21	3.76	0.16	1.82	0.08	3.44	0.15	3.49	0.15	5.15	0.22
VR 0596	Sugar beet, raw	RAC	0.02	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Sugar beet, sugar	PP	0.012	0.01	0.00	NC	-	0.01	0.00	NC	-	NC	-	NC	-
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	226.09	0.00	234.58	0.00	161.10	0.00	185.04	0.00	234.85	0.00	100.25	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
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
GS 0659	Sugar cane, raw	RAC	0.0205	NC	-	NC	-	4.27	0.09	0.01	0.00	NC	-	3.24	0.07
-	Sugar cane, molasses	PP	0.027	NC	-	NC	-	0.08	0.00	NC	-	NC	-	NC	-
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.002	92.24	0.18	95.72	0.19	24.12	0.05	77.39	0.15	117.73	0.24	100.67	0.20
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0	8.52	0.00	8.94	0.00	15.09	0.00	9.60	0.00	14.57	0.00	26.26	0.00
SO 0495	Rape seed, raw	RAC	0.02	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.032	12.52	0.40	7.63	0.24	3.00	0.10	6.01	0.19	NC	-	NC	-
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.089	23.43	2.09	29.34	2.61	1.24	0.11	14.00	1.25	6.48	0.58	6.91	0.61
OR 0691	Cotton seed oil, edible	PP	0.004	1.68	0.01	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 butter, excl oil)	RAC	0.04	3.26	0.13	2.22	0.09	5.38	0.22	4.85	0.19	1.54	0.06	1.82	0.07
OR 0697	Peanut oil, edible	PP	0.056	1.02	0.06	0.23	0.01	1.81	0.10	0.42	0.02	5.23	0.29	0.01	0.00
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

**METCONAZOLE (313)**

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 µg/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												
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	0.037	15.17	0.56	5.19	0.19	6.30	0.23	6.78	0.25	3.32	0.12	3.17	0.12												
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	0.019	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	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 (µg/person)=				12.9				13.9				8.1				16.3				13.8				17.1			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (µg/person)=				2400				2400				2200				2400				2400							
%ADI=				0.5%				0.6%				0.4%				0.7%				0.6%				0.7%			
Rounded %ADI=				1%				1%				0%				1%				1%							

**METCONAZOLE (313)**

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				Intake = daily intake: µg/person							
				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	0.07	0.01	0.00	0.01	0.00	5.96	0.42	0.01	0.00	NC	-		
FS 0014	Subgroup of Plums, raw	RAC	0.04	0.07	0.00	0.01	0.00	15.56	0.62	0.01	0.00	NC	-		
DF 0014	Plums, dried (prunes)	PP	0.092	0.01	0.00	0.01	0.00	0.37	0.03	0.01	0.00	NC	-		
FS 2001	Subgroup of peaches, raw (incl dried apricots)	RAC	0.045	0.02	0.00	0.01	0.00	10.76	0.48	0.01	0.00	NC	-		
FB 0020	Blueberries, raw	RAC	0.14	NC	-	NC	-	0.20	0.03	NC	-	NC	-		
FI 0327	Banana, raw (incl plantains) (incl dried)	RAC	0.1	44.80	4.48	118.17	11.82	25.25	2.53	454.49	45.45	310.23	31.02		
VA 0381	Garlic, raw	RAC	0.05	0.82	0.04	2.06	0.10	3.79	0.19	0.03	0.00	0.29	0.01		
-	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		
VP 2060	Subgroup of beans with pods (all commodities within this group)	RAC	0	NC	-	NC	-	NC	-	NC	-	NC	-		
VD 2065	Subgroup of dry beans, raw (incl processed)	RAC	0.04	41.93	1.68	19.42	0.78	108.31	4.33	66.18	2.65	42.47	1.70		
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	0.005	2.32	0.01	2.54	0.01	18.70	0.09	2.51	0.01	6.29	0.03		
VD 2066	Subgroup of dry peas, raw	RAC	0.0425	4.43	0.19	11.36	0.48	4.22	0.18	9.36	0.40	1.21	0.05		
VR 0596	Sugar beet, raw	RAC	0.02	0.01	0.00	NC	-	NC	-	NC	-	NC	-		

**METCONAZOLE (313)**

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			Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
-	Sugar beet, sugar	PP	0.012	0.56	0.01	0.24	0.00	NC	-	NC	-	5.13	0.06	
VR 2071	Subgroup of tuberous and corm vegetables, raw (incl processed)	RAC	0	250.41	0.00	208.74	0.00	213.64	0.00	602.70	0.00	388.95	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	
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	
GS 0659	Sugar cane, raw	RAC	0.0205	5.62	0.12	50.91	1.04	NC	-	11.04	0.23	0.10	0.00	
-	Sugar cane, molasses	PP	0.027	NC	-	NC	-	NC	-	NC	-	NC	-	
-	Sugar cane, sugar (incl non-centrifugal sugar, incl refined sugar and maltose)	PP	0.002	28.13	0.06	55.38	0.11	78.09	0.16	18.04	0.04	45.60	0.09	
TN 0085	Group of Tree nuts, raw (incl processed)	RAC	0	4.39	0.00	135.53	0.00	6.11	0.00	0.72	0.00	317.74	0.00	
SO 0495	Rape seed, raw	RAC	0.02	NC	-	0.01	0.00	NC	-	NC	-	NC	-	
OR 0495	Rape seed oil, edible	PP	0.032	0.07	0.00	0.03	0.00	4.62	0.15	0.03	0.00	NC	-	
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.089	0.99	0.09	0.22	0.02	32.01	2.85	12.12	1.08	0.48	0.04	
OR 0691	Cotton seed oil, edible	PP	0.004	1.28	0.01	0.05	0.00	0.45	0.00	0.42	0.00	0.15	0.00	
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.04	7.14	0.29	0.45	0.02	1.87	0.07	6.22	0.25	0.53	0.02	
OR 0697	Peanut oil, edible	PP	0.056	5.02	0.28	0.05	0.00	0.17	0.01	0.29	0.02	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	0.037	4.64	0.17	1.97	0.07	10.01	0.37	3.27	0.12	3.98	0.15	
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	0.019	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	3.84	0.00	4.41	0.00	27.25	0.00	1.13	0.00	7.39	0.00	
Total intake (µg/person)=					9.1		15.8		14.6		51.5		33.6	
Bodyweight per region (kg bw) =					60		60		60		60		60	
ADI (µg/person)=					2400		2400		2400		2400		2400	
%ADI=					0.4%		0.7%		0.6%		2.1%		1.4%	
Rounded %ADI=					0%		1%		1%		2%		1%	

PENTHIOPYRAD (253)				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 µg/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
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.15	19.79	2.97	38.25	5.74	17.96	2.69	32.56	4.88	8.08	1.21	64.45	9.67
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	1.3	11.60	15.08	23.79	30.93	0.25	0.33	11.84	15.39	2.41	3.13	33.44	43.47
FB 2005	Subgroup of Caneberries, raw	RAC	3.7	0.42	1.55	1.05	3.89	0.01	0.04	0.02	0.07	0.02	0.07	1.24	4.59
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.7	0.53	0.90	1.31	2.23	0.40	0.68	1.66	2.82	0.01	0.02	0.99	1.68
FB 0267	Elderberries, raw (incl processed)	RAC	1.7	0.44	0.75	0.27	0.46	0.34	0.58	1.41	2.40	NC	-	0.87	1.48
FB 0275	Strawberry, raw	RAC	0.8	0.70	0.56	2.01	1.61	0.04	0.03	1.36	1.09	0.37	0.30	2.53	2.02
VA 2031	Subgroup of bulb onions	RAC	0.074	31.65	2.34	43.28	3.20	3.68	0.27	38.48	2.85	20.46	1.51	47.29	3.50
VA 2032	Subgroup of Green Onions	RAC	0.89	2.64	2.35	3.09	2.75	1.05	0.93	2.89	2.57	0.61	0.54	5.24	4.66
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	1.4	2.54	3.56	0.49	0.69	0.01	0.01	3.57	5.00	7.79	10.91	3.12	4.37
VB 0041	Cabbages, head, raw	RAC	0.4	2.73	1.09	27.92	11.17	0.55	0.22	4.47	1.79	4.27	1.71	10.25	4.10
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.13	10.52	1.37	39.36	5.12	2.07	0.27	25.74	3.35	2.80	0.36	44.83	5.83
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 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.27	67.79	18.30	99.85	26.96	31.70	8.56	125.86	33.98	55.22	14.91	262.82	70.96
VL 0053	Group of Leafy vegetables, raw	RAC	3.15	8.47	26.68	22.36	70.43	7.74	24.38	25.51	80.36	45.77	144.18	21.22	66.84
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	11	0.03	0.33	0.31	3.41	0.01	0.11	0.05	0.55	0.47	5.17	0.11	1.21
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.9	0.68	0.61	NC	-	NC	MO 0105	0.39	0.35	0.22	0.20	0.49	0.44
<b>014B</b>	<b>Peas with pods</b>	-	0.9	-	-	-	-	-	-	-	-	-	-	-	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.0685	1.56	0.11	0.60	0.04	0.49	0.03	1.18	0.08	0.90	0.06	7.79	0.53
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.0685	1.97	0.13	0.51	0.03	0.02	0.00	0.79	0.05	3.68	0.25	3.80	0.26
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.01	87.29	0.87	64.04	0.64	37.15	0.37	89.82	0.90	91.02	0.91	98.20	0.98
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 0494	Radish roots, raw	RAC	0.305	2.31	0.70	4.09	1.25	2.53	0.77	6.15	1.88	5.88	1.79	2.97	0.91
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.105	0.13	0.01	NC	-	0.08	0.01	0.66	0.07	0.47	0.05	88.94	9.34
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
VS 0624	Celery	RAC	3.1	2.14	6.63	3.79	11.75	2.35	7.29	5.69	17.64	0.02	0.06	2.75	8.53
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.13	0.00	19.38	0.19	0.10	0.00	0.12	0.00	0.03	0.00	2.15	0.02
GC 0653	Triticale, raw (incl flour)	RAC	0.01	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.00	NC	-

**PENTHIOPYRAD (253)**

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 µg/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 0654	Wheat, raw (incl bulgur, incl fermented beverages, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.01	381.15	3.81	341.54	3.42	38.34	0.38	281.87	2.82	172.65	1.73	434.06	4.34												
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												
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.086	19.91	1.71	31.16	2.68	5.04	0.43	3.10	0.27	9.77	0.84	4.31	0.37												
GC 0647	Oats, raw (incl rolled)	RAC	0.086	0.05	0.00	7.05	0.61	0.10	0.01	1.71	0.15	0.96	0.08	0.04	0.00												
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.22	1.46	0.32	2.32	0.51	5.84	1.28	0.89	0.20	16.17	3.56	0.01	0.00												
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.22	4.34	0.95	0.01	0.00	16.25	3.58	15.82	3.48	10.97	2.41	2.92	0.64												
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	0.014	22.72	0.32	35.61	0.50	87.27	1.22	34.92	0.49	46.71	0.65	49.12	0.69												
OR 0645	Maize oil	PP	0.027	0.96	0.03	0.85	0.02	0.29	0.01	5.42	0.15	0.42	0.01	2.10	0.06												
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	0.084	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.06	0.01	0.00												
OR 0700	Sesame seed oil, edible	PP	0.11	0.17	0.02	0.01	0.00	0.02	0.00	0.94	0.10	0.21	0.02	0.53	0.06												
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.12	7.40	0.89	35.86	4.30	1.15	0.14	8.76	1.05	5.45	0.65	13.62	1.63												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.17	20.53	3.49	9.80	1.67	6.42	1.09	4.73	0.80	7.14	1.21	18.68	3.18												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	0.46	0.00	1.21	0.01	6.64	0.07	2.71	0.03	1.26	0.01	1.84	0.02												
OR 0697	Peanut oil, edible	PP	0.04	0.36	0.01	0.01	0.00	2.57	0.10	0.07	0.00	2.29	0.09	0.36	0.01												
HS 0444	Peppers, chili, dried	PP	0.27	0.42	0.11	0.53	0.14	0.84	0.23	0.50	0.14	0.95	0.26	0.37	0.10												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.012	31.20	0.37	72.44	0.87	20.88	0.25	47.98	0.58	33.08	0.40	36.25	0.44												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.031	3.29	0.10	6.14	0.19	0.82	0.03	1.57	0.05	2.23	0.07	1.07	0.03												
MO 0105	Edible offal (mammalian), raw	RAC	0.043	4.79	0.21	9.68	0.42	2.97	0.13	5.49	0.24	3.84	0.17	5.03	0.22												
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	0.02	14.63	0.29	29.76	0.60	8.04	0.16	129.68	2.59	25.04	0.50	35.66	0.71												
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 (µg/person)=				105.4				211.6				57.4				197.0				204.0				263.6			





**PENTHIOPYRAD (253)**

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 µg/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
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.0685	2.21	0.15	5.25	0.36	4.17	0.29	1.61	0.11	16.95	1.16	0.17	0.01
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.0685	10.72	0.73	1.99	0.14	2.72	0.19	4.26	0.29	4.23	0.29	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.01	112.88	1.13	123.05	1.23	47.73	0.48	204.75	2.05	227.52	2.28	110.05	1.10
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 0494	Radish roots, raw	RAC	0.305	3.83	1.17	11.99	3.66	NC	-	5.26	1.60	2.19	0.67	4.37	1.33
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.105	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	0.01	225.03	2.25	234.24	2.34	71.48	0.71	177.55	1.78	234.55	2.35	37.71	0.38
VS 0624	Celery	RAC	3.1	7.68	23.81	2.85	8.84	NC	-	3.34	10.35	16.83	52.17	4.04	12.52
GC 0650	Rye, raw (incl flour)	RAC	0.01	3.21	0.03	35.38	0.35	0.21	0.00	6.50	0.07	1.49	0.01	NC	-
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, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.01	252.06	2.52	244.62	2.45	134.41	1.34	235.10	2.35	216.33	2.16	167.34	1.67
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
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.086	36.18	3.11	53.45	4.60	9.39	0.81	35.25	3.03	46.68	4.01	15.92	1.37
GC 0647	Oats, raw (incl rolled)	RAC	0.086	7.50	0.65	6.26	0.54	0.15	0.01	4.87	0.42	3.16	0.27	2.98	0.26
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.22	0.03	0.01	0.16	0.04	1.75	0.39	0.69	0.15	NC	-	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.22	NC	-	NC	-	1.44	0.32	1.15	0.25	NC	-	7.12	1.57
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	0.014	14.27	0.20	12.86	0.18	19.71	0.28	12.55	0.18	4.21	0.06	52.30	0.73
OR 0645	Maize oil	PP	0.027	0.90	0.02	0.47	0.01	0.15	0.00	3.01	0.08	1.86	0.05	0.36	0.01
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	0.084	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0700	Sesame seed oil, edible	PP	0.11	0.17	0.02	0.01	0.00	0.40	0.04	0.11	0.01	NC	-	0.05	0.01
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.12	23.40	2.81	29.33	3.52	1.24	0.15	13.85	1.66	6.48	0.78	6.91	0.83
SO 0691	Cotton seed, raw (incl oil)	RAC	0.17	10.71	1.82	4.23	0.72	7.19	1.22	7.54	1.28	5.66	0.96	2.38	0.40
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	3.26	0.03	2.22	0.02	5.38	0.05	4.85	0.05	1.54	0.02	1.82	0.02
OR 0697	Peanut oil, edible	PP	0.04	1.02	0.04	0.23	0.01	1.81	0.07	0.42	0.02	5.23	0.21	0.01	0.00
HS 0444	Peppers, chili, dried	PP	0.27	0.11	0.03	0.21	0.06	0.36	0.10	0.21	0.06	0.25	0.07	0.15	0.04

PENTHIOPYRAD (253)				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 µg/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
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.012	140.03	1.68	150.89	1.81	79.32	0.95	111.24	1.33	120.30	1.44	51.27	0.62
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.031	6.44	0.20	15.51	0.48	3.79	0.12	8.29	0.26	18.44	0.57	8.00	0.25
MO 0105	Edible offal (mammalian), raw	RAC	0.043	15.17	0.65	5.19	0.22	6.30	0.27	6.78	0.29	3.32	0.14	3.17	0.14
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	0.02	73.76	1.48	53.86	1.08	23.98	0.48	87.12	1.74	53.38	1.07	84.45	1.69
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 (µg/person)=				219.1		226.6		449.7		272.9		228.1		116.7	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	
ADI (µg/person)=				6000		6000		5500		6000		6000		6000	
%ADI=				3.7%		3.8%		8.2%		4.5%		3.8%		1.9%	
Rounded %ADI=				4%		4%		8%		5%		4%		2%	

PENTHIOPYRAD (253)				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				Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
FP 0009	Group of Pome fruits, raw (incl. apple juice, incl apple cider)	RAC	0.15	68.89	10.33	11.06	1.66	80.62	12.09	189.82	28.47	19.56	2.93		
FS 0012	Group of Stone fruits, raw (incl dried plums, incl dried apricots)	RAC	1.3	0.09	0.12	0.03	0.04	33.36	43.37	0.01	0.01	NC	-		
FB 2005	Subgroup of Caneberries, raw	RAC	3.7	0.01	0.04	7.30	27.01	2.29	8.47	0.01	0.04	NC	-		
FB 2006	Subgroup of Bush berries, raw (including processed)	RAC	1.7	0.82	1.39	4.05	6.89	5.94	10.10	0.43	0.73	2.66	4.52		
FB 0267	Elderberries, raw (incl processed)	RAC	1.7	0.71	1.21	3.52	5.98	NC	-	0.38	0.65	2.32	3.94		
FB 0275	Strawberry, raw	RAC	0.8	0.01	0.01	0.01	0.01	3.35	2.68	0.01	0.01	0.01	0.01		
VA 2031	Subgroup of bulb onions	RAC	0.074	9.83	0.73	22.30	1.65	34.69	2.57	9.65	0.71	2.39	0.18		
VA 2032	Subgroup of Green Onions	RAC	0.89	1.45	1.29	1.50	1.34	1.42	1.26	0.01	0.01	6.30	5.61		
VB 0042	Subgroup of Flowerhead Brassica, raw	RAC	1.4	0.02	0.03	0.02	0.03	4.86	6.80	0.01	0.01	NC	-		
VB 0041	Cabbages, head, raw	RAC	0.4	3.82	1.53	2.99	1.20	49.16	19.66	0.01	0.00	NC	-		

**PENTHIOPYRAD (253)**

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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VC 2039	Subgroup of Cucumbers and Squashes, raw	RAC	0.13	0.92	0.12	3.20	0.42	13.55	1.76	1.91	0.25	0.05	0.01
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 0050	Group of Fruiting vegetables other than cucurbits, raw, (incl processed commodities, excl dried chilli peppers)	RAC	0.27	32.01	8.64	28.27	7.63	100.61	27.16	2.91	0.79	12.50	3.38
VL 0053	Group of Leafy vegetables, raw	RAC	3.15	12.42	39.12	8.75	27.56	7.53	23.72	7.07	22.27	14.11	44.45
VL 0485	Mustard greens, raw (i.e. Indian mustard, Amsoi, mustard cabbage)	RAC	11	0.04	0.44	0.03	0.33	NC	-	0.01	0.11	NC	-
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds)	RAC	0.9	NC	-	NC	-	NC	-	NC	-	NC	-
014B	Peas with pods	-	0.9	-	-	-	-	-	-	-	-	-	-
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds), raw	RAC	0.0685	0.30	0.02	3.13	0.21	4.11	0.28	0.01	0.00	NC	-
VP 0064	Peas without pods (Pisum spp) (succulent seeds)	RAC	0.0685	0.21	0.01	0.02	0.00	5.51	0.38	0.02	0.00	NC	-
VD 0070	Group of Pulses, raw (incl processed)	RAC	0.01	46.57	0.47	30.77	0.31	112.53	1.13	75.53	0.76	43.68	0.44
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 0494	Radish roots, raw	RAC	0.305	3.96	1.21	2.86	0.87	3.30	1.01	2.67	0.81	5.34	1.63
VR 0596	Sugar beet, raw (incl sugar)	RAC	0.105	3.93	0.41	1.68	0.18	NC	-	NC	-	36.12	3.79
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
VS 0624	Celery	RAC	3.1	3.66	11.35	2.65	8.22	4.84	15.00	2.47	7.66	4.94	15.31
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.03	0.00	0.01	0.00	13.95	0.14	0.01	0.00	0.88	0.01
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, incl white flour products, incl white bread, excl germ, excl wholemeal bread)	RAC	0.01	57.15	0.57	110.46	1.10	272.58	2.73	25.81	0.26	132.04	1.32
CF 1210	Wheat, germ	PP	0.019	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
GC 0640	Barley, raw (incl malt extract, incl pot&pearled, incl flour & grits, incl beer, incl malt)	RAC	0.086	11.58	1.00	2.33	0.20	46.71	4.02	3.72	0.32	16.26	1.40
GC 0647	Oats, raw (incl rolled)	RAC	0.086	0.37	0.03	0.07	0.01	2.79	0.24	0.10	0.01	NC	-
GC 0646	Millet, raw (incl flour, incl beer)	RAC	0.22	61.13	13.45	0.78	0.17	NC	-	33.55	7.38	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.22	89.16	19.62	2.02	0.44	NC	-	35.38	7.78	NC	-
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	-

## PENTHIOPYRAD (253)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.1 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets: g/person/day				Intake = daily intake: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.014	94.34	1.32	8.09	0.11	28.03	0.39	55.94	0.78	28.07	0.39		
OR 0645	Maize oil	PP	0.027	0.33	0.01	0.07	0.00	0.81	0.02	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	0.084	NC	-	0.01	0.00	NC	-	NC	-	NC	-		
OR 0700	Sesame seed oil, edible	PP	0.11	0.52	0.06	0.11	0.01	0.04	0.00	1.70	0.19	NC	-		
SO 0702	Sunflower seed, raw (incl oil)	RAC	0.12	0.94	0.11	0.22	0.03	32.01	3.84	12.12	1.45	0.48	0.06		
SO 0691	Cotton seed, raw (incl oil)	RAC	0.17	8.14	1.38	0.32	0.05	2.84	0.48	2.69	0.46	0.97	0.16		
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.01	7.14	0.07	0.45	0.00	1.87	0.02	6.22	0.06	0.53	0.01		
OR 0697	Peanut oil, edible	PP	0.04	5.02	0.20	0.05	0.00	0.17	0.01	0.29	0.01	NC	-		
HS 0444	Peppers, chili, dried	PP	0.27	0.58	0.16	1.27	0.34	1.21	0.33	0.12	0.03	NC	-		
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.012	29.18	0.35	50.89	0.61	121.44	1.46	22.58	0.27	72.14	0.87		
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.031	1.05	0.03	1.14	0.04	18.69	0.58	0.94	0.03	3.12	0.10		
MO 0105	Edible offal (mammalian), raw	RAC	0.043	4.64	0.20	1.97	0.08	10.01	0.43	3.27	0.14	3.98	0.17		
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	0.02	3.92	0.08	12.03	0.24	57.07	1.14	5.03	0.10	55.56	1.11		
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 (µg/person)=				119.2				98.0				204.5			
Bodyweight per region (kg bw) =				60				60				60			
ADI (µg/person)=				6000				6000				6000			
%ADI=				2.0%				1.6%				3.4%			
Rounded %ADI=				2%				2%				3%			

**PICOXYSTROBIN (243)**

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 µg/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 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.0105	2.39	0.03	1.61	0.02	10.47	0.11	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	0.0105	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 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.0105	0.05	0.00	NC	-	1.74	0.02	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	0.0105	0.63	0.01	1.09	0.01	0.40	0.00	1.40	0.01	1.68	0.02	0.48	0.01
OR 0541	Soya oil, refined	PP	0.034	12.99	0.44	10.43	0.35	3.63	0.12	13.10	0.45	10.70	0.36	13.10	0.45
-	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	0.0105	1.70	0.02	0.01	0.00	3.00	0.03	1.80	0.02	1.64	0.02	1.33	0.01
VD 2066	Subgroup of dry peas, raw	RAC	0.0105	9.09	0.10	3.35	0.04	1.06	0.01	9.48	0.10	15.11	0.16	10.58	0.11
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.13	0.00	19.38	0.19	0.10	0.00	0.12	0.00	0.03	0.00	2.15	0.02
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	0.032	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	0.01	301.24	3.01	268.64	2.69	30.21	0.30	222.51	2.23	134.73	1.35	343.12	3.43
GC 0640	Barley, raw (incl malt extract, incl flour & grits, excl pot&pearled, excl beer, excl malt)	RAC	0.017	7.91	0.13	0.64	0.01	0.15	0.00	0.18	0.00	1.21	0.02	0.41	0.01
-	Barley beer	PP	0.01	4.87	0.05	93.78	0.94	24.28	0.24	12.76	0.13	39.28	0.39	18.15	0.18
-	Barley Malt	PP	0.01	0.09	0.00	1.04	0.01	0.18	0.00	0.33	0.00	0.04	0.00	0.10	0.00
GC 0647	Oats, raw (incl rolled)	RAC	0.017	0.05	0.00	7.05	0.12	0.10	0.00	1.71	0.03	0.96	0.02	0.04	0.00
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.01	4.34	0.04	0.01	0.00	16.25	0.16	15.82	0.16	10.97	0.11	2.92	0.03
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0.01	0.84	0.01	0.24	0.00	1.56	0.02	0.46	0.00	2.21	0.02	13.13	0.13
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.011	22.72	0.25	35.61	0.39	87.27	0.96	34.92	0.38	46.71	0.51	49.12	0.54
-	Maize, germ	PP	0.01	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	0.22	0.00	NC	-
-	Maize starch	PP	0.01	0.08	0.00	NC	-	0.01	0.00	2.29	0.02	0.08	0.00	0.11	0.00

PICOXYSTROBIN (243)				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 µg/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												
OR 0645	Maize oil	PP	0.069	0.96	0.07	0.85	0.06	0.29	0.02	5.42	0.37	0.42	0.03	2.10	0.14												
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												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.205	20.53	4.21	9.80	2.01	6.42	1.32	4.73	0.97	7.14	1.46	18.68	3.83												
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												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	1.2	2.28	2.74	1.98	2.38	0.46	0.55	2.43	2.92	1.29	1.55	3.04	3.65												
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	0.008	6.24	0.05	14.49	0.12	4.18	0.03	9.60	0.08	6.62	0.05	7.25	0.06												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.008	3.29	0.03	6.14	0.05	0.82	0.01	1.57	0.01	2.23	0.02	1.07	0.01												
MO 0105	Edible offal (mammalian), raw	RAC	0.006	4.79	0.03	9.68	0.06	2.97	0.02	5.49	0.03	3.84	0.02	5.03	0.03												
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	0.01	1.46	0.01	2.98	0.03	0.80	0.01	12.97	0.13	2.50	0.03	3.57	0.04												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	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 (µg/person)=				11.3				9.5				4.0				8.2				6.3				12.8			
Bodyweight per region (kg bw) =				60				60				60				60				60				60			
ADI (µg/person)=				5400				5400				5400				5400				5400				5400			
%ADI=				0.2%				0.2%				0.1%				0.2%				0.1%				0.2%			
Rounded %ADI=				0%				0%				0%				0%				0%				0%			

PICOXYSTROBIN (243)				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 µg/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 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.0105	1.51	0.02	1.50	0.02	1.90	0.02	5.11	0.05	1.36	0.01	23.43	0.25
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.0105	0.02	0.00	0.01	0.00	1.16	0.01	0.40	0.00	NC	-	0.06	0.00

**PICOXYSTROBIN (243)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.09 mg/kg bw

Codex Code	Commodity description	Expr as	STM mg/kg	Diets as g/person/day				Intake as µg/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 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.0105	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	0.0105	0.47	0.00	0.77	0.01	9.12	0.10	8.05	0.08	0.04	0.00	6.06	0.06
OR 0541	Soya oil, refined	PP	0.034	19.06	0.65	21.06	0.72	5.94	0.20	33.78	1.15	40.05	1.36	13.39	0.46
-	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	0.0105	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	0.0105	5.01	0.05	3.76	0.04	1.82	0.02	3.44	0.04	3.49	0.04	5.15	0.05
GC 0650	Rye, raw (incl flour)	RAC	0.01	3.21	0.03	35.38	0.35	0.21	0.00	6.50	0.07	1.49	0.01	NC	-
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	0.032	0.97	0.03	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	0.01	198.08	1.98	193.03	1.93	106.24	1.06	185.09	1.85	168.67	1.69	131.59	1.32
GC 0640	Barley, raw (incl malt extract, incl flour & grits, excl pot&pearled, excl beer, excl malt)	RAC	0.017	0.82	0.01	0.21	0.00	0.09	0.00	1.53	0.03	1.58	0.03	0.63	0.01
-	Barley beer	PP	0.01	180.21	1.80	259.46	2.59	45.91	0.46	172.36	1.72	234.42	2.34	65.30	0.65
-	Barley Malt	PP	0.01	0.19	0.00	NC	-	0.04	0.00	0.08	0.00	NC	-	2.14	0.02
GC 0647	Oats, raw (incl rolled)	RAC	0.017	7.50	0.13	6.26	0.11	0.15	0.00	4.87	0.08	3.16	0.05	2.98	0.05
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.01	NC	-	NC	-	1.44	0.01	1.15	0.01	NC	-	7.12	0.07
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, 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	0.04	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.011	14.27	0.16	12.86	0.14	19.71	0.22	12.55	0.14	4.21	0.05	52.30	0.58
-	Maize, germ	PP	0.01	0.01	0.00	NC	-	NC	-	0.01	0.00	NC	-	0.01	0.00
-	Maize starch	PP	0.01	NC	-	NC	-	0.19	0.00	7.13	0.07	NC	-	NC	-
OR 0645	Maize oil	PP	0.069	0.90	0.06	0.47	0.03	0.15	0.01	3.01	0.21	1.86	0.13	0.36	0.02
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
SO 0691	Cotton seed, raw (incl oil)	RAC	0.205	10.71	2.20	4.23	0.87	7.19	1.47	7.54	1.55	5.66	1.16	2.38	0.49
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

**PICOXYSTROBIN (243)**

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 µg/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												
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	1.2	2.91	3.49	1.73	2.08	1.14	1.37	1.85	2.22	2.29	2.75	0.74	0.89												
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	0.008	28.01	0.22	30.18	0.24	15.86	0.13	22.25	0.18	24.06	0.19	10.25	0.08												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.008	6.44	0.05	15.51	0.12	3.79	0.03	8.29	0.07	18.44	0.15	8.00	0.06												
MO 0105	Edible offal (mammalian), raw	RAC	0.006	15.17	0.09	5.19	0.03	6.30	0.04	6.78	0.04	3.32	0.02	3.17	0.02												
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	0.01	7.38	0.07	5.39	0.05	2.40	0.02	8.71	0.09	5.34	0.05	8.45	0.08												
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	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	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 (µg/person)=				11.3				9.6				5.2				10.0				10.3				5.3			
Bodyweight per region (kg bw) =				60				60				55				60				60							
ADI (µg/person)=				5400				5400				4950				5400				5400							
%ADI=				0.2%				0.2%				0.1%				0.2%				0.2%							
Rounded %ADI=				0%				0%				0%				0%				0%							

**PICOXYSTROBIN (243)**

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: µg/person							
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake		
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.0105	7.11	0.07	2.33	0.02	3.76	0.04	44.70	0.47	3.27	0.03		
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.0105	3.70	0.04	0.03	0.00	0.17	0.00	0.01	0.00	NC	-		
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.0105	12.77	0.13	0.99	0.01	0.01	0.00	4.33	0.05	NC	-		
VD 0541	Soya bean, dry, raw (incl flour, incl paste, incl curd, incl sauce, excl oil)	RAC	0.0105	2.89	0.03	0.21	0.00	0.48	0.01	3.16	0.03	0.26	0.00		
OR 0541	Soya oil, refined	PP	0.034	2.32	0.08	2.54	0.09	18.70	0.64	2.51	0.09	6.29	0.21		
-	Beans (dry) NES: including inter alia lablab or hyacinth bean (Dolichos spp.); jack or sword bean (Canavalia spp.); winged bean (Psophocarpus	RAC	0.0105	2.54	0.03	1.77	0.02	0.03	0.00	0.03	0.00	3.99	0.04		



**PICOXYSTROBIN (243)**

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: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	tetragonolobus); guar bean (Cyamopsis tetragonoloba); velvet bean (Stizolobium spp.); yam bean (Pachyrhizus erosus)												
VD 2066	Subgroup of dry peas, raw	RAC	0.0105	4.43	0.05	11.36	0.12	4.22	0.04	9.36	0.10	1.21	0.01
GC 0650	Rye, raw (incl flour)	RAC	0.01	0.03	0.00	0.01	0.00	13.95	0.14	0.01	0.00	0.88	0.01
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	0.032	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	0.01	44.78	0.45	86.96	0.87	214.05	2.14	20.31	0.20	103.60	1.04
GC 0640	Barley, raw (incl malt extract, incl flour & grits, excl pot&pearled, excl beer, excl malt)	RAC	0.017	0.09	0.00	0.01	0.00	0.80	0.01	0.01	0.00	0.11	0.00
-	Barley beer	PP	0.01	16.25	0.16	11.36	0.11	225.21	2.25	19.49	0.19	52.17	0.52
-	Barley Malt	PP	0.01	0.01	0.00	0.11	0.00	0.67	0.01	0.01	0.00	4.61	0.05
GC 0647	Oats, raw (incl rolled)	RAC	0.017	0.37	0.01	0.07	0.00	2.79	0.05	0.10	0.00	NC	-
GC 0651	Sorghum, raw (incl flour, incl beer) (i.e. Chicken corn, Dari seed, Durra, Feterita)	RAC	0.01	89.16	0.89	2.02	0.02	NC	-	35.38	0.35	NC	-
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0.01	0.54	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	0.011	94.34	1.04	8.09	0.09	28.03	0.31	55.94	0.62	28.07	0.31
-	Maize, germ	PP	0.01	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Maize starch	PP	0.01	0.02	0.00	0.01	0.00	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0.069	0.33	0.02	0.07	0.00	0.81	0.06	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
SO 0691	Cotton seed, raw (incl oil)	RAC	0.205	8.14	1.67	0.32	0.07	2.84	0.58	2.69	0.55	0.97	0.20
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
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	1.2	0.53	0.64	5.25	6.30	0.86	1.03	0.56	0.67	0.88	1.06
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	0.008	5.84	0.05	10.18	0.08	24.29	0.19	4.52	0.04	14.43	0.12

**PICOXYSTROBIN (243)**

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: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.008	1.05	0.01	1.14	0.01	18.69	0.15	0.94	0.01	3.12	0.02
MO 0105	Edible offal (mammalian), raw	RAC	0.006	4.64	0.03	1.97	0.01	10.01	0.06	3.27	0.02	3.98	0.02
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	0.01	0.39	0.00	1.20	0.01	5.71	0.06	0.50	0.01	5.56	0.06
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.01	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 (µg/person)=				5.4		8.1		8.0		3.5		3.9	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg/person)=				5400		5400		5400		5400		5400	
%ADI=				0.1%		0.1%		0.1%		0.1%		0.1%	
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 µg/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	1.7	8.01	13.62	5.87	9.98	0.18	0.31	8.19	13.92	1.64	2.79	22.46	38.18
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 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 pineapple juice, incl dried pineapple)	RAC	0.16	0.61	0.10	1.56	0.25	7.89	1.26	9.36	1.50	8.76	1.40	1.30	0.21
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
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
GS 0659	Sugar cane, raw	RAC	0	38.16	0.00	NC	-	12.58	0.00	0.34	0.00	17.79	0.00	42.78	0.00

**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 µg/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												
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												
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)	RAC	0.064	31.20	2.00	72.44	4.64	20.88	1.34	47.98	3.07	33.08	2.12	36.25	2.32												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	3.29	0.16	6.14	0.31	0.82	0.04	1.57	0.08	2.23	0.11	1.07	0.05												
MO 0105	Edible offal (mammalian), raw	RAC	0.5	4.79	2.40	9.68	4.84	2.97	1.49	5.49	2.75	3.84	1.92	5.03	2.52												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.035	289.65	10.14	485.88	17.01	26.92	0.94	239.03	8.37	199.91	7.00	180.53	6.32												
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												
PE 0112	Eggs, raw, (incl dried)	RAC	0.05	7.84	0.39	23.08	1.15	2.88	0.14	14.89	0.74	9.81	0.49	14.83	0.74												
Total intake (µg/person)=				111.4				154.5				39.3				162.5				67.5				292.23			
Bodyweight per region (kg bw) =				60				60				60				60				60				60.00			
ADI (µg/person)=				4200				4200				4200				4200				4200				4200.00			
%ADI=				2.7%				3.7%				0.9%				3.9%				1.6%				0.07			
Rounded %ADI=				3%				4%				1%				4%				2%				0.07			

**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 µg/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	0.05	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	1.00	1.40	1.40	4.21	4.21	0.04	0.04	2.93	2.93	1.50	1.50	NC	-

**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 µg/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
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	1.70	13.03	22.15	16.29	27.69	8.29	14.09	12.95	22.02	5.35	9.10	0.04	0.07
FB 0265	Cranberry, raw	RAC	0.30	0.06	0.02	0.01	0.00	0.01	0.00	1.22	0.37	0.11	0.03	NC	-
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 pineapple juice, incl dried pineapple)	RAC	0.16	13.13	2.10	11.13	1.78	6.94	1.11	14.36	2.30	36.74	5.88	18.81	3.01
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	0.80	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	0.26	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
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
GS 0659	Sugar cane, raw	RAC	0.00	NC	-	NC	-	4.27	0.00	0.01	0.00	NC	-	3.24	0.00
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	-
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)	RAC	0.06	140.03	8.96	150.89	9.66	79.32	5.08	111.24	7.12	120.30	7.70	51.27	3.28
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	6.44	0.32	15.51	0.78	3.79	0.19	8.29	0.41	18.44	0.92	8.00	0.40
MO 0105	Edible offal (mammalian), raw	RAC	0.50	15.17	7.59	5.19	2.60	6.30	3.15	6.78	3.39	3.32	1.66	3.17	1.59

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 µg/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												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.04	388.92	13.61	335.88	11.76	49.15	1.72	331.25	11.59	468.56	16.40	245.45	8.59												
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												
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												
Total intake (µg/person)=				160.20				171.20				78.64				172.12				143.14				136.34			
Bodyweight per region (kg bw) =				60.00				60.00				55.00				60.00				60.00				60.00			
ADI (µg/person)=				4200.00				4200.00				3850.00				4200.00				4200.00				4200.00			
%ADI=				0.04				0.04				0.02				0.04				0.03				0.03			
Rounded %ADI=				0.04				0.04				0.02				0.04				0.03				0.03			

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				Intake = daily intake: µg/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	0.22	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	0.05	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	1.00	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	1.70	0.02	0.03	0.01	0.02	10.76	18.29	0.01	0.02	NC	-		
FB 0265	Cranberry, raw	RAC	0.30	NC	-	NC	-	0.03	0.01	NC	-	NC	-		
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 pineapple juice, incl dried pineapple)	RAC	0.16	8.51	1.36	6.27	1.00	6.89	1.10	0.18	0.03	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	-		

**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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
VO 0448	Tomato, raw (incl juice, incl paste, incl canned)	RAC	0.80	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	0.26	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	-
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
GS 0659	Sugar cane, raw	RAC	0.00	5.62	0.00	50.91	0.00	NC	-	11.04	0.00	0.10	0.00
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	-
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)	RAC	0.06	29.18	1.87	50.89	3.26	121.44	7.77	22.58	1.45	72.14	4.62
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.05	1.05	0.05	1.14	0.06	18.69	0.93	0.94	0.05	3.12	0.16
MO 0105	Edible offal (mammalian), raw	RAC	0.50	4.64	2.32	1.97	0.99	10.01	5.01	3.27	1.64	3.98	1.99
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.04	108.75	3.81	70.31	2.46	436.11	15.26	61.55	2.15	79.09	2.77
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
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

Total intake (µg/person)=	42.84	30.28	164.01	41.61	64.24
Bodyweight per region (kg bw) =	60.00	60.00	60.00	60.00	60.00
ADI (µg/person)=	4200.00	4200.00	4200.00	4200.00	4200.00
%ADI=	0.01	0.01	0.04	0.01	0.02
Rounded %ADI=	0.01	0.01	0.04	0.01	0.02

PYDIFLUMETOFEN (309)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.1 mg/kg bw							
Codex Code	Commodity description	Expras	STMR mg/kg	Diets as g/person/day				Intake as µg/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 (i.e. table grapes)	RAC	0.29	12.68	3.68	9.12	2.64	0.03	0.01	16.88	4.90	3.70	1.07	54.42	15.78
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.71	0.51	0.36	0.51	0.36	0.01	0.01	1.27	0.90	0.12	0.09	2.07	1.47
JF 0269	Grape juice (from wine grapes)	PP	0.017	0.14	0.00	0.29	0.00	0.05	0.00	0.30	0.01	0.24	0.00	0.05	0.00
-	Graps must (from wine-grapes)	PP	0.31	0.33	0.10	0.13	0.04	0.01	0.00	0.02	0.01	0.01	0.00	0.02	0.01
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.091	0.67	0.06	12.53	1.14	2.01	0.18	1.21	0.11	3.53	0.32	4.01	0.36
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 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.12	53.14	6.38	86.21	10.35	6.28	0.75	92.76	11.13	15.64	1.88	155.30	18.64
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	0.005	0.20	0.00	0.31	0.00	0.02	0.00	1.11	0.01	0.11	0.00	1.50	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.075	2.34	0.18	1.33	0.10	1.57	0.12	4.24	0.32	0.34	0.03	2.83	0.21
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.005	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 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.11	5.42	0.60	9.91	1.09	3.97	0.44	7.63	0.84	2.59	0.28	23.68	2.60
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.02	1.97	0.04	NC	-	3.68	0.07	3.24	0.06	5.72	0.11	1.57	0.03
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 2050	Subgroup of Leafy greens	RAC	12.5	3.93	49.13	5.28	66.00	3.07	38.38	14.53	181.63	8.25	103.13	12.75	159.38
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.02	2.63	0.05	9.27	0.19	1.86	0.04	5.82	0.12	19.53	0.39	4.90	0.10
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.02	0.18	0.00	0.31	0.01	0.84	0.02	0.47	0.01	2.06	0.04	0.23	0.00
VP 0060	Group of Legume vegetables, raw	RAC	0.02	7.73	0.15	1.53	0.03	0.51	0.01	2.95	0.06	5.08	0.10	12.86	0.26
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.028	2.39	0.07	1.61	0.05	10.47	0.29	1.84	0.05	12.90	0.36	7.44	0.21
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.028	1.27	0.04	0.01	0.00	0.12	0.00	2.49	0.07	0.23	0.01	5.54	0.16
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.028	0.05	0.00	NC	-	1.74	0.05	0.01	0.00	0.01	0.00	0.07	0.00
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.028	0.58	0.02	0.05	0.00	0.37	0.01	0.03	0.00	1.65	0.05	0.30	0.01
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.005	12.99	0.06	10.43	0.05	3.63	0.02	13.10	0.07	10.70	0.05	13.10	0.07
-	Soya sauce	PP	0.002	0.01	0.00	0.02	0.00	0.01	0.00	0.34	0.00	0.03	0.00	0.01	0.00
-	Soya flour	PP	0.002	0.05	0.00	0.86	0.00	0.02	0.00	1.02	0.00	0.01	0.00	0.15	0.00



**PYDIFLUMETOFEN (309)**

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 µg/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
-	Beans (dry) NES: including inter alia lablab or hyacinth bean ( <i>Dolichos</i> spp.); jack or sword bean ( <i>Canavalia</i> spp.); winged bean ( <i>Psophocarpus tetragonolobus</i> ); guar bean ( <i>Cyamopsis tetragonoloba</i> ); velvet bean ( <i>Stizolobium</i> spp.); yam bean ( <i>Pachyrhizus erosus</i> )	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 2066	Subgroup of dry peas, raw	RAC	0.028	9.09	0.25	3.35	0.09	1.06	0.03	9.48	0.27	15.11	0.42	10.58	0.30
VR 2070	Subgroup of Root vegetables, raw	RAC	0.02	24.72	0.49	57.71	1.15	17.01	0.34	49.58	0.99	9.33	0.19	114.41	2.29
VR 0573	Arrowroot, raw	RAC	0.03	1.53	0.05	0.01	0.00	0.93	0.03	1.33	0.04	0.47	0.01	0.02	0.00
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.03	0.08	0.00	0.01	0.00	482.56	14.48	0.99	0.03	25.75	0.77	3.29	0.10
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.03	1.57	0.05	0.01	0.00	0.96	0.03	1.36	0.04	0.48	0.01	0.02	0.00
VR 0589	Potato, raw (incl frozen, incl tapioca, excl flour, excl starch)	RAC	0.03	59.36	1.78	315.64	9.47	9.38	0.28	55.58	1.67	53.71	1.61	119.55	3.59
-	Potato, flour	PP	0.014	0.05	0.00	0.10	0.00	0.09	0.00	0.88	0.01	0.09	0.00	0.06	0.00
-	Potato, starch	PP	0.014	0.03	0.00	0.01	0.00	0.01	0.00	0.15	0.00	0.01	0.00	0.01	0.00
VR 0508	Sweet potato, raw (incl dried)	RAC	0.03	0.18	0.01	0.18	0.01	42.16	1.26	1.61	0.05	3.06	0.09	6.67	0.20
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.03	NC	-	NC	-	NC	-	0.01	0.00	0.26	0.01	1.27	0.04
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.03	0.01	0.00	NC	-	25.12	0.75	0.04	0.00	0.01	0.00	0.97	0.03
VR 0600	Yams, raw (incl dried)	RAC	0.03	0.02	0.00	NC	-	90.40	2.71	6.45	0.19	0.74	0.02	0.65	0.02
VS 2080	Subgroup of stems and petioles	RAC	4.4	3.11	13.68	5.52	24.29	3.42	15.05	8.29	36.48	0.02	0.09	4.00	17.60
GC 0648	Quinoa, raw	RAC	0.063	NC	-	NC	-	NC	-	NC	-	0.07	0.00	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.063	0.13	0.01	19.38	1.22	0.10	0.01	0.12	0.01	0.03	0.00	2.15	0.14
GC 0653	Triticale, raw (incl flour)	RAC	0.063	NC	-	NC	-	NC	-	0.01	0.00	0.39	0.02	NC	-
GC 0654	Wheat, raw (incl bulgur, incl fermented beverages, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.063	0.01	0.00	1.12	0.07	NC	-	0.03	0.00	0.56	0.04	NC	-
CF 1210	Wheat, germ	PP	0.091	NC	-	NC	-	0.01	0.00	0.01	0.00	0.14	0.01	0.01	0.00
CP 1212	Wheat, wholemeal bread	PP	0.027	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	0.02	0.25	0.01	0.63	0.01	0.12	0.00	0.43	0.01	1.39	0.03	0.22	0.00
CF 1211	Wheat, white flour	PP	0.02	299.27	5.99	263.32	5.27	27.93	0.56	214.18	4.28	133.47	2.67	340.03	6.80
-	Wheat, starch	PP	0.002	0.02	0.00	NC	-	0.01	0.00	0.05	0.00	0.13	0.00	0.01	0.00
-	Wheat, gluten	PP	0.11	0.01	0.00	0.01	0.00	0.01	0.00	0.27	0.03	0.01	0.00	0.03	0.00
-	Wheat, macaroni, dry	PP	0.02	0.72	0.01	2.20	0.04	1.22	0.02	3.99	0.08	0.53	0.01	1.66	0.03
-	Wheat, pastry, baked	PP	0.02	1.21	0.02	3.13	0.06	1.05	0.02	4.02	0.08	0.60	0.01	1.40	0.03

**PYDIFLUMETOFEN (309)**

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 µg/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 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.23	3.55	0.82	19.31	4.44	4.98	1.15	3.02	0.69	7.85	1.81	3.98	0.92
-	Barley, pot&pearled	PP	0.01	7.12	0.07	7.34	0.07	0.02	0.00	0.03	0.00	0.67	0.01	0.20	0.00
-	Barley, flour (white flour and wholemeal flour)	PP	0.053	2.93	0.16	0.30	0.02	0.02	0.00	0.01	0.00	0.48	0.03	0.01	0.00
GC 0641	Buckwheat, raw (incl flour)	RAC	0.23	NC	-	0.40	0.09	0.01	0.00	0.01	0.00	0.07	0.02	0.09	0.02
GC 0647	Oats, raw	RAC	0.23	0.01	0.00	NC	-	0.01	0.00	0.45	0.10	0.01	0.00	0.01	0.00
GC 0647	Oats, rolled (i.e. oatmeal dry)	PP	0.003	0.03	0.00	3.88	0.01	0.05	0.00	0.69	0.00	0.53	0.00	0.02	0.00
GC 2088	Subgroup of rice cereals	REP	0.03	45.40	1.36	14.99	0.45	84.88	2.55	111.73	3.35	194.75	5.84	93.12	2.79
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0.03	0.84	0.03	0.24	0.01	1.56	0.05	0.46	0.01	2.21	0.07	13.13	0.39
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.048	22.72	1.09	35.61	1.71	87.27	4.19	34.92	1.68	46.71	2.24	49.12	2.36
-	Maize, germ	PP	0.063	0.01	0.00	NC	-	0.01	0.00	0.01	0.00	0.22	0.01	NC	-
-	Maize starch	PP	0.013	0.08	0.00	NC	-	0.01	0.00	2.29	0.03	0.08	0.00	0.11	0.00
OR 0645	Maize oil	PP	0.057	0.96	0.05	0.85	0.05	0.29	0.02	5.42	0.31	0.42	0.02	2.10	0.12
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.03	2.04	0.06	2.99	0.09	1.86	0.06	19.17	0.58	3.33	0.10	1.66	0.05
GC 2090	Subgroup of Sweet Corns	RAC	0.03	0.14	0.00	0.94	0.03	5.70	0.17	2.61	0.08	1.94	0.06	0.22	0.01
SO 0090	Subgroup of Mustard seeds, raw (incl flour, incl oil)	RAC	0.0945	0.02	0.00	0.05	0.00	0.01	0.00	0.31	0.03	0.03	0.00	0.04	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.0945	0.02	0.00	NC	-	NC	-	0.01	0.00	0.13	0.01	NC	-
SO 0698	Poppy seed, raw (incl oil)	RAC	0.0945	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	RAC	0.0945	0.02	0.00	NC	-	NC	-	0.01	0.00	0.75	0.07	0.01	0.00
OR 0495	Rape seed oil, edible	PP	0.035	0.35	0.01	0.44	0.02	0.19	0.01	0.97	0.03	3.28	0.11	0.77	0.03
SO 0700	Sesame seed, raw (incl oil)	RAC	0.0945	1.22	0.12	0.01	0.00	0.54	0.05	4.23	0.40	0.82	0.08	2.77	0.26
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.08	7.43	0.59	36.06	2.88	1.15	0.09	8.77	0.70	5.74	0.46	13.63	1.09
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	20.53	1.64	9.80	0.78	6.42	0.51	4.73	0.38	7.14	0.57	18.68	1.49
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.03	0.46	0.01	1.21	0.04	6.64	0.20	2.71	0.08	1.26	0.04	1.84	0.06
OR 0697	Peanut oil, edible	PP	0.072	0.36	0.03	0.01	0.00	2.57	0.19	0.07	0.01	2.29	0.16	0.36	0.03
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) -80% as muscle	RAC	0.02	24.96	0.50	57.95	1.16	16.70	0.33	38.38	0.77	26.46	0.53	29.00	0.58
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.015	6.24	0.09	14.49	0.22	4.18	0.06	9.60	0.14	6.62	0.10	7.25	0.11

**PYDIFLUMETOFEN (309)**

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 µg/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												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.015	3.29	0.05	6.14	0.09	0.82	0.01	1.57	0.02	2.23	0.03	1.07	0.02												
MO 0105	Edible offal (mammalian), raw	RAC	0.051	4.79	0.24	9.68	0.49	2.97	0.15	5.49	0.28	3.84	0.20	5.03	0.26												
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)	RAC	0.02	14.63	0.29	29.76	0.60	8.04	0.16	129.68	2.59	25.04	0.50	35.66	0.71												
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 (µg/person)=				102.3				157.4				88.8				272.9				136.8				270.8			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (µg/person)=				6000				6000				6000				6000				6000							
%ADI=				1.7%				2.6%				1.5%				4.5%				2.3%				4.5%			
Rounded %ADI=				2%				3%				1%				5%				2%				5%			

**PYDIFLUMETOFEN (309)**

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 µg/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 (i.e. table grapes)	RAC	0.29	6.33	1.84	11.22	3.25	5.21	1.51	9.38	2.72	4.55	1.32	0.78	0.23
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.71	3.09	2.19	1.51	1.07	0.03	0.02	1.38	0.98	4.26	3.02	0.42	0.30
JF 0269	Grape juice (from wine grapes)	PP	0.017	0.56	0.01	1.96	0.03	0.02	0.00	2.24	0.04	2.27	0.04	0.34	0.01
-	Graps must (from wine-grapes)	PP	0.31	0.16	0.05	0.09	0.03	0.01	0.00	0.12	0.04	0.11	0.03	NC	-
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.091	88.93	8.09	62.41	5.68	1.84	0.17	25.07	2.28	61.17	5.57	5.84	0.53
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 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.12	27.81	3.34	41.93	5.03	123.30	14.80	49.47	5.94	15.95	1.91	35.99	4.32
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	0.005	7.57	0.04	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.04	0.41	0.00
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.075	4.96	0.37	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	0.005	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 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.11	5.57	0.61	14.00	1.54	16.50	1.82	8.80	0.97	6.44	0.71	3.44	0.38

PYDIFLUMETOFEN (309)			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 µg/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
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.02	NC	-	NC	-	0.04	0.00	0.17	0.00	NC	-	0.72	0.01
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 2050	Subgroup of Leafy greens	RAC	12.5	18.38	229.75	18.73	234.13	82.36	1029.50	25.32	316.50	17.60	220.00	7.37	92.13
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.02	0.10	0.00	NC	-	26.78	0.54	5.00	0.10	0.58	0.01	5.68	0.11
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.02	NC	-	NC	-	NC	-	NC	-	NC	-	0.33	0.01
VP 0060	Group of Legume vegetables, raw	RAC	0.02	18.21	0.36	8.91	0.18	7.22	0.14	10.04	0.20	23.22	0.46	0.17	0.00
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.028	1.51	0.04	1.50	0.04	1.90	0.05	5.11	0.14	1.36	0.04	23.43	0.66
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.028	0.02	0.00	0.01	0.00	1.16	0.03	0.40	0.01	NC	-	0.06	0.00
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.028	NC	-	NC	-	0.16	0.00	0.01	0.00	NC	-	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.028	0.02	0.00	0.33	0.01	6.64	0.19	3.94	0.11	NC	-	5.78	0.16
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	1.87	0.01	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.004	NC	-	NC	-	0.68	0.00	0.87	0.00	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.005	19.06	0.10	21.06	0.11	5.94	0.03	33.78	0.17	40.05	0.20	13.39	0.07
-	Soya sauce	PP	0.002	0.45	0.00	0.29	0.00	2.93	0.01	4.35	0.01	0.09	0.00	0.70	0.00
-	Soya flour	PP	0.002	0.22	0.00	0.27	0.00	0.29	0.00	0.17	0.00	NC	-	NC	-
-	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 2066	Subgroup of dry peas, raw	RAC	0.028	5.01	0.14	3.76	0.11	1.82	0.05	3.44	0.10	3.49	0.10	5.15	0.14
VR 2070	Subgroup of Root vegetables, raw	RAC	0.02	64.22	1.28	65.78	1.32	49.73	0.99	57.68	1.15	113.82	2.28	37.27	0.75
VR 0573	Arrowroot, raw	RAC	0.03	0.02	0.00	0.01	0.00	2.05	0.06	0.21	0.01	NC	-	0.76	0.02
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.03	0.01	0.00	NC	-	20.96	0.63	0.14	0.00	NC	-	9.62	0.29
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.03	0.11	0.00	0.01	0.00	NC	-	0.22	0.01	NC	-	0.78	0.02
VR 0589	Potato, raw (incl frozen, incl tapioca, excl flour, excl starch)	RAC	0.03	221.34	6.64	224.14	6.72	70.42	2.11	172.24	5.17	227.39	6.82	37.41	1.12
-	Potato, flour	PP	0.014	0.81	0.01	0.48	0.01	0.19	0.00	0.25	0.00	1.57	0.02	0.07	0.00
-	Potato, starch	PP	0.014	NC	-	1.74	0.02	0.05	0.00	0.92	0.01	NC	-	NC	-
VR 0508	Sweet potato, raw (incl dried)	RAC	0.03	0.93	0.03	0.32	0.01	64.65	1.94	5.37	0.16	0.30	0.01	3.13	0.09
VR 0504	Tannia, raw (i.e. Taniel, Yautia)	RAC	0.03	NC	-	NC	-	NC	-	0.01	0.00	NC	-	10.74	0.32
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.03	NC	-	NC	-	1.93	0.06	0.84	0.03	NC	-	19.94	0.60
VR 0600	Yams, raw (incl dried)	RAC	0.03	NC	-	NC	-	0.03	0.00	0.71	0.02	NC	-	17.57	0.53

**PYDIFLUMETOFEN (309)**

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 µg/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
VS 2080	Subgroup of stems and petioles	RAC	4.4	9.31	40.96	8.57	37.71	NC	-	3.88	17.07	24.46	107.62	5.89	25.92
GC 0648	Quinoa, raw	RAC	0.063	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.063	3.21	0.20	35.38	2.23	0.21	0.01	6.50	0.41	1.49	0.09	NC	-
GC 0653	Triticale, raw (incl flour)	RAC	0.063	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, excl germ, excl wholemeal bread, excl white flour products, excl white bread)	RAC	0.063	NC	-	NC	-	0.02	0.00	0.83	0.05	NC	-	NC	-
CF 1210	Wheat, germ	PP	0.091	0.97	0.09	0.10	0.01	0.03	0.00	0.01	0.00	NC	-	0.04	0.00
CP 1212	Wheat, wholemeal bread	PP	0.027	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	0.02	1.30	0.03	0.46	0.01	0.06	0.00	0.22	0.00	2.44	0.05	0.77	0.02
CF 1211	Wheat, white flour	PP	0.02	182.77	3.66	187.54	3.75	103.82	2.08	180.42	3.61	164.00	3.28	118.84	2.38
-	Wheat, starch	PP	0.002	NC	-	NC	-	0.01	0.00	0.31	0.00	NC	-	NC	-
-	Wheat, gluten	PP	0.11	0.68	0.07	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-
-	Wheat, macaroni, dry	PP	0.02	6.71	0.13	4.98	0.10	2.12	0.04	1.90	0.04	2.89	0.06	4.12	0.08
-	Wheat, pastry, baked	PP	0.02	7.93	0.16	0.51	0.01	0.29	0.01	2.44	0.05	1.78	0.04	8.64	0.17
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.23	35.17	8.09	49.45	11.37	8.86	2.04	34.31	7.89	44.87	10.32	15.82	3.64
-	Barley, pot&pearled	PP	0.01	0.57	0.01	2.56	0.03	0.33	0.00	0.56	0.01	0.36	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.053	0.08	0.00	0.03	0.00	0.01	0.00	0.05	0.00	0.68	0.04	0.05	0.00
GC 0641	Buckwheat, raw (incl flour)	RAC	0.23	0.01	0.00	0.79	0.18	0.18	0.04	0.35	0.08	NC	-	NC	-
GC 0647	Oats, raw	RAC	0.23	NC	-	NC	-	0.01	0.00	0.01	0.00	NC	-	0.23	0.05
GC 0647	Oats, rolled (i.e. oatmeal dry)	PP	0.003	4.12	0.01	3.44	0.01	0.08	0.00	2.67	0.01	1.74	0.01	1.51	0.00
GC 2088	Subgroup of rice cereals	REP	0.03	20.96	0.63	16.04	0.48	339.67	10.19	75.51	2.27	16.86	0.51	86.13	2.58
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0.03	0.10	0.00	9.93	0.30	1.40	0.04	10.26	0.31	0.33	0.01	0.04	0.00
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.048	14.27	0.68	12.86	0.62	19.71	0.95	12.55	0.60	4.21	0.20	52.30	2.51
-	Maize, germ	PP	0.063	0.01	0.00	NC	-	NC	-	0.01	0.00	NC	-	0.01	0.00
-	Maize starch	PP	0.013	NC	-	NC	-	0.19	0.00	7.13	0.09	NC	-	NC	-
OR 0645	Maize oil	PP	0.057	0.90	0.05	0.47	0.03	0.15	0.01	3.01	0.17	1.86	0.11	0.36	0.02
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.03	6.17	0.19	3.01	0.09	0.76	0.02	3.30	0.10	3.38	0.10	15.84	0.48
GC 2090	Subgroup of Sweet Corns	RAC	0.03	11.43	0.34	3.71	0.11	0.74	0.02	13.63	0.41	3.07	0.09	1.50	0.05
SO 0090	Subgroup of Mustard seeds, raw (incl flour, incl oil)	RAC	0.0945	0.30	0.03	0.48	0.05	0.33	0.03	0.63	0.06	1.03	0.10	0.40	0.04
SO 0693	Linseed, raw (incl oil)	RAC	0.0945	NC	-	NC	-	0.02	0.00	0.01	0.00	NC	-	NC	-

## PYDIFLUMETOFEN (309)

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 µg/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												
SO 0698	Poppy seed, raw (incl oil)	RAC	0.0945	0.02	0.00	0.25	0.02	0.01	0.00	0.02	0.00	NC	-	NC	-												
SO 0495	Rape seed, raw	RAC	0.0945	NC	-	NC	-	0.01	0.00	NC	-	NC	-	NC	-												
OR 0495	Rape seed oil, edible	PP	0.035	12.52	0.44	7.63	0.27	3.00	0.11	6.01	0.21	NC	-	NC	-												
SO 0700	Sesame seed, raw (incl oil)	RAC	0.0945	0.61	0.06	0.09	0.01	1.53	0.14	0.85	0.08	0.08	0.01	0.14	0.01												
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.08	23.43	1.87	29.34	2.35	1.24	0.10	14.00	1.12	6.48	0.52	6.91	0.55												
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	10.71	0.86	4.23	0.34	7.19	0.58	7.54	0.60	5.66	0.45	2.38	0.19												
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.03	3.26	0.10	2.22	0.07	5.38	0.16	4.85	0.15	1.54	0.05	1.82	0.05												
OR 0697	Peanut oil, edible	PP	0.072	1.02	0.07	0.23	0.02	1.81	0.13	0.42	0.03	5.23	0.38	0.01	0.00												
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) -80% as muscle	RAC	0.02	112.02	2.24	120.71	2.41	63.46	1.27	88.99	1.78	96.24	1.92	41.02	0.82												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.015	28.01	0.42	30.18	0.45	15.86	0.24	22.25	0.33	24.06	0.36	10.25	0.15												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.015	6.44	0.10	15.51	0.23	3.79	0.06	8.29	0.12	18.44	0.28	8.00	0.12												
MO 0105	Edible offal (mammalian), raw	RAC	0.051	15.17	0.77	5.19	0.26	6.30	0.32	6.78	0.35	3.32	0.17	3.17	0.16												
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	0.02	73.76	1.48	53.86	1.08	23.98	0.48	87.12	1.74	53.38	1.07	84.45	1.69												
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 (µg/person)=				331.1				338.3				1082.4				393.5				383.5				151.1			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (µg/person)=				6000				6000				5500				6000				6000				6000			
%ADI=				5.5%				5.6%				19.7%				6.6%				6.4%				2.5%			
Rounded %ADI=				6%				6%				20%				7%				6%				3%			

**PYDIFLUMETOFEN (309)**

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				Intake = daily intake: µg/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 (i.e. table grapes)	RAC	0.29	0.14	0.04	0.36	0.10	15.22	4.41	0.01	0.00	0.09	0.03
DF 0269	Grapes, dried (= currants, raisins and sultanas) (from table-grapes)	PP	0.71	0.01	0.01	0.13	0.09	1.06	0.75	0.01	0.01	0.03	0.02
JF 0269	Grape juice (from wine grapes)	PP	0.017	0.01	0.00	0.01	0.00	0.41	0.01	0.01	0.00	NC	-
-	Graps must (from wine-grapes)	PP	0.31	0.01	0.00	0.01	0.00	0.11	0.03	0.01	0.00	0.19	0.06
-	Grape wine (incl vermouths) (from wine-grapes)	PP	0.091	0.31	0.03	0.23	0.02	60.43	5.50	0.52	0.05	31.91	2.90
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 0045	Group of Fruiting vegetables, cucurbits, raw	RAC	0.12	5.96	0.72	9.74	1.17	51.82	6.22	13.61	1.63	0.05	0.01
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	0.005	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	0.075	0.58	0.04	0.22	0.02	2.21	0.17	0.24	0.02	3.10	0.23
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.005	0.05	0.00	0.01	0.00	0.42	0.00	0.01	0.00	0.02	0.00
VO 0051	Subgroup of peppers, raw (Capsicum spp. Only), excl okra	RAC	0.11	4.72	0.52	4.83	0.53	16.30	1.79	0.01	0.00	NC	-
VO 0442	Okra, raw (i.e. Lady's Finger, Gombo)	RAC	0.02	6.23	0.12	0.10	0.00	NC	-	NC	-	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 2050	Subgroup of Leafy greens	RAC	12.5	4.99	62.38	3.29	41.13	7.53	94.13	3.05	38.13	6.09	76.13
VL 0054	Subgroup of Leaves of Brassicaceae, raw	RAC	0.02	3.58	0.07	2.64	0.05	NC	-	1.83	0.04	3.65	0.07
VL 2052	Subgroup of Leaves of Root and Tuber Vegetables	RAC	0.02	0.30	0.01	0.22	0.00	NC	-	0.20	0.00	0.41	0.01
VP 0060	Group of Legume vegetables, raw	RAC	0.02	0.58	0.01	3.16	0.06	10.38	0.21	0.04	0.00	NC	-
VD 0071	Beans, dry, raw (Phaseolus spp)	RAC	0.028	7.11	0.20	2.33	0.07	3.76	0.11	44.70	1.25	3.27	0.09
VD 0523	Broad bean, dry, raw (incl horse-bean, field bean) (Vicia faba)	RAC	0.028	3.70	0.10	0.03	0.00	0.17	0.00	0.01	0.00	NC	-
VD 0527	Cowpea, dry, raw (Vigna sinensis, Dolichos sinensis)	RAC	0.028	12.77	0.36	0.99	0.03	0.01	0.00	4.33	0.12	NC	-
VD 0541	Soya bean, dry, raw (Glycine soja)	RAC	0.028	2.76	0.08	0.07	0.00	0.33	0.01	3.16	0.09	NC	-
-	Soya paste (i.e. miso)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-
-	Soya curd (i.e. tofu)	PP	0.004	NC	-	NC	-	NC	-	NC	-	NC	-
OR 0541	Soya oil, refined	PP	0.005	2.32	0.01	2.54	0.01	18.70	0.09	2.51	0.01	6.29	0.03
-	Soya sauce	PP	0.002	0.01	0.00	0.13	0.00	0.17	0.00	0.01	0.00	0.56	0.00
-	Soya flour	PP	0.002	0.11	0.00	0.08	0.00	0.07	0.00	0.01	0.00	0.03	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	RAC	0.028	2.54	0.07	1.77	0.05	0.03	0.00	0.03	0.00	3.99	0.11

PYDIFLUMETOFEN (309)				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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
	tetragonoloba); velvet bean ( <i>Stizolobium</i> spp.); yam bean ( <i>Pachyrrhizus erosus</i> )												
VD 2066	Subgroup of dry peas, raw	RAC	0.028	4.43	0.12	11.36	0.32	4.22	0.12	9.36	0.26	1.21	0.03
VR 2070	Subgroup of Root vegetables, raw	RAC	0.02	31.84	0.64	23.38	0.47	68.28	1.37	17.52	0.35	71.01	1.42
VR 0573	Arrowroot, raw	RAC	0.03	13.83	0.41	18.24	0.55	0.01	0.00	0.05	0.00	19.60	0.59
VR 0463	Cassava raw (incl starch, incl tapioca, incl flour) (i.e. Manioc)	RAC	0.03	91.92	2.76	34.12	1.02	NC	-	259.92	7.80	45.48	1.36
VR 0585	Jerusalem artichoke, raw (i.e. Topinambur)	RAC	0.03	14.22	0.43	18.75	0.56	0.01	0.00	0.06	0.00	20.14	0.60
VR 0589	Potato, raw (incl frozen, incl tapioca, excl flour, excl starch)	RAC	0.03	23.72	0.71	12.61	0.38	211.06	6.33	101.89	3.06	8.53	0.26
-	Potato, flour	PP	0.014	0.05	0.00	0.20	0.00	0.52	0.01	0.54	0.01	0.01	0.00
-	Potato, starch	PP	0.014	0.01	0.00	0.01	0.00	NC	-	NC	-	NC	-
VR 0508	Sweet potato, raw (incl dried)	RAC	0.03	28.83	0.86	61.55	1.85	0.15	0.00	221.94	6.66	NC	-
VR 0504	Tannia, raw (i.e. Tanier, Yautia)	RAC	0.03	NC	-	NC	-	0.01	0.00	NC	-	NC	-
VR 0505	Taro, raw (i.e. Dasheen, Eddoe)	RAC	0.03	6.71	0.20	31.91	0.96	NC	-	10.73	0.32	264.31	7.93
VR 0600	Yams, raw (incl dried)	RAC	0.03	70.93	2.13	30.62	0.92	0.07	0.00	5.65	0.17	30.85	0.93
VS 2080	Subgroup of stems and petioles	RAC	4.4	5.33	23.45	3.85	16.94	5.80	25.52	3.60	15.84	7.20	31.68
GC 0648	Quinoa, raw	RAC	0.063	NC	-	NC	-	NC	-	NC	-	NC	-
GC 0650	Rye, raw (incl flour)	RAC	0.063	0.03	0.00	0.01	0.00	13.95	0.88	0.01	0.00	0.88	0.06
GC 0653	Triticale, raw (incl flour)	RAC	0.063	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	0.063	0.01	0.00	NC	-	NC	-	NC	-	0.97	0.06
CF 1210	Wheat, germ	PP	0.091	0.04	0.00	0.01	0.00	0.01	0.00	0.01	0.00	NC	-
CP 1212	Wheat, wholemeal bread	PP	0.027	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	0.02	0.43	0.01	0.41	0.01	1.56	0.03	0.11	0.00	0.07	0.00
CF 1211	Wheat, white flour	PP	0.02	43.75	0.88	85.81	1.72	206.68	4.13	19.38	0.39	92.92	1.86
-	Wheat, starch	PP	0.002	0.01	0.00	0.02	0.00	NC	-	NC	-	NC	-
-	Wheat, gluten	PP	0.11	0.01	0.00	0.01	0.00	0.01	0.00	0.01	0.00	0.19	0.02
-	Wheat, macaroni, dry	PP	0.02	0.52	0.01	0.63	0.01	2.99	0.06	0.26	0.01	5.18	0.10
-	Wheat, pastry, baked	PP	0.02	0.51	0.01	0.51	0.01	4.36	0.09	0.67	0.01	5.32	0.11
GC 0640	Barley, raw (incl malt extract, incl beer, incl malt, excl pot&pearled, excl flour & grits)	RAC	0.23	3.15	0.72	2.31	0.53	43.92	10.10	3.72	0.86	16.26	3.74
-	Barley, pot&pearled	PP	0.01	5.46	0.05	0.01	0.00	1.44	0.01	0.01	0.00	NC	-
-	Barley, flour (white flour and wholemeal flour)	PP	0.053	0.02	0.00	NC	-	0.32	0.02	0.01	0.00	NC	-
GC 0641	Buckwheat, raw (incl flour)	RAC	0.23	0.04	0.01	2.82	0.65	0.01	0.00	0.01	0.00	NC	-



**PYDIFLUMETOFEN (309)**

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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
GC 0647	Oats, raw	RAC	0.23	0.01	0.00	0.02	0.00	NC	-	0.09	0.02	NC	-
GC 0647	Oats, rolled (i.e. oatmeal dry)	PP	0.003	0.20	0.00	0.03	0.00	1.54	0.00	0.01	0.00	NC	-
GC 2088	Subgroup of rice cereals	REP	0.03	52.55	1.58	286.02	8.58	18.64	0.56	19.67	0.59	75.09	2.25
GC 0645	Maize, raw (incl glucose & dextrose & isoglucose, incl beer, excl flour, excl oil, excl germ, excl starch)	RAC	0.03	0.54	0.02	0.51	0.02	3.26	0.10	7.96	0.24	NC	-
CF 1255	Maize, flour (white flour and wholemeal flour)	PP	0.048	94.34	4.53	8.09	0.39	28.03	1.35	55.94	2.69	28.07	1.35
-	Maize, germ	PP	0.063	0.01	0.00	NC	-	NC	-	NC	-	NC	-
-	Maize starch	PP	0.013	0.02	0.00	0.01	0.00	NC	-	NC	-	NC	-
OR 0645	Maize oil	PP	0.057	0.33	0.02	0.07	0.00	0.81	0.05	0.01	0.00	NC	-
-	Cereals, NES, raw (including processed) : canagua, quihuicha, Job's tears and wild rice	RAC	0.03	17.71	0.53	2.00	0.06	9.61	0.29	0.45	0.01	4.55	0.14
GC 2090	Subgroup of Sweet Corns	RAC	0.03	3.63	0.11	20.50	0.62	8.78	0.26	0.02	0.00	0.17	0.01
SO 0090	Subgroup of Mustard seeds, raw (incl flour, incl oil)	RAC	0.0945	0.04	0.00	0.19	0.02	0.32	0.03	0.06	0.01	0.01	0.00
SO 0693	Linseed, raw (incl oil)	RAC	0.0945	0.07	0.01	NC	-	0.03	0.00	NC	-	NC	-
SO 0698	Poppy seed, raw (incl oil)	RAC	0.0945	0.01	0.00	0.01	0.00	0.11	0.01	NC	-	NC	-
SO 0495	Rape seed, raw	RAC	0.0945	NC	-	0.01	0.00	NC	-	NC	-	NC	-
OR 0495	Rape seed oil, edible	PP	0.035	0.07	0.00	0.03	0.00	4.62	0.16	0.03	0.00	NC	-
SO 0700	Sesame seed, raw (incl oil)	RAC	0.0945	2.34	0.22	0.66	0.06	0.26	0.02	9.84	0.93	NC	-
SO 2091	Subgroup of Sunflower seeds, raw (incl processed)	RAC	0.08	0.99	0.08	0.22	0.02	32.01	2.56	12.12	0.97	0.48	0.04
SO 0691	Cotton seed, raw (incl oil)	RAC	0.08	8.14	0.65	0.32	0.03	2.84	0.23	2.69	0.22	0.97	0.08
SO 0697	Peanuts, nutmeat, raw (incl roasted, incl butter, excl oil)	RAC	0.03	7.14	0.21	0.45	0.01	1.87	0.06	6.22	0.19	0.53	0.02
OR 0697	Peanut oil, edible	PP	0.072	5.02	0.36	0.05	0.00	0.17	0.01	0.29	0.02	NC	-
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) -80% as muscle	RAC	0.02	23.34	0.47	40.71	0.81	97.15	1.94	18.06	0.36	57.71	1.15
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat) - 20% as fat	RAC	0.015	5.84	0.09	10.18	0.15	24.29	0.36	4.52	0.07	14.43	0.22
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.015	1.05	0.02	1.14	0.02	18.69	0.28	0.94	0.01	3.12	0.05
MO 0105	Edible offal (mammalian), raw	RAC	0.051	4.64	0.24	1.97	0.10	10.01	0.51	3.27	0.17	3.98	0.20
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	0.02	3.92	0.08	12.03	0.24	57.07	1.14	5.03	0.10	55.56	1.11
PF 0111	Poultry fat, raw (incl rendered)	RAC	0.02	NC	-	NC	-	0.32	0.01	NC	-	NC	-

<b>PYDIFLUMETOFEN (309)</b>				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				Intake = daily intake: µg/person					
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake
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 (µg/person)=				112.0		85.8		190.7		85.2		138.8	
Bodyweight per region (kg bw) =				60		60		60		60		60	
ADI (µg/person)=				6000		6000		6000		6000		6000	
%ADI=				1.9%		1.4%		3.2%		1.4%		2.3%	
Rounded %ADI=				2%		1%		3%		1%		2%	

<b>PYFLUBUMIDE (314)</b>				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.007 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.41	13.49	5.53	26.63	10.92	15.05	6.17	16.28	6.67	6.47	2.65	47.88	19.63
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.001	0.32	0.00	3.07	0.00	0.07	0.00	5.00	0.01	0.29	0.00	5.57	0.01
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	13	2.28	29.64	1.98	25.74	0.46	5.98	2.43	31.59	1.29	16.77	3.04	39.52
Total intake (ug/person)=				35.2		36.7		12.2		38.3		19.4		59.2	
Bodyweight per region (kg bw) =				60		60		60		60		60		60	
ADI (ug/person)=				420		420		420		420		420		420	
%ADI=				8.4%		8.7%		2.9%		9.1%		4.6%		14.1%	
Rounded %ADI=				8%		9%		3%		9%		5%		10%	

<b>PYFLUBUMIDE (314)</b>				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.007 mg/kg bw							
Codex Code	Commodity description	Expr as	STMR mg/kg	Diets as g/person/day				Intake as µg/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
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.41	41.14	16.87	56.49	23.16	26.64	10.92	31.58	12.95	51.94	21.30	3.05	1.25
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.001	14.88	0.01	11.98	0.01	0.15	0.00	9.98	0.01	30.32	0.03	3.47	0.00
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	13	2.91	37.83	1.73	22.49	1.14	14.82	1.85	24.05	2.29	29.77	0.74	9.62
Total intake (ug/person)=				54.7		45.7		25.7		37.0		51.1		10.9	
Bodyweight per region (kg bw) =				60		60		55		60		60		60	

ADI (ug/person)=	420	420	385	420	420	420
%ADI=	13.0%	10.9%	6.7%	8.8%	12.2%	2.6%
Rounded %ADI=	10%	10%	7%	9%	10%	3%

**PYFLUBUMIDE (314)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.007 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
FP 0226	Apple, raw (incl cider, excl juice)	RAC	0.41	66.67	27.33	2.06	0.84	55.83	22.89	188.29	77.20	1.38	0.57
JF 0226	Apple juice, single strength (incl. concentrated)	PP	0.001	0.03	0.00	0.10	0.00	7.19	0.01	0.03	0.00	NC	-
DT 1114	Tea, green or black, fermented and dried, (including concentrates)	RAC	13	0.53	6.89	5.25	68.25	0.86	11.18	0.56	7.28	0.88	11.44

Total intake (ug/person)=	34.2	69.1	34.1	84.5	12.0
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	420	420	420	420	420
%ADI=	8.1%	16.5%	8.1%	20.1%	2.9%
Rounded %ADI=	8%	20%	8%	20%	3%



**PYRIPROXYFEN (200)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.1 mg/kg bw

Codex Code	Commodity description	Expras	STMR mg/kg	Diets as g/person/day				Intake as µg/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	0.013	10.12	0.13	15.69	0.20	2.88	0.04	12.30	0.16	22.32	0.29	6.59	0.09
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.013	12.42	0.16	14.99	0.19	16.08	0.21	10.78	0.14	9.94	0.13	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.013	15.68	0.20	24.00	0.31	6.80	0.09	29.09	0.38	15.39	0.20	160.47	2.09
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0036	33.31	0.12	1.78	0.01	0.28	0.00	18.97	0.07	14.01	0.05	13.36	0.05
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.013	8.21	0.11	4.60	0.06	0.64	0.01	5.85	0.08	19.98	0.26	368.86	4.80
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	0.07	0.31	0.02	0.18	0.01	1.50	0.11	0.51	0.04	0.54	0.04	1.08	0.08
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
VC 0424	Cucumber, raw	RAC	0.01	6.72	0.07	11.03	0.11	32.10	0.32	15.10	0.15	4.05	0.04	9.57	0.10
VC 0425	Gherkin, raw	RAC	0.01	0.41	0.00	5.89	0.06	NC	-	0.06	0.00	0.37	0.00	2.07	0.02
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.01	NC	-	NC	-	5.48	0.05	NC	-	NC	-	1.03	0.01
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.016	9.20	0.15	11.95	0.19	14.63	0.23	8.99	0.14	7.86	0.13	2.46	0.04
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	0.018	7.57	0.14	2.66	0.05	0.30	0.01	0.97	0.02	7.31	0.13	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	0.018	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 0444	Peppers, chili, raw	RAC	0.17	5.57	0.95	14.00	2.38	8.25	1.40	5.77	0.98	6.44	1.09	2.53	0.43
VO 0445	Peppers, sweet, raw (incl dried)	RAC	1.7	0.82	1.39	1.53	2.60	10.85	18.45	4.59	7.80	1.84	3.13	2.00	3.40
VO 0445	Peppers, sweet, raw	RAC	0.17	NC	-	NC	-	8.25	1.40	3.03	0.52	NC	-	0.91	0.15
SO 0691	Cotton seed, raw (incl oil)	RAC	0.002	10.71	0.02	4.23	0.01	7.19	0.01	7.54	0.02	5.66	0.01	2.38	0.00
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	15.17	0.00	5.19	0.00	6.30	0.00	6.78	0.00	3.32	0.00	3.17	0.00

PYRIPROXYFEN (200)				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 µg/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
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
	Total intake (µg/person)=				7.5		11.8		26.1		18.2		8.3		12.7
	Bodyweight per region (kg bw) =				60		60		55		60		60		60
	ADI (µg/person)=				6000		6000		5500		6000		6000		6000
	%ADI=				0.1%		0.2%		0.5%		0.3%		0.1%		0.2%
	Rounded %ADI=				0%		0%		0%		0%		0%		0%

PYRIPROXYFEN (200)				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				Intake = daily intake: µg/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	0.013	18.97	0.25	0.97	0.01	6.23	0.08	0.09	0.00	3.35	0.04
FC 0003	Subgroup of Mandarins, raw (incl mandarin juice)	RAC	0.013	0.16	0.00	0.27	0.00	9.06	0.12	0.01	0.00	0.02	0.00
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.013	1.18	0.02	1.11	0.01	14.28	0.19	0.05	0.00	1.08	0.01
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.0036	0.08	0.00	0.26	0.00	12.61	0.05	0.14	0.00	0.33	0.00
FC 0005	Subgroup of Pummelo and grapefruits, raw (incl grapefruit juice)	RAC	0.013	0.68	0.01	0.05	0.00	3.21	0.04	0.01	0.00	NC	-
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	0.07	6.47	0.45	0.25	0.02	0.19	0.01	0.01	0.00	26.42	1.85
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
VC 0424	Cucumber, raw	RAC	0.01	0.68	0.01	1.81	0.02	10.40	0.10	0.01	0.00	0.04	0.00
VC 0425	Gherkin, raw	RAC	0.01	0.15	0.00	0.39	0.00	3.15	0.03	0.01	0.00	0.01	0.00
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini), raw	RAC	0.01	0.09	0.00	1.01	0.01	NC	-	1.91	0.02	NC	-
VC 0046	Melons, except watermelon, raw (Cantaloupe)	RAC	0.016	0.19	0.00	0.10	0.00	4.98	0.08	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	0.018	0.07	0.00	0.08	0.00	2.42	0.04	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	0.018	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00
VO 0444	Peppers, chili, raw	RAC	0.17	3.47	0.59	3.56	0.61	16.30	2.77	0.01	0.00	NC	-

**PYRIPROXYFEN (200)**

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				Intake = daily intake: µg/person						
				G13 diet	G13 intake	G14 diet	G14 intake	G15 diet	G15 intake	G16 diet	G16 intake	G17 diet	G17 intake	
VO 0445	Peppers, sweet, raw (incl dried)	RAC	1.7	5.49	9.33	10.57	17.97	8.84	15.03	0.91	1.55	NC	-	
VO 0445	Peppers, sweet, raw	RAC	0.17	1.24	0.21	1.27	0.22	NC	-	0.01	0.00	NC	-	
SO 0691	Cotton seed, raw (incl oil)	RAC	0.002	8.14	0.02	0.32	0.00	2.84	0.01	2.69	0.01	0.97	0.00	
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	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	
Total intake (µg/person)=					12.6		19.6		24.7		1.7		2.9	
Bodyweight per region (kg bw) =					60		60		60		60		60	
ADI (µg/person)=					6000		6000		6000		6000		6000	
%ADI=					0.2%		0.3%		0.4%		0.0%		0.0%	
Rounded %ADI=					0%		0%		0%		0%		0%	

**TOLCLOFOS-METHYL (191)**

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												
VL 0460	Amaranth leaves, raw (i.e. Bledo)	RAC	0.36	1.09	0.39	1.94	0.70	1.20	0.43	2.91	1.05	NC	-	1.41	0.51												
VL 0465	Chervil, raw	RAC	0.36	0.19	0.07	0.34	0.12	0.21	0.08	0.52	0.19	NC	-	0.25	0.09												
VL 2752	Chrysanthemum, edible leaved	RAC	0.36	0.02	0.01	0.04	0.01	0.02	0.01	0.06	0.02	NC	-	0.03	0.01												
VL 0470	Corn salad (Lambs lettuce)	RAC	0.36	0.64	0.23	1.13	0.41	0.70	0.25	1.70	0.61	NC	-	0.82	0.30												
VL 0474	Dandelion, raw (i.e. Laiteron, Pissenlit)	RAC	0.36	0.13	0.05	0.23	0.08	0.14	0.05	0.34	0.12	1.44	0.52	0.16	0.06												
VL 0476	Endive, raw (i.e. scarole)	RAC	0.36	0.03	0.01	0.02	0.01	0.01	0.00	0.40	0.14	0.05	0.02	0.39	0.14												
VL 0483	Lettuce, leaf, raw	RAC	0.36	0.53	0.19	0.36	0.13	0.16	0.06	6.21	2.24	1.90	0.68	6.05	2.18												
VL 2765	Perilla leaves (Sesame leaves)	RAC	0.36	0.15	0.05	0.27	0.10	0.17	0.06	0.40	0.14	NC	-	0.19	0.07												
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.06	59.74	3.58	316.14	18.97	9.78	0.59	60.26	3.62	54.12	3.25	119.82	7.19												
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	0.0055	4.79	0.03	9.68	0.05	2.97	0.02	5.49	0.03	3.84	0.02	5.03	0.03												
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)=				4.6				20.6				1.5				8.2				4.5				10.6			
Bodyweight per region (kg bw) =				60				60				60				60				60							
ADI (ug/person)=				4200				4200				4200				4200				4200							
%ADI=				0.1%				0.5%				0.0%				0.2%				0.1%				0.3%			
Rounded %ADI=				0%				0%				0%				0%				0%							



**TOLCLOFOS-METHYL (191)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.07 mg/kg bw

Codex Code	Commodity description	Expr as	STM <sup>R</sup> 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												
VL 0460	Amaranth leaves, raw (i.e. Bledo)	RAC	0.36	NC	-	NC	-	47.45	17.08	NC	-	NC	-	2.07	0.75												
VL 0465	Chervil, raw	RAC	0.36	NC	-	NC	-	8.39	3.02	NC	-	NC	-	0.37	0.13												
VL 2752	Chrysanthemum, edible leaved	RAC	0.36	NC	-	NC	-	NC	-	0.32	0.12	NC	-	0.04	0.01												
VL 0470	Corn salad (Lambs lettuce)	RAC	0.36	1.41	0.51	4.28	1.54	NC	-	0.03	0.01	5.11	1.84	1.20	0.43												
VL 0474	Dandelion, raw (i.e. Laiteron, Pissenlit)	RAC	0.36	0.05	0.02	0.01	0.00	NC	-	NC	-	0.01	0.00	0.24	0.09												
VL 0476	Endive, raw (i.e. scarole)	RAC	0.36	0.21	0.08	0.93	0.33	NC	-	0.30	0.11	2.14	0.77	0.14	0.05												
VL 0483	Lettuce, leaf, raw	RAC	0.36	14.50	5.22	11.76	4.23	13.14	4.73	19.50	7.02	4.81	1.73	2.23	0.80												
VL 2765	Perilla leaves (Sesame leaves)	RAC	0.36	NC	-	NC	-	NC	-	2.23	0.80	NC	-	0.29	0.10												
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.06	225.03	13.50	234.24	14.05	71.48	4.29	177.55	10.65	234.55	14.07	37.71	2.26												
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	0.0055	15.17	0.08	5.19	0.03	6.30	0.03	6.78	0.04	3.32	0.02	3.17	0.02												
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)=				19.4				20.2				29.2				18.7				18.4				4.6			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (ug/person)=				4200				4200				3850				4200				4200				4200			
%ADI=				0.5%				0.5%				0.8%				0.4%				0.4%				0.1%			
Rounded %ADI=				0%				0%				1%				0%				0%				0%			

TOLCLOFOS-METHYL (191)				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				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	
VL 0460	Amaranth leaves, raw (i.e. Bledo)	RAC	0.36	1.87	0.67	1.35	0.49	NC	-	1.27	0.46	2.53	0.91	
VL 0465	Chervil, raw	RAC	0.36	0.33	0.12	0.24	0.09	NC	-	0.22	0.08	0.45	0.16	
VL 2752	Chrysanthemum, edible leaved	RAC	0.36	0.04	0.01	0.03	0.01	NC	-	0.03	0.01	0.05	0.02	
VL 0470	Corn salad (Lambs lettuce)	RAC	0.36	1.09	0.39	0.79	0.28	NC	-	0.74	0.27	1.47	0.53	
VL 0474	Dandelion, raw (i.e. Laiteron, Pissenlit)	RAC	0.36	0.22	0.08	0.16	0.06	NC	-	0.15	0.05	0.29	0.10	
VL 0476	Endive, raw (i.e. scarole)	RAC	0.36	0.02	0.01	0.01	0.00	0.01	0.00	0.01	0.00	NC	-	
VL 0483	Lettuce, leaf, raw	RAC	0.36	0.29	0.10	0.03	0.01	6.71	2.42	0.01	0.00	NC	-	
VL 2765	Perilla leaves (Sesame leaves)	RAC	0.36	0.26	0.09	0.19	0.07	NC	-	0.18	0.06	0.35	0.13	
VR 0589	Potato, raw (incl flour, incl frozen, incl starch, incl tapioca)	RAC	0.06	23.96	1.44	13.56	0.81	213.41	12.80	104.35	6.26	8.56	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	0.0055	4.64	0.03	1.97	0.01	10.01	0.06	3.27	0.02	3.98	0.02	
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)=				2.9				1.8		15.3		7.2		2.4
Bodyweight per region (kg bw) =				60				60		60		60		60
ADI (ug/person)=				4200				4200		4200		4200		4200
% ADI=				0.1%				0.0%		0.4%		0.2%		0.1%
Rounded % ADI=				0%				0%		0%		0%		0%

**TOLFENPYRAD (269)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.006 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 kumquat commodities)	RAC	0.085	4.78	0.41	2.42	0.21	3.61	0.31	25.18	2.14	8.25	0.70	15.77	1.34
-	Lemon, juice (single strength, incl. concentrated)	PP	0.058	0.01	0.00	0.01	0.00	0.11	0.01	0.09	0.01	0.18	0.01	0.17	0.01
FC 0003	Subgroup of Mandarins, raw	RAC	0.085	6.18	0.53	3.66	0.31	0.25	0.02	6.82	0.58	3.49	0.30	19.38	1.65
-	Subgroup of Mandarins, juice	PP	0.058	NC	-	NC	-	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.061	20.66	1.26	5.23	0.32	11.90	0.73	37.90	2.31	21.16	1.29	56.46	3.44
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.042	1.27	0.05	2.20	0.09	0.09	0.00	11.81	0.50	0.46	0.02	1.69	0.07
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.042	0.64	0.03	0.35	0.01	0.93	0.04	6.10	0.26	1.01	0.04	1.36	0.06
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.029	0.01	0.00	0.16	0.00	0.02	0.00	1.97	0.06	0.12	0.00	0.77	0.02
VA 2031	Subgroup of bulb onions	RAC	0.0125	31.65	0.40	43.28	0.54	3.68	0.05	38.48	0.48	20.46	0.26	47.29	0.59
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.13	42.41	5.51	76.50	9.95	10.69	1.39	85.07	11.06	24.98	3.25	203.44	26.45
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.14	2.34	0.33	1.33	0.19	1.57	0.22	4.24	0.59	0.34	0.05	2.83	0.40
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilepeppers), excl okra	RAC	0.11	8.48	0.93	13.74	1.51	10.13	1.11	11.29	1.24	9.52	1.05	26.36	2.90
VO 2046	Subgroup of eggplants	RAC	0.13	5.58	0.73	4.31	0.56	0.89	0.12	9.31	1.21	13.64	1.77	20.12	2.62
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
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
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	RAC	5.65	2.28	12.88	1.92	10.85	0.46	2.60	2.40	13.56	1.29	7.29	3.04	17.18
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.0043	31.20	0.13	72.44	0.31	20.88	0.09	47.98	0.21	33.08	0.14	36.25	0.16
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0022	3.29	0.01	6.14	0.01	0.82	0.00	1.57	0.00	2.23	0.00	1.07	0.00
MO 0105	Edible offal (mammalian), raw	RAC	0.29	4.79	1.39	9.68	2.81	2.97	0.86	5.49	1.59	3.84	1.11	5.03	1.46
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0038	289.65	1.10	485.88	1.85	26.92	0.10	239.03	0.91	199.91	0.76	180.53	0.69
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)=	26.1	30.1	8.6	37.3	19.1	59.4
Bodyweight per region (kg bw) =	60	60	60	60	60	60
ADI (ug/person)=	360	360	360	360	360	360
% ADI=	7.3%	8.4%	2.4%	10.3%	5.3%	16.5%
Rounded % ADI=	7%	8%	2%	10%	5%	20%

## TOLFENPYRAD (269)

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.006 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 kumquat commodities)	RAC	0.085	8.45	0.72	14.69	1.25	2.88	0.24	8.16	0.69	21.14	1.80	5.93	0.50												
-	Lemon, juice (single strength, incl. concentrated)	PP	0.058	0.60	0.03	0.36	0.02	0.01	0.00	1.49	0.09	0.43	0.02	0.24	0.01												
FC 0003	Subgroup of Mandarins, raw	RAC	0.085	12.34	1.05	14.99	1.27	16.08	1.37	10.76	0.91	9.94	0.84	NC	-												
-	Subgroup of Mandarins, juice	PP	0.058	0.04	0.00	NC	-	0.01	0.00	0.01	0.00	NC	-	NC	-												
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.061	15.68	0.96	24.00	1.46	6.80	0.41	29.09	1.77	15.39	0.94	160.47	9.79												
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.042	33.31	1.40	1.78	0.07	0.28	0.01	18.97	0.80	14.01	0.59	13.36	0.56												
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.042	2.19	0.09	1.24	0.05	0.60	0.03	3.44	0.14	4.60	0.19	299.96	12.60												
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.029	2.89	0.08	1.61	0.05	0.02	0.00	1.15	0.03	7.39	0.21	33.07	0.96												
VA 2031	Subgroup of bulb onions	RAC	0.0125	20.67	0.26	31.32	0.39	37.52	0.47	35.08	0.44	11.77	0.15	13.74	0.17												
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.13	44.88	5.83	55.49	7.21	35.44	4.61	75.65	9.83	27.00	3.51	9.61	1.25												
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.14	4.96	0.69	3.20	0.45	0.15	0.02	1.61	0.23	6.88	0.96	0.52	0.07												
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.11	6.39	0.70	15.53	1.71	19.09	2.10	10.36	1.14	8.29	0.91	4.53	0.50												
VO 2046	Subgroup of eggplants	RAC	0.13	1.01	0.13	1.69	0.22	21.37	2.78	3.00	0.39	1.40	0.18	NC	-												
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												
TN 0672	Pecan, nutmeat	RAC	0.01	0.38	0.00	NC	-	NC	-	0.27	0.00	NC	-	0.26	0.00												
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	RAC	5.65	2.71	15.31	0.82	4.63	1.14	6.44	1.59	8.98	1.82	10.28	0.53	2.99												
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.0043	140.03	0.60	150.89	0.65	79.32	0.34	111.24	0.48	120.30	0.52	51.27	0.22												
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0022	6.44	0.01	15.51	0.03	3.79	0.01	8.29	0.02	18.44	0.04	8.00	0.02												
MO 0105	Edible offal (mammalian), raw	RAC	0.29	15.17	4.40	5.19	1.51	6.30	1.83	6.78	1.97	3.32	0.96	3.17	0.92												
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0038	388.92	1.48	335.88	1.28	49.15	0.19	331.25	1.26	468.56	1.78	245.45	0.93												
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)=				33.9				22.5				21.2				29.4				24.2				31.7			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (ug/person)=				360				360				330				360				360				360			
%ADI=				9.4%				6.2%				6.4%				8.2%				6.7%				8.8%			
Rounded %ADI=				9%				6%				6%				8%				7%				9%			

**TOLFENPYRAD (269)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.006 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 kumquat commodities)	RAC	0.085	18.96	1.61	0.97	0.08	5.79	0.49	0.09	0.01	3.35	0.28
-	Lemon, juice (single strength, incl. concentrated)	PP	0.058	0.01	0.00	0.01	0.00	0.16	0.01	0.01	0.00	NC	-
FC 0003	Subgroup of Mandarins, raw	RAC	0.085	0.16	0.01	0.27	0.02	9.06	0.77	0.01	0.00	0.02	0.00
-	Subgroup of Mandarins, juice	PP	0.058	0.01	0.00	NC	-	NC	-	NC	-	NC	-
FC 0004	Subgroup of Oranges, sweet, sour, raw	RAC	0.061	1.18	0.07	1.11	0.07	14.28	0.87	0.05	0.00	1.08	0.07
JF 0004	Subgroup of Oranges, juice (single strength, incl. concentrated)	PP	0.042	0.08	0.00	0.26	0.01	12.61	0.53	0.14	0.01	0.33	0.01
FC 0005	Subgroup of Pummelo and grapefruits, raw	RAC	0.042	0.63	0.03	0.01	0.00	1.58	0.07	0.01	0.00	NC	-
JF 0203	Grapefruits, juice (single strength, incl. concentrated)	PP	0.029	0.03	0.00	0.02	0.00	0.78	0.02	0.01	0.00	NC	-
VA 2031	Subgroup of bulb onions	RAC	0.0125	9.83	0.12	22.30	0.28	34.69	0.43	9.65	0.12	2.39	0.03
VO 0448	Tomato, raw (incl juice, incl canned, excl paste)	RAC	0.13	13.17	1.71	4.92	0.64	62.69	8.15	1.04	0.14	0.11	0.01
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.14	0.58	0.08	0.22	0.03	2.21	0.31	0.24	0.03	3.10	0.43
VO 0051	Subgroup of peppers, raw (incl dried sweet peppers, excl dried chilipeppers), excl okra	RAC	0.11	8.97	0.99	14.13	1.55	25.14	2.77	0.91	0.10	NC	-
VO 2046	Subgroup of eggplants	RAC	0.13	1.31	0.17	8.26	1.07	3.95	0.51	0.01	0.00	NC	-
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
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
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	RAC	5.65	0.53	2.99	5.25	29.66	0.63	3.56	0.56	3.16	0.82	4.63
MM 0095	MEAT FROM MAMMALS other than marine mammals, raw (incl prepared meat)	RAC	0.0043	29.18	0.13	50.89	0.22	121.44	0.52	22.58	0.10	72.14	0.31
MF 0100	Mammalian fats, raw, excl milk fats (incl rendered fats)	RAC	0.0022	1.05	0.00	1.14	0.00	18.69	0.04	0.94	0.00	3.12	0.01
MO 0105	Edible offal (mammalian), raw	RAC	0.29	4.64	1.35	1.97	0.57	10.01	2.90	3.27	0.95	3.98	1.15
ML 0106	Milks, raw or skimmed (incl dairy products)	RAC	0.0038	108.75	0.41	70.31	0.27	436.11	1.66	61.55	0.23	79.09	0.30
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)=	10.3	35.9	24.9	5.0	7.2
Bodyweight per region (kg bw) =	60	60	60	60	60
ADI (ug/person)=	360	360	360	360	360
%ADI=	2.9%	10.0%	6.9%	1.4%	2.0%
Rounded %ADI=	3%	10%	7%	1%	2%



**VALIFENALATE (318)**

International Estimated Daily Intake (IEDI)

ADI = 0 - 0.2 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												
JF 0269	Grape juice (from wine grapes)	PP	0.043	0.56	0.02	1.96	0.08	0.02	0.00	2.24	0.10	2.27	0.10	0.34	0.01												
-	Graps must (from wine-grapes)	PP	0.079	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	0.051	88.93	4.54	62.41	3.18	1.84	0.09	25.07	1.28	61.17	3.12	5.84	0.30												
FB 1235	Table grapes, raw (incl dried grapes)	RAC	0.079	19.22	1.52	17.53	1.38	5.32	0.42	15.12	1.19	22.29	1.76	2.51	0.20												
-	Onions, dry, raw	RAC	0.0375	19.69	0.74	29.83	1.12	24.64	0.92	31.35	1.18	9.72	0.36	12.59	0.47												
VO 0448	Tomato, raw	RAC	0.049	32.13	1.57	51.27	2.51	34.92	1.71	73.37	3.60	15.15	0.74	8.88	0.44												
-	Tomato, canned (& peeled)	PP	0.005	7.57	0.04	2.66	0.01	0.30	0.00	0.97	0.00	7.31	0.04	0.41	0.00												
-	Tomato, paste (i.e. concentrated tomato sauce/puree)	PP	0.04	4.96	0.20	3.20	0.13	0.15	0.01	1.61	0.06	6.88	0.28	0.52	0.02												
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.016	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 0440	Egg plant, raw (i.e. aubergine)	RAC	0.049	1.01	0.05	1.69	0.08	21.37	1.05	3.00	0.15	1.40	0.07	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	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)	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)=				8.7				8.5				4.2				7.6				6.5				1.4			
Bodyweight per region (kg bw) =				60				60				55				60				60				60			
ADI (ug/person)=				12000				12000				11000				12000				12000				12000			
%ADI=				0.1%				0.1%				0.0%				0.1%				0.1%				0.0%			
Rounded %ADI=				0%				0%				0%				0%				0%				0%			

VALIFENALATE (318)				International Estimated Daily Intake (IEDI)				ADI = 0 - 0.2 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	
JF 0269	Grape juice (from wine grapes)	PP	0.043	0.01	0.00	0.01	0.00	0.41	0.02	0.01	0.00	NC	-	
-	Graps must (from wine-grapes)	PP	0.079	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	0.051	0.31	0.02	0.23	0.01	60.43	3.08	0.52	0.03	31.91	1.63	
FB 1235	Table grapes, raw (incl dried grapes)	RAC	0.079	0.16	0.01	0.92	0.07	19.62	1.55	0.02	0.00	0.21	0.02	
-	Onions, dry, raw	RAC	0.0375	9.01	0.34	20.24	0.76	30.90	1.16	9.61	0.36	2.11	0.08	
VO 0448	Tomato, raw	RAC	0.049	12.99	0.64	4.79	0.23	58.40	2.86	0.92	0.05	0.09	0.00	
-	Tomato, canned (& peeled)	PP	0.005	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	0.04	0.58	0.02	0.22	0.01	2.21	0.09	0.24	0.01	3.10	0.12	
JF 0448	Tomato, juice (single strength, incl concentrated)	PP	0.016	0.05	0.00	0.01	0.00	0.42	0.01	0.01	0.00	0.02	0.00	
VO 0440	Egg plant, raw (i.e. aubergine)	RAC	0.049	1.31	0.06	8.26	0.40	3.95	0.19	0.01	0.00	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	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)	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)=				1.1				1.5		9.0		0.4		1.9
Bodyweight per region (kg bw) =				60				60		60		60		60
ADI (ug/person)=				12000				12000		12000		12000		12000
% ADI=				0.0%				0.0%		0.1%		0.0%		0.0%
Rounded % ADI=				0%				0%		0%		0%		0%



## Annex 4: International estimates of short-term dietary exposure of pesticide residues

ACETAMIPRID (246)

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

IESTI

Maximum %ARFD:

0%

0%

0%

all

gen pop

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
HS 0771	Anise, seed (all commodities)	highest utilisation: Total	0.57		1.000	PRIMO-DE	Gen pop	P95	7.64	<25	NR	3	0-0.06	0-0%	0-0%	0-0%
HS 3285	Black caraway (all commodities)	highest utilisation: Total	0.57		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	3	0.06-0.06	0-0%	0-0%	0-0%
HS 0774	Caraway, seed (all commodities)	highest utilisation: Total	0.57		1.000	PRIMO-CZ	child, 4-6 yrs	P97.5	0.43	<25	NR	3	0-0.01	0-0%	0-0%	0-0%
HS 0779	Coriander, seed (all commodities)	highest utilisation: Total	0.57		1.000	AU	Gen pop, > 2 yrs	129	7.76	<25	NR	3	0-0.07	0-0%	0-0%	0-0%
HS 0780	Cumin, seed (all commodities)	highest utilisation: Total	0.57		1.000	AU	Child, 2-16 yrs	584	3.99	<25	NR	3	0-0.06	0-0%	0-0%	0-0%
HS 0730	Dill, seed (all commodities)	highest utilisation: Total	0.57		1.000	US	Child, < 6 yrs	325	1.89	<25	NR	3	0-0.07	0-0%	0-0%	0-0%
HS 0731	Fennel, seed (all commodities)	highest utilisation: Total	0.57		1.000	PRIMO-DE	child	P97.5	12.44	<25	NR	3	0-0.44	0-0%	0-0%	0-0%
HS 0782	Fenugreek, seed (all commodities)	highest utilisation: Total	0.57		1.000	AU	Gen pop, > 2 yrs	129	7.76	<25	NR	3	0-0.07	0-0%	0-0%	0-0%
HS 3296	Guarana	Total	0.57		1.000	AU	Child, 2-16 yrs	13	1.36	<25	NR	3	0.020	0%	-	0%
HS 0789	Nutmeg (all commodities)	highest utilisation: Total	0.57		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	3	0-0.06	0-0%	0-0%	0-0%

## AFIDOPYROPEN (312)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum %ARfD:

100%  
all50%  
gen pop100%  
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
FC 0303	Kumquats (all commodities)	highest utilisation: Total		0.086	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.02–0.21	0–0%	0–0%	0–0%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.012–0.0535	0.086	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0.02–1.43	0–0%	0–0%	0–0%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.012–0.0535	0.086	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0–0.46	0–0%	0–0%	0–0%
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.012–0.0535	0.086	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0.01–4.45	0–1%	0–1%	0–1%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.012–0.0535	0.086	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0.04–5.04	0–2%	0–1%	0–2%
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: Total	0.012–0.0535	0.086	1.000	PRIMO-DE	child	P90	253.56	270	3	2b	0.01–4.05	0–1%	0–1%	0–1%
FP 0226	Apple (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.013–0.021	0.019–0.029	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	0.03–1.64	0–1%	0–0%	0–1%
FP 2220	Azarole (Mediterranean medlar) (all commodities)	highest utilisation: juice (pasteurised)	0.021	0.029	1.000	PRIMO-DE	child	P97.5	89.63	NR	NR	3	0.03–0.12	0–0%	0–0%	0–0%
FP 0227	Crab-apple (all commodities)	highest utilisation: raw with peel		0.029	1.000	CN	Gen pop, > 1 yrs	204	488.33	<25	NR	1	0.27–0.27	0–0%	0–0%	0–0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel		0.029	1.000	JP	Gen pop, > 1 yrs	113	326.40	49	3	2a	0.05–0.23	0–0%	0–0%	0–0%
FP 0229	Medlar (all commodities)	highest utilisation: Total		0.029	1.000	PRIMO-ES	child	P97.5	116.99	60	3	2a	0.2–0.2	0–0%	0–0%	0–0%
FP 0230	Pear (all commodities)	highest utilisation: Total	0.021	0.029	1.000	CA	Child, <6 yrs	175	498.28	255	3	2a	0.01–2.01	0–1%	0–0%	0–1%

**AFIDOPYROPEN (312)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

100%  
all

50%  
gen pop

100%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	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
FP 0307	Persimmon, Japanese (i.e. Kaki fruit) (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.029	1.000	TH	Child, 3-6 yrs	20	264.88	228	3	2a	1.1–1.22	0–0%	0–0%	0–0%
FP 0231	Quince (all commodities)	highest utilisation: Total	0.021	0.029	1.000	PRIMO-ES	child	P97.5	169.60	301	3	2b	0–0.43	0–0%	0–0%	0–0%
FS 0013	Subgroup of Cherries (all commodities)	highest utilisation: Total	0.02	0.031	1.000	PRIMO-DK	child	P97.5	269.00	<25	NR	1	0.01–0.38	0–0%	0–0%	0–0%
FS 0014	Subgroup of Plums (all commodities)	highest utilisation: dried (prunes)	0.02	0.02	3.500	AU	Child, 2-6 yrs	13	447.59	10	NR	1	0.01–1.65	0–1%	0–0%	0–1%
FS 0302	Jujube, Chinese	Total		0.02	1.000	CN	Gen pop, > 1 yrs	1328	286.17	15	NR	1	0.108	0%	0%	-
FS 0240	Apricot (all commodities)	highest utilisation: Total	0.02	0.022	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	0.01–0.5	0–0%	0–0%	0–0%
FS 2237	Japanese apricot (ume)	Total		0.022	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	0.031	0%	0%	0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.02	0.022	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	0.01–0.96	0–0%	0–0%	0–0%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.02	0.022	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0.01–1.16	0–0%	0–0%	0–0%
VB 0400	Broccoli (all commodities)	highest utilisation: cooked/boiled	0.135	0.34	1.000	PRIMO-NL	toddler	P97.5	160.70	286	3	2b	0.24–16.07	0–5%	0–2%	0–5%
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled	0.135	0.34	1.000	PRIMO-NL	toddler	P97.5	142.00	749	3	2b	0.02–14.2	0–5%	0–3%	0–5%
VB 0041	Cabbages, head (all commodities)	highest utilisation: raw	0.02	0.1	1.000	CN	Child, 1-6 yrs	287	255.54	1403	3	2b	0.01–4.75	0–2%	0–1%	0–2%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.17	0.6	1.000	CN	Child, 1-6 yrs	340	212.11	458	3	2b	0.06–23.66	0–8%	0–5%	0–8%
VC 0431	Squash, Summer (Courgette, Marrow, Zucchetti, Zucchini) (all commodities)	highest utilisation: Total	0.039	0.05	1.000	US	Child, < 6 yrs	252	149.52	186	3	2b	0.02–1.55	0–1%	0–0%	0–1%

AFIDOPYROPEN (312)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

100%  
all

50%  
gen pop

100%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	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
VC 0046	Melons, except watermelon (Cantaloupe) (all commodities)	highest utilisation: Total	0.027	0.048	1.000	PRIMO-BE	toddler	P100	540.00	540	3	2b	0-4.37	0-1%	0-1%	0-1%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.027	0.048	1.000	CN	Child, 1-6 yrs	561	322.71	1852	3	2b	0.04-2.88	0-1%	0-1%	0-1%
VC 0432	Watermelon (all commodities)	highest utilisation: Total	0.027	0.048	1.000	CA	Child, <6 yrs	171	953.64	4302	3	2b	4.14-8.9	1-3%	1-2%	1-3%
VO 2704	Goji berry (all commodities)	highest utilisation: Dried		0.12	3.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0.11-0.54	0-0%	0-0%	0-0%
VO 0448	Tomato (all commodities)	highest utilisation: raw with peel	0.0026-0.03	0.065-0.7	1.000	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	0.02-4.56	0-2%	0-1%	0-2%
VO 0444	Peppers, chili (all commodities)	highest utilisation: raw with skin	0.036	0.11-1.1	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43	3	2a	0-0.79	0-0%	0-0%	0-0%
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all commodities)	highest utilisation: raw with skin	0.036	0.11	1.000	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	0.01-3.47	0-1%	0-0%	0-1%
VO 0440	Egg plant (Aubergine) (all commodities)	highest utilisation: raw with skin	0.03	0.12	1.000	CN	Child, 1-6 yrs	969	253.44	444	3	2b	0.03-5.65	0-2%	0-1%	0-2%
VO 0443	Pepino (Melon pear, Tree melon)	Total		0.12	1.000	AU	Gen pop, > 2 yrs	3	73.89	123	3	2b	0.397	0%	0%	-
VO 2713	Scarlet eggplant (gilo, Ethiopian eggplant) (all commodities)	highest utilisation: cooked/boiled (with skin)		0.12	1.000	BR	Gen pop, > 10 yrs	280	360.50	28	3	2a	0.78-0.78	0-0%	0-0%	0-0%
VL 0460	Amaranth leaves (Bledo) (all commodities)	highest utilisation: raw		2.6	1.000	CN	Gen pop, > 1 yrs	714	581.72	86	3	2a	12.22-36.79	4-10%	4-10%	2-2%
VL 0464	Chard (Beet leaves, Silver beet) (all commodities)	highest utilisation: cooked/boiled		2.6	1.000	PRIMO-NL	child	P100	81.80	105	3	2b	9.22-34.68	3-10%	3-10%	8-10%
VL 0465	Chervil (all commodities)	highest utilisation: Total	0.88	2.6	1.000	PRIMO-BE	toddler	P100	23.00	<25	NR	1	0.1-3.36	0-1%	0-0%	0-1%
VL 0469	Chicory leaves (green and red cultivars) (Sugar loaf) (all commodities)	highest utilisation: raw		2.6	1.000	DE	Child, 2-4 yrs	16	82.40	280	3	2b	5.42-39.8	2-10%	1-4%	2-10%
VL 2752	Chrysanthemum, edible leaved (all commodities)	highest utilisation: raw		2.6	1.000	CN	Gen pop, > 1 yrs	993	332.67	<25	NR	1	9.06-16.25	3-5%	2-5%	3-3%

**AFIDOPYROPEN (312)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

100%  
all

50%  
gen pop

100%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	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
VL 0470	Corn salad (Lambs lettuce) (all commodities)	highest utilisation: Total		2.6	1.000	PRIMO-BE	toddler	P100	50.00	<25	NR	1	2.2–7.3	1–2%	1–2%	0–2%
VL 0510	Cos lettuce (all commodities)	highest utilisation: Total	0.88	2.6	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	0.52–59.39	0–20%	0–9%	0–20%
VL 0474	Dandelion (Laiteron, Pissenlit) (all commodities)	highest utilisation: raw		2.6	1.000	NL	gen pop, > 1 yrs	E	49.88	35	3	2a	1.82–4.74	1–2%	2–2%	0–0%
VL 0476	Endive (i.e. Scarole) (all commodities)	highest utilisation: cooked/boiled	0.88	2.6	1.000	PRIMO-NL	toddler	P95	135.20	251	3	2b	3.51–103.39	1–30%	0–10%	1–30%
VL 0482	Lettuce, head (all commodities)	highest utilisation: Total	0.88	2.6	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	0.52–59.39	0–20%	0–9%	0–20%
VL 0483	Lettuce, leaf (all commodities)	highest utilisation: Total	0.88	2.6	1.000	CN	Child, 1-6 yrs	243	387.25	305	3	2a	0.52–160.81	0–50%	0–20%	0–50%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled		2.6	1.000	PRIMO-NL	Gen pop	P100	271.20	<25	NR	1	2.84–10.72	1–4%	1–4%	0–0%
VL 0501	Sowthistle (all commodities)	highest utilisation: raw		2.6	1.000	CN	Gen pop, > 1 yrs	1187	592.49	35	3	2a	32.36–32.36	10–10%	10–10%	0–0%
VL 0502	Spinach (all commodities)	highest utilisation: Total	0.88	2.6	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	0.09–58.76	0–20%	0–10%	0–20%
VL 0401	Broccoli, Chinese (i.e. kailan) (all commodities)	highest utilisation: raw		4.8	1.000	CN	Child, 1-6 yrs	334	222.48	311	3	2b	10.07–198.55	3–70%	3–30%	1–70%
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard) (all other commodities)	highest utilisation: Total	2.5	4.8	1.000	CA	Gen pop, all ages	341	428.62	1548	3	2b	0.72–97.71	0–30%	0–30%	1–20%
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard)	raw		4.8	1.000	CN	Child, 1-6 yrs	1966	327.07	1548	3	2b	291.892	100%	50%	100%
VL 0472	Cress, Garden (all commodities)	highest utilisation: raw		4.8	1.000	CN	Gen pop, > 1 yrs	1443	352.50	<25	NR	1	1.81–31.79	1–10%	1–10%	0–0%
VL 0468	Flowering white cabbage (Choisum) (all commodities)	highest utilisation: raw	2.5	4.8	1.000	CN	Gen pop, > 1 yrs	1639	556.56	300	3	2a	8.23–104.3	3–30%	3–30%	0–0%
VL 0480	Kale (Borecole, Collards) (all commodities)	highest utilisation: Total	2.5	4.8	1.000	PRIMO-DE	child	P100	142.12	672	3	2b	4.75–126.72	2–40%	2–20%	7–40%

**AFIDOPYROPEN (312)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

100%  
all

50%  
gen pop

100%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	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
VL 0481	Komatsuna	Total		4.8	1.000	JP	Child, 1-6 yrs	73	71.40	<25	NR	1	20.400	7%	4%	7%
VL 2781	Mizuna	Total		4.8	1.000	JP	Gen pop, > 1 yrs	1787	137.70	<25	NR	1	11.803	4%	4%	4%
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards) (all commodities)	highest utilisation: raw	2.5	4.8	1.000	CN	Child, 1-6 yrs	635	299.31	245	3	2a	10.81–234.66	4–80%	4–30%	80–80%
VL 0494	Radish leaves	Total		4.8	1.000	BR	Gen pop, > 10 yrs	-	258.24	<25	NR	1	19.200	6%	6%	-
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled		4.8	1.000	JP	Gen pop, > 1 yrs	533	147.90	34	3	2a	18.61–18.61	6–6%	6–6%	9–9%
VL 0496	Rucola (Arrugula, Rocket salad, Roquette, Roman rocket) (all commodities)	highest utilisation: Total		4.8	1.000	PRIMO-DE	child	P100	43.44	<25	NR	1	5.67–12.91	2–4%	2–10%	4–4%
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: Total		4.8	1.000	DE	Child, 2-4 yrs	1	67.00	35	3	2a	7.87–40.72	3–10%	2–7%	3–10%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.02		1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0–0.3	0–0%	0–0%	0–0%
VR 0573	Arrowroot (all commodities)	highest utilisation: starch	0	0	1.000	PRIMO-NL	child	E	12.40	NR	NR	3	0–0	0–0%	0–0%	0–0%
VR 0463	Cassava (Manioc) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0	1.000	PRIMO-NL	Gen pop	E	250.00	356	3	2b	0–0	0–0%	0–0%	0–0%
VR 0585	Jerusalem artichoke (i.e. Topinambur) (all commodities)	highest utilisation: cooked/boiled (without peel)		0	1.000	PRIMO-NL	child	E	133.30	56	3	2a	0–0	0–0%	0–0%	0–0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0	0	1.000	PRIMO-UK	infant	P97.5	191.10	216	3	2b	0–0	0–0%	0–0%	0–0%
VR 0508	Sweet potato (all commodities)	highest utilisation: Total	0	0	1.000	CA	Child, <6 yrs	91	358.61	546	3	2b	0–0	0–0%	0–0%	0–0%
VR 0504	Tannia (Tanier, Yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0	1.000	NL	Gen pop, > 1 yrs	E	249.97	170	3	2a	0–0	0–0%	0–0%	0–0%

**AFIDOPYROPEN (312)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

100%  
all

50%  
gen pop

100%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	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
VR 0505	Taro (Dasheen, Eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)		0	1.000	CN	Child, 1-6 yrs	199	384.18	668	3	2b	0-0	0-0%	0-0%	0-0%
VR 0600	Yams (all commodities)	highest utilisation: Total		0	1.000	PRIMO-UK	adult	P97.5	693.70	365	3	2a	0-0	0-0%	0-0%	0-0%
VS 0623	Cardoon (all commodities)	highest utilisation: cooked/boiled		2.2	1.000	PRIMO-NL	Gen pop	E	200.00	100	3	2a	9.79-13.37	3-4%	3-4%	0-0%
VS 0624	Celery (all commodities)	highest utilisation: raw	0.54	2.2	1.000	CN	Child, 1-6 yrs	454	180.29	861	3	2b	0.03-73.74	0-20%	0-10%	0-20%
VS 0380	Fennel, bulb (Florence fennel) (all commodities)	highest utilisation: cooked/boiled	0.54	2.2	1.000	PRIMO-NL	child	E	166.80	251	3	2b	0.03-59.83	0-20%	0-9%	1-20%
VS 0627	Rhubarb (all commodities)	highest utilisation: Total	0.54	2.2	1.000	AU	gen pop, > 2 yrs	58	539.42	57	3	2a	8.31-21.44	3-7%	1-7%	3-10%
TN 0660	Almonds (all commodities)	highest utilisation: Total	0.02	0.02	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0-0.08	0-0%	0-0%	0-0%
TN 0662	Brazil nut (all commodities)	highest utilisation: Total		0.02	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0.02-0.02	0-0%	0-0%	0-0%
TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted	0.02	0.02	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0.06-0.12	0-0%	0-0%	0-0%
TN 0664	Chestnut (all commodities)	highest utilisation: Total		0.02	1.000	CN	Gen pop, > 1 yrs	807	475.25	<25	NR	1	0.05-0.18	0-0%	0-0%	0-0%
TN 0665	Coconut (all commodities)	highest utilisation: raw (i.e. nutmeat)	0.02	0.02	1.000	TH	child, 3-6 yrs	826	423.40	383	3	2a	0.01-1.39	0-0%	0-0%	0-0%
TN 0666	Hazelnut (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-IE	child	P97.5	65.42	<25	NR	1	0.01-0.07	0-0%	0-0%	0-0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0-0.04	0-0%	0-0%	0-0%
TN 0672	Pecan (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-DE	child	P100	44.41	<25	NR	1	0.01-0.06	0-0%	0-0%	0-0%
TN 0673	Pine nut (all commodities)	highest utilisation: Total		0.02	1.000	BR	Gen pop, > 10 yrs	47	200.00	<25	NR	1	0.01-0.06	0-0%	0-0%	0-0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-IE	child	P97.5	115.86	<25	NR	1	0-0.12	0-0%	0-0%	0-0%
TN 0678	Walnut (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0-0.07	0-0%	0-0%	0-0%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.0013-0.02	0.11	1.000	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0-0	0-0%	0-0%	0-0%

**AFIDOPYROPEN (312)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

100%  
all

50%  
gen pop

100%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	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
HH 3209	Coriander, leaves (Cilantro) (all commodities)	highest utilisation: raw	2.5	4.8	1.000	CN	Gen pop, > 1 yrs	1073	157.79	<25	NR	1	3.4–14.23	1–5%	0–5%	1–1%
HH 0730	Dill, leaves (all commodities)	highest utilisation: cooked/boiled		4.8	1.000	NL	Gen pop, > 1 yrs	291	13.69	<25	NR	1	0.62–1	0–0%	0–0%	0–0%
HH 0740	Parsley, leaves (all commodities)	highest utilisation: Total	2.5	4.8	1.000	PRIMO-UK	vegetarian	P97.5	79.90	<25	NR	1	0.12–5.75	0–2%	0–2%	0–2%
HS 0784	Ginger, rhizome (all commodities)	highest utilisation: Total	0	0	1.000	CN	Gen pop, > 1 yrs	1652	231.42	208	3	2a	0–0	0–0%	0–0%	0–0%
HS 0794	Turmeric, root (all commodities)	highest utilisation: Total	0	0	1.000	AU	Child, 2-16 yrs	398	5.35	<25	NR	1	0–0	0–0%	0–0%	0–0%
HS 3381	Lemon, peel (all commodities)	highest utilisation: raw peel (C. limon Burm.f.)	0.22	0.15	1.000	AU	Child, 2-6 yrs	602	1.15	67	3	2b	0.03–0.03	0–0%	0–0%	0–0%
HS 3382	Orange, peel (all commodities)	highest utilisation: raw peel (C. sinensis Osbeck)	0.22	0.15	1.000	AU	Gen pop, > 2 yrs	698	15.10	49	3	2b	0.1–0.1	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	302	264.84	NR	NR	1	NA	1%	1%	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.13	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.427	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.26	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	3.414	1%	1%	1%
MF 0100	Mammalian fats (except milk fats)	Total		0.13	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.264	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.34	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	3.196	1%	1%	1%
ML 0106	Milks	Total	0.02		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	2.484	1%	0%	1%
PM 0110	Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	1%	0%	1%
PM 0110	Poultry meat: 10% as fat	Total		0.098	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.211	0%	0%	0%



**AFIDOPYROPEN (312)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

100%  
all

50%  
gen pop

100%  
child

Codex Code	Commodity	Processing	STM or STM-R-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
PM 0110	Poultry meat: 90% as muscle	Total		0.098	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	1.897	1%	0%	1%
PF 0111	Poultry, fats	Total		0.098	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.284	0%	0%	0%
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0.11	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.714	0%	0%	0%
PE 0112	Eggs	Total		0.091	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	1.130	0%	0%	0%

**AFIDOPYROPEN (312)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI  
Maximum % ARfD:

80%  
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
FC 0303	Kumquats (all commodities)	highest utilisation: Total		0.086	1.000	JP	Women, 15-49 yrs	17	56.40	<25	NR	1	0.02-0.1	0-0%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.012-0.0535	0.086	1.000	PRIMO-CZ	females, 15-17 yrs	P97.5	71.17	71	3	2b	0.01-0.33	0-0%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.012-0.0535	0.086	1.000	US	women, 13-49 yrs	8	263.27	56	3	2a	0-0.44	0-0%
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: Total	0.012-0.0535	0.086	1.000	US	women, 13-49 yrs	142	464.37	124	3	2a	0.01-0.84	0-0%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.012-0.0535	0.086	1.000	US	women, 13-49 yrs	606	370.96	96	3	2a	0.02-0.66	0-0%
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: Total	0.012-0.0535	0.086	1.000	PRIMO-FI	women	P97.5	498.19	194	3	2a	0.01-1.07	0-1%
FP 0226	Apple (all commodities)	highest utilisation: Total	0.013-0.021	0.019-0.029	1.000	CA	women, 15-49 yrs	1203	396.66	255	3	2a	0.01-0.39	0-0%
FP 2220	Azarole (Mediterranean medlar) (all commodities)	highest utilisation: juice (pasteurised)	0.021	0.029	1.000	-	-	-	-	-	-	-	0-0	0-0%
FP 0227	Crab-apple (all commodities)	highest utilisation: raw with peel		0.029	1.000	CN	gen pop, > 1 yrs	204	488.33	<25	NR	1	0.27-0.27	0-0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel		0.029	1.000	JP	Gen pop, > 1 yrs	113	326.40	49	3	2a	0.05-0.23	0-0%
FP 0229	Medlar (all commodities)	highest utilisation: Total		0.029	1.000	PRIMO-ES	adult	P97.5	108.83	60	3	2a	0.1-0.1	0-0%
FP 0230	Pear (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.021	0.029	1.000	DE	Women, 14-50 yrs	540	303.37	192	3	2a	0-0.3	0-0%
FP 0307	Persimmon, Japanese (i.e. Kaki fruit) (all commodities)	highest utilisation: raw with peel (incl consumption without peel)		0.029	1.000	DE	Women, 14-50 yrs	42	500.00	228	3	2a	0.39-0.41	0-0%
FP 0231	Quince (all commodities)	highest utilisation: Total	0.021	0.029	1.000	AU	gen pop, > 2 yrs	10	209.20	283	3	2b	0-0.27	0-0%

**AFIDOPYROPEN (312)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI

Maximum % ARfD:

80%  
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
FS 0013	Subgroup of Cherries (all commodities)	highest utilisation: raw	0.02	0.031	1.000	DE	Women, 14-50 yrs	123	740.52	<25	NR	1	0.01–0.34	0–0%
FS 0014	Subgroup of Plums (all commodities)	highest utilisation: dried (prunes)	0.02	0.02	3.500	AU	Gen pop, > 2 yrs	216	512.69	10	NR	1	0.01–0.54	0–0%
FS 0302	Jujube, Chinese	Total		0.02	1.000	CN	gen pop, > 1 yrs	1328	286.17	15	NR	1	0.108	0%
FS 0240	Apricot (all commodities)	highest utilisation: dried	0.02	0.022	4.900	FR	gen pop, > 3 yrs	7	176.95	7	NR	1	0–0.37	0–0%
FS 2237	Japanese apricot (ume)	Total		0.022	1.000	JP	Gen pop, > 1 yrs	2829	30.60	<25	NR	1	0.012	0%
FS 0245	Nectarine (all commodities)	highest utilisation: Total	0.02	0.022	1.000	CA	women, 15-49 yrs	111	495.04	128	3	2a	0–0.24	0–0%
FS 0247	Peach (all commodities)	highest utilisation: Total	0.02	0.022	1.000	CA	women, 15-49 yrs	172	262.51	255	3	2a	0–0.25	0–0%
VB 0400	Broccoli (all commodities)	highest utilisation: raw	0.135	0.34	1.000	NL	gen pop, > 1 yrs	13	424.54	304	3	2a	0.16–5.34	0–3%
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled	0.135	0.34	1.000	PRIMO-NL	Gen pop	P97.5	548.30	749	3	2b	0.02–8.5	0–4%
VB 0041	Cabbages, head (all commodities)	highest utilisation: Total	0.02	0.1	1.000	PRIMO-CZ	females, 15-17 yrs	P97.5	467.60	1148	3	2b	0.03–2.52	0–1%
VC 0424	Cucumber (all commodities)	highest utilisation: cooked/boiled (without skin)	0.17	0.6	1.000	NL	gen pop, > 1 yrs	E	200.03	333	3	2b	0.03–5.47	0–3%
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini) (all commodities)	highest utilisation: Total	0.039	0.05	1.000	CA	women, 15-49 yrs	174	354.20	328	3	2a	0.02–0.8	0–0%
VC 0046	Melons, except watermelon (Cantaloupe) (all commodities)	highest utilisation: Total	0.027	0.048	1.000	CA	women, 15-49 yrs	179	1254.36	998	3	2a	0–2.32	0–1%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.027	0.048	1.000	CN	Gen pop, > 1 yrs	10137	701.51	1852	3	2b	0.02–1.9	0–1%
VC 0432	Watermelon (all commodities)	highest utilisation: Total	0.027	0.048	1.000	CA	women, 15-49 yrs	184	1713.94	4302	3	2b	0.85–3.7	0–2%
VO 2704	Goji berry (all commodities)	highest utilisation: Dried		0.12	3.000	-	-	-	-	-	-	-	0–0	0–0%
VO 0448	Tomato (all commodities)	highest utilisation: Total	0.0026–0.03	0.065–0.7	1.000	CA	women, 15-49 yrs	1660	271.01	175	3	2a	0.02–1.1	0–1%

**AFIDOPYROPEN (312)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI

Maximum % ARfD:

80%  
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
VO 0444	Peppers, chili (all commodities)	highest utilisation: raw with skin	0.036	0.11–1.1	1.000	CN	gen pop, > 1 yrs	1743	295.71	43	3	2a	0–0.79	0–0%
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all commodities)	highest utilisation: raw with skin	0.036	0.11	1.000	DE	Women, 14-50 yrs	518	191.73	119	3	2a	0–0.7	0–0%
VO 0440	Egg plant (Aubergine) (all commodities)	highest utilisation: raw with skin	0.03	0.12	1.000	CN	gen pop, > 1 yrs	####	483.89	444	3	2a	0.01–3.09	0–2%
VO 0443	Pepino (Melon pear, Tree melon)	Total		0.12	1.000	AU	gen pop, > 2 yrs	3	73.89	123	3	2b	0.397	0%
VO 2713	Scarlet eggplant (gilo, Ethiopian eggplant) (all commodities)	highest utilisation: cooked/boiled (with skin)		0.12	1.000	BR	Gen pop, > 10 yrs	280	360.50	28	3	2a	0.78–0.78	0–0%
VL 0460	Amaranth leaves (Bledo) (all commodities)	highest utilisation: raw		2.6	1.000	CN	gen pop, > 1 yrs	714	581.72	86	3	2a	0–36.79	0–20%
VL 0464	Chard (Beet leaves, Silver beet) (all commodities)	highest utilisation: cooked/boiled		2.6	1.000	PRIMO-NL	Gen pop	P100	193.50	105	3	2a	9.22–15.94	5–8%
VL 0465	Chervil (all commodities)	highest utilisation: raw	0.88	2.6	1.000	DE	Women, 14-50 yrs	1685	9.40	<25	NR	1	0.04–0.36	0–0%
VL 0469	Chicory leaves (green and red cultivars) (Sugar loaf) (all commodities)	highest utilisation: raw		2.6	1.000	DE	Women, 14-50 yrs	40	113.90	280	3	2b	3.44–13.17	2–7%
VL 2752	Chrysanthemum, edible leaved (all commodities)	highest utilisation: raw		2.6	1.000	CN	gen pop, > 1 yrs	993	332.67	<25	NR	1	5.56–16.25	3–8%
VL 0470	Corn salad (Lambs lettuce) (all commodities)	highest utilisation: Total		2.6	1.000	PRIMO-IT	adult	P97.5	125.00	<25	NR	1	1.54–4.89	1–2%
VL 0510	Cos lettuce (all commodities)	highest utilisation: Total	0.88	2.6	1.000	AU	gen pop, > 2 yrs	54	242.90	457	3	2b	0.52–28.28	0–10%
VL 0474	Dandelion (Laiteron, Pissenlit) (all commodities)	highest utilisation: Total		2.6	1.000	US	women, 13-49 yrs	1	17.12	35	3	2b	1.16–1.82	1–1%
VL 0476	Endive (i.e. Scarole) (all commodities)	highest utilisation: cooked/boiled	0.88	2.6	1.000	PRIMO-NL	Gen pop	P97.5	340.80	251	3	2a	0.48–33.3	0–20%
VL 0482	Lettuce, head (all commodities)	highest utilisation: cooked/boiled	0.88	2.6	1.000	NL	gen pop, > 1 yrs	2	220.89	227	3	2b	0.52–26.18	0–10%

**AFIDOPYROPEN (312)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI

Maximum % ARfD:

80%

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
VL 0483	Lettuce, leaf (all commodities)	highest utilisation: Total	0.88	2.6	1.000	CA	women, 15-49 yrs	2159	322.00	305	3	2a	0.52–35.86	0–20%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled		2.6	1.000	PRIMO-NL	Gen pop	P100	271.20	<25	NR	1	2.84–10.72	1–5%
VL 0501	Sowthistle (all commodities)	highest utilisation: raw		2.6	1.000	CN	gen pop, > 1 yrs	1187	592.49	35	3	2a	32.36–32.36	20–20%
VL 0502	Spinach (all commodities)	highest utilisation: Total	0.88	2.6	1.000	CA	women, 15-49 yrs	380	469.10	245	3	2a	0.04–38.1	0–20%
VL 0401	Broccoli, Chinese (i.e. kailan) (all commodities)	highest utilisation: raw		4.8	1.000	CN	gen pop, > 1 yrs	6965	385.09	311	3	2a	10.07–90.82	5–50%
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard) (all commodities)	highest utilisation: raw	2.5	4.8	1.000	CN	gen pop, > 1 yrs	38811	601.64	1548	3	2b	0.72–162.77	0–80%
VL 0472	Cress, Garden (all commodities)	highest utilisation: Total		4.8	1.000	PRIMO-UK	vegetarian	P97.5	25.20	<25	NR	1	0.21–1.81	0–1%
VL 0468	Flowering white cabbage (Choisum) (all commodities)	highest utilisation: raw	2.5	4.8	1.000	CN	gen pop, > 1 yrs	1639	556.56	300	3	2a	8.23–104.3	4–50%
VL 0480	Kale (Borecole, Collards) (all commodities)	highest utilisation: Total	2.5	4.8	1.000	US	women, 13-49 yrs	20	380.64	672	3	2b	4.75–74.88	2–40%
VL 0481	Komatsuna	Total		4.8	1.000	JP	Gen pop, > 1 yrs	2594	147.90	<25	NR	1	12.978	6%
VL 2781	Mizuna	Total		4.8	1.000	JP	Gen pop, > 1 yrs	1787	137.70	<25	NR	1	11.803	6%
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red mustards) (all commodities)	highest utilisation: raw	2.5	4.8	1.000	CN	gen pop, > 1 yrs	9701	554.45	245	3	2a	10.81–94.14	5–50%
VL 0494	Radish leaves	Total		4.8	1.000	BR	Gen pop, > 10 yrs	-	258.24	<25	NR	1	19.200	10%
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled		4.8	1.000	JP	Gen pop, > 1 yrs	533	147.90	34	3	2a	18.61–18.61	9–9%
VL 0496	Rucola (Arrugula, Rocket salad, Roquette, Roman rocket) (all commodities)	highest utilisation: Total		4.8	1.000	US	women, 13-49 yrs	5	46.96	213	3	2b	5.67–9.24	3–5%

**AFIDOPYROPEN (312)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI  
Maximum % ARfD:

80%  
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
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: cooked/boiled		4.8	1.000	NL	gen pop, > 1 yrs	97	292.68	<25	NR	1	6.57–21.35	3–10%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: flour	0.02		1.000	CN	gen pop, > 1 yrs	1227	353.50	NR	NR	3	0–0.13	0–0%
VR 0573	Arrowroot (all commodities)	highest utilisation: starch	0	0	1.000	PRIMO-NL	Gen pop	E	18.40	NR	NR	3	0–0	0–0%
VR 0463	Cassava (Manioc) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0	1.000	PRIMO-NL	Gen pop	E	250.00	356	3	2b	0–0	0–0%
VR 0585	Jerusalem artichoke (i.e. Topinambur) (all commodities)	highest utilisation: cooked/boiled (without peel)		0	1.000	PRIMO-NL	Gen pop	E	200.00	56	3	2a	0–0	0–0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0	0	1.000	CA	women, 15-49 yrs	1652	453.94	216	3	2a	0–0	0–0%
VR 0508	Sweet potato (all commodities)	highest utilisation: Total	0	0	1.000	US	women, 13-49 yrs	135	389.54	105	3	2a	0–0	0–0%
VR 0504	Tannia (Tanier, Yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0	1.000	NL	gen pop, > 1 yrs	E	249.97	170	3	2a	0–0	0–0%
VR 0505	Taro (Dasheen, Eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)		0	1.000	CN	gen pop, > 1 yrs	3948	564.91	668	3	2b	0–0	0–0%
VR 0600	Yams (all commodities)	highest utilisation: Total		0	1.000	US	women, 13-49 yrs	21	541.40	129	3	2a	0–0	0–0%
VS 0623	Cardoon (all commodities)	highest utilisation: cooked/boiled		2.2	1.000	PRIMO-NL	Gen pop	E	200.00	100	3	2a	9.79–13.37	5–7%
VS 0624	Celery (all commodities)	highest utilisation: cooked/boiled	0.54	2.2	1.000	PRIMO-NL	Gen pop	P97.5	444.30	607	3	2b	0.03–44.57	0–20%
VS 0380	Fennel, bulb (Florence fennel) (all commodities)	highest utilisation: cooked/boiled	0.54	2.2	1.000	PRIMO-NL	Gen pop	P100	271.20	251	3	2a	0.03–25.85	0–10%
VS 0627	Rhubarb (all commodities)	highest utilisation: Total	0.54	2.2	1.000	US	women, 13-49 yrs	2	62.73	89	3	2b	3.48–5.66	2–3%
TN 0660	Almonds (all commodities)	highest utilisation: raw incl roasted	0.02	0.02	1.000	DE	Women, 14-50 yrs	24	100.00	<25	NR	1	0–0.03	0–0%
TN 0662	Brazil nut (all commodities)	highest utilisation: raw incl roasted		0.02	1.000	DE	Women, 14-50 yrs	3	23.00	<25	NR	1	0.01–0.01	0–0%

**AFIDOPYROPEN (312)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI  
Maximum % ARfD:

80%  
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
TN 0295	Cashew nut (all commodities)	highest utilisation: Total	0.02	0.02	1.000	CA	women, 15-49 yrs	137	68.22	<25	NR	1	0.02-0.02	0-0%
TN 0664	Chestnut (all commodities)	highest utilisation: raw incl roasted		0.02	1.000	DE	Women, 14-50 yrs	15	153.90	<25	NR	1	0.03-0.05	0-0%
TN 0665	Coconut (all commodities)	highest utilisation: raw (i.e. nutmeat)	0.02	0.02	1.000	TH	gen pop, > 3 yrs	6946	823.45	383	3	2a	0.01-0.59	0-0%
TN 0666	Hazelnut (all commodities)	highest utilisation: raw incl roasted	0.02	0.02	1.000	DE	Women, 14-50 yrs	25	45.00	<25	NR	1	0.01-0.01	0-0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0-0.04	0-0%
TN 0672	Pecan (all commodities)	highest utilisation: raw incl roasted	0.02	0.02	1.000	BR	Gen pop, > 10 yrs	9	39.00	5	NR	1	0.01-0.01	0-0%
TN 0673	Pine nut (all commodities)	highest utilisation: Total		0.02	1.000	US	women, 13-49 yrs	13	88.65	<25	NR	1	0-0.02	0-0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.02	0.02	1.000	CA	women, 15-49 yrs	32	214.87	<25	NR	1	0-0.06	0-0%
TN 0678	Walnut (all commodities)	highest utilisation: raw incl roasted	0.02	0.02	1.000	DE	Women, 14-50 yrs	89	175.00	<25	NR	1	0-0.05	0-0%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.0013-0.02	0.11	1.000	US	women, 13-49 yrs	10804	5.75	NR	NR	3	0-0	0-0%
HH 3209	Coriander, leaves (Cilantro) (all commodities)	highest utilisation: raw	2.5	4.8	1.000	CN	Gen pop, > 1 yrs	1073	157.79	<25	NR	1	0.03-14.23	0-7%
HH 0730	Dill, leaves (all commodities)	highest utilisation: cooked/boiled		4.8	1.000	NL	gen pop, > 1 yrs	291	13.69	<25	NR	1	0.12-1	0-0%
HH 0740	Parsley, leaves (all commodities)	highest utilisation: Total	2.5	4.8	1.000	US	women, 13-49 yrs	534	10.63	94	3	2b	0.12-2.09	0-1%
HS 0784	Ginger, rhizome (all commodities)	highest utilisation: Total	0	0	1.000	DE	Women, 14-50 yrs	1945	1.90	208	3	2b	0-0	0-0%
HS 0794	Turmeric, root (all commodities)	highest utilisation: Total	0	0	1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	1	0-0	0-0%
HS 3381	Lemon, peel (all commodities)	highest utilisation: raw peel (C. limon Burm.f.)	0.22	0.15	1.000	AU	gen pop, > 2 yrs	145	2.18	56	3	2b	0.01-0.01	0-0%
HS 3382	Orange, peel (all commodities)	highest utilisation: raw peel (C. sinensis Osbeck)	0.22	0.15	1.000	AU	gen pop, > 2 yrs	698	15.10	49	3	2b	0.1-0.1	0-0%

**AFIDOPYROPEN (312)**

Acute RfD= 0.2 mg/kg bw (200 µg/kg bw)

IESTI  
Maximum % ARfD:

80%  
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
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	DE	Women, 14-50 yrs	25	521.10	NR	NR	1	NA	1%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.13	1.000	DE	Women, 14-50 yrs	25	104.22	NR	NR	1	0.201	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.26	1.000	DE	Women, 14-50 yrs	25	416.88	NR	NR	1	1.606	1%
MF 0100	Mammalian fats (except milk fats)	Total		0.13	1.000	US	women, 13-49 yrs	6730	45.60	NR	NR	1	0.081	0%
MO 0105	Edible offal (mammalian)	Total		0.34	1.000	PRIMO-DE	women, 14-50 yrs	P100	188.92	NR	NR	1	0.952	0%
ML 0106	Milks	Total	0.02		1.000	DE	Women, 14-50 yrs	6554	1276.50	NR	NR	3	0.378	0%
PM 0110	Poultry meat	Total	NA	NA	1.000	CA	women, 15-49 yrs	2127	384.47	NR	NR	1	NA	0%
PM 0110	Poultry meat: 10% as fat	Total		0.098	1.000	CA	women, 15-49 yrs	2127	38.45	NR	NR	1	0.056	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.098	1.000	CA	women, 15-49 yrs	2127	346.02	NR	NR	1	0.502	0%
PF 0111	Poultry, fats	Total		0.098	1.000	CA	women, 15-49 yrs	195	78.63	NR	NR	1	0.117	0%
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0.11	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.714	0%
PE 0112	Eggs	Total		0.098	1.000	CA	women, 15-49 yrs	3395	136.90	NR	NR	1	0.200	0%



**BENZOVINDIFLUPYR (261)**

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

IESTI  
Maximum %ARfD: 2% 2% 1%  
all gen pop 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	0.015	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0-0.28	0-0%	0-0%	0-0%
GS 0659	Sugar cane (all commodities)	highest utilisation: thick juice	0.003-0.069		1.000	CN	Gen pop, > 1 yrs	436	1817.52	NR	NR	3	0.03-2.36	0-2%	0-2%	0-1%

**BIFENTHRIN (178)**

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

IESTI  
Maximum %ARfD: 380% 210% 380%  
all gen pop 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 0275	Strawberry	Total		2.3	1.000	PRIMO-NL	toddler	P97.5	166.70	<25	NR	1	37.589	380%	210%	380%
FB 0275	Strawberry	Raw with skin		2.3	1.000	NL	toddler, 8-20 m	52	166.73	18	NR	1	37.596	380%	170%	380%
FB 0275	Strawberry (all other commodities)	highest utilisation: canned/preserved	0.46	2.3	1.000	NL	Child, 2-6 yrs	E	71.70	7	NR	1	0.26-8.96	3-90%	1-60%	2-90%

**BUPROFEZIN (173)**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

IESTI

Maximum % ARfD:

10%

5%  
gen pop

10%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	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	
FC 0204	Lemon (all commodities)	highest utilisation: juice (pasteurised)	0.039–0.12	0.078	1.000	PRIMO-NL	Gen pop	P97.5	125.00	NR	NR	3	0.14–0.23	0–0%	0–0%	0–0%
FC 0205	Lime (all commodities)	highest utilisation: juice (pasteurised)	0.039–0.12	0.078	1.000	AU	Gen pop, > 2 yrs	579	129.61	NR	NR	3	0.2–0.23	0–0%	0–0%	0–0%
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.039–0.12	0.078	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	1.57–4.04	0–1%	0–0%	0–1%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Juice (pasteurised)	0.039–0.25	0.078	1.000	PRIMO-DE	child	P97.5	851.75	NR	NR	3	1.27–6.33	0–1%	0–0%	0–1%
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: raw, without peel	0.039–0.12	0.078	1.000	DE	Child, 2-4 yrs	12	358.60	179	3	2a	1.88–3.46	0–1%	0–0%	0–1%
FP 0226	Apple (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.015–0.28	0.59–0.99	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	0.08–56.04	0–10%	0–4%	0–10%
DF 0269	Grapes (all commodities)	highest utilisation: dried (currants, raisins, sultanas)	0.073–0.27	1.2	1.000	AU	Child, 2-6 yrs	918	83.50	1	NR	1	2.98–5.27	1–1%	0–1%	0–1%
FB 1235	Table grapes (all commodities)	highest utilisation: raw with skin	0.17–0.27	0.12–0.74	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	2.48–50.45	0–10%	0–5%	0–10%
FB 1236	Wine grapes (all commodities)	highest utilisation: red wine	0.063–0.2	0	1.000	AU	gen pop, > 2 yrs	1876	997.63	NR	NR	3	2.75–2.98	1–1%	0–1%	0–1%
DM 0305	Table olives	canned/preserved (& fermented)		1.2	1.000	BR	Gen pop, > 10 yrs	74	132.00	4	NR	1	2.454	0%	0%	0%
TN 0660	Almonds (all commodities)	highest utilisation: Total	0.05	0.05	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0–0.2	0–0%	0–0%	0–0%
TN 0662	Brazil nut (all commodities)	highest utilisation: Total	0	0.05	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0.04–0.04	0–0%	0–0%	0–0%

**BUPROFEZIN (173)**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

IESTI

Maximum % ARfD:

10%  
all

5%  
gen pop

10%  
child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	DCF	Country	Population group	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	
TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted	0.05	0.05	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0.14–0.29	0–0%	0–0%	0–0%
TN 0664	Chestnut (all commodities)	highest utilisation: Total	0	0.05	1.000	CN	Gen pop, > 1 yrs	807	475.25	<25	NR	1	0.12–0.45	0–0%	0–0%	0–0%
TN 0666	Hazelnut (all commodities)	highest utilisation: Total	0.05	0.05	1.000	PRIMO-IE	child	P97.5	65.42	<25	NR	1	0.03–0.16	0–0%	0–0%	0–0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total	0.05	0.05	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0.01–0.11	0–0%	0–0%	0–0%
TN 0672	Pecan (all commodities)	highest utilisation: Total	0.05	0.05	1.000	PRIMO-DE	child	P100	44.41	<25	NR	1	0.03–0.14	0–0%	0–0%	0–0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total	0.05	0.05	1.000	PRIMO-IE	child	P97.5	115.86	<25	NR	1	0–0.29	0–0%	0–0%	0–0%
TN 0678	Walnut (all commodities)	highest utilisation: Total	0.05	0.05	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0–0.17	0–0%	0–0%	0–0%
OR 0305	Olives for oil production	oil	3.9		1.000	PRIMO-NL	toddler	P97.5	9.40	NR	NR	3	3.594	1%	1%	1%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.000	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.000	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.000	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.000	0%	0%	0%
ML 0106	Milks	Total	0		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	0.000	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	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.000	0%	0%	0%

**BUPROFEZIN (173)**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

IESTI

Maximum % ARfD:

10%  
all

5%  
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	Variability factor	Case	IESTI µg/kg bw/day	Maximum % ARfD:		
														% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
PM 0110	Poultry meat: 90% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.30	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%

**ANILINE**

Acute RfD= 0.02 mg/kg bw (20 µg/kg bw)

**IESTI**

Maximum % ARfD:

0%

0%

0%

all

gen pop

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
FC 0303	Kumquats (all commodities)	highest utilisation: Total	0	0.00043	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0-0	0-0%	0-0%	0-0%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.00018-0.00048	0.00033-0.00043	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0-0.01	0-0%	0-0%	0-0%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.00018-0.00021	0.00033-0.00043	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0-0	0-0%	0-0%	0-0%
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.00018-0.00048	0.00033-0.00043	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0-0.02	0-0%	0-0%	0-0%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.00018-0.00048	0.00033-0.00043	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0-0.03	0-0%	0-0%	0-0%
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: Total	0.00018-0.00021	0.00033-0.00043	1.000	PRIMO-DE	child	P90	253.56	270	3	2b	0-0.02	0-0%	0-0%	0-0%

**CARBENDAZIM (072)**

Acute RfD= 0.5 mg/kg bw (500 µg/kg bw)

**IESTI**

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
HS 0771	Anise, seed (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	Gen pop	P95	7.64	<25	NR	3	0-0.05	0-0%	0-0%	0-0%
HS 3285	Black caraway (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	3	0.05-0.05	0-0%	0-0%	0-0%
HS 0774	Caraway, seed (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-CZ	child, 4-6 yrs	P97.5	0.43	<25	NR	3	0-0.01	0-0%	0-0%	0-0%
HS 0779	Coriander, seed (all commodities)	highest utilisation: Total	0.525		1.000	AU	Gen pop, > 2 yrs	129	7.76	<25	NR	3	0-0.06	0-0%	0-0%	0-0%
HS 0780	Cumin, seed (all commodities)	highest utilisation: Total	0.525		1.000	AU	Child, 2-16 yrs	584	3.99	<25	NR	3	0-0.06	0-0%	0-0%	0-0%
HS 0730	Dill, seed (all commodities)	highest utilisation: Total	0.525		1.000	US	Child, < 6 yrs	325	1.89	<25	NR	3	0-0.07	0-0%	0-0%	0-0%
HS 0731	Fennel, seed (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	child	P97.5	12.44	<25	NR	3	0-0.4	0-0%	0-0%	0-0%
HS 0782	Fenugreek, seed (all commodities)	highest utilisation: Total	0.525		1.000	AU	Gen pop, > 2 yrs	129	7.76	<25	NR	3	0-0.06	0-0%	0-0%	0-0%
HS 3296	Guarana	Total	0.525		1.000	AU	Child, 2-16 yrs	13	1.36	<25	NR	3	0.019	0%	-	0%
HS 0789	Nutmeg (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	3	0-0.05	0-0%	0-0%	0-0%

**CARBENDAZIM (072)**

Acute RfD= 0.1 mg/kg bw (100 µg/kg bw)

IESTI

Maximum % ARfD:

0%  
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
HS 0771	Anise, seed (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	Gen pop	P95	7.64	<25	NR	3	0-0	0-0%
HS 3285	Black caraway (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	3	0-0	0-0%
HS 0774	Caraway, seed (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-CZ	females, 15-17 yrs	P97.5	1.11	<25	NR	3	0-0	0-0%
HS 0779	Coriander, seed (all commodities)	highest utilisation: Total	0.525		1.000	US	women, 13-49 yrs	3790	0.08	<25	NR	3	0-0	0-0%
HS 0780	Cumin, seed (all commodities)	highest utilisation: composite foods; unspecified ind processed	0.525		1.000	PRIMO-NL	Gen pop	P97.5	2.40	NR	NR	3	0.02-0.02	0-0%
HS 0730	Dill, seed (all commodities)	highest utilisation: Total	0.525		1.000	US	women, 13-49 yrs	1198	1.90	<25	NR	3	0-0	0-0%
HS 0731	Fennel, seed (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	Gen pop	P100	7.64	<25	NR	3	0-0	0-0%
HS 0782	Fenugreek, seed (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	3	0-0	0-0%
HS 3296	Guarana	Total	0.525		1.000	-	-	-	-	-	-	-	-	-
HS 0789	Nutmeg (all commodities)	highest utilisation: Total	0.525		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	6.75	<25	NR	3	0-0	0-0%

**CYPERMETHRIN (118)**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)

IESTI

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
DT 9999	Ginseng root, dried	Total		0.1	1.000	PRIMO-EFSA	adults	E	36.00	<25	NR	1	0.060	0%	0%	0%

FLUAZIFOP-P-BUTYL (283)

Acute RfD= 0.4 mg/kg bw (400 µg/kg bw)

IESTI

Maximum %ARfD:

6%  
all

3%  
gen pop

6%  
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	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FB 0264	Blackberries (all commodities)	highest utilisation: Total	0.021	0.074	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0-0.79	0-0%	0-0%	0-0%
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilisation: Total		0.074	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	0.13-0.13	0-0%	0-0%	0-0%
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	0.021	0.074	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	0.01-0.68	0-0%	0-0%	0-0%
FB 0020	Blueberries (all commodities)	highest utilisation: Total	0.021	0.26	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0-2.98	0-1%	0-1%	0-1%
FB 0021	Currants, black, red, white (all commodities)	highest utilisation: Total	0.021	0.26	1.000	AU	Gen pop, > 2 yrs	322	797.60	<25	NR	1	0.01-3.1	0-1%	0-1%	0-1%
FB 0268	Gooseberry (all commodities)	highest utilisation: Total	0.021	0.26	1.000	PRIMO-DE	child	P100	94.96	<25	NR	1	0-1.53	0-0%	0-0%	0-0%
FB 0273	Rose hips (all commodities)	highest utilisation: Total	0.021	0.26	1.000	PRIMO-FI	women	P97.5	156.60	<25	NR	1	0.01-0.57	0-0%	0-0%	0-0%
FB 0267	Elderberries (all commodities)	highest utilisation: Total	0.021	0.26	1.000	CN	Gen pop, > 1 yrs	136	420.22	29	3	2a	0.01-2.34	0-1%	0-1%	0-0%
FB 0275	Strawberry (all commodities)	highest utilisation: Raw with skin	0.685	1.5	1.000	NL	toddler, 8-20 m	52	166.73	18	NR	1	0.39-24.52	0-6%	0-3%	0-6%



FLUENSULFONE (265)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

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	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0303	Kumquats (all commodities)	highest utilisation: Total		0.063	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.01–0.15	0–0%	0–0%	0–0%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.01	0.063	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0.01–1.05	0–0%	0–0%	0–0%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.01	0.063	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0–0.34	0–0%	0–0%	0–0%
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.01	0.063	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0–3.26	0–1%	0–0%	0–1%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.01	0.063	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0.01–3.69	0–1%	0–1%	0–1%
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: Total	0.01	0.063	1.000	PRIMO-DE	child	P90	253.56	270	3	2b	0–2.97	0–1%	0–1%	0–1%
FP 0226	Apple (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	0–0	0–0%	0–0%	0–0%
FP 2220	Azarole (Mediterranean medlar) (all commodities)	highest utilisation: juice (pasteurised)	0	0	1.000	PRIMO-DE	child	P97.5	89.63	NR	NR	3	0–0	0–0%	0–0%	0–0%
FP 0227	Crab-apple (all commodities)	highest utilisation: raw with peel		0	1.000	CN	Gen pop, > 1 yrs	204	488.33	<25	NR	1	0–0	0–0%	0–0%	0–0%
FP 0228	Loquat (Japanese medlar) (all commodities)	highest utilisation: raw without peel		0	1.000	JP	Gen pop, > 1 yrs	113	326.40	49	3	2a	0–0	0–0%	0–0%	0–0%
FP 0229	Medlar (all commodities)	highest utilisation: Total		0	1.000	PRIMO-ES	child	P97.5	116.99	60	3	2a	0–0	0–0%	0–0%	0–0%

FLUENSULFONE (265)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

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	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FP 0230	Pear (all commodities)	highest utilisation: Total	0	0	0.000	CA	Child, <6 yrs	175	498.28	255	3	2a	0-0	0-0%	0-0%	0-0%
FP 0231	Quince (all commodities)	highest utilisation: Total	0	0	1.000	PRIMO-ES	child	P97.5	169.60	301	3	2b	0-0	0-0%	0-0%	0-0%
FS 0013	Subgroup of Cherries (all commodities)	highest utilisation: Total	0	0	1.000	PRIMO-DK	child	P97.5	269.00	<25	NR	1	0-0	0-0%	0-0%	0-0%
FS 0014	Subgroup of Plums (all commodities)	highest utilisation: dried (prunes)	0	0	3.500	AU	Child, 2-6 yrs	13	447.59	10	NR	1	0-0	0-0%	0-0%	0-0%
FS 0302	Jujube, Chinese	Total		0	1.000	CN	Gen pop, > 1 yrs	1328	286.17	15	NR	1	0.000	0%	0%	-
FS 0240	Apricot (all commodities)	highest utilisation: Total	0	0	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	0-0	0-0%	0-0%	0-0%
FS 2237	Japanese apricot (ume)	Total		0	1.000	JP	Child, 1-6 yrs	25	25.50	<25	NR	1	0.000	0%	0%	0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	NL	toddler, 8-20 m	6	183.60	131	3	2a	0-0	0-0%	0-0%	0-0%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0	0	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0-0	0-0%	0-0%	0-0%
FB 0269	Grapes (all commodities)	highest utilisation: raw with skin	0	0	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	0-0	0-0%	0-0%	0-0%
GC 0648	Quinoa	Total	0.01		1.000	AU	Child, 2-16 yrs	32	78.18	<25	NR	3	0.021	0%	-	0%
GC 0650	Rye (all commodities)	highest utilisation: flakes	0.01		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.01-0.34	0-0%	0-0%	0-0%
GC 0653	Triticale	Total	0.01		1.000	DE	Gen pop, 14-80 yrs	27100	394.70	<25	NR	3	0.052	0%	0%	0%
GC 0654	Wheat (all commodities)	highest utilisation: flakes	0.01		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.01-0.34	0-0%	0-0%	0-0%
GC 0640	Barley (all commodities)	highest utilisation: beer	0.01		0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0-0.51	0-0%	0-0%	0-0%
GC 0641	Buckwheat (all commodities)	highest utilisation: flakes	0.01		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.01-0.34	0-0%	0-0%	0-0%
GC 0647	Oats (all commodities)	highest utilisation: flakes (rolled oats)	0.01		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.01-0.34	0-0%	0-0%	0-0%

FLUENSULFONE (265)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

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	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
GC 0649	Rice (all commodities)	highest utilisation: Total	0.01		1.000	CA	Child, <6 yrs	666	461.40	<25	NR	3	0-0.3	0-0%	0-0%	0-0%
GC 0655	Wild rice (all commodities)	highest utilisation: cooked/boiled	0.01	0.01	0.400	CN	Child, 1-6 yrs	129	552.59	<25	NR	3	0.04-0.14	0-0%	0-0%	0-0%
GC 0644	Job's tears (all commodities)	highest utilisation: cooked/boiled	0.01	0.01	0.300	TH	Child, 3-6 yrs	134	85.50	<25	NR	3	0.02-0.02	0-0%	0-0%	0-0%
GC 0646	Millet (common millet, proso millet) (all commodities)	highest utilisation: Total	0.01		1.000	CN	Child, 1-6 yrs	826	219.53	<25	NR	3	0.01-0.14	0-0%	0-0%	0-0%
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilisation: cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.02-0.1	0-0%	0-0%	0-0%
GC 0645	Maize (corn) (all commodities)	highest utilisation: beer	0.01		0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0.01-0.51	0-0%	0-0%	0-0%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilisation: Total	0.01		1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0.03-0.04	0-0%	0-0%	0-0%
GC 3081	Baby corn (all commodities)	highest utilisation: canned/preserved (imm cobs)		0.01	1.000	NL	Child, 2-6 yrs	E	75.00	12	NR	1	0.04-0.04	0-0%	0-0%	0-0%
GC 0447	Sweet corn (corn-on-the-cob) (kernels plus cob with husks removed) (all commodities)	highest utilisation: cooked/boiled (corn-on-the-cob)	0.01	0.01	1.000	TH	Child, 3-6 yrs	1383	196.99	191	3	2a	0.01-0.34	0-0%	0-0%	0-0%
GC 1275	Sweet corn (whole kernel without cob or husk) (all commodities)	highest utilisation: canned/preserved (kernels)	0.01	0.01	1.000	CA	Child, <6 yrs	289	153.76	NR	NR	3	0.01-0.1	0-0%	0-0%	0-0%
GS 0659	Sugar cane (all commodities)	highest utilisation: thick juice	0	0	1.000	CN	Gen pop, > 1 yrs	436	1817.52	NR	NR	3	0-0	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		0.01	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%

FLUENSULFONE (265)

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

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	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
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		0.01	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		0.01	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%
SB 0716	Coffee bean (all commodities)	highest utilisation: extract (beverage)	0		0.180	CA	women, 15-49 yrs	2666	2088.65	NR	NR	3	0–0	0–0%	0–0%	0–0%
HS 3381	Lemon, peel	Oil (refined)	0.34		1.000	NL	Gen pop, > 1 yrs	0	NC	NR	NR	3	NC	NC	NC	NC
HS 3382	Orange, peel	Oil (refined)	0.34		1.000	NL	Gen pop, > 1 yrs	0	NC	NR	NR	3	NC	NC	NC	NC

**FLUXAPYROXAD (256)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

**IESTI**

Maximum % ARfD:

10%  
all

6%  
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	Variability factor	Case	IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FC 0303	Kumquats (all commodities)	highest utilisation: Total		0.87	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.16–2.08	0–1%	0–1%	1–1%
FC 0204	Lemon (all commodities)	highest utilisation: Total	0.015–0.72	0.87	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0.03–14.45	0–5%	0–2%	0–5%
FC 0205	Lime (all commodities)	highest utilisation: Total	0.015–0.38	0.46	1.000	AU	Gen pop, > 2 yrs	579	259.21	49	3	2a	0.03–2.45	0–1%	0–1%	0–0%
FC 0003	Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.015–0.38	0.46	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0.08–23.82	0–8%	0–4%	0–8%
FC 0004	Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.016–0.395	0.59	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0.13–34.54	0–10%	0–6%	0–10%
FC 0005	Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: Total	0.006–0.15	0.27	1.000	PRIMO-DE	child	P90	253.56	270	3	2b	0.03–12.72	0–4%	0–2%	0–4%

MANDESTROBIN (307)

Acute RfD= 3 mg/kg bw (3000 µg/kg bw)

IESTI

Maximum % ARfD:

4%  
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
FB 0269	Grapes (all commodities)	highest utilisation: Total	1.4	3.7-7.4	1.000	CA	women, 15-49 yrs	417	708.16	637	3	2a	3.5-114.29	0-4%
FB 1235	Table grapes (all commodities)	highest utilisation: raw with skin	1.4	3.7-7.4	1.000	DE	Women, 14-50 yrs	430	381.22	637	3	2b	3.5-62.72	0-2%
FB 1236	Wine grapes (all commodities)	highest utilisation: Total	1.4		1.000	PRIMO-UK	adult	P97.5	1802.62	NR	NR	3	9.46-33.21	0-1%
FB 0275	Strawberry (all commodities)	highest utilisation: Total	0.87	2.2	1.000	PRIMO-DE	women, 14-50 yrs	P97.5	629.36	<25	NR	1	0.2-20.52	0-1%
SO 0495	Rape seed (Canola) (all commodities)	highest utilisation: Total	0.0012-0.02		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	35.56	<25	NR	3	0-0.01	0-0%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	DE	Women, 14-50 yrs	25	521.10	NR	NR	1	NA	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.000	DE	Women, 14-50 yrs	25	104.22	NR	NR	1	0.000	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	DE	Women, 14-50 yrs	25	416.88	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	1.000	PRIMO-DE	women, 14-50 yrs	P100	188.92	NR	NR	1	0.000	0%
ML 0106	Milks	Total	0		1.000	DE	Women, 14-50 yrs	6554	1276.50	NR	NR	3	0.000	0%
FM 0812	Cattle milk fat	Total	0		1.000	BR	Gen pop, > 10 yrs	441	150.00	NR	NR	3	0.000	0%
PM 0110	Poultry meat	Total	NA	NA	1.000	CA	women, 15-49 yrs	2127	384.47	NR	NR	1	NA	0%
PM 0110	Poultry meat: 10% as fat	Total		0	1.000	CA	women, 15-49 yrs	2127	38.45	NR	NR	1	0.000	0%
PM 0110	Poultry meat: 90% as muscle	Total		0	1.000	CA	women, 15-49 yrs	2127	346.02	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%

**MANDESTROBIN (307)**

Acute RfD= 3 mg/kg bw (3000 µg/kg bw)

IESTI

Maximum % ARfD:

4%  
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
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%
PE 0112	Eggs	Total		0	1.000	CA	women, 15-49 yrs	3395	136.90	NR	NR	1	0.000	0%

**METCONAZOLE (313)**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)

IESTI

Maximum % ARfD:

20%

10%

20%

all

gen pop

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	0.07	0.16	1.000	PRIMO-DK	child	P97.5	269.00	<25	NR	1	0.03–1.96	0–5%	0–4%	0–5%
FS 0014	Subgroup of Plums (all commodities)	highest utilisation: dried (prunes)	0.04	0.05–0.115	1.000	AU	Child, 2–6 yrs	13	447.59	10	NR	1	0.02–2.71	0–7%	0–2%	0–7%
FS 0302	Jujube, Chinese	Total		0.05	1.000	CN	Gen pop, > 1 yrs	1328	286.17	15	NR	1	0.269	1%	1%	-
FS 0240	Apricot (all commodities)	highest utilisation: Total	0.045	0.09	1.000	PRIMO-DE	child	P95	264.86	50	3	2a	0.02–2.03	0–5%	0–4%	0–5%
FS 2237	Japanese apricot (ume)	Total		0.09	1.000	JP	Child, 1–6 yrs	25	25.50	<25	NR	1	0.127	0%	0%	0%
FS 0245	Nectarine (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.045	0.09	1.000	NL	toddler, 8–20 m	6	183.60	131	3	2a	0.02–3.93	0–10%	0–3%	0–10%
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	0.045	0.09	1.000	JP	Child, 1–6 yrs	76	306.00	255	3	2a	0.02–4.74	0–10%	0–4%	0–10%
FB 0020	Blueberries (all commodities)	highest utilisation: Total	0.14	0.33	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0.02–3.78	0–9%	0–8%	0–9%
FI 0327	Banana (incl Dwarf banana & Plantain) (all commodities)	highest utilisation: raw without peel	0.1	0.1	1.000	CN	Child, 1–6 yrs	286	455.81	767	3	2b	0.05–8.47	0–20%	0–10%	0–20%
VA 0381	Garlic (all commodities)	highest utilisation: raw without skin	0.05	0.05	1.000	CN	Child, 1–6 yrs	290	174.44	62	3	2a	0–0.93	0–2%	0–1%	0–2%
VA 0385	Onion, bulb (all commodities)	highest utilisation: raw without skin	0.05	0.05	1.000	JP	Child, 1–6 yrs	748	102.00	244	3	2b	0.02–0.93	0–2%	0–1%	0–2%
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilisation: Total	0	0	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0–0	0–0%	0–0%	0–0%
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: Total	0.04		1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.08–0.73	0–2%	0–1%	0–2%
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilisation: cooked/boiled	0.04		0.400	CN	Gen pop, > 1 yrs	737	1190.24	<25	NR	3	0.03–0.36	0–1%	0–1%	0–0%



**METCONAZOLE (313)**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)

IESTI

Maximum % ARfD:

20%

10%

20%

all gen pop child

Codex Code	Commodity	Processing	STMR or 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
			STMR-P mg/kg	HR or HR-P mg/kg	DCF											
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilisation: cooked/boiled	0.04		0.400	CN	Gen pop, > 1 yrs	1219	972.42	<25	NR	3	0.29–0.29	1–1%	1–1%	0–0%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.005–0.01		1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0–0.15	0–0%	0–0%	0–0%
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilisation: cooked/boiled	0.041		0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.03–0.52	0–1%	0–1%	0–1%
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilisation: canned/preserved	0.041		0.400	PRIMO-NL	child	P100	328.80	<25	NR	3	0.03–0.29	0–1%	0–0%	0–1%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.041		1.000	PRIMO-UK	Child, 11-14 yrs	P97.5	321.50	<25	NR	3	0.08–0.27	0–1%	0–1%	0–1%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.041		1.000	AU	Gen pop, > 2 yrs	129	95.83	<25	NR	3	0.059	0%	0%	0%
VR 0596	Sugar beet (all commodities)	highest utilisation: composite foods; unspecified ind processed	0.012–0.02		1.000	NL	Child, 2-6 yrs	2554	168.93	NR	NR	3	0.05–0.18	0–0%	0–0%	0–0%
VR 0573	Arrowroot (all commodities)	highest utilisation: starch	0	0	1.000	PRIMO-NL	child	E	12.40	NR	NR	3	0–0	0–0%	0–0%	0–0%
VR 0463	Cassava (Manioc) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0	1.000	PRIMO-NL	Gen pop	E	250.00	356	3	2b	0–0	0–0%	0–0%	0–0%
VR 0585	Jerusalem artichoke (i.e. Topinambur) (all commodities)	highest utilisation: cooked/boiled (without peel)		0	1.000	PRIMO-NL	child	E	133.30	56	3	2a	0–0	0–0%	0–0%	0–0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0	0	1.000	PRIMO-UK	infant	P97.5	191.10	216	3	2b	0–0	0–0%	0–0%	0–0%
VR 0508	Sweet potato (all commodities)	highest utilisation: Total	0	0	1.000	CA	Child, <6 yrs	91	358.61	546	3	2b	0–0	0–0%	0–0%	0–0%
VR 0504	Tannia (Tanier, Yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)	0	0	1.000	NL	Gen pop, > 1 yrs	E	249.97	170	3	2a	0–0	0–0%	0–0%	0–0%
VR 0505	Taro (Dasheen, Eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)		0	1.000	CN	Child, 1-6 yrs	199	384.18	668	3	2b	0–0	0–0%	0–0%	0–0%
VR 0600	Yams (all commodities)	highest utilisation: Total		0	1.000	PRIMO-UK	adult	P97.5	693.70	365	3	2a	0–0	0–0%	0–0%	0–0%

**METCONAZOLE (313)**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)

IESTI

Maximum % ARfD:

20%

10%

20%

all

gen pop

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
GC 0645	Maize (corn) (all commodities)	highest utilisation: beer	0.01		0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0.01–0.51	0–1%	0–1%	0–1%
GC 0447	Sweet corn (corn-on-the-cob) (kernels plus cob with husks removed) (all commodities)	highest utilisation: cooked/boiled (corn-on-the-cob)	0.01	0.01	1.000	TH	Child, 3-6 yrs	1383	196.99	191	3	2a	0.01–0.34	0–1%	0–0%	0–1%
GS 0659	Sugar cane (all commodities)	highest utilisation: thick juice	0.002–0.027		1.000	CN	Gen pop, > 1 yrs	436	1817.52	NR	NR	3	0.02–0.7	0–2%	0–2%	0–0%
TN 0660	Almonds (all commodities)	highest utilisation: Total	0	0	1.000	CA	Child, <6 yrs	62	63.32	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0662	Brazil nut (all commodities)	highest utilisation: Total		0	1.000	PRIMO-UK	child, 4-6 yrs	P97.5	17.80	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0295	Cashew nut (all commodities)	highest utilisation: raw incl roasted		0	1.000	TH	child, 3-6 yrs	374	98.84	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0664	Chestnut (all commodities)	highest utilisation: Total		0	1.000	CN	Gen pop, > 1 yrs	807	475.25	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0665	Coconut (all commodities)	highest utilisation: raw (i.e. nutmeat)		0	1.000	TH	child, 3-6 yrs	826	423.40	383	3	2a	0–0	0–0%	0–0%	0–0%
TN 0666	Hazelnut (all commodities)	highest utilisation: Total		0	1.000	PRIMO-IE	child	P97.5	65.42	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0669	Macadamia nut (all commodities)	highest utilisation: Total		0	1.000	PRIMO-DE	women, 14-50 yrs	P100	141.69	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0672	Pecan (all commodities)	highest utilisation: Total		0	1.000	PRIMO-DE	child	P100	44.41	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0673	Pine nut (all commodities)	highest utilisation: Total		0	1.000	BR	Gen pop, > 10 yrs	47	200.00	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0675	Pistachio nut (all commodities)	highest utilisation: Total		0	1.000	PRIMO-IE	child	P97.5	115.86	<25	NR	1	0–0	0–0%	0–0%	0–0%
TN 0678	Walnut (all commodities)	highest utilisation: Total		0	1.000	PRIMO-BE	toddler	P100	60.00	<25	NR	1	0–0	0–0%	0–0%	0–0%
SO 0495	Rape seed (Canola) (all commodities)	highest utilisation: Oil (refined)	0.02–0.032		1.000	CA	Child, <6 yrs	1127	26.46	NR	NR	3	0.02–0.05	0–0%	0–0%	0–0%
SO 0699	Safflower seed (all commodities)	highest utilisation: Total	0.068		1.000	PRIMO-DE	child	P95	49.74	<25	NR	3	0–0.21	0–1%	0–0%	0–1%
SO 0702	Sunflower seed (all commodities)	highest utilisation: Total	0.068		1.000	CA	women, 15-49 yrs	121	296.25	<25	NR	3	0.04–0.32	0–1%	0–1%	0–1%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.004–0.0345		1.000	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0–0	0–0%	0–0%	0–0%

**METCONAZOLE (313)**

Acute RfD= 0.04 mg/kg bw (40 µg/kg bw)

IESTI

Maximum % ARfD:

20% 10% 20%  
all gen pop child

Codex Code	Commodity	Processing	STMR or 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
			STMR-P mg/kg	HR or HR-P mg/kg	DCF											
SO 0697	Peanut, shelled (groundnut) (all commodities)	highest utilisation: raw incl roasted	0.006-0.04		1.000	CN	Child, 1-6 yrs	290	163.07	<25	NR	3	0.01-0.4	0-1%	0-1%	0-1%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.000	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.000	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.000	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.037	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.348	1%	1%	1%
ML 0106	Milks	Total	0		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	0.000	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	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.000	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.30	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		0.02	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.130	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%

## PENTHIOPYRAD (253)

Acute RfD= 1 mg/kg bw (1000 µg/kg bw)

## IESTI

Maximum %ARfD:

5%  
all5%  
gen pop5%  
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 0264	Blackberries (all commodities)	highest utilisation: Total	3.7	4.8	1.000	PRIMO-UK	toddler	P97.5	155.40	<25	NR	1	0.64–51.44	0–5%	0–4%	0–5%
FB 0266	Dewberries (incl Boysenberry, Loganberry) (all commodities)	highest utilisation: Total		4.8	1.000	PRIMO-UK	toddler	P97.5	25.50	<25	NR	1	8.44–8.44	1–1%	1–1%	1–1%
FB 0272	Raspberries, red, black (all commodities)	highest utilisation: Total	3.7	4.8	1.000	PRIMO-IE	child	P97.5	184.76	<25	NR	1	1.58–44.34	0–4%	0–3%	0–4%
FB 0020	Blueberries (all commodities)	highest utilisation: Total	1.7	4	1.000	CA	Child, <6 yrs	189	176.21	<25	NR	1	0.25–45.78	0–5%	0–4%	0–5%
FB 0021	Currants, black, red, white (all commodities)	highest utilisation: juice (pasteurised)	1.7	4	1.000	PRIMO-NL	child	E	525.80	NR	NR	3	1.1–48.58	0–5%	0–5%	0–5%
FB 0268	Gooseberry (all commodities)	highest utilisation: Total	1.7	4	1.000	PRIMO-DE	child	P100	94.96	<25	NR	1	0.32–23.52	0–2%	0–2%	0–2%
FB 0273	Rose hips (all commodities)	highest utilisation: Total	1.7	4	1.000	PRIMO-FI	women	P97.5	156.60	<25	NR	1	1.08–8.8	0–1%	0–1%	0–1%
FB 0267	Elderberries (all commodities)	highest utilisation: Total	1.7	4	1.000	CN	Gen pop, > 1 yrs	136	420.22	29	3	2a	1.16–35.94	0–4%	0–4%	0–3%

PICOXYSTROBIN (243)

Acute RfD= 0.09 mg/kg bw (90 µg/kg bw)

IESTI

Maximum % ARfD:

2% all  
1% gen pop  
2% child

Codex Code	Commodity	Processing	STMR or STMR-P mg/kg	HR or HR-P mg/kg	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
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilisation: cooked/boiled	0.01		0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.02-0.1	0-0%	0-0%	0-0%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.205		1.000	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0.04-0.04	0-0%	0-0%	0-0%
SB 0716	Coffee bean (all commodities)	highest utilisation: extract (beverage)	0.01		0.180	CA	women, 15-49 yrs	2666	2088.65	NR	NR	3	0-0.05	0-0%	0-0%	0-0%
DT 1114	Tea, green, black (black, fermented and dried)	Total	1.2		1.000	PRIMO-IE	child	P97.5	30.60	<25	NR	3	1.836	2%	1%	2%
MM 0095	Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.015	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.049	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total	0.008	0.015	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.030	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total	0.006	0.01	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	0.094	0%	0%	0%
ML 0106	Milks	Total	0	0	1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	0.000	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	0.01	0.01	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.022	0%	0%	0%

**PROPICONAZOLE (160)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

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			
													IESTI µg/kg bw/day	% acute RfD rounded	% acute RfD rounded	% acute RfD rounded
FS 0247	Peach (all commodities)	highest utilisation: raw with peel (incl consumption without peel)	1.7	2.5	1.000	JP	Child, 1-6 yrs	76	306.00	255	3	2a	0.7–131.61	0–40%	0–20%	0–40%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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	0.017–0.29	0.85–2.1	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	0.58–57.95	0–20%	0–9%	0–20%
FB 1235	Table grapes (all commodities)	highest utilisation: raw with skin	0.29	0.85–2.1	1.000	CN	Child, 1-6 yrs	232	366.72	637	3	2b	1.85–57.95	1–20%	0–9%	1–20%
FB 1236	Wine grapes (all commodities)	highest utilisation: Total	0.017–0.29		1.000	PRIMO-UK	adult	P97.5	1802.62	NR	NR	3	0.58–6.88	0–2%	0–2%	0–0%
VB 0400	Broccoli (all commodities)	highest utilisation: cooked/boiled	0.02	0.09	1.000	PRIMO-NL	toddler	P97.5	160.70	286	3	2b	0.04–4.25	0–1%	0–0%	0–1%
VB 0404	Cauliflower (all commodities)	highest utilisation: cooked/boiled	0.02	0.09	1.000	PRIMO-NL	toddler	P97.5	142.00	749	3	2b	0–3.76	0–1%	0–1%	0–1%
VB 0402	Brussels sprouts (all commodities)	highest utilisation: cooked/boiled	0.02	0.09	1.000	PRIMO-NL	toddler	P90	103.80	<25	NR	1	0–0.92	0–0%	0–0%	0–0%
VB 0041	Cabbages, head (all commodities)	highest utilisation: raw	0.02	0.09	1.000	CN	Child, 1-6 yrs	287	255.54	1403	3	2b	0.01–4.28	0–1%	0–1%	0–1%
VB 0467	Chinese cabbage (type Pe-tsai) (all commodities)	highest utilisation: Total	0.02	0.09	1.000	CN	Child, 1-6 yrs	2788	336.16	2162	3	2b	0.01–5.63	0–2%	0–1%	0–2%
VB 0405	Kohlrabi (all commodities)	highest utilisation: Total		0.09	1.000	PRIMO-DE	child	P95	167.96	265	3	2b	0.28–2.81	0–1%	0–0%	1–1%
VC 0421	Bitter melon (Balsam pear, Bitter cucumber, Bitter gourd) (all commodities)	highest utilisation: raw without peel		0.27	1.000	CN	Gen pop, > 1 yrs	1387	400.21	608	3	2b	1.36–6.09	0–2%	0–2%	1–1%
VC 0422	Bottle gourd (Cucuzzi) (all commodities)	highest utilisation: raw with skin		0.27	1.000	CN	Gen pop, > 1 yrs	519	453.00	325	3	2a	5.6–5.6	2–2%	2–2%	0–0%
VC 0423	Chayote (Christophine) (all commodities)	highest utilisation: raw with skin		0.27	1.000	CN	Child, 1-6 yrs	124	284.75	197	3	2a	9.23–11.37	3–4%	2–2%	3–4%
VC 0424	Cucumber (all commodities)	highest utilisation: raw with skin	0.12	0.27	1.000	CN	Child, 1-6 yrs	340	212.11	458	3	2b	0.05–10.65	0–4%	0–2%	0–4%
VC 0425	Gherkin (all commodities)	highest utilisation: raw with skin	0.12	0.27	1.000	JP	Child, 1-6 yrs	484	91.80	55	3	2a	0.09–3.23	0–1%	0–1%	0–1%
VC 0427	Loofah, Angled (Sinkwa, Sinkwa towel gourd) (all commodities)	highest utilisation: raw without peel		0.27	1.000	TH	Child, 3-6 yrs	759	129.62	133	3	2b	6.14–6.14	2–2%	1–1%	2–2%
VC 0428	Loofah, Smooth (all commodities)	highest utilisation: raw without peel		0.27	1.000	CN	Child, 1-6 yrs	196	296.64	133	3	2a	9.41–9.41	3–3%	1–1%	3–3%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%  
all

110%  
gen pop

350%  
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
VC 0430	Snake gourd (all commodities)	highest utilisation: raw without peel		0.27	1.000	TH	Child, 3-6 yrs	759	129.62	133	3	2b	6.14-6.14	2-2%	1-1%	2-2%
VC 0431	Squash, Summer (Courgette, Marrow, Zucchini, Zucchini) (all commodities)	highest utilisation: Total	0.12	0.27	1.000	US	Child, < 6 yrs	252	149.52	186	3	2b	0.08-8.35	0-3%	0-1%	0-3%
VC 0046	Melons, except watermelon (Cantaloupe) (all commodities)	highest utilisation: Total	0.12	0.27	1.000	PRIMO-BE	toddler	P100	540.00	540	3	2b	0.01-24.57	0-8%	0-4%	0-8%
VC 0429	Pumpkins (all commodities)	highest utilisation: raw without peel	0.12	0.27	1.000	CN	Child, 1-6 yrs	561	322.71	1852	3	2b	0.2-16.2	0-5%	0-4%	0-5%
VC 0432	Watermelon (all commodities)	highest utilisation: Total	0.12	0.27	1.000	CA	Child, <6 yrs	171	953.64	4302	3	2b	23.3-50.07	8-20%	8-10%	8-20%
VO 2704	Goji berry (all commodities)	highest utilisation: Dried		0.42	3.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0.4-1.88	0-1%	0-0%	0-1%
VO 0448	Tomato (all commodities)	highest utilisation: raw with peel	0.005-0.11	0.019-4.4	1.000	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	0.1-15.95	0-5%	0-2%	0-5%
VO 0442	Okra (Lady's finger, Gombo) (all commodities)	highest utilisation: Total		0.02	1.000	US	Child, < 6 yrs	26	82.30	17	NR	1	0.11-0.11	0-0%	0-0%	0-0%
VO 0444	Peppers, chili (all commodities)	highest utilisation: raw with skin	0.11	0.42-4.2	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43	3	2a	0-3.02	0-1%	0-1%	0-0%
VO 0445	Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all commodities)	highest utilisation: raw with skin	0.11	0.42	1.000	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	0.02-13.26	0-4%	0-2%	0-4%
VO 0440	Egg plant (Aubergine) (all commodities)	highest utilisation: raw with skin	0.11	0.42	1.000	CN	Child, 1-6 yrs	969	253.44	444	3	2b	0.12-19.79	0-7%	0-4%	0-7%
VO 0443	Pepino (Melon pear, Tree melon)	Total		0.42	1.000	AU	Gen pop, > 2 yrs	3	73.89	123	3	2b	1.390	0%	0%	-
VO 2713	Scarlet eggplant (gilo, Ethiopian eggplant) (all commodities)	highest utilisation: cooked/boiled (with skin)		0.42	1.000	BR	Gen pop, > 10 yrs	280	360.50	28	3	2a	2.72-2.72	1-1%	1-1%	0-0%
VL 0460	Amaranth leaves (Bledo) (all commodities)	highest utilisation: raw		17	1.000	CN	Gen pop, > 1 yrs	714	581.72	86	3	2a	79.9-240.57	30-80%	30-80%	20-20%



**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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
VL 0464	Chard (Beet leaves, Silver beet) (all commodities)	highest utilisation: cooked/boiled		17	1.000	PRIMO-NL	child	P100	81.80	105	3	2b	60.28–226.73	20–80%	20–70%	50–80%
VL 0465	Chervil (all commodities)	highest utilisation: Total	12.5	17	1.000	PRIMO-BE	toddler	P100	23.00	<25	NR	1	1.38–21.97	0–7%	0–1%	0–7%
VL 0469	Chicory leaves (green and red cultivars) (Sugar loaf) (all commodities)	highest utilisation: raw		17	1.000	DE	Child, 2-4 yrs	16	82.40	280	3	2b	35.42–260.21	10–90%	8–30%	10–90%
VL 2752	Chrysanthemum, edible leaved (all commodities)	highest utilisation: raw		17	1.000	CN	Gen pop, > 1 yrs	993	332.67	<25	NR	1	59.24–106.25	20–40%	10–40%	20–20%
VL 0470	Corn salad (Lambs lettuce) (all commodities)	highest utilisation: Total		17	1.000	PRIMO-BE	toddler	P100	50.00	<25	NR	1	14.38–47.75	5–20%	5–10%	0–20%
VL 0510	Cos lettuce	Total		17	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	388.321	130%	60%	130%
VL 0510	Cos lettuce	raw		17	1.000	NL	Child, 2-6 yrs	91	140.10	290	3	2b	388.314	130%	40%	130%
VL 0510	Cos lettuce (all other commodities)	highest utilisation: cooked/boiled	12.5	17	1.000	NL	Gen pop, > 1 yrs	2	220.89	194	3	2a	7.35–157.31	2–50%	2–50%	1%
VL 0474	Dandelion (Laiteron, Pissenlit) (all commodities)	highest utilisation: raw		17	1.000	NL	gen pop, > 1 yrs	E	49.88	35	3	2a	11.93–30.97	4–10%	10–10%	0–0%
VL 0476	Endive (i.e. Scarole)	Total		17	1.000	PRIMO-BE	toddler	P100	143.00	440	3	2b	409.719	140%	80%	140%
VL 0476	Endive (i.e. Escarole)	raw		17	1.000	NL	Child, 2-6 yrs	35	133.34	375	3	2b	369.597	120%	80%	120%
VL 0476	Endive (i.e. Escarole)	cooked/boiled		17	1.000	PRIMO-NL	toddler	P95	135.20	251	3	2b	676.000	230%	70%	230%
VL 0476	Endive (i.e. Scarole) (all other commodities)	highest utilisation: frozen	12.5		1.000	NL	Child, 2-6 yrs	E	150.00	NR	NR	3	49.8–101.9	20–30%	2–10%	20–30%
VL 0482	Lettuce, head	Total		17	1.000	PRIMO-NL	child	P97.5	140.10	290	3	2b	388.321	130%	50%	130%
VL 0482	Lettuce, head	raw		17	1.000	NL	Child, 2-6 yrs	91	140.10	339	3	2b	388.314	130%	40%	130%
VL 0482	Lettuce, head (all other commodities)	highest utilisation: cooked/boiled	12.5	17	1.000	NL	Gen pop, > 1 yrs	2	220.89	227	3	2b	7.35–171.21	2–60%	2–60%	1%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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
VL 0483	Lettuce, leaf	Total		17	1.000	CN	Child, 1-6 yrs	243	387.25	305	3	2a	1051.437	350%	110%	350%
VL 0483	Lettuce, leaf	raw		17	1.000	NL	Child, 2-6 yrs	91	140.10	118	3	2a	347.038	120%	30%	120%
VL 0483	Lettuce, leaf (all other commodities)	highest utilisation: cooked/boiled	12.5	17	1.000	NL	Gen pop, > 1 yrs	2	220.89	79	3	2a	7.35-97.89	2-30%	2-30%	1%
VL 0492	Purslane (all commodities)	highest utilisation: cooked/boiled		17	1.000	PRIMO-NL	Gen pop	P100	271.20	<25	NR	1	18.55-70.07	6-20%	6-20%	0-0%
VL 0501	Sowthistle (all commodities)	highest utilisation: raw		17	1.000	CN	Gen pop, > 1 yrs	1187	592.49	35	3	2a	211.59-211.59	70-70%	70-70%	0-0%
VL 0502	Spinach	Total		17	1.000	PRIMO-BE	toddler	P97.5	402.30	<25	NR	1	384.219	130%	80%	130%
VL 0502	Spinach (all other commodities)	highest utilisation: raw	12.5	17	1.000	JP	Child, 1-6 yrs	229	86.70	90	3	2b	1.25-263.2	0-90%	0-40%	0-90%
VL 0502	Spinach	frozen	12.5		1.000	PRIMO-NL	toddler	P97.5	334.20	NR	NR	3	409.559	140%	30%	140%
VL 0401	Broccoli, Chinese (i.e. kailan) (all commodities)	highest utilisation: raw		0.09	1.000	CN	Child, 1-6 yrs	334	222.48	311	3	2b	0.19-3.72	0-1%	0-1%	0-1%
VL 0466	Chinese cabbage (type Pak-choi) (i.e. celery mustard) (all commodities)	highest utilisation: raw	0.02	0.09	1.000	CN	Child, 1-6 yrs	1966	327.07	1548	3	2b	0.01-5.47	0-2%	0-1%	0-2%
VL 0472	Cress, Garden (all commodities)	highest utilisation: raw		0.09	1.000	CN	Gen pop, > 1 yrs	1443	352.50	<25	NR	1	0.03-0.6	0-0%	0-0%	0-0%
VL 0468	Flowering white cabbage (Choisum) (all commodities)	highest utilisation: raw	0.02	0.09	1.000	CN	Gen pop, > 1 yrs	1639	556.56	300	3	2a	0.07-1.96	0-1%	0-1%	0-0%
VL 0480	Kale (Borecole, Collards) (all commodities)	highest utilisation: Total	0.02	0.09	1.000	PRIMO-DE	child	P100	142.12	672	3	2b	0.04-2.38	0-1%	0-0%	0-1%
VL 0481	Komatsuna	Total		0.09	1.000	JP	Child, 1-6 yrs	73	71.40	<25	NR	1	0.383	0%	0%	0%
VL 2781	Mizuna	Total		0.09	1.000	JP	Gen pop, > 1 yrs	1787	137.70	<25	NR	1	0.221	0%	0%	0%
VL 0485	Mustard greens (Indian mustard, Amsoi, mustard cabbage, red)	highest utilisation: raw	0.02	0.09	1.000	CN	Child, 1-6 yrs	635	299.31	245	3	2a	0.09-4.4	0-1%	0-1%	1-1%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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
	mustards) (all commodities)															
VL 0494	Radish leaves	Total		0.09	1.000	BR	Gen pop, > 10 yrs	-	258.24	<25	NR	1	0.360	0%	0%	-
VL 0495	Rape greens (all commodities)	highest utilisation: cooked/boiled		0.09	1.000	JP	Gen pop, > 1 yrs	533	147.90	34	3	2a	0.35–0.35	0–0%	0–0%	0–0%
VL 0496	Rucola (Arrugula, Rocket salad, Roquette, Roman rocket) (all commodities)	highest utilisation: Total		0.09	1.000	PRIMO- DE	child	P100	43.44	<25	NR	1	0.11–0.24	0–0%	0–0%	0–0%
VL 0506	Turnip greens (Namenia, Tendergreen) (all commodities)	highest utilisation: Total		0.09	1.000	DE	Child, 2-4 yrs	1	67.00	35	3	2a	0.15–0.76	0–0%	0–0%	0–0%
VL 0505	Taro leaves (all commodities)	highest utilisation: raw		0.05	1.000	NL	Gen pop, > 1 yrs	E	77.78	86	3	2b	0.05–0.18	0–0%	0–0%	0–0%
VP 0061	Beans with pods (Phaseolus spp): (immature pods + succulent seeds) (all commodities)	highest utilisation: Total	0.02	0.02	1.000	CA	Child, <6 yrs	261	203.31	<25	NR	1	0.03–0.27	0–0%	0–0%	0–0%
VP 0522	Broad bean with pods (immature pods + succulent seeds) (Vicia spp) (all commodities)	highest utilisation: Total		0.02	1.000	US	Child, < 6 yrs	221	93.96	9	NR	1	0.06–0.13	0–0%	0–0%	0–0%
VP 0542	Sword bean with pods (immature pods + succulent seeds) (Canavalia spp) (all commodities)	highest utilisation: cooked/boiled		0.02	1.000	CN	Gen pop, > 1 yrs	891	316.83	<25	NR	1	0.12–0.12	0–0%	0–0%	0–0%
VP 0063	Peas with pods (Pisum spp) immature pods + succulent seeds) (all commodities)	highest utilisation: cooked/boiled	0.02	0.02	1.000	CN	Child, 1-6 yrs	1056	290.21	6	NR	1	0.1–0.36	0–0%	0–0%	0–0%
VP 0553	Lentil with pods (immature pods + succulent seeds) (Lens	highest utilisation: cooked/boiled		0.02	1.000	CN	Child, 1-6 yrs	371	345.76	<25	NR	1	0.12–0.43	0–0%	0–0%	0–0%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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
	spp) (all commodities)															
VP 0062	Beans without pods: (Phaseolus spp.) (succulent seeds) (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-IE	child	P97.5	157.79	<25	NR	1	0-0.16	0-0%	0-0%	0-0%
VP 0523	Broad bean without pods (succulent seeds) (Vicia spp) (all commodities)	highest utilisation: frozen	0.02	0.02	1.000	NL	Child, 2-6 yrs	E	100.00	6	NR	1	0-0.11	0-0%	0-0%	0-0%
VP 0541	Soya bean without pods (succulent seeds) (Glycine max) (all commodities)	highest utilisation: cooked/boiled		0.02	1.000	CN	Child, 1-6 yrs	195	260.25	<25	NR	1	0.03-0.32	0-0%	0-0%	0-0%
VP 0064	Peas without pods (Pisum spp) (succulent seeds) (all commodities)	highest utilisation: Total	0.02	0.02	1.000	PRIMO-UK	infant	P97.5	71.30	<25	NR	1	0.02-0.16	0-0%	0-0%	0-0%
VP 0520	Bambara groundnut without pods (succulent seeds) (Vigna subterranea)	Total		0.02	1.000	AU	Gen pop, > 2 yrs	22	186.07	<25	NR	1	0.056	0%	0%	-
VD 0071	Beans (dry) (Phaseolus spp) (all commodities)	highest utilisation: Total	0.028		1.000	PRIMO-UK	infant	P97.5	159.00	<25	NR	3	0.06-0.51	0-0%	0-0%	0-0%
VD 0523	Broad bean (dry) (Vicia spp) (all commodities)	highest utilisation: cooked/boiled	0.028		0.400	CN	Gen pop, > 1 yrs	737	1190.24	<25	NR	3	0.02-0.25	0-0%	0-0%	0-0%
VD 0531	Lablab bean (dry) (Lablab spp) (all commodities)	highest utilisation: cooked/boiled	0.028		0.400	CN	Gen pop, > 1 yrs	1219	972.42	<25	NR	3	0.2-0.2	0-0%	0-0%	0-0%
VD 0541	Soya bean (dry) (Glycine spp) (all commodities)	highest utilisation: Total	0.002-0.028		1.000	CN	Child, 1-6 yrs	179	239.05	<25	NR	3	0-0.41	0-0%	0-0%	0-0%
VD 0072	Peas (dry) (Pisum spp) (all commodities)	highest utilisation: cooked/boiled	0.028		0.400	CN	Gen pop, > 1 yrs	268	1673.82	<25	NR	3	0.02-0.35	0-0%	0-0%	0-0%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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
VD 0524	Chick-pea (dry) (Cicer spp) (all commodities)	highest utilisation: canned/preserved	0.028		0.400	PRIMO-NL	child	P100	328.80	<25	NR	3	0.02–0.2	0–0%	0–0%	0–0%
VD 0533	Lentil (dry) (Lens spp) (all commodities)	highest utilisation: Total	0.028		1.000	PRIMO-UK	Child, 11-14 yrs	P97.5	321.50	<25	NR	3	0.05–0.19	0–0%	0–0%	0–0%
VD 0537	Pigeon pea (dry) (Cajanus spp)	Total	0.028		1.000	AU	Gen pop, > 2 yrs	129	95.83	<25	NR	3	0.040	0%	0%	0%
VR 0574	Beetroot (all commodities)	highest utilisation: Total	0.02	0.07	1.000	AU	Child, 2-6 yrs	53	314.08	135	3	2a	0.01–2.16	0–1%	0–0%	0–1%
VR 0575	Burdock, greater or edible	Total		0.07	1.000	JP	Child, 1-6 yrs	122	35.70	68	3	2b	0.457	0%	0%	0%
VR 0577	Carrot (all commodities)	highest utilisation: raw with skin	0.02	0.07	1.000	CN	Child, 1-6 yrs	400	234.68	300	3	2b	0–3.05	0–1%	0–0%	0–1%
VR 0578	Celeriac (Turnip rooted celery) (all commodities)	highest utilisation: Total	0.02	0.07	1.000	PRIMO-BE	toddler	P100	196.90	749	3	2b	0–2.32	0–1%	0–0%	0–1%
VR 0469	Chicory, roots (all commodities)	highest utilisation: Total	0.02	0.07	1.000	AU	Gen pop, > 2 yrs	175	26.16	48	3	2b	0.01–0.08	0–0%	0–0%	0–0%
VR 0583	Horseradish (all commodities)	highest utilisation: Total		0.07	1.000	PRIMO-DE	Gen pop	P97.5	79.50	220	3	2b	0–0.22	0–0%	0–0%	0–0%
VR 0587	Parsley, turnip-rooted (Hamburg roots) (all commodities)	highest utilisation: Total	0.02	0.07	1.000	PRIMO-NL	Gen pop	P97.5	96.60	140	3	2b	0.14–0.31	0–0%	0–0%	0–0%
VR 0588	Parsnip (all commodities)	highest utilisation: cooked/boiled (without skin)	0.02	0.07	1.000	PRIMO-NL	child	E	133.30	227	3	2b	0.16–1.52	0–1%	0–0%	0–1%
VR 0494	Radish (all commodities)	highest utilisation: Total	0.02	0.07	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0–0.74	0–0%	0–0%	0–0%
VR 0590	Radish, black (all commodities)	highest utilisation: Total	0.02	0.07	1.000	PRIMO-NL	child	E	64.40	172	3	2b	0–0.74	0–0%	0–0%	0–0%
VR 0591	Radish, Japanese (Chinese radish, Daikon) (all commodities)	highest utilisation: raw without skin	0.02	0.07	1.000	CN	Child, 1-6 yrs	1187	293.37	1000	3	2b	0–3.82	0–1%	0–1%	0–1%
VR 0498	Salsify (Oyster plant) (all commodities)	highest utilisation: Total	0.02	0.07	1.000	PRIMO-BE	toddler	P100	99.90	75	3	2a	0–0.99	0–0%	0–0%	0–0%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%  
all

110%  
gen pop

350%  
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
VR 0596	Sugar beet (all commodities)	highest utilisation: composite foods; unspecified ind processed	0.02		1.000	NL	Child, 2-6 yrs	2554	168.93	NR	NR	3	0.05–0.18	0–0%	0–0%	0–0%
VR 0497	Swede (Rutabaga) (all commodities)	highest utilisation: Total	0.02	0.07	1.000	PRIMO-UK	infant	P97.5	90.00	500	3	2b	0–2.17	0–1%	0–0%	0–1%
VR 0506	Turnip, garden (all commodities)	highest utilisation: Total	0.02	0.07	1.000	US	Gen pop, 0-85 yrs	53	1533.22	105	3	2a	0.15–1.73	0–1%	0–1%	0–0%
VR 0573	Arrowroot (all commodities)	highest utilisation: starch	0.03	0.084	1.000	PRIMO-NL	child	E	12.40	NR	NR	3	0–0.02	0–0%	0–0%	0–0%
VR 0463	Cassava (Manioc) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.03	0.084	1.000	PRIMO-NL	Gen pop	E	250.00	356	3	2b	0.03–0.96	0–0%	0–0%	0–0%
VR 0585	Jerusalem artichoke (i.e. Topinambur) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.084	1.000	PRIMO-NL	child	E	133.30	56	3	2a	0.46–1.12	0–0%	0–0%	0–0%
VR 0589	Potato (all commodities)	highest utilisation: Total	0.014–0.03	0.038–0.084	1.000	PRIMO-UK	infant	P97.5	191.10	216	3	2b	0.01–5.54	0–2%	0–0%	0–2%
VR 0508	Sweet potato (all commodities)	highest utilisation: Total	0.03	0.084	1.000	CA	Child, <6 yrs	91	358.61	546	3	2b	0.21–7.08	0–2%	0–1%	1–2%
VR 0504	Tannia (Tanier, Yautia) (all commodities)	highest utilisation: cooked/boiled (without peel)	0.03	0.084	1.000	NL	Gen pop, > 1 yrs	E	249.97	170	3	2a	0.02–0.75	0–0%	0–0%	0–0%
VR 0505	Taro (Dasheen, Eddoe) (all commodities)	highest utilisation: cooked/boiled (without peel)		0.084	1.000	CN	Child, 1-6 yrs	199	384.18	668	3	2b	0.62–6	0–2%	0–1%	0–2%
VR 0600	Yams (all commodities)	highest utilisation: Total		0.084	1.000	PRIMO-UK	adult	P97.5	693.70	365	3	2a	0.61–1.57	0–1%	0–1%	0–1%
VS 0623	Cardoon (all commodities)	highest utilisation: cooked/boiled		9.3	1.000	PRIMO-NL	Gen pop	E	200.00	100	3	2a	41.37–56.53	10–20%	10–20%	0–0%
VS 0624	Celery (all other commodities)	highest utilisation: Total	4.4	9.3	1.000	PRIMO-BE	toddler	P100	133.20	462	3	2b	0.26–208.78	0–70%	0–60%	2–70%
VS 0624	Celery	raw		9.3	1.000	CN	Child, 1-6 yrs	454	180.29	861	3	2b	311.732	100%	50%	100%
VS 0380	Fennel, bulb (Florence fennel) (all commodities)	highest utilisation: cooked/boiled	4.4	9.3	1.000	PRIMO-NL	child	E	166.80	251	3	2b	0.26–252.92	0–80%	0–40%	8–80%
VS 0627	Rhubarb (all commodities)	highest utilisation: Total	4.4	9.3	1.000	AU	gen pop, > 2 yrs	58	539.42	57	3	2a	67.67–90.62	20–30%	9–30%	20–50%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%  
all

110%  
gen pop

350%  
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
GC 0648	Quinoa	Total	0.063		1.000	AU	Child, 2-16 yrs	32	78.18	<25	NR	3	0.130	0%	-	0%
GC 0650	Rye (all commodities)	highest utilisation: flakes	0.063		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.09–2.16	0–1%	0–0%	0–1%
GC 0653	Triticale	Total	0.063		1.000	DE	Gen pop, 14-80 yrs	27100	394.70	<25	NR	3	0.326	0%	0%	0%
GC 0654	Wheat (all commodities)	highest utilisation: flakes	0.02–0.14		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.06–2.16	0–1%	0–0%	0–1%
GC 0640	Barley (all commodities)	highest utilisation: beer	0.01–0.23		0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0.02–11.81	0–4%	0–4%	0–3%
GC 0641	Buckwheat (all commodities)	highest utilisation: flakes	0.23		1.000	CA	Child, <6 yrs	1909	539.23	NR	NR	3	0.13–7.89	0–3%	0–0%	0–3%
GC 0647	Oats (all commodities)	highest utilisation: Total	0.003–0.23		1.000	CN	Gen pop, > 1 yrs	1740	330.61	<25	NR	3	0–1.43	0–0%	0–0%	0–0%
GC 0649	Rice (all commodities)	highest utilisation: Total	0.03		1.000	CA	Child, <6 yrs	666	461.40	<25	NR	3	0–0.91	0–0%	0–0%	0–0%
GC 0655	Wild rice (all commodities)	highest utilisation: cooked/boiled	0.03		0.400	CN	Child, 1-6 yrs	129	552.59	<25	NR	3	0.13–0.41	0–0%	0–0%	0–0%
GC 0644	Job's tears (all commodities)	highest utilisation: cooked/boiled	0.03		0.300	TH	Child, 3-6 yrs	134	85.50	<25	NR	3	0.05–0.05	0–0%	0–0%	0–0%
GC 0646	Millet (common millet, proso millet) (all commodities)	highest utilisation: Total	0.03		1.000	CN	Child, 1-6 yrs	826	219.53	<25	NR	3	0.02–0.41	0–0%	0–0%	0–0%
GC 0651	Sorghum grain (Chicken corn, Dari seed, Durra, Feterita) (all commodities)	highest utilisation: cooked/boiled	0.03		0.400	CN	Gen pop, > 1 yrs	356	1348.67	<25	NR	3	0.05–0.3	0–0%	0–0%	0–0%
GC 0645	Maize (corn) (all commodities)	highest utilisation: beer	0.013–0.14		0.190	CA	Gen pop, all ages	2514	21271.20	NR	NR	3	0.01–1.54	0–1%	0–1%	0–0%
GC 0656	Popcorn (i.e. maize destined for popcorn preparation) (all commodities)	highest utilisation: Total	0.03		1.000	AU	Child, 2-6 yrs	120	73.67	<25	NR	3	0.09–0.12	0–0%	0–0%	0–0%
GC 3081	Baby corn (all commodities)	highest utilisation: canned/preserved (imm cobs)		0.03	1.000	NL	Child, 2-6 yrs	E	75.00	12	NR	1	0.12–0.12	0–0%	0–0%	0–0%

**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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
GC 0447	Sweet corn (corn-on-the-cob) (kernels plus cob with husks removed) (all commodities)	highest utilisation: cooked/boiled (corn-on-the-cob)	0.03	0.03	1.000	TH	Child, 3-6 yrs	1383	196.99	191	3	2a	0.02–1.02	0–0%	0–0%	0–0%
GC 1275	Sweet corn (whole kernel without cob or husk) (all commodities)	highest utilisation: canned/preserved (kernels)	0.03	0.03	1.000	CA	Child, <6 yrs	289	153.76	NR	NR	3	0.02–0.3	0–0%	0–0%	0–0%
SO 0090	Subgroup of mustard seeds (all commodities)	highest utilisation: Total	0.0945		1.000	PRIMO-CZ	Child, child, 7-10 yrs	P97.5	32.95	<25	NR	3	0–0.1	0–0%	0–0%	0–0%
SO 3140	Borage seeds (all commodities)	highest utilisation: raw	0.0945		1.000	DE	Gen pop, 14-80 yrs	2	42.00	<25	NR	3	0.05–0.05	0–0%	0–0%	0–0%
SO 0693	Linseed (Flax-seed) (all commodities)	highest utilisation: Total	0.0945		1.000	CA	Gen pop, all ages	291	81.08	<25	NR	3	0.03–0.11	0–0%	0–0%	0–0%
SO 0698	Poppy seed (all commodities)	highest utilisation: Total	0.0945		1.000	PRIMO-DE	women, 14-50 yrs	P97.5	47.23	<25	NR	3	0–0.07	0–0%	0–0%	0–0%
SO 0495	Rape seed (Canola) (all commodities)	highest utilisation: Total	0.035–0.0945		1.000	PRIMO-DE	child	P95	22.29	<25	NR	3	0.06–0.13	0–0%	0–0%	0–0%
SO 0700	Sesame seed (all commodities)	highest utilisation: butter/paste (nuts/oilseeds)	0.0945		1.000	CN	Gen pop, > 1 yrs	174	151.21	NR	NR	3	0.01–0.27	0–0%	0–0%	0–0%
SO 0699	Safflower seed (all commodities)	highest utilisation: Total	0.08		1.000	PRIMO-DE	child	P95	49.74	<25	NR	3	0–0.25	0–0%	0–0%	0–0%
SO 0702	Sunflower seed (all commodities)	highest utilisation: Total	0.08		1.000	CA	women, 15-49 yrs	121	296.25	<25	NR	3	0.04–0.37	0–0%	0–0%	0–0%
SO 0691	Cotton seed (all commodities)	highest utilisation: Oil (refined)	0.08		1.000	US	Child, < 6 yrs	6354	3.13	NR	NR	3	0.02–0.02	0–0%	0–0%	0–0%
SO 0697	Peanut, shelled (groundnut) (all commodities)	highest utilisation: raw incl roasted	0.03–0.072		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	302	264.84	NR	NR	1	NA	0%	0%	0%
MM 0095	Meat from mammals other than marine mammals: 20% as fat	Total		0.069	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.227	0%	0%	0%



**PYDIFLUMETOFEN (309)**

Acute RfD= 0.3 mg/kg bw (300 µg/kg bw)

IESTI

Maximum % ARfD:

350%

110%

350%

all gen pop 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
MM 0095	Meat from mammals other than marine mammals: 80% as muscle	Total		0.02	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.263	0%	0%	0%
MF 0100	Mammalian fats (except milk fats)	Total		0.069	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.140	0%	0%	0%
MO 0105	Edible offal (mammalian)	Total		0.43	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	4.042	1%	1%	1%
ML 0106	Milks	Total	0.02		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	2.484	1%	0%	1%
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		0.02	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.043	0%	0%	0%
PM 0110	Poultry meat: 90% as muscle	Total		0.02	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	0.387	0%	0%	0%
PF 0111	Poultry, fats	Total		0.02	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.058	0%	0%	0%
PO 0111	Poultry, edible offal (includes kidney, liver and skin)	Total		0.02	1.000	CN	Gen pop, > 1 yrs	421	345.63	NR	NR	1	0.130	0%	0%	0%
PE 0112	Eggs	Total		0.03	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.372	0%	0%	0%

**PYFLUBUMIDE (314)**

Acute RfD= 0.008 mg/kg bw (8 µg/kg bw)

IESTI

Maximum % ARfD:

390%

230%

390%

all gen pop 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
FP 0226	Apple	Total		0.55	1.000	AU	Child, 2-6 yrs	1997	668.41	153	3	2a	28.190	350%	160%	350%
FP 0226	Apple	raw with peel (incl consumption without peel)		0.55	1.000	CN	Child, 1-6 yrs	1314	403.39	255	3	2a	31.134	390%	160%	390%
FP 0226	Apple (all other commodities)	highest utilisation: composite foods; unspecified ind processed	0.001 - 0.41	0.028	1.000	AU	Gen pop, > 2 yrs	74	575.63	NR	NR	3	0.04 - 3.52	1 - 40%	1 - 40%	1 - 40%
DT 1114	Tea, green, black (black, fermented and dried)	Total	13		1.000	PRIMO-IE	child	P97.5	30.60	<25	NR	3	19.890	250%	80%	250%
DT 1114	Tea, green, black (black, fermented and dried)	raw = dried	13		1.000	CN	Gen pop, > 1 yrs	679	75.88	<25	NR	3	18.534	230%	230%	150%
DT 1114	Tea, green, black (black, fermented and dried)	infusion (brew/beverage)	0.004		1.000	BR	Gen pop, > 10 yrs	3534	2723.42	NR	NR	3	0.164	2%	2%	-

**TOLFENPYRAD (269)**

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

IESTI

Maximum % ARfD:

240%

130%

240%

all

gen pop

child

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
Kumquats (all commodities)	highest utilisation: Total		0.18–0.57	1.000	JP	Gen pop, > 1 yrs	135	120.00	<25	NR	1	0.1–0.43	1–4%	1–4%	4–4%
Lemon (all commodities)	highest utilisation: Total	0.032–0.085	0.18	1.000	PRIMO-DE	child	P95	125.50	71	3	2a	0.05–2.99	0–30%	0–10%	0–30%
Lime (all commodities)	highest utilisation: juice (pasteurised)	0.085–0.58	0.18	1.000	AU	Gen pop, > 2 yrs	579	129.61	NR	NR	3	0.01–1.12	0–10%	0–10%	0–5%
Subgroup of Mandarins (incl mandarin-like hybrids) (all commodities)	highest utilisation: raw, without peel	0.032–0.085	0.18	1.000	CN	Child, 1-6 yrs	151	586.75	124	3	2a	0.02–9.32	0–90%	0–40%	0–90%
Subgroup of Oranges, sweet, sour (incl orange-like hybrids) (all commodities)	highest utilisation: Total	0.023–0.061	0.13	1.000	AU	Child, 2-6 yrs	1735	800.83	156	3	2a	0.04–7.61	0–80%	0–40%	0–80%
Subgroup of Pummelo and Grapefruits (incl Shaddock-like hybrids, among others Grapefruit) (all commodities)	highest utilisation: Total	0.029–0.042	0.099	1.000	PRIMO-DE	child	P90	253.56	270	3	2b	0.01–4.66	0–50%	0–30%	0–50%
Garlic (all commodities)	highest utilisation: raw without skin	0.0125	0.057	1.000	CN	Child, 1-6 yrs	290	174.44	62	3	2a	0–1.06	0–10%	0–4%	0–10%
Onion, bulb (all commodities)	highest utilisation: raw without skin	0.0125	0.057	1.000	JP	Child, 1-6 yrs	748	102.00	244	3	2b	0–1.06	0–10%	0–5%	0–10%
Onion, Chinese (all commodities)	highest utilisation: raw		0.057	1.000	CN	Child, 1-6 yrs	196	136.53	130	3	2a	0.23–1.4	2–10%	2–6%	2–10%
Shallot (all commodities)	highest utilisation: raw without skin	0.0125	0.057	1.000	CN	Child, 1-6 yrs	480	115.81	51	3	2a	0.01–0.77	0–8%	1–3%	0–8%
Goji berry (all commodities)	highest utilisation: Dried		0.5	3.000	AU	Child, 2-6 yrs	1	28.36	<25	NR	1	0.48–2.24	5–20%	0–0%	5–20%
Tomato	Total		0.5	1.000	CA	Child, <6 yrs	340	250.22	175	3	2a	18.314	180%	50%	180%
Tomato	raw with peel		0.5	1.000	CN	Child, 1-6 yrs	1117	263.76	175	3	2a	18.994	190%	70%	190%
Tomato	cooked/boiled (with peel)		0.5	1.000	NL	toddler, 8-20 m	31	81.77	86	3	2b	12.026	120%	30%	120%
Tomato	canned/preserved (without peel)		0.5	1.000	AU	Child, 2-6 yrs	561	152.36	129	3	2a	10.783	110%	50%	110%

**TOLFENPYRAD (269)**

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

IESTI

Maximum % ARfD:

240%

130%

240%

all

gen pop

child

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
Tomato (all other commodities)	highest utilisation: dried	0.042– 0.14	0.042– 0.5	14.000	NL	Gen pop, > 1 yrs	E	50.01	8	NR	1	0.14–5.32	1–50%	1–50%	7–30%
Okra (Lady's finger, Gombo) (all commodities)	highest utilisation: Total		0.32	1.000	US	Child, < 6 yrs	26	82.30	17	NR	1	1.71–1.82	20–20%	10–20%	20–20%
Peppers, chili (all commodities)	highest utilisation: raw with skin	0.11– 1.1	0.32– 3.2	1.000	CN	Gen pop, > 1 yrs	1743	295.71	43	3	2a	0–2.3	0–20%	0–20%	0–4%
Peppers, sweet (incl. pimiento) (Bell pepper, Paprika) (all other commodities)	highest utilisation: Total	0.11	0.32	1.000	PRIMO- DE	child	P97.5	137.28	155	3	2b	0.02–8.16	1–80%	1–20%	0–80%
Peppers, sweet (incl. pimiento) (Bell pepper, Paprika)	raw with skin		0.32	1.000	CN	Child, 1-6 yrs	1002	169.85	170	3	2b	10.105	100%	40%	100%
Egg plant (Aubergine)	Total		0.5	1.000	AU	Child, 2-6 yrs	29	128.25	318	3	2b	10.125	100%	80%	100%
Egg plant (Aubergine)	raw with skin		0.5	1.000	CN	Child, 1-6 yrs	969	253.44	444	3	2b	23.560	240%	130%	240%
Egg plant (Aubergine) (all other commodities)	highest utilisation: cooked/boiled (with skin)	0.13	0.5	1.000	NL	Gen pop, > 1 yrs	30	424.02	258	3	2a	0.15–7.14	1–70%	1–70%	1–70%
Pepino (Melon pear, Tree melon)	Total		0.5	1.000	AU	Gen pop, > 2 yrs	3	73.89	123	3	2b	1.654	20%	20%	-
Scarlet eggplant (gilo, Ethiopian eggplant) (all commodities)	highest utilisation: cooked/boiled (with skin)		0.5	1.000	BR	Gen pop, > 10 yrs	280	360.50	28	3	2a	3.23–3.23	30–30%	30–30%	0–0%
Lemon, peel (all commodities)	highest utilisation: raw peel (C. limon Burm.f.)	22	2.7	1.000	AU	Child, 2-6 yrs	602	1.15	67	3	2b	0.49–0.49	5–5%	3–3%	5–5%
Orange, peel (all commodities)	highest utilisation: raw peel (C. sinensis Osbeck)	22	2	1.000	AU	Gen pop, > 2 yrs	698	15.10	49	3	2b	1.35–1.35	10–10%	10–10%	3–3%
Meat from mammals other than marine mammals	Total	NA	NA	1.000	CN	Child, 1-6 yrs	302	264.84	NR	NR	1	NA	1%	0%	1%

**TOLFENPYRAD (269)**

Acute RfD= 0.01 mg/kg bw (10 µg/kg bw)

IESTI

Maximum % ARfD:

240%

130%

240%

all

gen pop

child

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
Meat from mammals other than marine mammals: 20% as fat	Total		0.0022	1.000	CN	Child, 1-6 yrs	302	52.97	NR	NR	1	0.007	0%	0%	0%
Meat from mammals other than marine mammals: 80% as muscle	Total		0.0043	1.000	CN	Child, 1-6 yrs	302	211.87	NR	NR	1	0.056	1%	0%	1%
Mammalian fats (except milk fats)	Total		0.0022	1.000	PRIMO-FR	adult	P97.5	134.79	NR	NR	1	0.004	0%	0%	0%
Edible offal (mammalian)	Total		0.38	1.000	ZA	Gen pop, > 10 yrs	-	523.58	NR	NR	1	3.572	40%	40%	30%
Milks	Total	0.0038		1.000	PRIMO-UK	infant	P97.5	1080.70	NR	NR	3	0.472	5%	2%	5%
Poultry meat	Total	NA	NA	1.000	CN	Child, 1-6 yrs	175	347.00	NR	NR	1	NA	0%	0%	0%
Poultry meat: 10% as fat	Total		0	1.000	CN	Child, 1-6 yrs	175	34.70	NR	NR	1	0.000	0%	0%	0%
Poultry meat: 90% as muscle	Total		0	1.000	CN	Child, 1-6 yrs	175	312.30	NR	NR	1	0.000	0%	0%	0%
Poultry, fats	Total		0	1.000	CA	Child, <6 yrs	66	49.38	NR	NR	1	0.000	0%	0%	0%
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%
Eggs	Total		0	1.000	PRIMO-UK	infant	P97.5	108.00	NR	NR	1	0.000	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.
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9. 1967 Evaluations of some pesticide residues in food. FAO/PL:1967/M/11/1; WHO/Food Add./68.30, 1968.
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17. 1971 Evaluations of some pesticide residues in food. AGP:1971/M/9/1; WHO Pesticide Residue Series, No. 1, 1972.
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## Annex 6: Livestock dietary burdens

### AFIDOPYROPEN (312)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4.8	HR	15	32.00		20				6.4		
Cotton gin byproducts	AM/AV	0.65	HR	90	0.72	5				0.036			
Tomato pomace,wet	AB	0.045	STMR	20	0.23			10				0.023	
Apple pomace, wet	AB	0.084	STMR	40	0.21		20	10			0.042	0.021	
Citrus dried pulp	AB	0.13	STMR	91	0.14	10		10		0.014		0.014	
Almond hulls	AM/AV	0.064	STMR	90	0.07			10				0.007	
Soybean asp gr fn	SM	0.02	STMR	85	0.02	5				0.001			
Cotton undelinted seed	SO	0.02	STMR	88	0.02			30				0.007	
Soybean meal	SM	0.02	STMR	92	0.02		20	10	65		0.004	0.002	0.014
Soybean hulls	SM	0.02	STMR	90	0.02	10				0.002			
Cotton hulls	SM	0.018	STMR	90	0.02			10				0.002	
Cotton meal	SM	0.0052	STMR	89	0.01			10				6E-04	
Total						30	60	100	65	0.054	6.446	0.076	0.014

ESTIMATED MAXIMUM DIETARY BURDEN													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4.8	HR	15	32.00		20	40			6.4	12.8	
Tomato pomace,wet	AB	0.045	STMR	20	0.23			10				0.023	
Apple pomace, wet	AB	0.084	STMR	40	0.21	10	10			0.021	0.021		
Citrus dried pulp	AB	0.13	STMR	91	0.14		10	20			0.014	0.029	
Almond hulls	AM/AV	0.064	STMR	90	0.07	10				0.007			
Cotton undelinted seed	SO	0.02	STMR	88	0.02	10	10	20		0.002	0.002	0.005	
Soybean meal	SM	0.02	STMR	92	0.02	10	25	10	60	0.002	0.005	0.002	0.013
Total						40	75	100	60	0.033	6.443	12.86	0.013

ESTIMATED MAXIMUM DIETARY BURDEN													
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 meal	SM	0.02	STMR	92	0.02	25	40	25	35	0.005	0.009	0.005	0.008
Total						25	40	25	35	0.005	0.009	0.005	0.008

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	0.43	HR	15	2.87		5				0.143			
Soybean meal	SM	0.02	STMR	92	0.02	25	25	25	30	0.005	0.005	0.005	0.007	
Total						25	30	25	30	0.005	0.149	0.005	0.007	

## AFIDOPYROPEN (312)

ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Kale leaves	AM/AV	2.5	STMR/STMR-P	15	16.67		20				3.333			
Cotton gin byproducts	AM/AV	1	STMR/STMR-P	90	1.11	5				0.055556				
Tomato pomace, wet	AB	0.045	STMR/STMR-P	20	0.23			10				0.023		
Apple pomace, wet	AB	0.084	STMR/STMR-P	40	0.21		20	10			0.042	0.021		
Citrus dried pulp	AB	0.13	STMR/STMR-P	91	0.14	10		10		0.014286		0.014		
Almond hulls	AM/AV	0.064	STMR/STMR-P	90	0.07			10				0.007		
Soybean asp gr fn	SM	0.02	STMR/STMR-P	85	0.02	5				0.001176				
Cotton undelinted seed	SO	0.02	STMR/STMR-P	88	0.02			30				0.007		
Soybean meal	SM	0.02	STMR/STMR-P	92	0.02		20	10	65		0.004	0.002	0.014	
Soybean hulls	SM	0.02	STMR/STMR-P	90	0.02	10				0.002				
Cotton hulls	SM	0.018	STMR/STMR-P	90	0.02			10				0.002		
Cotton meal	SM	0.0052	STMR/STMR-P	89	0.01			10				6E-04		
Total						30	60	100	65	0.073	3.38	0.076	0.014	



DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Kale leaves	AM/AV	2.5	STMR/STMR-P	15	16.67		20	40			3.333	6.667		
Tomato pomace, wet	AB	0.045	STMR/STMR-P	20	0.23	0		10		0		0.023		
Apple pomace, wet	AB	0.084	STMR/STMR-P	40	0.21	10	10			0.021	0.021			
Citrus dried pulp	AB	0.13	STMR/STMR-P	91	0.14	0	10	20		0	0.014	0.029		
Almond hulls	AM/AV	0.064	STMR/STMR-P	90	0.07	10				0.007111				
Cotton undelinted seed	SO	0.02	STMR/STMR-P	88	0.02	10	10	20		0.002273	0.002	0.005		
Soybean meal	SM	0.02	STMR/STMR-P	92	0.02	10	25	10	60	0.002174	0.005	0.002	0.013	
Total						40	75	100	60	0.032558	3.376	6.724	0.013	

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	
Soybean meal	SM	0.02	STMR/STMR-P	92	0.02	25	40	25	35	0.01	0.009	0.005	0.008	
Total						25	40	25	35	0.005	0.009	0.005	0.008	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	0.0865	STMR/STMR-P	15	0.58		5				0.029			
Soybean meal	SM	0.02	STMR/STMR-P	92	0.02	25	25	25	30	0.005435	0.005	0.005	0.007	
Total						25	30	25	30	0.005435	0.034	0.005	0.007	

## BENZOVINDIFLUPYR (261)

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	3.7	HR	25	14.80		20	100			2.96	14.8	
Barley hay	AF/AS	12	HR	88	13.64	15				2.045			
Barley straw	AF/AS	12	HR	89	13.48		10				1.348		
Pea hay	AL	3.8	HR	88	4.32		25				1.08		
Soybean asp gr fn	SM	1.91	STMR	85	2.25	5				0.112			
Wheat asp gr fn	CM/CF	1.7	STMR	85	2.00	5				0.100			
Apple pomace, wet	AB	0.2	STMR	40	0.50		20				0.1		
Barley grain	GC	0.18	STMR	88	0.20	50	25		70	0.102	0.051		0.143
Potato process waste	AB	0.01	STMR	12	0.08	25				0.021			
Barley bran fractions	CM/CF	0.07	STMR	90	0.08				10				0.008
Soybean hulls	SM	0.018	STMR	90	0.02				5				0.001
Rape meal	SM	0.012	STMR	88	0.01				10				0.001
Soybean seed	VD	0.01	STMR	89	0.01				5				6E-04
Total						100	100	100	100	2.381	5.54	14.80	0.15

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	3.7	HR	25	14.80	20	20	60		2.960	2.96	8.88	
Rye straw	AF/AS	12	HR	88	13.64				5				0.682
Triticale hay	AF/AS	12	HR	88	13.64			40				5.455	
Barley straw	AF/AS	12	HR	89	13.48		10				1.348		
Oat hay	AF/AS	12	HR	90	13.33	10				1.333			
Peanut hay	AL	7.6	HR	85	8.94	15				1.341			
Pea hay	AL	3.8	HR	88	4.32		30				1.295		
Apple pomace, wet	AB	0.2	STMR	40	0.50	10	10			0.050	0.05		
Barley grain	GC	0.18	STMR	88	0.20	45	30		40	0.092	0.061		0.082
Rape meal	SM	0.012	STMR	88	0.01				25				0.003
Soybean seed	VD	0.01	STMR	89	0.01				10				0.001
Soybean meal	SM	0.01	STMR	92	0.01				20				0.002
Total						100	100	100	100	5.777	5.715	14.33	0.77

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Barley grain	GC	0.18	STMR	88	0.20	75	70	15	10	0.153	0.143	0.031	0.02	
Barley bran fractions	CM/CF	0.07	STMR	90	0.08	8				0.006				
Rye grain	GC	0.023	STMR	88	0.03			35				0.009		
Wheat grain	GC	0.023	STMR	89	0.03			50				0.013		
Soybean hulls	SM	0.018	STMR	90	0.02		5				0.001			
Pea seed	VD	0.014	STMR	90	0.02	17	20			0.003	0.003			
Canola meal	SM	0.012	STMR	88	0.01		5				7E-04			
Rape meal	SM	0.012	STMR	88	0.01				5				7E-04	
Soybean meal	SM	0.01	STMR	92	0.01				30				0.003	
Total						100	100	100	45	0.162	0.148	0.053	0.024	

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	3.7	HR	25	14.80		10				1.48			
Pea hay	AL	3.8	HR	88	4.32		10				0.432			
Barley grain	GC	0.18	STMR	88	0.20	75	80	15		0.153	0.164	0.031		
Barley bran fractions	CM/CF	0.07	STMR	90	0.08				5				0.004	
Rye grain	GC	0.023	STMR	88	0.03			20				0.005		
Wheat grain	GC	0.023	STMR	89	0.03			20				0.005		
Pea seed	VD	0.014	STMR	90	0.02	20		5		0.003		8E-04		
Canola meal	SM	0.012	STMR	88	0.01	5		5		0.001		7E-04		
Rape meal	SM	0.012	STMR	88	0.01				15				0.00	
Bean seed	VD	0.011	STMR	88	0.01			35				0.004		
Soybean meal	SM	0.01	STMR	92	0.01				15				0.002	
Total						100	100	100	35	0.157	2.075	0.047	0.008	

### BENZOVINDIFLUPYR (261)

ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Grape pomace, wet	AB	1.2	STMR/STMR-P	15	8.00			20				1.6		
Barley hay	AF/AS	3.9	STMR/STMR-P	88	4.43	15		80		0.664773		3.545		
Rye straw	AF/AS	3.9	STMR/STMR-P	88	4.43		20				0.886			
Barley straw	AF/AS	3.9	STMR/STMR-P	89	4.38		10				0.438			
Pea hay	AL	2.2	STMR/STMR-P	88	2.50		25				0.625			
Soybean asp gr fn	SM	1.91	STMR/STMR-P	85	2.25	5				0.112353				
Wheat asp gr fn	CM/CF	1.7	STMR/STMR-P	85	2.00	5				0.1				

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.2	STMR/STMR-P	40	0.50		20				0.1		
Barley grain	GC	0.18	STMR/STMR-P	88	0.20	50	25		70	0.102	0.051		0.143
Potato process waste	AB	0.01	STMR/STMR-P	12	0.08	25				0.021			
Barley bran fractions	CM/CF	0.07	STMR/STMR-P	90	0.08				10				0.008
Soybean hulls	SM	0.018	STMR/STMR-P	90	0.02				5				0.001
Rape meal	SM	0.012	STMR/STMR-P	88	0.01				10				0.001
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01				5				6E-04
Total						100	100	100	100	1.0002	2.101	5.145	0.1539

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	JP
Grape pomace, wet	AB	1.2	STMR/STMR-P	15	8.00		0	20			0	1.6	
Barley hay	AF/AS	3.9	STMR/STMR-P	88	4.43	20		50		0.886364		2.216	
Rye straw	AF/AS	3.9	STMR/STMR-P	88	4.43	0	20		5	0	0.886		0.222
Triticale hay	AF/AS	3.9	STMR/STMR-P	88	4.43	0		30		0		1.33	
Barley straw	AF/AS	3.9	STMR/STMR-P	89	4.38	0	10			0	0.438		
Oat hay	AF/AS	3.9	STMR/STMR-P	90	4.33	10				0.433333			
Peanut hay	AL	2.2	STMR/STMR-P	85	2.59	15				0.388235			
Pea hay	AL	2.2	STMR/STMR-P	88	2.50	0	30			0	0.75		
Apple pomace, wet	AB	0.2	STMR/STMR-P	40	0.50	10	10			0.05	0.05		
Barley grain	GC	0.18	STMR/STMR-P	88	0.20	45	30		40	0.092045	0.061		0.082
Rape meal	SM	0.012	STMR/STMR-P	88	0.01	0			25	0			0.003
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	0			10	0			0.001
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01	0			20	0			0.002
Total						100	100	100	100	1.849978	2.186	5.145	0.31

ESTIMATED MEAN DIETARY BURDEN													
POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley grain	GC	0.18	STMR/STMR-P	88	0.20	75	70	15	10	0.15	0.143	0.031	0.02
Barley bran fractions	CM/CF	0.07	STMR/STMR-P	90	0.08	8				0.01			
Rye grain	GC	0.023	STMR/STMR-P	88	0.03			35				0.009	
Wheat grain	GC	0.023	STMR/STMR-P	89	0.03			50				0.013	
Soybean hulls	SM	0.018	STMR/STMR-P	90	0.02		5				0.001		
Pea seed	VD	0.014	STMR/STMR-P	90	0.02	17	20			0.00	0.003		
Canola meal	SM	0.012	STMR/STMR-P	88	0.01		5				7E-04		
Rape meal	SM	0.012	STMR/STMR-P	88	0.01				5				7E-04

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	
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01				30				0.003	
Total						100	100	100	45	0.162276	0.148	0.053	0.024	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat hay	AF/AS	3.9	STMR/STMR-P	88	4.43		10				0.443			
Pea hay	AL	2.2	STMR/STMR-P	88	2.50		10				0.25			
Barley grain	GC	0.18	STMR/STMR-P	88	0.20	75	80	15		0.153409	0.164	0.031		
Barley bran fractions	CM/CF	0.07	STMR/STMR-P	90	0.08				5				0.004	
Rye grain	GC	0.023	STMR/STMR-P	88	0.03			20				0.005		
Wheat grain	GC	0.023	STMR/STMR-P	89	0.03			20				0.005		
Pea seed	VD	0.014	STMR/STMR-P	90	0.02	20		5		0.003111		8E-04		
Canola meal	SM	0.012	STMR/STMR-P	88	0.01	5		5		0.000682		7E-04		
Rape meal	SM	0.012	STMR/STMR-P	88	0.01				15				0.00	
Bean seed	VD	0.011	STMR/STMR-P	88	0.01			35				0.004		
Soybean meal	SM	0.01	STMR/STMR-P	92	0.01				15				0.002	
Total						100	100	100	35	0.157202	0.857	0.047	0.008	

**BIFENTHRIN (178)**

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
Cabbage heads, leaves	AM/AV	3.1	HR	15	20.67		20				4.133		
Soybean asp gr fn	SM	9.5	STMR	85	11.18	5				0.559			
Corn, field stover	AF/AS	5.5	HR	83	6.63	15	25	40		0.994	1.657	2.651	
Corn, field forage/silage	AF/AS	2	HR	40	5.00		55	60			2.75	3	
Wheat milled bypds	CM/CF	0.79	STMR	88	0.90	40			55	0.359			0.494
Wheat grain	GC	0.25	STMR	89	0.28	20			25	0.056			0.07
Distiller's grain dried	SM	0.25	STMR	92	0.27	20			10	0.054			0.027
Soybean seed	VD	0.05	STMR	89	0.06				10				0.006
Total						100	100	100	100	2.022	8.54	5.651	0.597

DAIRY CATTLE													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Cabbage heads, leaves	AM/AV	3.1	HR	15	20.67		20				4.133		
Corn, field stover	AF/AS	5.5	HR	83	6.63	15	20	40		0.994	1.325	2.651	
Corn, field forage/silage	AF/AS	2	HR	40	5.00	30	40	60	50	1.500	2	3	2.5
Wheat milled bypds	CM/CF	0.79	STMR	88	0.90	30	20		45	0.269	0.18		0.404
Carrot culls	VR	0.05	HR	12	0.42	10				0.042			
Wheat grain	GC	0.25	STMR	89	0.28	15			5	0.042			0.014
Total						100	100	100	100	2.847	7.638	5.651	2.918

POULTRY BROILER													
													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat milled bypds	CM/CF	0.79	STMR	88	0.90	50	20	20	5	0.449	0.18	0.18	0.045
Carrot culls	VR	0.05	HR	12	0.42		10				0.042		
Wheat grain	GC	0.25	STMR	89	0.28	50	70	70	10	0.140	0.197	0.197	0.028
Distiller's grain dried	SM	0.25	STMR	92	0.27				5				0.014
Soybean seed	VD	0.05	STMR	89	0.06			10				0.006	
Total						100	100	100	20	0.589	0.418	0.382	0.087

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	3.1	HR	15	20.67		5				1.033			
Wheat milled bypds	CM/CF	0.79	STMR	88	0.90	50	20	20	30	0.449	0.18	0.18	0.269	
Wheat straw	AF/AS	0.45	HR	88	0.51		10				0.051			
Carrot culls	VR	0.05	HR	12	0.42		10				0.042			
Wheat grain	GC	0.25	STMR	89	0.28	50	55	55		0.140	0.154	0.154		
Distiller's grain dried	SM	0.25	STMR	92	0.27				5					0.014
Soybean seed	VD	0.05	STMR	89	0.06			15					0.008	
Canola meal	SM	0.027	STMR	88	0.03			5					0.002	
Total						100	100	95	35	0.59	1.46	0.344	0.28	

**BIFENTHRIN (178)**

ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Soybean asp gr fn	SM	9.5	STMR/STMR-P	85	11.18	5				0.558824				
Cabbage heads, leaves	AM/AV	1.5	STMR/STMR-P	15	10.00		20				2			
Corn, field stover	AF/AS	2.2	STMR/STMR-P	83	2.65	15	25	40		0.39759	0.663	1.06		
Corn, field forage/silage	AF/AS	0.585	STMR/STMR-P	40	1.46		55	60			0.804	0.878		
Wheat milled bypds	CM/CF	0.79	STMR/STMR-P	88	0.90	40			55	0.359091				0.494
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	20			25	0.05618				0.07
Distiller's grain dried	SM	0.25	STMR/STMR-P	92	0.27	20			10	0.054348				0.027
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06				10					0.006
Total						100	100	100	100	1.426	3.467	1.938	0.597	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Cabbage heads, leaves	AM/AV	1.5	STMR/STMR-P	15	10.00		20	0			2	0		
Corn, field stover	AF/AS	2.2	STMR/STMR-P	83	2.65	15	20	40		0.39759	0.53	1.06		
Corn, field forage/silage	AF/AS	0.585	STMR/STMR-P	40	1.46	30	40	60	50	0.43875	0.585	0.878	0.731	
Wheat milled bypds	CM/CF	0.79	STMR/STMR-P	88	0.90	30	20		45	0.269318	0.18			0.404
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42	10				0.041667				
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	15			5	0.042135				0.014
Total						100	100	100	100	1.18946	3.295	1.938	1.149	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat milled bypds	CM/CF	0.79	STMR/STMR-P	88	0.90	50	20	20	5	0.45	0.18	0.18	0.045	
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42		10				0.042			
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	50	70	70	10	0.14	0.197	0.197	0.028	
Distiller's grain dried	SM	0.25	STMR/STMR-P	92	0.27				5				0.014	
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06			10				0.006		
Total						100	100	100	20	0.59	0.418	0.382	0.087	

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	
Cabbage heads, leaves	AM/AV	1.5	STMR/STMR-P	15	10.00		5				0.5			
Wheat milled bypds	CM/CF	0.79	STMR/STMR-P	88	0.90	50	20	20	30	0.448864	0.18	0.18	0.269	
Carrot culls	VR	0.05	STMR/STMR-P	12	0.42		10				0.042			
Wheat straw	AF/AS	0.26	STMR/STMR-P	88	0.30		10				0.03			
Wheat grain	GC	0.25	STMR/STMR-P	89	0.28	50	55	55		0.140449	0.154	0.154		
Distiller's grain dried	SM	0.25	STMR/STMR-P	92	0.27				5				0.014	
Soybean seed	VD	0.05	STMR/STMR-P	89	0.06			15				0.008		
Canola meal	SM	0.027	STMR/STMR-P	88	0.03			5				0.002		
Total						100	100	95	35	0.589	0.905	0.344	0.28	



**BUPROFEZIN (173)**

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.56	STMR	40	1.40		20	20			0.28	0.28	
Citrus dried pulp	AB	0.97	STMR	91	1.07	10		10		0.107		0.107	
Almond hulls	AM/AV	0.22	STMR	90	0.24			10				0.024	
Soybean seed	VD	0.01	STMR	89	0.01	5	10	20	15	0.001	0.001	0.002	0.002
Total						15	30	60	15	0.107	0.281	0.413	0.002

DAIRY CATTLE													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.56	STMR	40	1.40	10	10	10		0.140	0.14	0.14	
Citrus dried pulp	AB	0.97	STMR	91	1.07		10	20			0.107	0.213	
Almond hulls	AM/AV	0.22	STMR	90	0.24	10		10		0.024		0.024	
Soybean seed	VD	0.01	STMR	89	0.01	10	10	20	10	0.001	0.001	0.002	0.001
Total						30	30	60	10	0.166	0.248	0.38	0.001

POULTRY BROILER													
Commodity	CC	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	0.01	STMR	89	0.01	20	20	15		0.002	0.002	0.002	
Total						20	20	15		0.002	0.002	0.002	

POULTRY LAYER													
Commodity	CC	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	0.01	STMR	89	0.01	20	15	15		0.002	0.002	0.002	
Total						20	15	15		0.002	0.002	0.002	

**BUPROFEZIN (173)**

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.56	STMR/STMR-P	40	1.40		20	20			0.28	0.28	
Citrus dried pulp	AB	0.97	STMR/STMR-P	91	1.07	10		10		0.106593		0.107	
Almond hulls	AM/AV	0.22	STMR/STMR-P	90	0.24			10				0.024	
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	5	10	20	15	0.000562	0.001	0.002	0.002
Total						15	30	60	15	0.107155	0.281	0.413	0.002

DAIRY CATTLE													
DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Apple pomace, wet	AB	0.56	STMR/STMR-P	40	1.40	10	10	10		0.14	0.14	0.14	
Citrus dried pulp	AB	0.97	STMR/STMR-P	91	1.07	0	10	20		0	0.107	0.213	
Almond hulls	AM/AV	0.22	STMR/STMR-P	90	0.24	10		10		0.024444		0.024	
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	10	10	20	10	0.001124	0.001	0.002	0.001
Total						30	30	60	10	0.165568	0.248	0.38	0.001

POULTRY BROILER													
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
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01	20	20	15		0.00	0.002	0.002	
Total						20	20	15		0.00	0.002	0.002	

POULTRY LAYER													
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 seed	VD	0.01	STMR/STMR-P	89	0.01	20	15	15		0.002247	0.002	0.002	
Total						20	15	15		0.002247	0.002	0.002	

## CYCLANILIPROLE (296)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4.4	HR	15	29.33		20				5.867		
Rape forage	AM/AV	4.4	HR	30	14.67			100				14.67	
Turnip tops (leaves)	AM/AV	4.4	HR	30	14.67		20				2.933		
Apple pomace, wet	AB	0.15	STMR	40	0.38		20				0.075		
Corn, field stover	AF/AS	0.18	HR	83	0.22	15	25			0.033	0.054		
Barley straw	AF/AS	0.18	HR	89	0.20		15				0.03		
Rice straw	AF/AS	0.18	HR	90	0.20				55				0.11
Citrus dried pulp	AB	0.11	STMR	91	0.12	10				0.012			
Potato culls	VR	0.01	HR	20	0.05	30				0.015			
Total						55	100	100	55	0.060	8.96	14.67	0.11

ESTIMATED MAXIMUM DIETARY BURDEN													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	4.4	HR	15	29.33		20	40			5.867	11.73	
Rape forage	AM/AV	4.4	HR	30	14.67	10				1.467			
Turnip tops (leaves)	AM/AV	4.4	HR	30	14.67	20				2.933			
Grape pomace, wet	AB	0.19	STMR	15	1.27			20				0.253	
Apple pomace, wet	AB	0.15	STMR	40	0.38	10	10			0.038	0.038		
Corn, field stover	AF/AS	0.18	HR	83	0.22	15	20	40		0.033	0.043	0.087	
Millet hay	AF/AS	0.18	HR	85	0.21	5				0.011			
Rye straw	AF/AS	0.18	HR	88	0.20				5				0.01
Barley straw	AF/AS	0.18	HR	89	0.20		10				0.02		
Oat hay	AF/AS	0.18	HR	90	0.20	10				0.020			
Rice straw	AF/AS	0.18	HR	90	0.20				20				0.04
Citrus dried pulp	AB	0.11	STMR	91	0.12		10				0.012		
Sorghum, grain forage	AF/AS	0.026	HR	35	0.07	30			15	0.022			0.01
Corn, field forage/silage	AF/AS	0.026	HR	40	0.07		30		10		0.02		0.007
Total						100	100	100	50	4.523	5.999	12.07	0.068

ESTIMATED MAXIMUM DIETARY BURDEN													
POULTRY BROILER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	HR	20	0.05		10				0.005		
Total							10				0.005		

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Rape forage	AM/AV	4.4	HR	30	14.67		10				1.467			
Sorghum, grain stover	AF/AS	0.18	HR	88	0.20		10				0.02			
Potato culls	VR	0.01	HR	20	0.05		10				0.005			
Total							30				1.492			

## CYCLANILIPROLE (296)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	3	STMR/STMR-P	15	20.00		20				4		
Rape forage	AM/AV	3	STMR/STMR-P	30	10.00			100				10	
Turnip tops (leaves)	AM/AV	3	STMR/STMR-P	30	10.00		20				2		
Apple pomace, wet	AB	0.15	STMR/STMR-P	40	0.38		20				0.075		
Citrus dried pulp	AB	0.11	STMR/STMR-P	91	0.12	10				0.012088			
Corn, field stover	AF/AS	0.0475	STMR/STMR-P	83	0.06	15	25			0.008584	0.014		
Barley straw	AF/AS	0.0475	STMR/STMR-P	89	0.05		15				0.008		
Rice straw	AF/AS	0.0475	STMR/STMR-P	90	0.05				55				0.029
Total						25	100	100	55	0.021	6.097	10	0.029

DAIRY CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Kale leaves	AM/AV	3	STMR/STMR-P	15	20.00		20	40			4	8	
Rape forage	AM/AV	3	STMR/STMR-P	30	10.00	10				1			
Turnip tops (leaves)	AM/AV	3	STMR/STMR-P	30	10.00	20				2			
Grape pomace, wet	AB	0.19	STMR/STMR-P	15	1.27	0		20		0		0.253	
Apple pomace, wet	AB	0.15	STMR/STMR-P	40	0.38	10	10			0.0375	0.038		
Citrus dried pulp	AB	0.11	STMR/STMR-P	91	0.12	0	10	10		0	0.012	0.012	
Corn, field stover	AF/AS	0.0475	STMR/STMR-P	83	0.06	15	20	30		0.008584	0.011	0.017	
Millet hay	AF/AS	0.0475	STMR/STMR-P	85	0.06	5				0.002794			
Rye straw	AF/AS	0.0475	STMR/STMR-P	88	0.05	0			5	0			0.003
Barley straw	AF/AS	0.0475	STMR/STMR-P	89	0.05	0	10			0	0.005		
Oat hay	AF/AS	0.0475	STMR/STMR-P	90	0.05	10				0.005278			

<b>DAIRY CATTLE</b>													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Rice straw	AF/AS	0.0475	STMR/STMR-P	90	0.05	0			20	0			0.011
Sorghum, grain forage	AF/AS	0.01	STMR/STMR-P	35	0.03	30			15	0.008571			0.004
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40	0.03	0	30		10	0	0.008		0.003
Total						100	100	100	50	3.06	4.07	8.28	0.02

<b>POULTRY BROILER</b>													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
No feed items applicable!													

<b>POULTRY LAYER</b>													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
Rape forage	AM/AV	3	STMR/STMR-P	30	10.00		10				1		
Sorghum, grain stover	AF/AS	0.0475	STMR/STMR-P	88	0.05		10				0.005		
Total							20				1.005		

## FLUENSULFONE (265)

ESTIMATED MAXIMUM DIETARY BURDEN														
BEEF CATTLE														
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				MAX
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	0.01	HR	25	0.04		20	100			0.008	0.04		
Barley forage	AF/AS	0.01	HR	30	0.03		10				0.003			
Sorghum, grain forage	AF/AS	0.01	0.01	35	0.03	15				0.004				
Corn, field forage/silage	AF/AS	0.01	HR	40	0.03		70				0.018			
Sugarcane molasses	DM	0.01	STMR	75	0.01	10				0.001				
Sorghum, grain grain	GC	0.01	STMR	86	0.01	40			35	0.005			0.004	
Rice straw	AF/AS	0.01	HR	90	0.01				55				0.006	
Barley grain	GC	0.01	STMR	88	0.01	35			10	0.004			0.001	
Total						100	100	100	100	0.014	0.029	0.04	0.011	

DAIRY CATTLE														
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				MAX
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	0.01	HR	25	0.04	20	20	60		0.008	0.008	0.024		
Barley forage	AF/AS	0.01	HR	30	0.03		10				0.003			
Oat forage	AF/AS	0.01	HR	30	0.03	10		40	5	0.003		0.013	0.002	
Sorghum, grain forage	AF/AS	0.01	0.01	35	0.03	10			35	0.003			0.01	
Corn, field forage/silage	AF/AS	0.01	HR	40	0.03	5	30		10	0.001	0.008		0.003	
Sugarcane molasses	DM	0.01	STMR	75	0.01	10	10			0.001	0.001			
Sorghum, grain grain	GC	0.01	STMR	86	0.01	45	30		30	0.005	0.003		0.003	
Rice straw	AF/AS	0.01	HR	90	0.01				20				0.002	
Total						100	100	100	100	0.022	0.024	0.037	0.02	

POULTRY BROILER														
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				MAX
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Sorghum, grain grain	GC	0.01	STMR	86	0.01	75	70	70	65	0.009	0.008	0.008	0.008	
Corn, field grain	GC	0.01	STMR	88	0.01				35				0.004	
Total						75	70	70	100	0.009	0.008	0.008	0.012	

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	0.01	HR	25	0.04		10				0.004			
Sorghum, grain grain	GC	0.01	STMR	86	0.01	75	70	70	55	0.009	0.008	0.008	0.006	
Barley grain	GC	0.01	STMR	88	0.01		20				0.002			
Corn, field grain	GC	0.01	STMR	88	0.01				45				0.005	
Total						75	100	70	100	0.009	0.014	0.008	0.012	

**FLUENSULFONE (265)**

ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	0.01	STMR/STMR-P	25	0.04		20	100			0.008	0.04		
Barley forage	AF/AS	0.01	STMR/STMR-P	30	0.03		10				0.003			
Sorghum, grain forage	AF/AS	0.01	STMR/STMR-P	35	0.03	15				0.004286				
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40	0.03		70				0.018			
Sugarcane molasses	DM	0.01	STMR/STMR-P	75	0.01	10				0.001333				
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	40			35	0.004651			0.004	
Rice straw	AF/AS	0.01	STMR/STMR-P	90	0.01				55				0.006	
Barley grain	GC	0.01	STMR/STMR-P	88	0.01	35			10	0.003977			0.001	
Total						100	100	100	100	0.014	0.029	0.04	0.011	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	0.01	STMR/STMR-P	25	0.04	20	20	60		0.008	0.008	0.024		
Barley forage	AF/AS	0.01	STMR/STMR-P	30	0.03	0	10			0	0.003			
Oat forage	AF/AS	0.01	STMR/STMR-P	30	0.03	10		40	5	0.003333		0.013	0.002	
Sorghum, grain forage	AF/AS	0.01	STMR/STMR-P	35	0.03	10			35	0.002857			0.01	
Corn, field forage/silage	AF/AS	0.01	STMR/STMR-P	40	0.03	5	30		10	0.00125	0.008		0.003	
Sugarcane molasses	DM	0.01	STMR/STMR-P	75	0.01	10	10			0.001333	0.001			
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	45	30		30	0.005233	0.003		0.003	
Rice straw	AF/AS	0.01	STMR/STMR-P	90	0.01	0			20	0			0.002	
Total						100	100	100	100	0.022006	0.024	0.037	0.02	

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	
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	75	70	70	65	0.01	0.008	0.008	0.008	
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				35				0.004	
Total						75	70	70	100	0.01	0.008	0.008	0.012	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	0.01	STMR/STMR-P	25	0.04		10				0.004			
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01	75	70	70	55	0.008721	0.008	0.008	0.006	
Barley grain	GC	0.01	STMR/STMR-P	88	0.01		20				0.002			
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				45				0.005	
Total						75	100	70	100	0.008721	0.014	0.008	0.012	



**KRESOXIM-METHYL (199)**

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													
Commodity	CC	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	0.8	STMR	15	5.33			20				1.067	
Rye straw	AF/AS	2.3	HR	88	2.61	10	20	20		0.261	0.523	0.523	
Wheat straw	AF/AS	2.3	HR	88	2.61			60				1.568	
Barley straw	AF/AS	2.3	HR	89	2.58		10				0.258		
Apple pomace, wet	AB	0.24	STMR	40	0.60		20				0.12		
Turnip roots	VR	0.05	HR	15	0.33		20				0.067		
Barley grain	GC	0.035	STMR	88	0.04	50	30		70	0.020	0.012		0.028
Total						60	100	100	70	0.281	0.98	3.158	0.028

DAIRY CATTLE													
Commodity	CC	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	0.8	STMR	15	5.33			20				1.067	
Rye straw	AF/AS	2.3	HR	88	2.61	10	20	20	5	0.261	0.523	0.523	0.131
Barley straw	AF/AS	2.3	HR	89	2.58		10				0.258		
Oat straw	AF/AS	2.3	HR	90	2.56			40				1.022	
Triticale straw	AF/AS	2.3	HR	90	2.56			20				0.511	
Apple pomace, wet	AB	0.24	STMR	40	0.60	10	10			0.060	0.06		
Turnip roots	VR	0.05	HR	15	0.33	10	20			0.033	0.067		
Barley grain	GC	0.035	STMR	88	0.04	45	40		40	0.018	0.016		0.016
Total						75	100	100	45	0.373	0.924	3.123	0.147

POULTRY BROILER													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Turnip roots	VR	0.05	HR	15	0.33		10				0.033		
Barley grain	GC	0.035	STMR	88	0.04	75	70	15	10	0.030	0.028	0.006	0.004
Rye grain	GC	0.02	STMR	88	0.02			35				0.008	
Wheat grain	GC	0.02	STMR	89	0.02			50				0.011	
Total						75	80	100	10	0.030	0.061	0.025	0.004

POULTRY LAYER													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat straw	AF/AS	2.3	HR	88	2.61		10				0.261		
Turnip roots	VR	0.05	HR	15	0.33		10				0.033		
Barley grain	GC	0.035	STMR	88	0.04	75	80	15		0.030	0.032	0.006	
Rye grain	GC	0.02	STMR	88	0.02			20				0.005	
Wheat grain	GC	0.02	STMR	89	0.02			20				0.004	
Total						75	100	55		0.030	0.327	0.015	

## KRESOXIM-METHYL (199)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grape pomace, wet	AB	0.8	STMR/STMR-P	15	5.33			20				1.067	
Apple pomace, wet	AB	0.24	STMR/STMR-P	40	0.60		20				0.12		
Rye straw	AF/AS	0.5	STMR/STMR-P	88	0.57	10	20	20		0.056818	0.114	0.114	
Wheat straw	AF/AS	0.5	STMR/STMR-P	88	0.57			60				0.341	
Barley straw	AF/AS	0.5	STMR/STMR-P	89	0.56		10				0.056		
Barley grain	GC	0.035	STMR/STMR-P	88	0.04	50	50		70	0.019886	0.02		0.028
Total						60	100	100	70	0.076705	0.31	1.521	0.028

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	JP
Grape pomace, wet	AB	0.8	STMR/STMR-P	15	5.33		0	20			0	1.067	
Apple pomace, wet	AB	0.24	STMR/STMR-P	40	0.60	10	10			0.06	0.06		
Rye straw	AF/AS	0.5	STMR/STMR-P	88	0.57	10	20	20	5	0.056818	0.114	0.114	0.028
Barley straw	AF/AS	0.5	STMR/STMR-P	89	0.56	0	10			0	0.056		
Oat straw	AF/AS	0.5	STMR/STMR-P	90	0.56	0		40		0		0.222	
Triticale straw	AF/AS	0.5	STMR/STMR-P	90	0.56	0		20		0		0.111	
Barley grain	GC	0.035	STMR/STMR-P	88	0.04	45	40		40	0.017898	0.016		0.016
Total						65	80	100	45	0.134716	0.246	1.514	0.044

ESTIMATED MEAN DIETARY BURDEN													
POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley grain	GC	0.035	STMR/STMR-P	88	0.04	75	70	15	10	0.03	0.028	0.006	0.004
Rye grain	GC	0.02	STMR/STMR-P	88	0.02			35				0.008	
Wheat grain	GC	0.02	STMR/STMR-P	89	0.02			50				0.011	
Total						75	70	100	10	0.03	0.028	0.025	0.004

ESTIMATED MEAN DIETARY BURDEN													
POULTRY LAYER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Wheat straw	AF/AS	0.5	STMR/STMR-P	88	0.57		10				0.057		
Barley grain	GC	0.035	STMR/STMR-P	88	0.04	75	90	15		0.02983	0.036	0.006	
Rye grain	GC	0.02	STMR/STMR-P	88	0.02			20				0.005	
Wheat grain	GC	0.02	STMR/STMR-P	89	0.02			20				0.004	
Total						75	100	55		0.02983	0.093	0.015	

**MANDESTROBIN (307)**

<b>ESTIMATED MAXIMUM DIETARY BURDEN</b>													
<b>BEEF CATTLE</b>													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Canola meal	SM	0.004	STMR	88	0.00	5		20		0.000		0.00091	
Total						5		20		0.0002		0.0009	

<b>DAIRY CATTLE</b>													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	E U	A U	JP	US-CAN	EU	AU	JP
Canola meal	SM	0.004	STMR	88	0.00	10	10	15		0.000	0.0005	0.00068	
Total						10	10	15		0.0005	0.0005	0.0007	

<b>POULTRY BROILER</b>													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Canola meal	SM	0.004	STMR	88	0.00	15	18	5		0.001	0.0008	0.00023	
Total						15	18	5		0.0007	0.0008	0.0002	

<b>POULTRY LAYER</b>													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Canola meal	SM	0.004	STMR	88	0.00	15	10	5		0.001	0.0005	0.00023	
Total						15	10	5		0.0007	0.0005	0.0002	

## MANDESTROBIN (307)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Canola meal	SM	0.004	STMR/STMR-P	88	0.00	5		20		0.000227		0.000909091	
Total						5		20		0.0002		0.0009	

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	JP
Canola meal	SM	0.004	STMR/STMR-P	88	0.00	10	10	15		0.000455	0.0004545	0.000681818	
Total						10	10	15		0.0005	0.0005	0.0007	

ESTIMATED MEAN DIETARY BURDEN													
POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Canola meal	SM	0.004	STMR/STMR-P	88	0.00	15	18	5		0.00	0.0008182	0.000227273	
Total						15	18	5		0.0007	0.0008	0.0002	

ESTIMATED MEAN DIETARY BURDEN													
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
Canola meal	SM	0.004	STMR/STMR-P	88	0.00	15	10	5		0.000682	0.0004545	0.000227273	
Total						15	10	5		0.0007	0.0005	0.0002	

## METCONAZOLE (313)

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 hay	AF/AS	13	HR	88	14.77	15		100		2.216		14.77	
Triticale hay	AF/AS	13	HR	88	14.77		20				2.955		
Barley straw	AF/AS	8.8	HR	89	9.89		10				0.989		
Corn, field forage/silage	AF/AS	2.7	HR	40	6.75		70				4.725		
Cotton gin byproducts	AM/AV	4.6	HR	90	5.11	5				0.256			
Sunflower meal	SM	0.089	STMR	92	0.10	5				0.005			
Corn, field grain	GC	0.01	STMR	88	0.01	75			75	0.009			0.00852
Soybean seed	VD	0.01	STMR	89	0.01				15				0.00169
Total						100	100	100	90	2.485	8.668	14.77	0.01021

ESTIMATED MAXIMUM DIETARY BURDEN													
DAIRY CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Barley hay	AF/AS	13	HR	88	14.77	20		50		2.955		7.386	
Triticale hay	AF/AS	13	HR	88	14.77		20	50			2.955	7.386	
Oat hay	AF/AS	13	HR	90	14.44	10			5	1.444			0.72222
Barley straw	AF/AS	8.8	HR	89	9.89		10				0.989		
Corn, field forage/silage	AF/AS	2.7	HR	40	6.75	15	30		45	1.013	2.025		3.0375
Beet, sugar tops	AM/AV	1.2	HR	23	5.22		30				1.565		
Corn, field stover	AF/AS	3.5	HR	83	4.22		10				0.422		
Soybean hay	AL	3.2	HR	85	3.76	20				0.753			
Rape forage	AM/AV	0.13	HR	30	0.43	10				0.043			
Sunflower meal	SM	0.089	STMR	92	0.10	10				0.010			
Corn, field grain	GC	0.01	STMR	88	0.01	15			50	0.002			0.00568
Total						100	100	100	100	6.219	7.955	14.77	3.7654

ESTIMATED MAXIMUM DIETARY BURDEN													
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
Sunflower meal	SM	0.089	STMR	92	0.10	25	10	15		0.024	0.01	0.015	
Pea seed	VD	0.0425	STMR	90	0.05	20	20	5		0.009	0.009	0.002	
Bean seed	VD	0.04	STMR	88	0.05			65				0.03	
Canola meal	SM	0.02	STMR	88	0.02		8				0.002		
Corn, field grain	GC	0.01	STMR	88	0.01	55	62		70	0.006	0.007		0.00795
Total						100	100	85	70	0.0399	0.0280	0.0464	0.0080

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 hay	AF/AS	13	HR	88	14.77		10				1.477			
Beet, sugar tops	AM/AV	1.2	HR	23	5.22		5				0.261			
Soybean hay	AL	3.2	HR	85	3.76		10				0.376			
Rape forage	AM/AV	0.13	HR	30	0.43		5				0.022			
Sunflower meal	SM	0.089	STMR	92	0.10	25	10	15		0.024	0.01	0.015		
Pea seed	VD	0.0425	STMR	90	0.05	20	20	5		0.009	0.009	0.002		
Bean seed	VD	0.04	STMR	88	0.05			65				0.03		
Corn, field grain	GC	0.01	STMR	88	0.01	55	40		80	0.006	0.005			0.00909
Total						100	100	85	80	0.040	2.160	0.046	0.009	

## METCONAZOLE (313)

ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Barley hay	AF/AS	5.9	STMR/STMR-P	88	6.70	15		100		1.005682		6.705		
Triticale hay	AF/AS	5.9	STMR/STMR-P	88	6.70		20				1.341			
Cotton gin byproducts	AM/AV	2.65	STMR/STMR-P	90	2.94	5				0.147222				
Barley straw	AF/AS	2.3	STMR/STMR-P	89	2.58		10				0.258			
Corn, field forage/silage	AF/AS	0.91	STMR/STMR-P	40	2.28		70				1.593			
Sunflower meal	SM	0.089	STMR/STMR-P	92	0.10	5				0.004837				
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	75			75	0.008523				0.00852
Soybean seed	VD	0.01	STMR/STMR-P	89	0.01				15					0.00169
Total						100	100	100	90	1.166	3.192	6.705	0.01021	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Barley hay	AF/AS	5.9	STMR/STMR-P	88	6.70	20	0	50		1.340909	0	3.352		
Triticale hay	AF/AS	5.9	STMR/STMR-P	88	6.70	0	20	50		0	1.341	3.352		
Oat hay	AF/AS	5.9	STMR/STMR-P	90	6.56	10			5	0.655556				0.32778
Barley straw	AF/AS	2.3	STMR/STMR-P	89	2.58	0	10			0	0.258			
Corn, field forage/silage	AF/AS	0.91	STMR/STMR-P	40	2.28	15	30		45	0.34125	0.683			1.02375
Soybean hay	AL	1.7	STMR/STMR-P	85	2.00	20				0.4				
Beet, sugar tops	AM/AV	0.15	STMR/STMR-P	23	0.65	0	30			0	0.196			
Rape forage	AM/AV	0.09	STMR/STMR-P	30	0.30	10				0.03				
Sunflower meal	SM	0.089	STMR/STMR-P	92	0.10	10	10			0.009674	0.01			
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	15			50	0.001705				0.00568
Total						100	100	100	100	2.779093	2.487	6.705	1.35721	

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	
Sunflower meal	SM	0.089	STMR/STMR-P	92	0.10	25	10	15		0.02	0.01	0.015		
Pea seed	VD	0.0425	STMR/STMR-P	90	0.05	20	20	5		0.01	0.009	0.002		
Bean seed	VD	0.04	STMR/STMR-P	88	0.05			65				0.03		
Canola meal	SM	0.02	STMR/STMR-P	88	0.02		8				0.002			
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	55	62		70	0.01	0.007		0.00795	
Total						100	100	85	70	0.040	0.028	0.046	0.008	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat hay	AF/AS	5.9	STMR/STMR-P	88	6.70		10				0.67			
Soybean hay	AL	1.7	STMR/STMR-P	85	2.00		10				0.2			
Beet, sugar tops	AM/AV	0.15	STMR/STMR-P	23	0.65		5				0.033			
Rape forage	AM/AV	0.09	STMR/STMR-P	30	0.30		5				0.015			
Sunflower meal	SM	0.089	STMR/STMR-P	92	0.10	25	10	15		0.024185	0.01	0.015		
Pea seed	VD	0.0425	STMR/STMR-P	90	0.05	20	20	5		0.009444	0.009	0.002		
Bean seed	VD	0.04	STMR/STMR-P	88	0.05			65				0.03		
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01	55	40		80	0.00625	0.005		0.00909	
Total						100	100	85	80	0.040	0.942	0.046	0.0091	

## PICOXYSTROBIN (258)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea hay	AL	64	HR	88	72.73		25	100			18.18	72.73	
Grass forage (fresh)	AF/AS	17	HR	25	68.00		50		5		34		3.4
Corn, field forage/silage	AF/AS	14	HR	100	14.00	15	25			2.100	3.5		
Cotton gin byproducts	AM/AV	7.5	HR	90	8.33	5				0.417			
Alfalfa hay	AL	7.4	HR	100	7.40	15			10	1.110			0.74
Soybean asp gr fn	SM	2.6	STMR	85	3.06	5				0.153			
Corn, field asp gr fn	CM/CF	0.15	STMR	85	0.18	5				0.009			
Soybean hulls	SM	0.043	STMR	90	0.05	10			5	0.005			0.002
Barley grain	GC	0.017	STMR	88	0.02	45			70	0.009			0.014
Brewer's grain dried	SM	0.011	STMR	92	0.01				10				0.001
Total						100	100	100	100	3.802	55.68	72.73	4.157

DAIRY CATTLE													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea hay	AL	64	HR	88	72.73	10	30	70		7.273	21.82	50.91	
Grass forage (fresh)	AF/AS	17	HR	25	68.00	45	60	30	10	30.600	40.8	20.4	6.8
Corn, field forage/silage	AF/AS	14	HR	100	14.00				40				5.6
Alfalfa forage	AL	3.1	HR	35	8.86	10	10			0.886	0.886		
Alfalfa hay	AL	7.4	HR	100	7.40				25				1.85
Cotton undelinted seed	SO	0.205	STMR	88	0.23	10				0.023			
Soybean hulls	SM	0.043	STMR	90	0.05	10				0.005			
Barley grain	GC	0.017	STMR	88	0.02	15			25	0.003			0.005
Total						100	100	100	100	38.789	63.5	71.31	14.25

POULTRY BROILER													
Commodity	CC	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 hulls	SM	0.043	STMR	90	0.05		5				0.002		
Barley grain	GC	0.017	STMR	88	0.02	75	70	15	10	0.014	0.014	0.003	0.002
Bean seed	VD	0.0105	STMR	88	0.01		20	70			0.002	0.008	
Sorghum, grain grain	GC	0.01	STMR	86	0.01			15	55			0.002	0.006
Brewer's grain dried	SM	0.011	STMR	92	0.01		5				6E-04		
Corn, field milled bypdts	CM/CF	0.01	STMR	85	0.01	25				0.003			
Corn, field grain	GC	0.01	STMR	88	0.01				35				0.004
Total						100	100	100	100	0.017	0.019	0.013	0.012



POULTRY LAYER													MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Pea hay	AL	64	HR	88	72.73		10				7.273		
Rye forage	AF/AS	31	HR	100	31.00		10				3.1		
Soybean hulls	SM	0.043	STMR	90	0.05		5				0.002		
Barley grain	GC	0.017	STMR	88	0.02	75	75	15		0.014	0.014	0.003	
Bean seed	VD	0.0105	STMR	88	0.01			70				0.008	
Sorghum, grain grain	GC	0.01	STMR	86	0.01			15	55			0.002	0.006
Corn, field milled bypds	CM/CF	0.01	STMR	85	0.01	25				0.003			
Corn, field grain	GC	0.01	STMR	88	0.01				45				0.005
Total						100	100	100	100	0.02	10.39	0.013	0.01

**PICOXYSTROBIN (258)**

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grass forage (fresh)	AF/AS	12.5	STMR/STMR-P	25	50.00		50	100	5		25	50	2.5
Pea vines	AL	20.5	STMR/STMR-P	100	20.50		20				4.1		
Pea hay	AL	12.5	STMR/STMR-P	88	14.20		5				0.71		
Cotton gin byproducts	AM/AV	6.8	STMR/STMR-P	90	7.56	5				0.377778			
Corn, field forage/silage	AF/AS	7.1	STMR/STMR-P	100	7.10	15	25			1.065	1.775		
Soybean asp gr fn	SM	2.6	STMR/STMR-P	85	3.06	5				0.152941			
Alfalfa hay	AL	1.3	STMR/STMR-P	100	1.30	15			10	0.195			0.13
Corn, field asp gr fn	CM/CF	0.15	STMR/STMR-P	85	0.18	5				0.008824			
Soybean hulls	SM	0.043	STMR/STMR-P	90	0.05	10			5	0.005			0.002
Barley grain	GC	0.017	STMR/STMR-P	88	0.02	45			70	0.009			0.014
Brewer's grain dried	SM	0.011	STMR/STMR-P	92	0.01				10				0.001
Total						100	100	100	100	1.813	31.59	50	2.647

DAIRY CATTLE													
													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Grass forage (fresh)	AF/AS	12.5	STMR/STMR-P	25	50.00	45	60	100	10	22.5	30	50	5
Pea vines	AL	20.5	STMR/STMR-P	100	20.50	10	20			2.05	4.1		
Pea hay	AL	12.5	STMR/STMR-P	88	14.20	0	20			0	2.841		
Corn, field forage/silage	AF/AS	7.1	STMR/STMR-P	100	7.10	0			40	0			2.84

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Soybean forage	AL	1.4	STMR/STMR-P	100	1.40	10				0.14				
Alfalfa hay	AL	1.3	STMR/STMR-P	100	1.30	0			25	0				0.325
Cotton undelinted seed	SO	0.205	STMR/STMR-P	88	0.23	10				0.023295				
Soybean hulls	SM	0.043	STMR/STMR-P	90	0.05	10				0.004778				
Barley grain	GC	0.017	STMR/STMR-P	88	0.02	15			25	0.002898				0.005
Total						100	100	100	100	24.72097	36.94	50		8.17

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	
Soybean hulls	SM	0.043	STMR/STMR-P	90	0.05		5				0.002			
Barley grain	GC	0.017	STMR/STMR-P	88	0.02	75	70	15	10	0.01	0.014	0.003		0.002
Bean seed	VD	0.0105	STMR/STMR-P	88	0.01		20	70			0.002	0.008		
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01			15	55			0.002		0.006
Brewer's grain dried	SM	0.011	STMR/STMR-P	92	0.01		5				6E-04			
Corn, field milled bypds	CM/CF	0.01	STMR/STMR-P	85	0.01	25				0.00				
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				35					0.004
Total						100	100	100	100	0.01743	0.019	0.013		0.012

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Pea vines	AL	20.5	STMR/STMR-P	100	20.50		10				2.05			
Rye forage	AF/AS	4.5	STMR/STMR-P	100	4.50		10				0.45			
Soybean hulls	SM	0.043	STMR/STMR-P	90	0.05		5				0.002			
Barley grain	GC	0.017	STMR/STMR-P	88	0.02	75	75	15		0.014489	0.014	0.003		
Bean seed	VD	0.0105	STMR/STMR-P	88	0.01			70				0.008		
Sorghum, grain grain	GC	0.01	STMR/STMR-P	86	0.01			15	55			0.002		0.006
Corn, field milled bypds	CM/CF	0.01	STMR/STMR-P	85	0.01	25				0.002941				
Corn, field grain	GC	0.01	STMR/STMR-P	88	0.01				45					0.005
Total						100	100	100	100	0.017	2.517	0.013		0.01

## PYDIFLUMETOFEN (309)

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 hay	AF/AS	40	HR	100	40.00	15				6.000			
Barley straw	AF/AS	40	HR	100	40.00		10				4		
Wheat asp gr fn	CM/CF	23	STMR	85	27.06	5				1.353			
Cowpea hay	AL	15	HR	100	15.00		35				5.25		
Corn, field forage/silage	AF/AS	4.9	HR	40	12.25		35				4.288		
Soybean asp gr fn	SM	3.9	STMR	85	4.59	5				0.229			
Potato process waste	AB	0.063	STMR	12	0.53	30				0.158			
Wheat milled bypds	CM/CF	0.38	STMR	88	0.43	35			55	0.151			0.238
Potato culls	VR	0.084	HR	20	0.42	10				0.042			
Vetch hay	AL	0.28	HR	85	0.33				5				0.016
Rice straw	AF/AS	0.28	HR	90	0.31				40				0.124
Total						100	100	100	100	7.933	22.34	44	0.378

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 straw	AF/AS	40	HR	100	40.00		10				4		
Oat hay	AF/AS	40	HR	100	40.00	10		40	5	4.000		16	2
Cowpea hay	AL	15	HR	100	15.00	20	35			3.000	5.25		
Corn, field forage/silage	AF/AS	4.9	HR	40	12.25	15	35		45	1.838	4.288		5.513
Corn, sweet forage	AF/AS	3.9	HR	48	8.13	35				2.844			
Wheat milled bypds	CM/CF	0.38	STMR	88	0.43				45				0.194
Vetch hay	AL	0.28	HR	85	0.33				5				0.016
Total						100	100	100	100	20.481	22.34	42.4	7.723

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	0.07	HR	10	0.70		10				0.07		
Wheat milled bypds	CM/CF	0.38	STMR	88	0.43	50	20	20	5	0.216	0.086	0.086	0.022
Barley grain	GC	0.23	STMR	88	0.26	50	70	15	10	0.131	0.183	0.039	0.026
Rye grain	GC	0.063	STMR	88	0.07			35				0.025	
Wheat grain	GC	0.063	STMR	89	0.07			30				0.021	
Corn, field grain	GC	0.03	STMR	88	0.03				60				0.02
Corn, pop grain	GC	0.03	STMR	88	0.03				25				0.009
Total						100	100	100	100	0.347	0.339	0.172	0.077

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			
Pea hay	AL	15	HR	100	15.00		10				1.5			
Swede roots	VR	0.07	HR	10	0.70		10				0.07			
Cabbage heads, leaves	AM/AV	0.09	HR	15	0.60		5				0.03			
Wheat milled bypds	CM/CF	0.38	STMR	88	0.43	50	20	20	30	0.216	0.086	0.086	0.13	
Barley grain	GC	0.23	STMR	88	0.26	50	45	15		0.131	0.118	0.039		
Rye grain	GC	0.063	STMR	88	0.07			20				0.014		
Wheat grain	GC	0.063	STMR	89	0.07			45				0.032		
Corn, field grain	GC	0.03	STMR	88	0.03				70				0.02	
Total						100	100	100	100	0.347	6.204	0.172	0.153	

## PYDIFLUMETOFEN (309)

ESTIMATED MEAN DIETARY BURDEN														
BEEF CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat asp gr fn	CM/CF	23	STMR/STMR-P	85	27.06	5				1.352941				
Wheat forage	AF/AS	2.7	STMR/STMR-P	25	10.80		20	100			2.16	10.8		
Barley hay	AF/AS	9.2	STMR/STMR-P	100	9.20	15				1.38				
Barley straw	AF/AS	9.2	STMR/STMR-P	100	9.20		10				0.92			
Cowpea hay	AL	9.2	STMR/STMR-P	100	9.20		35				3.22			
Soybean asp gr fn	SM	3.9	STMR/STMR-P	85	4.59	5				0.229412				
Corn, field forage/silage	AF/AS	1.15	STMR/STMR-P	40	2.88		35				1.006			
Potato process waste	AB	0.063	STMR/STMR-P	12	0.53	30				0.1575				
Wheat milled bypds	CM/CF	0.38	STMR/STMR-P	88	0.43	35			55	0.151			0.238	
Barley grain	GC	0.23	STMR/STMR-P	88	0.26	10			45	0.026			0.118	
Total						100	100	100	100	3.297	7.306	10.8	0.355	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	2.7	STMR/STMR-P	25	10.80	20	20	60		2.16	2.16	6.48		
Barley straw	AF/AS	9.2	STMR/STMR-P	100	9.20	0	10			0	0.92			
Cowpea hay	AL	9.2	STMR/STMR-P	100	9.20	20	35	40		1.84	3.22	3.68		
Oat hay	AF/AS	9.2	STMR/STMR-P	100	9.20	10			5	0.92			0.46	
Corn, field forage/silage	AF/AS	1.15	STMR/STMR-P	40	2.88	15	35		45	0.43125	1.006		1.294	
Corn, sweet forage	AF/AS	0.775	STMR/STMR-P	48	1.61	35				0.565104				
Wheat milled bypds	CM/CF	0.38	STMR/STMR-P	88	0.43	0			45	0			0.194	

DAIRY CATTLE														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Barley grain	GC	0.23	STMR/STMR-P	88	0.26	0			5	0			0.013	
Total						100	100	100	100	5.916354	7.306	10.16	1.961	

POULTRY BROILER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat milled bypds	CM/CF	0.38	STMR/STMR-P	88	0.43	50	20	20	5	0.22	0.086	0.086	0.022	
Barley grain	GC	0.23	STMR/STMR-P	88	0.26	50	70	15	10	0.13	0.183	0.039	0.026	
Swede roots	VR	0.02	STMR/STMR-P	10	0.20		10				0.02			
Rye grain	GC	0.063	STMR/STMR-P	88	0.07			35				0.025		
Wheat grain	GC	0.063	STMR/STMR-P	89	0.07			30				0.021		
Corn, field grain	GC	0.03	STMR/STMR-P	88	0.03				60				0.02	
Corn, pop grain	GC	0.03	STMR/STMR-P	88	0.03				25				0.009	
Total						100	100	100	100	0.346591	0.289	0.172	0.077	

POULTRY LAYER														MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Wheat forage	AF/AS	2.7	STMR/STMR-P	25	10.80		10				1.08			
Pea hay	AL	9.2	STMR/STMR-P	100	9.20		10				0.92			
Wheat milled bypds	CM/CF	0.38	STMR/STMR-P	88	0.43	50	20	20	30	0.215909	0.086	0.086	0.13	
Barley grain	GC	0.23	STMR/STMR-P	88	0.26	50	60	15		0.130682	0.157	0.039		
Rye grain	GC	0.063	STMR/STMR-P	88	0.07			20				0.014		
Wheat grain	GC	0.063	STMR/STMR-P	89	0.07			45				0.032		
Corn, field grain	GC	0.03	STMR/STMR-P	88	0.03				70				0.024	
Total						100	100	100	100	0.346591	2.243	0.172	0.153	

## PYRIFLUQUINAZON (316)

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 process waste	AB	0.02	STMR	12	0.17	30	40	5		0.050	0.067	0.008	
Potato culls	VR	0.02	HR	20	0.10	30	30	10		0.030	0.03	0.01	
Total						60	70	15		0.080	0.097	0.018	

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 process waste	AB	0.02	STMR	12	0.17	10	30			0.017	0.05			
Potato culls	VR	0.02	HR	20	0.10	10	30	10		0.010	0.03	0.01		
Total						20	60	10		0.027	0.08	0.01		

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	0.02	HR	20	0.10		10				0.01			
Total							10				0.01			

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	0.02	HR	20	0.10		10				0.01			
Total							10				0.01			

## PYRIFLUQUINAZON (316)

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato process waste	AB	0.02	STMR/STMR-P	12	0.17	30	40	5		0.05	0.067	0.008	
Potato culls	VR	0.02	STMR/STMR-P	20	0.10	30	30	10		0.03	0.03	0.01	
Total						60	70	15		0.08	0.097	0.018	

<b>DAIRY CATTLE</b>													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 process waste	AB	0.02	STM/STM-P	12	0.17	10	30	0		0.016667	0.05	0	
Potato culls	VR	0.02	STM/STM-P	20	0.10	10	30	10		0.01	0.03	0.01	
Total						20	60	10		0.026667	0.08	0.01	

<b>POULTRY BROILER</b>													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	0.02	STM/STM-P	20	0.10		10				0.01		
Total							10				0.01		

<b>POULTRY LAYER</b>													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	0.02	STM/STM-P	20	0.10		10				0.01		
Total							10				0.01		

**TOLCLOFOS-METHYL (191)**

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	0.21	HR	20	1.05	30	30	10		0.315	0.315	0.105	
Potato process waste	AB	0.044	STMR	12	0.37	30	40	5		0.110	0.146667	0.018	
Total						60	70	15		0.425	0.461667	0.123	

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	0.21	HR	20	1.05	10	30	10		0.105	0.315	0.105		
Potato process waste	AB	0.044	STMR	12	0.37	10	30			0.037	0.11			
Total						20	60	10		0.142	0.425	0.105		

POULTRY BROILER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	0.21	HR	20	1.05		10				0.105			
Total							10				0.105			

POULTRY LAYER														MAX
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)				
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP	
Potato culls	VR	0.21	HR	20	1.05		10				0.105			
Total							10				0.105			

**TOLCLOFOS-METHYL (191)**

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato process waste	AB	0.044	STMR/STMR-P	12	0.37	30	40	5		0.11	0.146667	0.018	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	30	30	10		0.015	0.015	0.005	
Total						60	70	15		0.125	0.161667	0.023	



<b>DAIRY CATTLE</b>													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 process waste	AB	0.044	STMR/STMR-P	12	0.37	10	30	0		0.036667	0.11	0	
Potato culls	VR	0.01	STMR/STMR-P	20	0.05	10	30	10		0.005	0.015	0.005	
Total						20	60	10		0.041667	0.125	0.005	

<b>POULTRY BROILER</b>													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Total							10				0.005		

<b>POULTRY LAYER</b>													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Potato culls	VR	0.01	STMR/STMR-P	20	0.05		10				0.005		
Total							10				0.005		





## TRIFLUMURON (317)

ESTIMATED MAXIMUM DIETARY BURDEN													
BEEF CATTLE													
Commodity	CC	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 hay	AL	13	HR	85	15.29			80				12.24	
Soybean hay	AL	13	HR	85	15.29			80				12.24	
Soybean forage	AL	3.4	HR	56	6.07			20				1.214	
Soybean hulls	SM	0.048	STMR	90	0.05	15	10			0.008	0.005		
Soybean seed	VD	0.014	STMR	89	0.02	5	10		15	0.000787	0.002		0.002
Soybean meal	SM	0.014	STMR	92	0.02		10		65		0.002		0.01
Total						20	30	180	80	0.008787	0.008	25.68	0.012

DAIRY CATTLE													
Commodity	CC	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 hay	AL	13	HR	85	15.29	20		40		3.058824		6.118	
Soybean hay	AL	13	HR	85	15.29	20		40		3.058824		6.118	
Soybean hulls	SM	0.048	STMR	90	0.05		10				0.005		
Soybean seed	VD	0.014	STMR	89	0.02	10	10	20	10	0.001573	0.002	0.003	0.002
Soybean meal	SM	0.014	STMR	92	0.02	10	15	15	60	0.001522	0.002	0.002	0.009
Total						60	35	115	70	6.120742	0.009	12.24	0.011

POULTRY BROILER													
Commodity	CC	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 hulls	SM	0.048	STMR	90	0.05		10	5			0.005	0.003	
Soybean hulls	SM	0.048	STMR	90	0.05		10	5			0.005	0.003	
Soybean seed	VD	0.014	STMR	89	0.02	20	20	15		0.003146	0.003	0.002	
Soybean meal	SM	0.014	STMR	92	0.02	25	30	20	35	0.003804	0.005	0.003	0.005
Total						45	70	45	35	0.00695	0.018	0.011	0.005

POULTRY LAYER													
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hay	AL	13	HR	85	15.29		10				1.529		
Soybean hay	AL	13	HR	85	15.29		10				1.529		
Soybean hulls	SM	0.048	STMR	90	0.05		5	5			0.003	0.003	
Soybean seed	VD	0.014	STMR	89	0.02	20	15	15		0.003146	0.002	0.002	
Soybean meal	SM	0.014	STMR	92	0.02	25	20	20	30	0.003804	0.003	0.003	0.005
Total						45	60	40	30	0.00695	3.067	0.008	0.005

ESTIMATED MEAN DIETARY BURDEN													
BEEF CATTLE													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hay	AL	13	STMR/STMR-P	85	15.29			80				12.24	
Soybean hay	AL	13	STMR/STMR-P	85	15.29			80				12.24	
Soybean forage	AL	3.4	STMR/STMR-P	56	6.07			20				1.214	
Soybean hulls	SM	0.048	STMR/STMR-P	90	0.05	15	10			0.008	0.005		
Soybean seed	VD	0.014	STMR/STMR-P	89	0.02	5	10		15	0.000787	0.002		0.002
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02		10		65		0.002		0.01
Total						20	30	180	80	0.008787	0.008	25.68	0.012

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	JP
Soybean hay	AL	13	STMR/STMR-P	85	15.29	20	0	40		3.058824	0	6.118	
Soybean hay	AL	13	STMR/STMR-P	85	15.29	20		40		3.058824		6.118	
Soybean hulls	SM	0.048	STMR/STMR-P	90	0.05	0	10			0	0.005		
Soybean seed	VD	0.014	STMR/STMR-P	89	0.02	10	10	20	10	0.001573	0.002	0.003	0.002
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02	10	15	15	60	0.001522	0.002	0.002	0.009
Total						60	35	115	70	6.120742	0.009	12.24	0.011

ESTIMATED MEAN DIETARY BURDEN													
POULTRY BROILER													MEAN
Commodity	CC	Residue (mg/kg)	Basis	DM (%)	Residue dw (mg/kg)	Diet content (%)				Residue Contribution (ppm)			
						US-CAN	EU	AU	JP	US-CAN	EU	AU	JP
Soybean hulls	SM	0.048	STMR/STMR-P	90	0.05		10	5			0.005	0.003	
Soybean hulls	SM	0.048	STMR/STMR-P	90	0.05		10	5			0.005	0.003	
Soybean seed	VD	0.014	STMR/STMR-P	89	0.02	20	20	15		0.003146	0.003	0.002	
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02	25	30	20	35	0.003804	0.005	0.003	0.005
Total						45	70	45	35	0.00695	0.018	0.011	0.005

ESTIMATED MEAN DIETARY BURDEN													
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 hay	AL	13	STMR/STMR-P	85	15.29		10				1.529		
Soybean hay	AL	13	STMR/STMR-P	85	15.29		10				1.529		

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 hulls	SM	0.048	STMR/STMR-P	90	0.05		5	5			0.003	0.003	
Soybean seed	VD	0.014	STMR/STMR-P	89	0.02	20	15	15		0.003146	0.002	0.002	
Soybean meal	SM	0.014	STMR/STMR-P	92	0.02	25	20	20	30	0.003804	0.003	0.003	0.005
Total						45	60	40	30	0.00695	3.067	0.008	0.005



The annual Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues was held in Geneva, Switzerland, from 17 to 26 September 2019. The FAO Panel of experts had met in preparatory sessions from 12 to 16 September. The Meeting was held in pursuance of recommendations made by previous Meetings and accepted by the governing bodies of FAO and WHO that studies should be undertaken jointly by experts to evaluate possible hazards to humans arising from the occurrence of pesticide residues in foods. During the meeting the FAO Panel of Experts was responsible for reviewing pesticide use patterns (use of good agricultural practices), data on the chemistry and composition of the pesticides and methods of analysis for pesticide residues and for estimating the maximum residue levels that might occur as a result of the use of the pesticides according to good agricultural use practices. The WHO Core Assessment Group was responsible for reviewing toxicological and related data and for estimating, where possible and appropriate, acceptable daily intakes (ADIs) and acute reference doses (ARfDs) of the pesticides for humans. This report contains information on ADIs, ARfDs, maximum residue levels, and general principles for the evaluation of pesticides. The recommendations of the Joint Meeting, including further research and information, are proposed for use by Member governments of the respective agencies and other interested parties.

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